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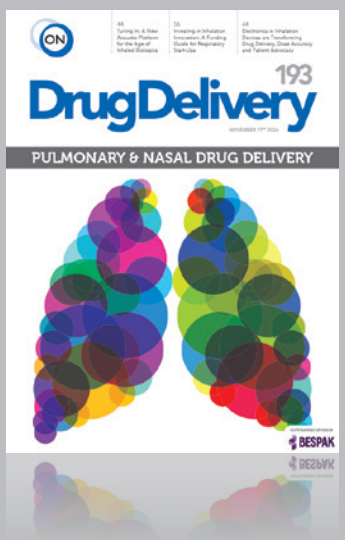
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PULMONARY & NASAL DRUG DELIVERY

ONdrugDelivery Issue N° 193, November 18th, 2026

This edition is one in the ONdrugDelivery series of publications. Each issue focuses on a specific topic within the field of drug delivery, and is supported by industry leaders in that field.

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Next-Generation Devices:

Broadening Horizons for OINDP Delivery

For the final issue of 2026, ONdrugDelivery returns to orally inhaled and nasal drug products. For much of its history, the sector has been primarily focused on locally acting therapeutics for respiratory and nasal conditions. In recent years, however, many innovators have been pushing towards using these delivery routes for systemic delivery, citing the promise of the deep lung for bypassing first-pass metabolism and the potential of direct nose-to-brain delivery. Achieving this ambition will require advanced delivery devices that are up to the challenge, along with the infrastructure to bring them to market.

Opening the issue, **Bespak**, our Outstanding Sponsor, discusses how its nasal drug delivery portfolio is positioned to support the next generation of nasal therapies, including its collaboration with Upperton and soft mist technology developed by its joint venture, Resyca (Page 10). Next, **Catalent Pharma Services** considers the role of spray-drying in the modern pharmaceutical industry (Page 14) and **Aptar Pharma** and **Nanopharm UK** dig into what is required to prepare inhaled therapeutics for clinical trials (Page 20).

The pulmonary and nasal delivery routes are notoriously challenging, so expert partners are often essential within the sector. Featured in this issue, **Orbia Fluor & Energy Materials** touches on the broader challenges for pressurised metered dose inhaler developers preparing for the switch over to low global warming potential propellants (Page 28); **Cormica** outlines the most valuable analytic techniques for characterising foreign particles in pulmonary and nasal devices (Page 32); **Copley Scientific** makes the case for integrating connectivity into device testing workflows (Page 60); and **Sanner** considers the role and potential of integrated electronics in inhalation devices (Page 64).

Alongside this shared expertise, this issue showcases some of the delivery devices positioning themselves for the next generation of inhaled and nasal therapies. Together, **Sanner** and **Nebu~Flow** discuss how Nebu~Flow's nebuliser platform takes a novel approach to aerosolisation that makes it ideally suited for delivering biologics to the lung (Page 44), and **HCMed** shares two case studies on how its AdheResp™ mesh nebuliser can be adapted for challenging molecules (Page 50). Turning to intranasal devices, **Aptar Pharma** takes a deep dive into dual-dose delivery with its BiDose™ system (Page 68) and **SGD Pharma** discusses its My Sterinity Nasal ready-to-use Type I glass vial platform for next-generation nasal formulations (Page 76).

Capping off the issue, **Phillips Medisize** takes a broad view of how bringing formulation, device and patient needs together in the early stages of respiratory biologic product development can improve decision-making and significantly reduce risks further down the line (Page 38). Lastly, ahead of the Drug Delivery to the Lungs 2026 conference in December, the **DDL Incubator Committee** shares insights into the opportunities that novel respiratory start-ups and early-stage companies have to raise the funding required to take their innovations from concept to commercial product (Page 56).

ONdrugDelivery is proud to be a Media Partner for **DDL** and we look forward to seeing many of you in Edinburgh next month!

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FROM DEVICE SELECTION TO REGULATORY APPROVAL: ACCELERATING THE NEXT GENERATION OF INTRANASAL THERAPIES

BESPAK

Joseph DePalo of **Bespak** discusses the increasingly diverse range of therapeutics that have the potential to be delivered nasally, delving into the offerings developed by Bespak in collaboration with other contract organisations that expand the possibilities of nasal drug delivery, as well as providing an integrated approach across device development.

Nasal drug delivery was once largely associated with locally acting treatments for relatively minor ailments such as congestion, nasal allergies and sinus infections. Today, the nasal route is being explored for systemic delivery for applications such as cardiac therapies, anaphylaxis and vaccinations, and increasingly for the treatment of central nervous system (CNS) disorders via potential nose-to-brain pathways.

That shift is opening new therapeutic possibilities, but it also raises the bar for what a nasal drug-device combination product needs to achieve. Different molecules and formulations have different device requirements, and the intended delivery target and therapeutic effect can place very different demands on where and how a formulation must be deposited within the nasal cavity. Patient anatomy and usability, delivered dose consistency, drug deposition, formulation stability and manufacturing constraints all need to be considered, with the choice of device being essential in addressing these factors.

As nasal applications become more diverse, the importance of selecting the right device is increasingly being reflected in the regulatory landscape. This means that a nasal drug delivery device can no longer be viewed simply as a mechanism for administering an otherwise complete drug product. Instead, it needs to be considered alongside the formulation, from the earliest stages of development.

The challenge is to connect the critical development decisions early enough

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"DEVELOPERS CAN ACCESS CO-ORDINATED SUPPORT ACROSS THE DEVELOPMENT JOURNEY, RATHER THAN MANAGING EACH ELEMENT INDEPENDENTLY, PROVIDING A BROADER VIEW OF THE CHALLENGES THAT NEED TO BE ADDRESSED AT EACH STAGE."

to ensure that the formulation, device, performance, patient needs and regulatory requirements are aligned as the product progresses towards commercialisation.

For Bespak, a specialist CDMO focused solely on inhaled and nasal drug delivery, this is driving an integrated approach to intranasal drug development, helping customers to navigate the complexity of nasal drug delivery from early feasibility testing through to commercialisation.

AN INTEGRATED APPROACH TO INTRANASAL DRUG PRODUCT DEVELOPMENT

At every stage, from device selection and design through to regulatory submission and manufacturing, decisions need to be aligned in order to avoid delays, minimise risk and support successful development. Despite this, expertise is often spread across multiple suppliers, resulting in decisions being made in silos. Problems may then only emerge at a later stage, leading to devices that are not fully compatible with the final formulation or scale-up risks that have not been addressed early enough. Late changes can result in rework, delays and regulatory uncertainty.

This is why Bespak has entered a strategic collaboration with Upperton (Nottingham, UK), a CDMO with specialist powder and liquid formulation development expertise, to provide an integrated pathway for the development and manufacture of nasal drug-device combination products. Upperton brings formulation development, analytical and clinical manufacturing expertise, while Bespak provides a robust device portfolio, alongside a track record of commercialising complex finished products.

Bespak's services in collaboration with Upperton enable access to specialist nasal delivery technology provided by Bespak and its partners, such as proprietary soft mist technology from its joint venture, Resyca® (Enschede, The Netherlands), and a proven dry powder delivery device from Shin Nippon Biomedical Laboratories Ltd (SNBL), a contract research organisation based in Tokyo, Japan. With these capabilities connected, developers can access co-ordinated support across the development journey, rather than managing each element independently, providing a broader view of the challenges that need to be addressed at each stage.

MATCHING DEVICES TO FORMULATION AND PATIENT NEEDS

As intranasal therapies continue to evolve, developers need greater flexibility in selecting an approach that aligns with their molecule, formulation, therapeutic requirements and target patient profile. This is where Bespak's broader nasal offering brings together its range of device technologies and the expertise needed to navigate integrated drug-device product development. Spanning liquid, dry powder and soft mist technologies across unit dose and multidose formats, the Bespak device portfolio gives developers a choice of established and novel platforms suited to different requirements, helping to provide a faster route to clinic.

At the heart of Bespak's nasal drug delivery device portfolio is its novel NasaDose® platform, which is designed to deliver consistent spray performance with reduced sensitivity to user actuation (Figure 1). The platform can be customised to meet the requirements of different formulations and target populations, with specific nozzles to suit paediatric use available.

The platform uses a patented spring-powered mechanism in order to provide consistent actuation independent of the speed at which the user presses the device, or its orientation in use. NasaDose requires no priming and incorporates an ergonomic push-button design, as well as an audible click and button retraction providing feedback that the dose has been delivered. Differences in strength, dexterity and technique can introduce variability into manually actuated devices, so designing the mechanism to reduce the influence of these variables can support more consistent delivery, as well as ease of use.

Soft mist technology offers a differentiated delivery approach. Through its joint venture Resyca, Bespak has access to proprietary soft mist spray technology that generates a fine, low-velocity aerosol, enabling gentle, low-shear aerosolisation, reproducible deposition and broad nasal



Figure 1: Bespak's NasaDose delivery platform.

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coverage (Figure 2). This makes soft mist delivery particularly well suited to proteins, peptides, nucleotides and other sensitive molecules.

Resyca's multidose Ultra Soft Nasal Spray platform is already progressing through late-stage clinical development. Building on this proven technology, Bespak's latest addition to its nasal portfolio, NasaDose® Ultra Soft Unit Dose Spray, combines the established capabilities of the NasaDose platform with Resyca's unique soft mist technology. Together, these multidose and unit-dose offerings expand the range of soft mist nasal delivery options available to developers, providing greater flexibility for complex nasal drug product development.

For dry powder applications, Bespak's recently announced agreement with SNBL provides access to the US FDA-approved Air Pump Unit Dose Intranasal Powder device (Figure 3). The proprietary platform further expands the options available to developers working on novel intranasal therapies and exploring dry powder formulations. This collaboration pairs established device technology with manufacturing expertise



Figure 3: Air Pump Unit Dose Intranasal Powder device.



Figure 2: NasaDose Ultra Soft Unit Dose Spray.

from Bespak, as the chosen contract manufacturer responsible for filling and assembly of this FDA-approved product into the broader nasal offering.

Together, these platforms give developers greater choice at an early stage of product development.

FROM DEVICE SELECTION TO OPTIMISATION

Selecting a platform is the starting point. The next challenge is to understand how it will perform in practice and identifying what needs to be optimised as the product progresses.

Bespak's advanced computational fluid dynamics and *in silico* nasal modelling capabilities can provide insight into device performance before extensive physical testing begins. Modelling can help with exploring factors such as spray behaviour and deposition, highlighting design variables that may need further investigation and focusing subsequent testing.

Rapid prototyping and device optimisation capabilities then allow designs to be tested and refined efficiently. Bespak's Injection Moulding Academy provides small-scale manufacturing capability to evaluate designs using representative processes and identify potential manufacturing complexities before industrialisation.

"BESPAK'S INJECTION MOULDING ACADEMY PROVIDES SMALL-SCALE MANUFACTURING CAPABILITY TO EVALUATE DESIGNS USING REPRESENTATIVE PROCESSES AND IDENTIFY POTENTIAL MANUFACTURING COMPLEXITIES BEFORE INDUSTRIALISATION."

Leveraging commercially available primary packaging with device platforms designed to be tailored allows Bespak to engineer products around patients and customer requirements while maintaining manufacturability and scalability, creating a clearer path from an initial device concept to a commercially ready solution.

NAVIGATING THE NASAL REGULATORY LANDSCAPE

As the range of nasal therapies and delivery technologies expands, regulatory expectations are evolving alongside them. However, there is no single regulatory pathway for nasal drug delivery – the requirements that a developer must address can vary according to the intended application, delivery technology, formulation and patient population. For example, a product intended for local action will raise different regulatory considerations from one designed for systemic delivery or a nose-to-brain application.

The formulation itself will also influence the evidence required during development. For liquid sprays, considerations can include spray characteristics, dose delivery and compatibility between the formulation, container and device, including extractables

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and leachables. For dry powders, particle size, moisture sensitivity and dose delivery performance will be important factors.

At the same time, regulators are placing increasing emphasis on the delivery device as part of the overall product. In the US for example, the FDA treats prefilled nasal sprays as combination products, meaning that the performance and characteristics of the delivery device are considered alongside the formulation (Figure 4).[1] In parallel, Article 117 of the EU's Medical Device Regulation introduces specific device requirements into the assessment of certain integral drug-device combination products, meaning that how a device delivers the formulation is an important part of understanding the complete product.[2]



Figure 4: Resyca Ultra Soft Nasal Pump Spray.

This makes device selection an increasingly essential development decision. The device needs to be considered not only in terms of whether it can deliver the formulation, but also in relation to the evidence required to demonstrate consistent performance, suitability for the intended product and usability for the target patient population. Selecting and optimising the device early can therefore help to shape the wider development and regulatory strategy. Rather than treating the device as a component to be addressed later, successful development programmes consider the device, formulation and patient holistically, in terms of a single integrated product, from the beginning of development.

"THE DEVICE NEEDS TO BE CONSIDERED NOT ONLY IN TERMS OF WHETHER IT CAN DELIVER THE FORMULATION, BUT ALSO IN RELATION TO THE EVIDENCE REQUIRED TO DEMONSTRATE CONSISTENT PERFORMANCE, SUITABILITY FOR THE INTENDED PRODUCT AND USABILITY FOR THE TARGET PATIENT POPULATION."

For developers, early access to the right team of experts can be especially important. Bringing regulatory, formulation, drug product manufacturing and device considerations together from the outset can help to shape an appropriate development strategy, identify potential requirements early and inform delivery technology decisions before significant development work has been committed. Bespak brings these considerations together through regulatory support tailored to the specific product, alongside expertise in formulation, device selection and manufacturing, helping developers to navigate the requirements of the complete product as it progresses towards market.

FROM BREAKTHROUGH TO MARKET

Nasal drug delivery is moving beyond its traditional role in locally acting treatments, opening opportunities for systemic therapies, vaccines and increasingly complex applications, including nose-to-brain delivery. As these opportunities grow, so does the challenge of developing products that are effective and suitable for regulatory approval.

For developers, successfully harnessing delivery opportunities requires more than just access to individual technologies or capabilities. It requires the ability to connect critical development decisions early, so that considerations can progress together.

For Bespak, this evolving landscape is driving a broader and more holistic approach to nasal drug delivery, bringing together device technologies, development expertise and manufacturing capabilities to support developers from early development through to commercialisation. Connecting these decisions early can help customers to navigate complexity, reach the market faster and, ultimately, bring promising nasal therapies to patients with greater certainty.

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Joseph DePalo

Joseph DePalo is a Director of Business Development at Bespak, with 13 years of experience delivering pharmaceutical drug products to the US market. Over the past four years, he has leveraged his foundation in biomechanical engineering, medical device development and pharmaceutical expertise to support the unique challenges of combination drug products for inhalation and nasal delivery. He earned his Bachelor of Science in Biomechanical Engineering from Marquette University (Milwaukee, WI, US).

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THE COMMERCIAL CASE FOR SPRAY-DRYING FOR MODERN DRUG PIPELINES

Itay Speicher of **Catalent** highlights how current conditions in the pharmaceutical pipeline, especially the high proportion of poorly soluble drugs in early-stage development and rise in amorphous solid dispersions, along with the cost-efficiency and flexibility of spray-drying, are providing the optimal conditions to maximise the value of spray-drying in drug development and commercial scale-up.

Published estimates now suggest that 70–90% of development-stage drug candidates are poorly soluble, compared with approximately 40% of already-marketed products.[1] Half of all drug molecules are estimated to fail during development due to poor aqueous solubility – not because the molecules lack pharmacological activity, but because they cannot be absorbed reliably after oral administration.

The commercial implications of the solubility challenge are direct. Poor bioavailability forces dose escalation, which increases both the safety risk and the cost of goods. It generates food effects that complicate dosing instructions and erode patient compliance. It introduces pharmacokinetic variability that weakens the clinical evidence base and complicates market-access negotiations. In late-stage programmes, a bioavailability failure represents one of the most expensive outcomes in drug development, consuming years of development investment that cannot be recovered.

Amorphous solid dispersions (ASDs) resolve this problem by converting a crystalline API into a molecularly dispersed amorphous form within a stabilising polymer matrix. The amorphous state, occupying a higher thermodynamic energy level than crystalline drug, exhibits greater apparent solubility and faster dissolution, generating sustained supersaturation in gastrointestinal fluids that drives absorption. Spray-drying is the most commercially proven and regulatory-accepted process for manufacturing these dispersions.[2]

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"BY CONTROLLING PROCESS PARAMETERS SUCH AS INLET TEMPERATURE, FEED CONCENTRATION AND ATOMISATION CONDITIONS, MANUFACTURERS CAN REPRODUCIBLY TUNE THE SIZE, DENSITY AND SURFACE CHARACTERISTICS OF THE DRIED PARTICLES."

Another development is pharmaceutical pipeline expansion beyond small molecules into messenger RNA (mRNA) therapeutics, nucleic acids and inhaled biologics. Taken together, these modalities all share a common manufacturing challenge: converting unstable liquid formulations into stable, deliverable solids.

A PLATFORM BUILT ON COMMERCIAL PROOF

A review by Moseson *et al* analysed all ASD drug products approved by the US FDA between 2012 and 2023, identifying 48 approved products comprising 36 unique amorphous drugs across 10 therapeutic categories.[2] Spray-drying was the most common manufacturing process, accounting for 54% of the ASD drug product intermediates, against 35% for hot-melt extrusion (HME). Approvals increased steadily throughout the 12-year period, spanning antiviral agents, antineoplastics, immunosuppressants and metabolic disease treatments, a breadth of therapeutic applications that reflects spray-drying's versatility across diverse chemistries and clinical contexts.

These commercial trends align closely with broader industry observations reported by Swm *et al*, who noted that approximately 70% to 90% of new chemical entities exhibit poor aqueous solubility,[3] with ASDs emerging as one of the most widely adopted enabling technologies to overcome this challenge. As increasingly complex molecules enter development, formulation strategies capable of enhancing solubility and bioavailability have become critical to advancing compounds that might otherwise fail.

61% of the approved amorphous drugs in this dataset had at least one physicochemical property outside the traditional Lipinski Rule of Five parameters, with molecular weight as the most frequently violated. This finding reinforces the trend observed by Swm *et al*: the industry's pipeline is increasingly populated by larger, more lipophilic and more structurally complex molecules. These are precisely the types of compound for which spray-drying often delivers the greatest value, underscoring its role as a strategic platform technology for modern drug development, rather than simply a niche formulation approach.

THE SCIENCE THAT DELIVERS COMMERCIAL RELIABILITY

The commercial reliability of spray-drying begins with its ability to engineer particle properties by design rather than by trial and error. By controlling process parameters such as inlet temperature, feed concentration and atomisation conditions, manufacturers can reproducibly tune the size, density and surface characteristics of the dried particles. The result is a technology that can produce fine, high-surface-area particles optimised for rapid dissolution in one programme, and denser, more slowly dissolving particles suited to controlled release in another. This morphological precision is not incidental to spray-drying's commercial performance; it is the mechanism through which bioavailability targets, stability profiles and downstream processability requirements can be engineered into the product from the outset.

"A MATURE SPRAY-DRYING PLATFORM COMMANDS THE FULL RANGE OF THESE CAPABILITIES AND CAN MATCH THE TECHNOLOGY TO THE MOLECULE, RATHER THAN FITTING THE MOLECULE TO AVAILABLE EQUIPMENT."

Achieving this level of control on an industrial scale requires the right tools. Leading CDMOs deploy modelling tools to predict drying kinetics, skin-formation behaviour and final particle morphology from milligram quantities of material, avoiding the costly consumption of expensive API during scale-up optimisation. The choice of atomisation technology matters equally: two-fluid nozzles for formulation versatility, rotary atomisers and pressure nozzles for high-throughput commercial production, and emerging vibrating mesh and ultrasonic systems for submicron particles and thermally sensitive biologics. A mature spray-drying platform commands the full range of these capabilities and can match the technology to the molecule, rather than fitting the molecule to available equipment.

A PLATFORM FOR THE FULL MODERN PIPELINE

The argument in favour of spray-drying becomes more compelling still when considered at the portfolio level rather than the molecule level. Spray-drying is not a single-application technology – it is a platform whose capabilities address the defining manufacturing challenges of the modern pharmaceutical pipeline across multiple modalities.

For poorly soluble small molecules, the ASD application is well-established and commercially validated, as previously discussed. With 70–90% of development candidates exhibiting poor solubility, this application alone justifies platform-level investment.

For mRNA therapeutics and lipid nanoparticles, spray-drying offers a pathway to cold-chain elimination. Current mRNA-based therapeutics typically require ultra-cold storage at temperatures as low as -90°C to -60°C to maintain liquid-state stability. Converting these formulations into spray-dried powders can facilitate room-temperature stability, removing the

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"THIS APPROACH COMBINES THE AERODYNAMIC PERFORMANCE REQUIRED FOR DEEP LUNG PENETRATION WITH THE BIOLOGICAL ACTIVITY OF NANOSCALE CARRIERS – A DELIVERY ARCHITECTURE SPECIFICALLY ENABLED BY THE PRECISE PARTICLE ENGINEERING OF SPRAY-DRYING."

logistics bottlenecks and access barriers that have constrained global distribution of cold-chain-dependent vaccines and therapeutics. For organisations with biological pipelines alongside small-molecule assets, spray-drying infrastructure serves both.

For pulmonary drug delivery, CDMOs are increasingly applying a "nano-into-micro" engineering strategy: nanoparticles, which are too small to deposit effectively in the deep lung and are typically exhaled, are embedded within a 1–5 µm microparticle matrix by spray-drying. In the moist environment of the alveoli, the matrix dissolves, releasing the bioactive nanoparticles in their functional state. This approach combines the aerodynamic performance required for deep lung penetration with the biological activity of nanoscale carriers – a delivery architecture specifically enabled by the precise particle engineering of spray-drying.

WHY SPRAY-DRYING LEADS THE TECHNOLOGY SELECTION

For development scientists and chemistry, manufacturing and controls leaders choosing between spray-drying and its primary manufacturing alternative, HME, the evidence across multiple dimensions favours spray-drying as the default option for the broadest range of applications.

Chemical Space

Because the spray-drying process dissolves the API in a volatile organic solvent before processing, it accommodates compounds across a wide range of physicochemical properties, including heat-sensitive molecules, high-melting-point APIs and those with complex polymorphic behaviour. HME, a solvent-free thermal process, is constrained to APIs with adequate thermal stability under extrusion conditions, thereby excluding a meaningful share of the modern development pipeline.

Particle Size and Dissolution Performance

A head-to-head comparison of posaconazole ASDs found that spray-dried dispersions achieved a median particle size (D50) of 22 µm, compared with 157 µm for the equivalent HME product, a seven-fold difference that drives meaningfully faster dissolution and greater gastrointestinal exposure in biorelevant testing.[4]

Physical Stability

A comparative stability study found that, after 60 days under stress conditions, spray-dried formulations demonstrated greater physical stability than equivalent HME products.[5] Both APIs in the study were fully converted to amorphous forms by spray-drying, whereas one remained partially crystalline under HME – a difference with direct implications for product performance and regulatory characterisation. Given the importance of maintaining the amorphous state throughout development and commercialisation, physical stability remains a key consideration for ASDs and should be assessed using appropriate analytical methods capable of detecting early signs of phase separation or recrystallisation.[6]

Early Development Efficiency

Spray-drying accommodates gram-scale API quantities during formulation screening, enabling systematic polymer selection and stability evaluation without depleting constrained early-stage API supplies. Scale-up, when governed by appropriate dimensionless parameters, preserves the formulation performance established at laboratory scale.

A FRAMEWORK FOR COMMERCIAL DECISION-MAKING

Define the Build-Versus-Partner Strategy

Internal capability delivers cost-of-goods-sold advantages on a commercial scale but requires substantial upfront capital and sustained technical investment. CDMO partnerships provide speed, flexibility and access to state-of-the-art equipment without needing to commit significant capital, but require rigorous partner selection. When evaluating CDMOs, move beyond equipment lists to assess scaling logic – specifically, whether the organisation uses dimensionless engineering parameters (Reynolds, Stokes and Euler numbers) to ensure that lab-scale formulation performance is preserved at commercial throughput, alongside quality by design maturity, risk management based on failure mode and effects analysis, and high-potency containment capability.

Invest in Formulation Science First

Polymer selection is the single most consequential decision in ASD development. Hydroxypropylmethylcellulose acetate succinate and copovidone account for nearly 80% of all polymer selections in FDA-approved ASD products,[2] a concentration that reflects accumulated evidence about their stabilisation performance across diverse chemical spaces. Systematic polymer screening, supported by characterisation, establishes the physical stability foundation upon which commercial product reliability depends. Compressing this investment in the name of development speed is the most reliable path to late-stage failure.

Design the Downstream Process in Parallel

The spray-dried intermediate is not the finished product. Granulation strategy, compression performance, film-coating compatibility and packaging requirements must be designed alongside the spray-drying process, not after it. Integrated formulation-to-finished-dosage-form development planning is the standard that distinguishes programmes that reach commercial launch on schedule from those that encounter late-stage manufacturing surprises.

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Cost Efficiency and Operational Flexibility at Commercial Scale

Beyond its scientific and regulatory validation, spray-drying delivers a set of economic and operational advantages that reinforce its position as a platform technology. These advantages are not secondary considerations; they are central to why spray-drying is increasingly embedded early in development strategy rather than deployed as a reactive approach.

From a cost perspective, spray-drying reduces overall development and manufacturing expenditure through process efficiency. It is an inherently continuous operation, enabling high throughput with lower labour intensity than batch-based alternatives. More importantly, it consolidates multiple unit operations, such as solvent evaporation, particle formation and drying, into a single step. This integration eliminates intermediate handling, reduces material loss and shortens processing timelines, all of which contribute directly to a lower cost of goods.

Material efficiency is particularly critical in early- and mid-stage development, where API availability is constrained and expensive. The ability of spray-drying to operate effectively at a small scale, while preserving a clear pathway to commercial scale, minimises API consumption during formulation screening and process optimisation. This reduces both direct material costs and the opportunity cost associated with limited supply.

Energy use further contributes to cost performance. While spray-drying is often perceived as energy-intensive, modern systems incorporating heat recovery, optimised airflow design and closed-loop solvent handling can significantly reduce the energy consumption per unit output.

> "A SINGLE SPRAY-DRYING PLATFORM CAN ACCOMMODATE A WIDE RANGE OF FORMULATIONS, INCLUDING SOLUTIONS, SUSPENSIONS AND EMULSIONS, ACROSS SMALL MOLECULES, BIOLOGICS AND ADVANCED DELIVERY SYSTEMS."

In solvent-based ASD manufacturing, solvent recovery systems can also mitigate raw material costs and support regulatory compliance, aligning economic and environmental objectives.

Flexibility is another major commercial advantage of spray-drying. A single spray-drying platform can accommodate a wide range of formulations, including solutions, suspensions and emulsions, across small molecules, biologics and advanced delivery systems. Process parameters can be rapidly adjusted to meet different product specifications, enabling the same equipment train to support multiple programmes without extensive reconfiguration.

This flexibility extends to commercial-scale production and lifecycle management. Spray-drying systems can be deployed from gram-scale development through pilot and commercial manufacturing using consistent engineering principles, reducing scale-up risk and avoiding the need for process reinvention. For organisations managing diverse pipelines, this creates a unified manufacturing approach that simplifies technology transfer, workforce training and facility design.

From a portfolio perspective, these characteristics translate into strategic optionality. Development teams can progress multiple API candidates through a common platform, reprioritise assets without incurring significant switching costs and respond more rapidly to clinical or market signals. In an environment where pipeline agility is increasingly a competitive differentiator, this operational flexibility is as valuable as the underlying science.

Taken together, the cost efficiency and adaptability of spray-drying do not merely support its technical strengths but amplify them. The result is a technology that improves not only the probability of technical success but also the economic viability and speed of bringing new therapies to market.

> "WHAT REMAINS IS AN ORGANISATIONAL QUESTION: WHETHER PHARMACEUTICAL LEADERS TREAT SPRAY-DRYING AS A REACTIVE PROBLEM-SOLVING CAPABILITY DEPLOYED WHEN FORMULATIONS FAIL, OR AS A PROACTIVE PLATFORM EMBEDDED IN DEVELOPMENT STRATEGY FROM THE MOMENT A CANDIDATE ENTERS THE PIPELINE."

SUMMARY

The modern pharmaceutical pipeline has, by its composition, created the conditions for the emergence of spray-drying as a platform technology. Up to 90% of new molecular entities having solubility limitations, a biologics landscape demanding cold-chain-free formulations and a growing category of inhaled and sterile biologic products have collectively elevated spray-drying from a specialist tool to a commercial necessity.

The abundance and variety of peer-reviewed evidence has settled the scientific question. The FDA's approval record has settled the regulatory question. The CDMO sector's capital commitments have settled the infrastructure question. What remains is an organisational question: whether pharmaceutical leaders treat spray-drying as a reactive problem-solving capability deployed when formulations fail, or as a proactive platform embedded in development strategy from the moment a candidate enters the pipeline.

The organisations that answer that question correctly, by building or partnering for robust spray-drying capability now, will move faster, waste less and put more molecules in front of patients. That is the commercial case. It is

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straightforward, it is evidence-based and the window for competitive advantage from early commitment is narrowing.

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ACHIEVING CLINICAL READINESS FOR INHALED DRUG PRODUCTS

Jonathan Mulpas of **Aptar Pharma** and **Dr William Ganley** of **Nanopharm UK** present an integrated framework for preparing inhaled drug products for clinical evaluation. They focus on the decisions that should be addressed prior to clinical studies, the avoidable detours that can delay development and the role of formulation science, device optimisation and predictive testing in building confidence in inhaled products before they enter the clinic.

Developing an inhaled drug product for clinical evaluation requires more than a promising formulation, a capable device or a promising set of performance data. While the objective may appear straightforward, advancing a therapy from concept to clinical studies is a path shaped by multiple interdependent decisions. Clinical readiness emerges when formulation, device, patient-use, analytical and regulatory considerations are aligned around a clear product objective – it is rarely a linear process.

This complexity is increasing as inhaled therapies move beyond established respiratory small-molecule treatments towards more sophisticated formulations, biologics, advanced drug classes and increasingly demanding product profiles. Simultaneously, developers are expected to make early decisions with limited material, evolving clinical assumptions and compressed development timelines.

Promising laboratory results can create a false sense of security during inhalation development. A formulation may be stable, a device may deliver the required dose and early aerosol data may appear encouraging, yet significant development risks can remain.

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In many cases, the challenge is not whether the individual components work, but whether they work together under conditions that reflect the intended patient population, clinical use scenario and regulatory pathway. Clinical readiness begins to emerge only when formulation, device and evidence-generation strategies are aligned around a common product objective (Box 1).

DEFINING SUCCESS BEFORE DEVELOPMENT BEGINS

Before developers decide how a product should be formulated or delivered, they need to define what success actually looks like. Who will use the product? What dose must reach the target site? Under what conditions will administration take place? What level of variability can the programme realistically accommodate? The target product profile (TPP) brings these questions together, translating a clinical ambition into practical development requirements and providing a common point of reference for formulation, device and evidence-generation activities.

For inhaled therapies, the TPP should clarify the intended patient population, route of administration, dosing objectives, target deposition region, administration context and usability expectations. It should also identify the product performance attributes that matter most for the intended clinical outcome, such as aerosol characteristics, inhalation-flow dependency, device handling and the evidence needed to support progression.

Many development programmes begin with technical feasibility questions. Can the molecule be formulated? Can the formulation be aerosolised? Can the device deliver the intended dose? Can the product meet early analytical expectations? While these questions are necessary, they should be guided by a broader understanding of what the final product must achieve.

Without that framework, teams may optimise attributes that are scientifically interesting but not decisive for clinical success. A formulation can perform well under controlled conditions during bench tests yet fail to support the intended use case if it is incompatible with the device, patient population or deposition objective.

BOX 1: COMMON DEVELOPMENT DETOURS THAT DELAY CLINICAL ENTRY

Detour One: Optimising the formulation before defining the TPP. A formulation can appear technically promising but still fails to support the intended patient, dose or deposition objective.

Detour Two: Selecting the device too late. Late device selection can reveal compatibility, performance or usability issues that require reformulation, device modification or additional testing.

Detour Three: Treating patient use as a late-stage question. Inspiratory capability, inhalation profile, co-ordination, training needs and use environment can all influence whether the product performs as intended.

Detour Four: Generating data without a clear decision objective. More data does not necessarily reduce risk. Evidence is most valuable when it informs a defined development decision.

Detour Five: Treating development functions independently. Formulation, device, patient-use, testing and regulatory activities need early alignment to avoid late-stage gaps or conflicting assumptions.

Key Message: The greatest development risks often emerge at the interfaces between disciplines.

Likewise, a technically capable device may be unsuitable if it imposes handling or inhalation requirements that do not match the treatment setting or needs of an intended patient group.

A well-defined TPP can help teams to avoid these disconnects and prioritise development activities. Not every parameter can be optimised at once and not every uncertainty carries the same level of risk. The TPP helps to determine which questions need to be answered first. It should also evolve as formulation, device, analytical and predictive insights become available, rather than being fixed in isolation and handed off to technical teams.

Often, clinical readiness is improved not by making better decisions later, but by asking better questions earlier. A strong TPP focuses development on the attributes that are most likely to have an impact on clinical performance, patient use and regulatory expectations. As illustrated in Figure 1, formulation development, device optimisation and evidence generation need to align around a shared TPP and the needs of the intended patient population.

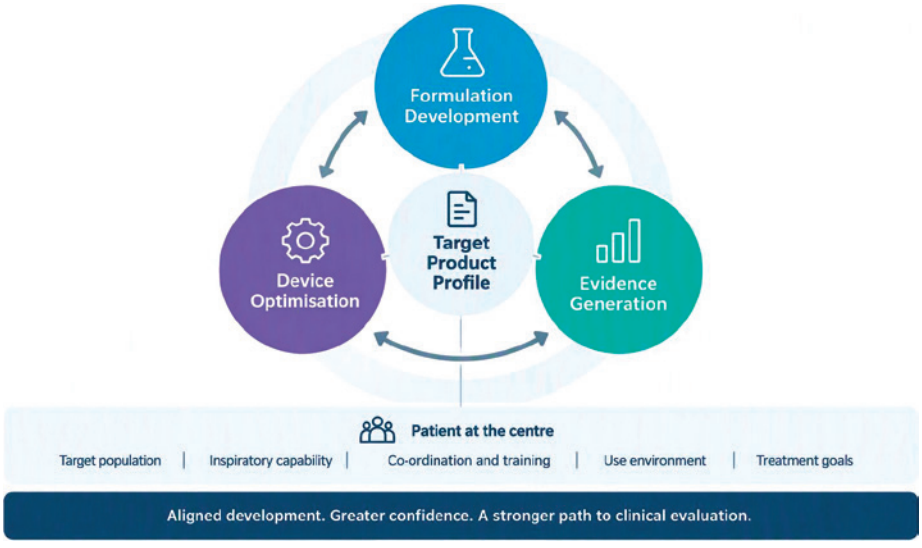


Figure 1: Clinical readiness emerges from the alignment of formulation development, device optimisation and evidence generation around a clearly defined TPP and the needs of the intended patient population.

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FORMULATION DEVELOPMENT AS THE FOUNDATION OF CLINICAL READINESS

A formulation can meet every laboratory target and still be wrong for the product. Stability, manufacturability and aerosol performance are all essential, but they do not guarantee successful delivery in the intended clinical setting. For inhaled products, relatively small changes in concentration, particle properties, viscosity or excipients can alter aerosol generation, emitted dose and deposition behaviour. Formulation development therefore needs to optimise more than the formulation itself. It must optimise how the formulation performs within the complete delivery system.

Formulation-related considerations may include solubility, excipient compatibility, rheological properties, concentration, powder characteristics, stability, material compatibility, aerodynamic particle size, delivered dose uniformity and interactions with the respiratory or nasal environment. These parameters cannot be considered separately from the wider product strategy.

In early development, formulation work often focuses on establishing feasibility. However, feasibility alone is not the endpoint; a formulation that performs well in isolation may not be optimal as part of the final drug-device combination.

For example, a formulation intended for nebulisation may need to balance drug concentration, viscosity, aerosol output, administration time and patient acceptability. A dry powder formulation may require careful attention to particle engineering, flow properties, moisture sensitivity and device resistance. A nasal or pulmonary liquid may need to account for spray pattern, droplet size and interactions with mucosal surfaces.

The risk in many programmes is that formulation and device work proceed as separate streams – the formulation team may focus on stability and laboratory performance while device selection is deferred. Difficulties can then emerge if the formulation proves incompatible with the delivery mechanics, dose requirements or patient-use assumptions of the chosen device.

A more effective approach is to view the formulation as part of an integrated product system from the beginning. This does not mean that every variable must be fixed early, rather, it means that formulation decisions should be made with an understanding of how they may influence device selection, analytical testing, manufacturability and clinical performance expectations.

A technically successful formulation is not automatically a clinically successful formulation. To achieve clinical readiness, it must support the intended clinical objective, perform within the delivery system and remain compatible with future development and manufacturing requirements.

DEVICE SELECTION SHOULD NOT BE AN AFTERTHOUGHT

For inhaled drug products, the delivery device is not a passive container – it is an active contributor to product performance and patient experience. Device characteristics can influence delivered dose, aerosol generation, inhalation-flow requirements, administration time, dose reproducibility, patient feedback and usability.

Despite this, device selection is sometimes treated as a downstream activity that follows formulation development. If the device does not align with the formulation, target dose, patient population or deposition objective, the development programme may require late reformulation, device modification or additional testing cycles.

Device strategy should therefore begin early, even if the final configuration is not yet fixed. Early consideration of the device helps to define the feasible design space for the formulation and exposes performance trade-offs that may shape the product concept. These can include dose delivery versus administration time, aerosol output versus deposition control and device functionality versus ease of use.

The device is also the interface between the product and the patient. Technical performance alone is not sufficient. Patient inspiratory capacity, co-ordination, disease severity, training requirements, treatment settings and the circumstances in which the product will be used can all influence which delivery approach is most appropriate. Studies evaluating realistic inhalation profiles have shown that inhalation behaviour can vary considerably across users and can be influenced by factors such as device resistance and training, highlighting the importance of considering patient-use conditions during development and performance testing.[1]

Increasingly, developers are moving beyond standardised breathing patterns and incorporating patient-relevant inhalation profiles into both experimental and modelling activities. Realistic breathing profiles can be generated from measured user data and may differ substantially from simplified sinusoidal or fixed flow rate testing conditions. Parameters such as peak inspiratory flow, time to peak, inhaled volume, inhalation duration and the effects of user training can all influence aerosol delivery and regional deposition. In practice, these profiles allow developers to characterise how patients actually inhale, rather than how they are expected to inhale, improving the relevance of both *in vitro* and *in silico* assessments while also helping to identify potential performance risks earlier.[1,2]

Human factors considerations can also be incorporated much earlier in development than has traditionally been the case.[3] Rather than evaluating patient behaviour only during later-stage usability studies, developers can investigate variables such as inspiratory-flow capability, inhalation duration, co-ordination requirements and the impact of training or feedback mechanisms on administration technique. Where guidance or feedback technologies are incorporated, breathing-profile data can help to determine whether

"FOR INHALED DRUG PRODUCTS, THE DELIVERY DEVICE IS NOT A PASSIVE CONTAINER – IT IS AN ACTIVE CONTRIBUTOR TO PRODUCT PERFORMANCE AND PATIENT EXPERIENCE."

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"AS INHALED PRODUCTS BECOME MORE SOPHISTICATED, DEVELOPMENT DECISIONS INCREASINGLY BENEFIT FROM THE INTEGRATION OF DEVICE EXPERTISE, FORMULATION SCIENCE AND PREDICTIVE ASSESSMENT."

users are able to achieve and maintain the intended inhalation pattern and whether variability is reduced relative to unguided use. These assessments provide an additional layer of evidence linking product design, patient behaviour and expected delivery performance. Their greatest value emerges when they are considered alongside formulation, device and predictive development activities rather than as separate workstreams.[2]

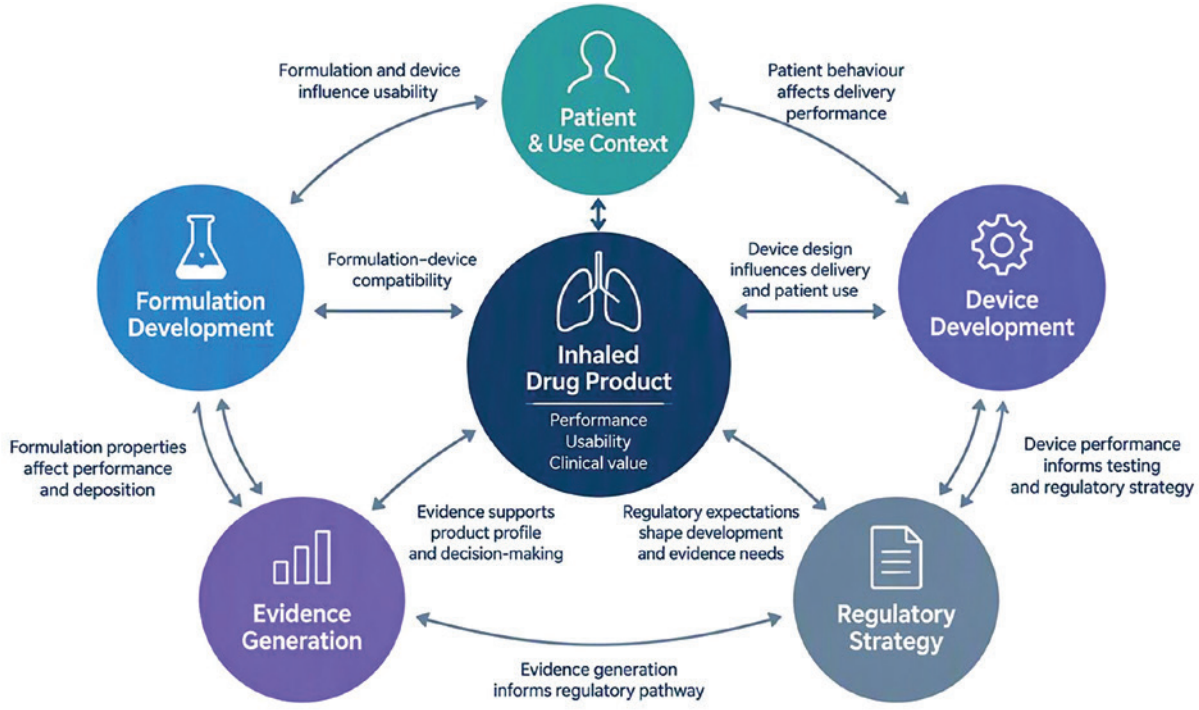
As inhaled products become more sophisticated, development decisions increasingly benefit from the integration of device expertise, formulation science and predictive assessments. Through the combination of Aptar Pharma's drug delivery device experience and Nanopharm's modelling and development capabilities, developers can investigate how formulation, device and patient-related factors interact before clinical studies are initiated. Bringing these capabilities together allows performance risks to be investigated earlier, while formulation and device choices can still be adapted, and can help to establish a more coherent evidence base before progression into clinical evaluation.

The critical question is not whether the formulation works or whether the device works; it is whether the formulation and device function effectively together in the context of the intended patient, dose, deposition objective and clinical use. Figure 2 summarises these interdependencies, showing how patient context, regulatory expectations, formulation, device, aerosol performance and supporting evidence contribute to the product objective.

USING *IN VITRO* AND *IN SILICO* TOOLS TO SUPPORT BETTER DECISIONS

Integration of *in silico* tools is increasingly important in inhaled drug product development because performance is influenced by interconnected factors, including formulation properties, device behaviour, aerosol characteristics, patient inhalation profiles and airway physiology. *In vitro* methods can characterise delivered dose, delivery rate, droplet or particle size distribution, spray characteristics and device reproducibility under standardised and realistic test conditions. *In silico* tools can then help to interpret these findings in relation to deposition, physiology or exposure.

Inhaled product performance cannot be understood by measuring a single parameter. Delivered dose, particle or droplet size and aerosol output are



A holistic, iterative approach helps to identify and manage risks early, enabling more confident progression to clinical evaluation.

Figure 2: Interdependencies in inhalation product development. The product objective is shaped by patient context, regulatory expectations, formulation, device, aerosol performance and *in vitro* and *in silico* evidence.

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essential data points, but they do not describe the complete product system. Developers also must understand how performance may change under patient-relevant conditions and how measured attributes may translate into regional deposition or exposure expectations.

Predictive approaches can help to bridge the gap between experimental observations and expected product behaviour by integrating formulation, device, physiological and deposition-related inputs. Physiologically based pharmacokinetic (PBPK) modelling, regional deposition modelling, patient-relevant breathing profiles and realistic *in vitro* testing can all contribute to a richer understanding of product performance.

Recent advances in data-driven regional deposition methodologies have also enabled more rapid assessment of aerosol behaviour while retaining patient-specific physiological considerations, helping developers to explore how changes in formulation, device performance and inhalation conditions may influence deposition patterns throughout the respiratory tract for healthy volunteers and multiple patient groups.[4]

PBPK modelling, regional-deposition modelling, patient-relevant breathing profiles and realistic *in vitro* testing can all contribute to a richer understanding of product performance. By combining these complementary approaches, developers can move beyond isolated performance measurements and begin to explore how formulation and device characteristics may ultimately influence regional deposition, local exposure and systemic PK behaviour.[5]

Such integrated methodologies can help to compare development options, investigate variability and identify critical product attributes before clinical evaluation. Through Nanopharm's combination of advanced *in vitro* characterisation, deposition modelling and PBPK capabilities, developers can evaluate product performance from multiple perspectives simultaneously rather than relying on individual datasets in isolation. This integrated approach can support earlier risk identification, more informed development decisions and greater confidence when progressing towards clinical evaluation. Importantly, its role is not to replace clinical evidence but to strengthen the rationale for the decisions that precede it.

LINKING PRODUCT PERFORMANCE TO PHARMACOKINETIC OUTCOMES

One of the persistent challenges in inhalation development is understanding how measured product performance translates into PK exposure. Aerosol characterisation metrics, such as aerodynamic particle size distribution, spray characteristics and delivered dose, inform regional deposition estimates and provide essential information about the product, but they do not always offer a complete mechanistic explanation for the systemic PK observed in a clinical study.

PBPK modelling provides a framework to connect these different layers of evidence. By integrating regional lung deposition data with human physiology and drug-specific parameters, a PBPK model can be used to investigate how formulation, device and patient-related factors may influence systemic plasma concentrations. This can be particularly useful when comparing development options, examining potential sources of variability or interpreting PK findings that cannot be fully explained from *in vitro* aerosol measurements alone.

At Nanopharm, Simhalation™ provides an inhalation- and nasal-specific PBPK framework that can interface with *in vitro* and *in silico* inputs. The platform is designed to accommodate physiological, product and molecule-specific information, allowing the model to be tailored to the question being investigated. In this context, the technical reason for naming Simhalation is clear: it provides the mechanistic bridge between product performance, regional deposition and expected PK behaviour, rather than functioning as a stand-alone simulation tool.

Example Application: Connecting Deposition to Exposure

One practical application of integrated modelling is understanding whether observed differences in aerosol performance are likely to translate into meaningful differences in PK exposure. In many development programmes, aerosol characterisation data and regional deposition estimates may already be available, yet the relationship between these measurements and the expected systemic PK profile remains unclear.

By combining regional deposition modelling with PBPK simulations, developers can investigate how formulation characteristics, device performance and patient-related variables influence local and systemic exposure. Rather than evaluating aerosol performance and PK independently, both datasets can be interpreted within a common mechanistic framework. The impact of *in vitro* product performance characteristics can then be interpreted in a physiologically meaningful way. This approach also allows for inverse design of inhaled products where, starting from the ideal experience for the patient, designers work backwards to the ideal *in vitro* characteristics and form a TPP or a product development safe space.

Simhalation allows developers to explore how changes in deposition patterns, formulation attributes or inhalation conditions may influence expected PK behaviour, while identifying the assumptions that contribute most strongly to variability in modelled outputs. In practice, this type of analysis can help to support prioritisation of development options, guide the design of subsequent experimental studies or determine whether observed differences in aerosol performance are likely to have a meaningful impact on systemic exposure.

The value of this type of modelling is not that it predicts clinical outcomes with certainty or replaces experimental and clinical evidence. Instead, it provides a structured way to test assumptions, explore scenarios and identify the parameters that are most likely to affect the observed PK profile. The reliability and regulatory relevance of the analysis depend on its intended context of use, the quality of the supporting data, the transparency of the model assumptions and appropriate evaluation of predictive performance.[6,7] Used appropriately, the analysis can show where uncertainty remains, what it could mean for product performance and which questions should be investigated prior to clinical evaluation (Box 2).

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BOX 2: WHAT *IN VITRO* AND *IN SILICO* TOOLS CAN, AND CANNOT, TELL US

- **They Can:** Characterise aerosol and device performance under relevant test conditions, compare formulation-device options, examine the influence of realistic breathing profiles, estimate regional deposition, explore how deposition may influence local or systemic exposure, investigate variability and identify questions that require further experimental study.
- **They Cannot:** Entirely replace clinical evidence, eliminate uncertainty, guarantee clinical success, predict every individual patient outcome, compensate for a poorly defined product strategy or make a model credible without appropriate data, assumptions and evaluation.
- **Key Message:** The purpose of predictive tools is not certainty. Their value lies in making uncertainty more visible, interpretable and useful for development decisions.

BUILDING AN INTEGRATED PATH TO CLINICAL READINESS

Many delays in inhaled product development do not arise from a single scientific failure – they result from disconnected decisions, late integration or data generation that is not tied to a clear development question.

Treating formulation, device and testing as independent workstreams may appear efficient because each team can progress in parallel. However, the most important product risks often emerge at the interfaces between disciplines. A formulation may be stable but difficult to deliver. A device may be technically capable but inappropriate for the intended patient population. A robust test may still be of limited value if it does not inform the next decision.

More information does not necessarily reduce risk. Relevant information reduces risk. A focused experiment that answers a critical development question may be more useful than a broad set of studies that do not change the decision pathway.

The same principle applies to patient-use considerations. Inhalation flow, co-ordination, training, handling, adherence and treatment context can all influence product performance. If these factors are introduced only after the product concept has matured, a technically promising programme may require avoidable rework.

Clinical readiness is the cumulative result of decisions made across the development pathway. An integrated approach begins with the TPP and connects formulation development, device strategy, *in vitro* characterisation, predictive assessment, patient-use understanding and regulatory planning in an iterative workflow.

Early predictive insights may inform the target deposition strategy. That strategy may shape formulation requirements. Formulation behaviour may influence device selection or tuning. *In vitro* testing may reveal variability that prompts further formulation optimisation, device adjustment or patient-use evaluation. Regulatory considerations may define the evidence needed to justify progression. As shown in Figure 3, this changes development from a sequence of functional hand-offs into continuous decision-making around a shared product objective.

Rather than completing one activity and handing the output to the next team, formulation scientists, device specialists, analytical experts, modellers, human factors teams and regulatory advisers work from a shared understanding of the product objective and the uncertainties that matter most. New evidence can then refine the programme while design choices remain adaptable.

The goal is not to remove every source of uncertainty before clinical evaluation. That is rarely achievable. The goal is to identify the uncertainties that matter, understand their potential impact and generate enough decision-relevant evidence to proceed responsibly.

INTEGRATING REGULATORY THINKING THROUGHOUT DEVELOPMENT

Regulatory planning should not be treated as a final checkpoint after technical development is complete. It should be integrated from the beginning, especially for inhaled drug-device combination products where formulation, device, usability, quality and performance evidence may all influence the development path.

Early regulatory thinking helps teams to understand what evidence will be needed, how test methods should be justified and how product performance should be characterised. It can also help to avoid generating evidence that is scientifically interesting but misaligned with development or submission needs.

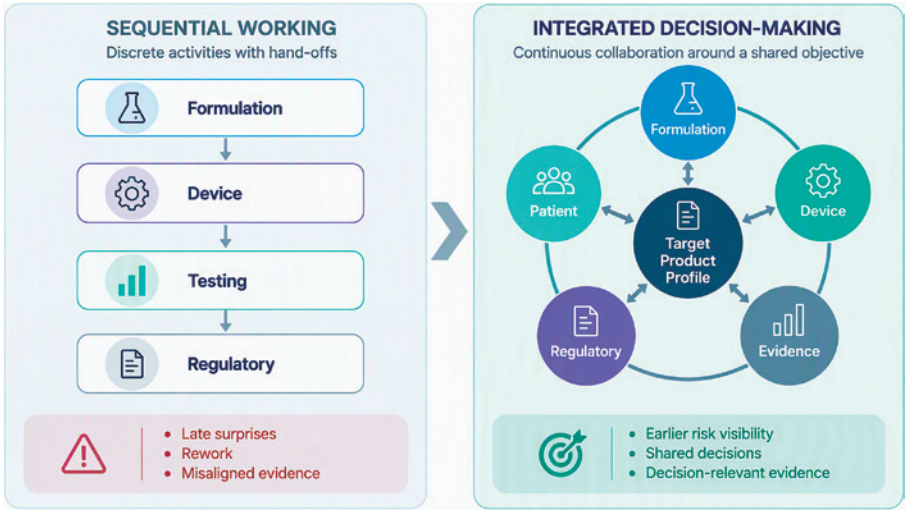


Figure 3: Moving from sequential working to integrated decision-making enables formulation, device, patient, evidence and regulatory considerations to be evaluated continuously around a shared TPP.

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For inhaled products, regulatory readiness may involve analytical method development, dose delivery assessment, aerosol performance characterisation, design verification, extractables and leachables, biological evaluation, risk assessment, human factors and documentation strategy. Integrated *in vitro* and *in silico* evidence prove that useful product development data can justify decisions post-submission and avoid costly additional testing. These activities are not simply administrative tasks at the end of development – they shape the evidence package required to justify progression and support interactions with regulators.

An integrated regulatory strategy also clarifies the role of each development activity. A method, model, usability study or design-verification activity should support a defined question, decision or evidence requirement. This is particularly important when several partners or specialist teams are involved, as misalignment may lead to duplicated work, inconsistent assumptions or late-stage gaps.

The strongest regulatory strategies are built progressively. They do not wait until the end of development to ask whether the evidence package is adequate. From the beginning, they ask "What decision, claim or development step must this evidence support next?"

BOX 3: WHAT DOES CLINICAL READINESS REALLY MEAN?

- **Clinical Readiness Is Not:** Complete certainty, finished development, perfect product understanding, absence of all risk or a single final checkpoint.
- **Clinical Readiness Is:** Understanding the risks that matter most, knowing which uncertainties remain, having evidence to support the next decision, aligning formulation, device, patient-use, testing and regulatory strategy, and entering clinical evaluation with a clear rationale.
- **Key Message:** Clinical readiness is built through connected decisions and a coherent understanding of the product, its remaining risks and the rationale for moving forwards.

CONCLUSION

Preparing an inhaled drug product for clinical evaluation requires more than a promising formulation, a capable delivery device or a set of performance data. It requires the alignment of multiple development dimensions into a coherent strategy.

The most successful programmes are not those that optimise each component independently – they are designed to recognise early that formulation, device, patient use, testing and regulatory requirements are interconnected. A decision made in one area can create constraints or opportunities in another, and clinical readiness depends on understanding those interactions before they become late-stage barriers.

By starting with a clear TPP, integrating formulation and device considerations early, using *in vitro* and *in silico* tools to support decision-making and embedding regulatory thinking throughout development, teams can build a stronger foundation for clinical evaluation.



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No development strategy can remove every uncertainty before an inhaled product enters the clinic, nor should that be the objective. The more important task is determining which uncertainties can be accepted and which could compromise dose delivery, patient use, clinical interpretation or regulatory progression (Box 3).

This is why clinical readiness cannot be created through a final round of testing. It is built through the decisions made throughout development: how the product objective is defined, when the device is introduced, which performance questions are explored and how evidence is used to refine the pathway forwards. When these decisions are connected, teams start clinical evaluation with more than a collection of completed activities – they enter with a coherent understanding of the product, its remaining risks and the rationale for moving forwards.

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Expert View

CHOOSING THE RIGHT PROPELLANT IS ONLY THE FIRST STEP TOWARDS LOW-GWP pMDI SUCCESS

Darren Bromley-Davenport of Orbia Fluor & Energy Materials considers the pressures being placed on pressurised metered dose inhaler developers and manufacturers by tightening regulations regarding fluorinated gases and the transition to lower global warming potential propellants, and lays out how those that invest in partnerships with industry experts are set to de-risk their development programmes and decrease their time to market.

"THE MANUFACTURERS REACHING THE MARKET FIRST ARE LIKELY TO HAVE ALREADY COMBINED TECHNICAL EXPERTISE, SPECIALIST TESTING CAPABILITIES, MANUFACTURING INFRASTRUCTURE AND REGULATORY SUPPORT INTO A SEAMLESS DEVELOPMENT PATHWAY."

As EU medical quotas under fluorinated gas (F-gas) regulations continue to phase down towards 2030, the strain on pressurised metered dose inhaler (pMDI) manufacturers has never been greater. Across the industry, development programmes focused on transitioning to lower global warming potential (GWP) propellants are accelerating. However, while significant attention has been placed on identifying an alternative propellant, the reality is that successful transition programmes will depend on much more than propellant selection alone.

The manufacturers reaching the market first are likely to have already combined technical expertise, specialist testing capabilities, manufacturing infrastructure and regulatory support into a seamless development pathway. As regulatory deadlines approach and more manufacturers move rapidly towards low-GWP submissions, the industry's biggest challenge is how quickly and efficiently that transition can be achieved.

PREVIOUS PROPELLANT TRANSITIONS

The industry has experienced a major propellant transition before. The move from chlorofluorocarbon (CFC) propellants to hydrofluoroalkane (HFA) alternatives was ultimately successful, but it was far from straightforward. Many manufacturers encountered unforeseen formulation challenges, longer-than-anticipated development timelines and supply constraints. Products often required extensive reformulation work, while seemingly minor changes in propellant behaviour had significant downstream implications for device performance, stability and manufacturability.

"DEVELOPMENT TEAMS MUST ASSESS NOT ONLY HOW THE PROPELLANT PERFORMS INDEPENDENTLY, BUT HOW IT INTERACTS WITH THE FORMULATION AS A WHOLE."

Today, low-GWP propellants offer promising pathways towards compliance with evolving environmental regulations. However, the physical and chemical properties of these alternatives differ from those of HFA-134a, a propellant currently used in pMDIs. As a result, developers cannot simply substitute one propellant for another and expect equivalent performance. Instead, every aspect of the product must be carefully evaluated to ensure that patients continue to receive the same therapeutic outcomes.

CRITICAL DEVELOPMENT CONSIDERATIONS

Successful low-GWP development begins with understanding how a new propellant behaves within the entire formulation system. A change in propellant can affect API compatibility, suspension behaviour, solubility, moisture sensitivity and long-term stability. These factors can introduce development risks that may not become apparent until later stages of testing. This is why formulation expertise is becoming increasingly important. Development teams must assess not only how the propellant performs independently, but how it interacts with the formulation as a whole.

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Compatibility testing is also essential. It provides confidence that products will continue to perform effectively throughout their entire lifecycle and helps to identify potential issues before they emerge in clinical studies or commercial manufacturing. This includes evaluating interactions between the propellant and elastomers, valves, canisters and other device materials.

Manufacturers must also demonstrate product equivalence following reformulation through evaluations such as single actuation content, aerodynamic particle size distribution (APSD) and realistic APSD testing, while also assessing the impact of any changes throughout the product's stability period. The organisations most likely to progress quickly are those capable of identifying and mitigating formulation risks early through industry partnerships. Investing in expertise and accuracy upfront can significantly reduce the likelihood of costly delays later in the development programme.

MANUFACTURING PARTNERSHIPS ARE ESSENTIAL FOR SUCCESS

Clinical manufacturing that follows GMP guidelines is a fundamental requirement for advancing low-GWP inhalers, yet development infrastructure across the market remains limited. Facilities that can accommodate formulation development, analytical testing, stability studies and clinical manufacturing are in high demand (Figure 1).

For many companies, building this capability internally is neither practical nor economical. Establishing specialist facilities requires substantial investment, highly trained personnel and significant lead times.

As a result, partnerships with organisations that already possess the necessary infrastructure are becoming a key component of the low-GWP propellant transition. Access to integrated facilities can enable developers to move more seamlessly from formulation development through testing and into clinical manufacturing. In the race to commercialisation, efficiency and continuity are major competitive advantages.



Figure 1: Five litre bulk suspension solution manufactured with HFA-152a in ATEX-rated equipment.

COMPLIANCE MUST BE PART OF THE DEVELOPMENT STRATEGY

The evolving F-gas landscape presents manufacturers with further considerations around quota allocation, security of supply and long-term commercial planning. As regulations tighten and available quotas become increasingly complex, manufacturers must ensure compliance strategies are developed alongside product development programmes.

Delaying these considerations can create unnecessary risk and uncertainty. However, working with organisations that can support quota management can help manufacturers to navigate an increasingly complex regulatory landscape. By building compliance into development plans from the outset, manufacturers can reduce regulatory hurdles and avoid delays to programme timelines.

BUILDING THE FASTEST PATH TO MARKET

As the 2030 deadline approaches, manufacturers are facing an increasingly limited window to bring new products to market, while navigating a complex range of technical, regulatory and commercial challenges. Companies that partner with industry specialists that can provide

"PARTNERSHIPS WITH ORGANISATIONS THAT ALREADY POSSESS THE NECESSARY INFRASTRUCTURE ARE BECOMING A KEY COMPONENT OF THE LOW-GWP PROPELLANT TRANSITION."

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support in critical areas, from formulation development to quota management, will be best placed to de-risk programmes, minimise delays, accelerate the path from concept to commercialisation and ensure continued supply of essential respiratory healthcare.

ABOUT THE COMPANY

Orbia's Fluor & Energy Materials (F&EM) business is a global developer, manufacturer and supplier of fluoroproducts used in a vast range of applications, including energy storage, infrastructure, indoor climate management, refrigeration and low-GWP propellants for pMDIs. Orbia F&EM has 1,700 employees and eight manufacturing facilities worldwide, serving 60 countries through a global sales and distribution network.



Darren Bromley-Davenport

Darren Bromley-Davenport, Technical Manager at Orbia Fluor & Energy Materials, has more than 30 years' experience in medical and pharmaceutical device markets, specialising in new product introduction, process development and regulatory compliance. He holds over 50 global patents and has developed and commercialised numerous products, including pioneering nanocoating technology designed to prevent drug adhesion in asthma inhaler canisters. In his current role, Mr Bromley-Davenport draws upon his extensive industry expertise to provide authoritative insights into the technical workings of respiratory propellants, their interactions with medicines and the implications for patient care.

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BEYOND PARTICLE COUNTS: CHARACTERISING FOREIGN PARTICULATES IN INHALED AND NASAL PRODUCTS

Dr Jabbar Gardy of Cormica discusses how to go beyond simple counting when investigating foreign particles in orally inhaled and nasal drug products using different analytical techniques and describes the advantages that performing a deeper characterisation of such particulates can confer.

FOREIGN PARTICLES: MORE THAN A COUNTING PROBLEM

Foreign particulate matter is not a new concern for developers of orally inhaled and nasal drug products (OINDPs) – it has been discussed within the pharmaceutical aerosol community for more than two decades, including work from the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) on testing, control and the clinical relevance of foreign particles in these products.[1,2] What has changed considerably is how much analytical science can now tell us about an individual particle.

In practice, finding a particle is often the straightforward part. The more difficult questions come afterwards. What is it? Where might it have come from? Is it associated with the formulation, manufacturing process, container closure system or delivery device? Is it part of the normal particulate background for that product, or is it telling us that something has changed? A particle count alone cannot answer those questions.

Foreign material can potentially originate from raw materials, device and packaging components or the manufacturing equipment and environment. A useful investigation therefore needs to move beyond showing that particles are present and towards understanding what those particles represent. Foreign particulate characterisation is increasingly an identification and investigation problem, rather than simply a counting exercise.

"FOREIGN PARTICULATE CHARACTERISATION IS INCREASINGLY AN IDENTIFICATION AND INVESTIGATION PROBLEM, RATHER THAN SIMPLY A COUNTING EXERCISE."

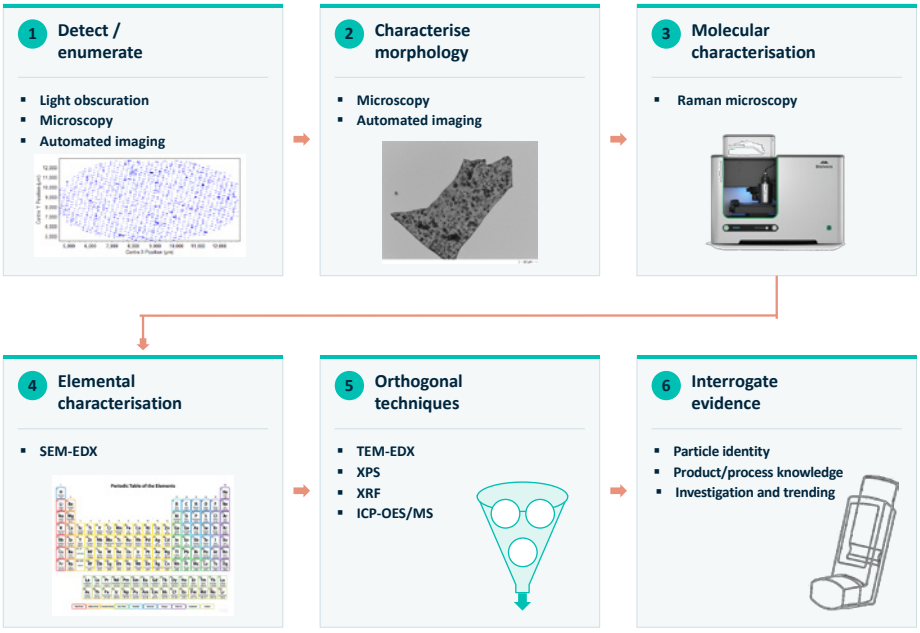


Figure 1: Orthogonal analytical approach to foreign particulate characterisation.

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COUNTING IS IMPORTANT, BUT IT IS ONLY THE BEGINNING

Particle counting remains fundamental. Light obscuration, microscopy and automated imaging can provide valuable information about particle number, size and morphology, depending on the product and the purpose of the investigation. Light obscuration, for example, has previously been investigated for quantitative determination of foreign particulate matter in pressurised metered dose inhalers (pMDIs).[3] This approach has its limitations, namely that particle number and size do not necessarily tell investigators what the particles are made from.

Two particles may have similar dimensions while being chemically quite different. One may be polymeric, another metallic and another formulation-derived. If an investigation stops at count and size, those differences can remain hidden. Earlier IPAC-RS work has recognised the need for developmental characterisation and appropriate quality-control strategies for foreign particles in OINDPs.[1,2] The principles remain relevant, but the analytical capability available to investigate individual particles has moved on considerably. Figure 1 summarises orthogonal progression from enumeration and morphology to molecular and elemental characterisation, with the analytical result interpreted alongside product and process knowledge.

A RISK-BASED REGULATORY PERSPECTIVE

The regulatory discussion around container closure systems provides useful context. In August 2026, the US FDA issued draft guidance on Container Closure Systems for Human Drugs and Biological Products.[4] It currently remains draft guidance, distributed for comment, and is not yet for implementation.

Nevertheless, the scientific thinking is relevant to OINDPs. The draft guidance describes a risk-based approach to establishing the suitability of container closure systems, including systems that are also device-constituent parts of combination products. In a pMDI, for example, the canister, metering valve and actuator form part of the system responsible for storing and delivering the medicine. When an unexpected particle is found, knowledge of those materials can therefore become highly relevant.

Identification of a polymer becomes more informative when it can be compared with known materials. Likewise, identification of metallic or other inorganic material may direct an investigation towards a different group of possible sources. Neither result proves the source, but both allow the investigation to become more focused.

WHY ORTHOGONAL CHARACTERISATION MATTERS

Expecting a single analytical technique to answer every question is rarely realistic. Different techniques elucidate different things. For example, morphologically directed Raman spectroscopy (MDRS) brings together automated particle imaging and Raman spectroscopy. Imaging provides information such as particle size and morphology, while Raman analysis provides molecular information for particles that produce a suitable spectrum.

Farias *et al* demonstrated its application in the characterisation of API particle-size distributions in mometasone furoate nasal suspension formulations,[5] and Kim *et al* have shown how morphological information and Raman identification can be combined for subvisible particle characterisation in therapeutic protein products.[6]

Raman spectroscopy, however, does not answer every question. Particle size, fluorescence, optical properties and the intrinsic Raman response of the material can all affect spectral quality. Some inorganic particles may provide little useful Raman information. A failed Raman identification should not therefore be treated as a failed particulate investigation – it may simply mean that another analytical question needs to be asked.

> "EXPECTING A SINGLE ANALYTICAL TECHNIQUE TO ANSWER EVERY QUESTION IS RARELY REALISTIC."

Energy-dispersive X-ray spectroscopy (EDX) provides a complementary view. Scanning electron microscopy (SEM) gives high-resolution morphological information, while EDX provides elemental composition. Its usefulness in foreign-matter investigations is well established, and combining microscopy, vibrational spectroscopy and elemental analysis can be particularly powerful when the identity of an unknown particle is not obvious.[7]

THE ORTHOGONAL TOOLBOX IS VARIED

SEM-EDX is not the only technique that can sensibly follow MDRS. In SEM-EDX, an electron beam generates characteristic X-rays from the interaction volume, so morphology and elemental composition can be linked to the same particle. For much smaller particles, transmission electron microscopy (TEM) combined with EDX can push imaging and elemental mapping to finer spatial scales, although the compromise is more demanding specimen preparation and a much smaller amount of material under examination.[8]

X-ray photoelectron spectroscopy asks a different question again. Given the photoelectrons it measures escape only from the near-surface region, it is particularly useful when surface composition or chemical state is important to characterise.[9] X-ray fluorescence (XRF) provides non-destructive elemental screening where there is sufficient mass, while atomic absorption technology, inductively coupled plasma optical emission spectroscopy (ICP-OES) and inductively coupled plasma mass spectrometry (ICP-MS) can provide sensitive elemental measurements after suitable sample preparation.[10,11]

Sample mass, composition, surface sensitivity, detection limits and the need to preserve the particle all influence the decision. The point is not to assemble the most expansive analytical toolbox – it is to understand the measurements well enough to choose the experiment that removes the next uncertainty.

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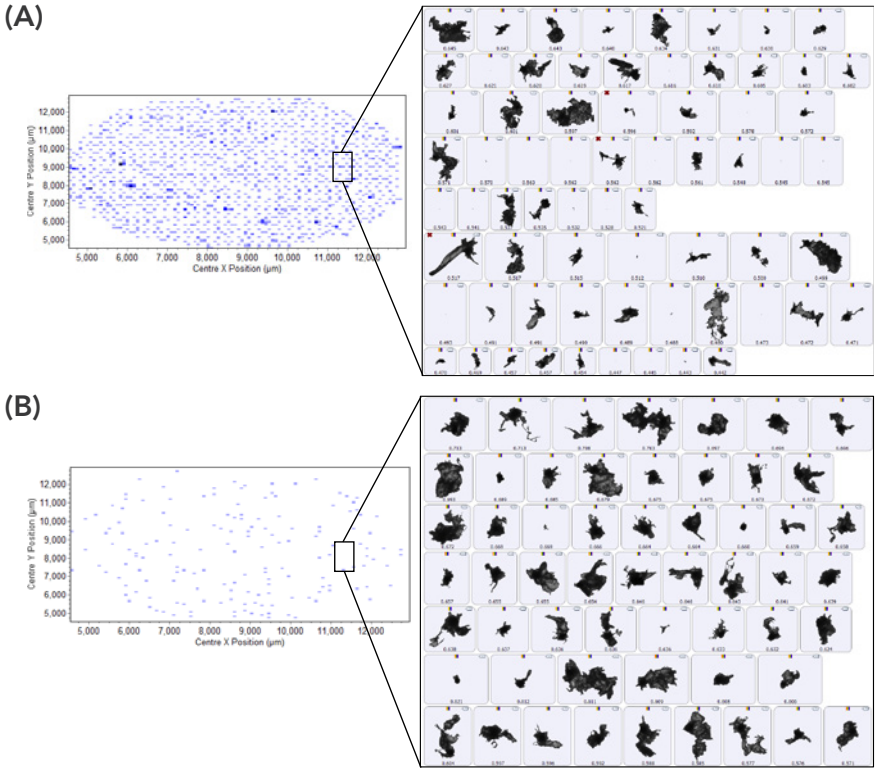


Figure 2: Example of MDRS scattergrams and automated particle images from two generic pMDI batches using mometasone furoate.

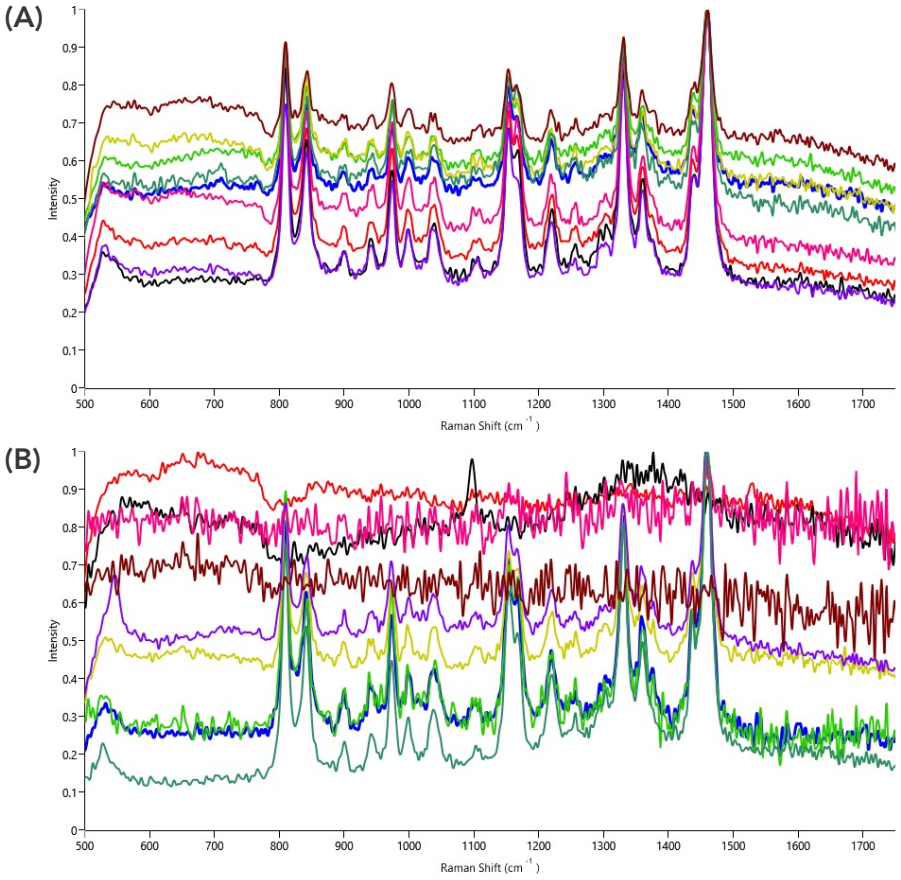


Figure 3: Example of Raman characterisation of foreign particulates detected by MDRS.

WHAT DID THE PARTICLES ACTUALLY TELL US?

In a practical example to be presented at the Drug Delivery to the Lungs conference in Dec 2026, MDRS detected 4,900 foreign particles in Batch A and 2,287 in Batch B. Automated imaging showed predominantly irregular particles across a broad particle-size distribution. Those numbers demonstrated a difference between the samples, but the counts alone did not explain it. The MDRS scattergrams and representative automated particle images are shown in Figure 2, illustrating the difference in detected particle populations between the two batches whilst retaining the morphological information associated with individual particles.

Raman analysis added another layer of information. In Batch A, the principal Raman-active contaminant produced spectra consistent with polypropylene. As polypropylene is used in pharmaceutical packaging and device components, its identification provided a sensible starting point for considering possible sources. Batch B was more complicated; some particles again produced spectra consistent with polypropylene, while others could not be adequately identified by Raman under the conditions used.

Examples of the Raman spectra results are shown in Figure 3. These data illustrate both the value of molecular identification for Raman-active particles and the analytical limitation encountered when a particle does not provide an adequate spectrum under the measurement conditions used.

SEM-EDX supplied the missing information. The particles examined from Batch A were predominantly organic in nature, consistent with the Raman findings. Batch B contained a more heterogeneous population; alongside organic material, elemental analysis identified particles containing iron and aluminium. As such, these were not simply two batches with different particle counts but evidence of different particulate profiles, which is a much more useful starting point for a root-cause investigation.

Examples of the SEM-EDX and elemental maps are shown in Figure 4. The complementary elemental information was particularly important for the Batch B population that could not be fully characterised by Raman spectroscopy alone.

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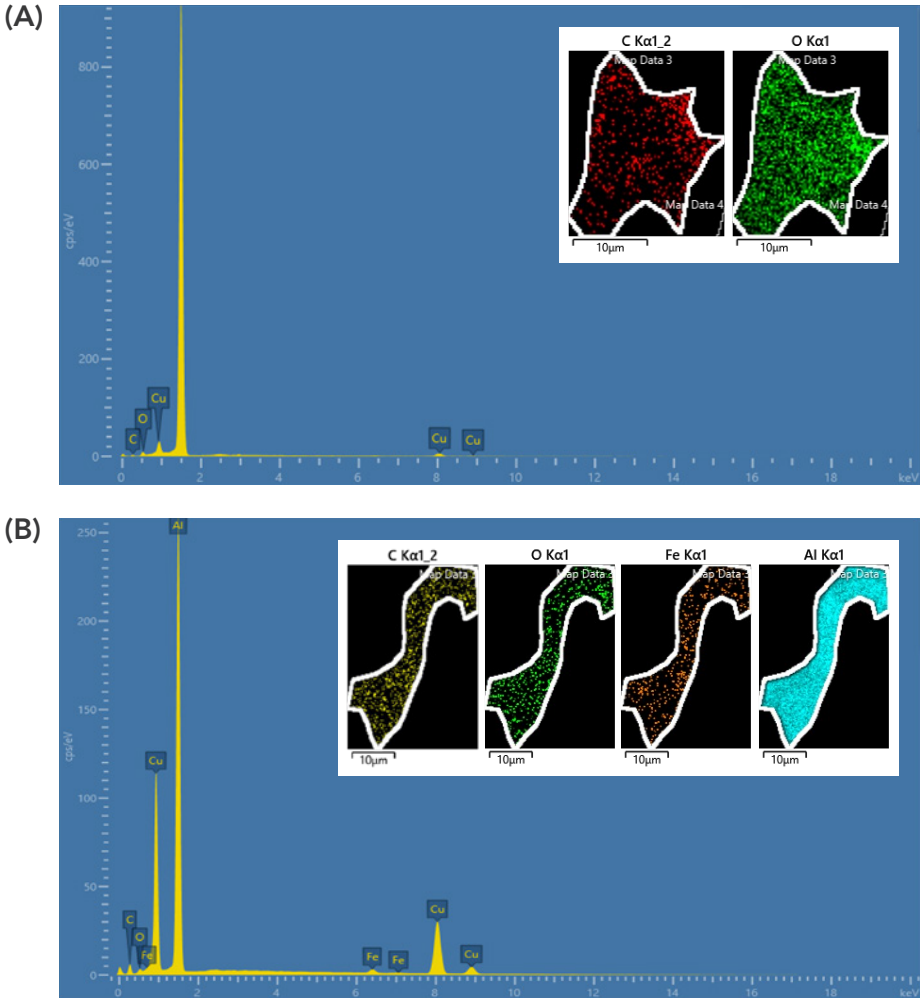


Figure 4: Example of SEM-EDX analysis of foreign particulates from batches A and B.

"IDENTIFYING THE COMPOSITION OF A PARTICLE IS NOT THE SAME AS PROVING ITS ORIGIN."

IDENTIFICATION DOES NOT PROVE THE SOURCE

Identifying the composition of a particle is not the same as proving its origin. Finding polypropylene does not demonstrate, by itself, that a particular valve or packaging component generated the particle. Similarly, finding iron does not automatically mean equipment wear and finding aluminium does not identify a particular manufacturing operation.

Analytical identification narrows the investigation; it does not replace it. Source attribution requires the result to be considered alongside the formulation, raw materials, device materials, manufacturing equipment, processing history, cleaning procedures, environmental controls and previous particulate data.

UNDERSTANDING WHAT IS NORMAL

Foreign-particle testing is often discussed reactively – something unusual has been observed, a complaint has been received or an investigation has been opened. By that stage, one of the most useful pieces of information is a good understanding of what is normally present in the product. That justifies characterisation earlier in the product lifecycle. A good investigation therefore moves through a series of questions:

- Is the particle genuinely present?
- What are its size and morphological characteristics?
- What is it made from?
- Which known materials within the product, device or process could reasonably be associated with it?
- Does the wider manufacturing evidence support that hypothesis?

If the typical particulate population is understood during development and process characterisation, later observations can be assessed against a meaningful baseline. A familiar particle type within an established profile raises a different question than that raised by the sudden appearance of a new material or a substantial change in an existing population. A trend based only on total particle count may show that something has changed; a trend that also considers morphology and identity may help explain what changed. This does not mean that every particle from every batch needs exhaustive spectroscopic and elemental analysis – a risk-based approach is more sensible.

LET THE QUESTION CHOOSE THE TECHNIQUE

There is a natural temptation with advanced analytical methods to ask which technique is best. The better question is: "What do we need to know?" Orthogonal analysis should not mean running a sample on every available instrument. Each technique should earn its place by answering a question that the preceding technique could not answer with sufficient confidence. More analytical data do not automatically produce more understanding.

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FROM PARTICLE DATA TO PRODUCT KNOWLEDGE

"FINDING THE PARTICLE IS THE BEGINNING OF THE INVESTIGATION, NOT THE END OF IT."

Foreign particulate characterisation in OINDPs has moved beyond simple enumeration. Counting remains essential but it is only one part of a wider picture. Imaging shows what particles look like. Molecular spectroscopy can help establish what they are made from. Elemental and surface-analysis techniques can provide another level of understanding. Knowledge of the formulation, device, container closure system and manufacturing processes then provides the context needed to interpret those findings.

This is the key point for future particulate investigations – the strongest investigation is not the one with the most measurements; it is the one in which each measurement tests a sensible scientific hypothesis. Certainly, investigators should continue asking how many particles are present, but also what they are, whether they are expected, what analytical uncertainty remains and where they might reasonably have come from. That is how particle data become product knowledge rather than simply another set of results.

Finding the particle is the beginning of the investigation, not the end of it. When particle count, morphology, molecular identity and elemental composition are brought together with sound knowledge of the product and process, foreign-particle analysis becomes more than a test result. It becomes part of the scientific understanding of the product throughout its lifecycle.

ABOUT THE COMPANY

Cormica is a global life sciences testing and consultancy group supporting pharmaceutical, medical device and combination product manufacturers across the full product lifecycle. With accredited laboratories across the US, UK and Europe, Cormica provides integrated services spanning microbiology, analytical chemistry, physical and packaging testing, biocompatibility and regulatory consultancy and support.

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HOW EARLY FORMULATION-DEVICE INTEGRATION CAN REDUCE RISK IN PRODUCT DEVELOPMENT FOR RESPIRATORY BIOLOGICS

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Dr Mireia Puig-Sellart of **Phillips Medisize** explains how integrating patient needs, formulation and device development from the outset of a development programme can reduce risk and improve development decisions for respiratory biologics.

Respiratory combination product development shares many commonalities with parenteral development, particularly when a molecule originally developed for injection is being considered for administration to the airways. While formulation-device integration is important across all drug-device combination products, it is particularly critical in respiratory delivery. For inhaled biologic products, the formulation must protect a structurally complex molecule, while the selected device must generate an aerosol with characteristics suited to the intended patient and use. Decisions made at one interface alter risks at the others, so inhaled medicines should be developed as integrated products from the outset.

A PRACTICAL FRAMEWORK FOR RESPIRATORY DEVELOPMENT

A practical way to organise these decisions is around three pillars: patient needs, formulation and device (Figure 1).

"THIS SIMPLE FRAMEWORK IS BECOMING INCREASINGLY IMPORTANT AS INHALATION EXPANDS BEYOND ESTABLISHED SMALL MOLECULES INTO PROTEINS AND PEPTIDES."

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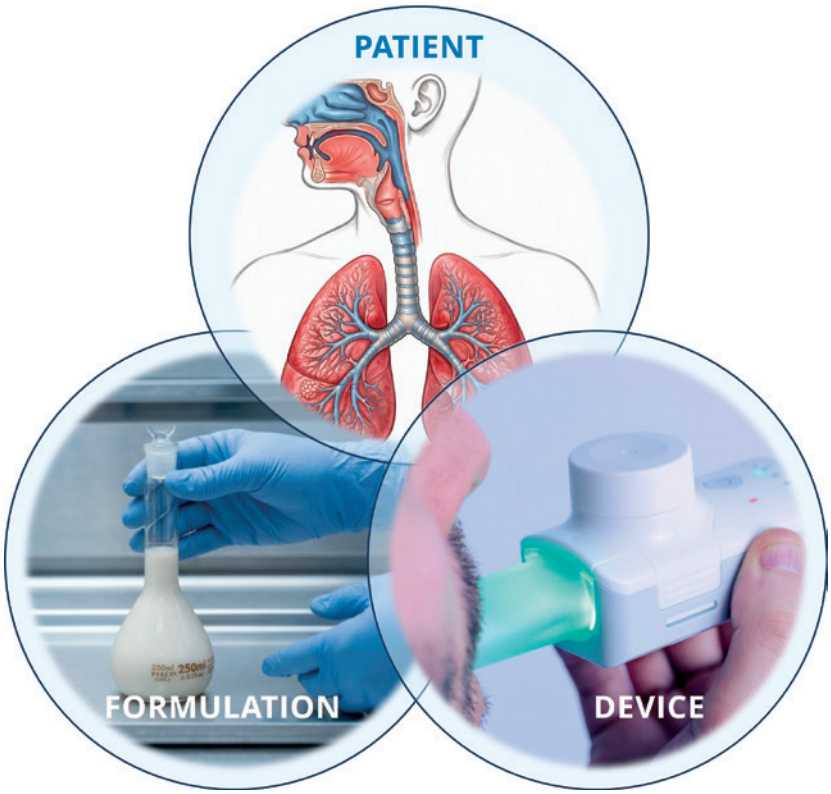


Figure 1: Patient, formulation and device considerations and their interdependencies in the early development of respiratory products.

Each pillar matters in its own right, but the main technical and commercial opportunities and risks often only become apparent when these three elements are brought together. Patient needs influence the route of administration, treatment time, dose frequency and the inspiratory effort that can reasonably be expected from the patient population. Formulation choices then have to reconcile biotherapeutic stability with tolerability, properties affecting aerosol generation and manufacturability. Device selection determines how that formulation is metered and aerosolised, and whether the intended dose can be delivered consistently by patients in the real world.

This simple framework is becoming increasingly important as inhalation expands beyond established small molecules into proteins and peptides; nucleic acid therapeutics, including messenger RNA (mRNA) delivery using lipid nanoparticle (LNP) systems; and biological agents such as bacteriophages. These biotherapeutics create new opportunities for local respiratory treatment, systemic delivery or mucosal immunisation. However, they also bring fragility, limited formulation space, stability constraints and analytical questions that cannot be solved by pursuing formulation science or device engineering independently. A formulation may be stable in a vial, yet change as a consequence of nebulisation, spray drying or reconstitution in lung fluid following deposition. Equally, a high-performing device is of limited value if the aerosolisation process compromises the biological activity of its formulation.

DELIVERY ROUTE AND DOSAGE FORM ARE CONNECTED DECISIONS

The respiratory tract is highly effective at capturing airborne particles and pathogens. Airway branching, mucociliary clearance and immune defences are essential to protect the nasal cavity and lungs, but they are also the main challenge for respiratory drug delivery. Local administration can place a biotherapeutic close to its site of action while limiting systemic exposure, which is an attractive proposition for diseases such as asthma, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis and respiratory infection. The nose and the lungs can also provide access to the systemic circulation for small peptides, potentially enabling a rapid onset of action and avoiding first-pass metabolism. In parallel, immune tissues in the nose and lungs create opportunities for mucosal vaccination against airborne pathogens.

> "ONCE THE BIOLOGICAL TARGET, SITE OF ACTION AND DOSE ARE UNDERSTOOD, THE DOSAGE FORM BECOMES A CRITICAL DECISION."

Once the biological target, site of action and dose are understood, the dosage form becomes a critical decision. Liquid formulations can offer a relatively direct route into preclinical and clinical trials, with requirements for cold-chain storage often being one of the main potential drawbacks. Nebulisation can also reduce dependence on the patient's inspiratory effort for the aerosolisation process, which may be critical in severe respiratory diseases. By contrast, dry powders can improve portability and convenience, as one inhalation can often deliver a complete dose, as well as potentially reducing cold-chain dependence. However, dry powders require particle engineering, moisture control and a device capable of consistently dispersing the required payload across a broad range of inhalation conditions. For respiratory biotherapeutics, the preferred option is therefore not determined by one favourable attribute. It is the option that creates the best overall balance of biologic stability, aerosol performance, patient usability, manufacturability and clinical intent.

CASE STUDY 1: TRANSLATING AN INJECTABLE PROTEIN TO LUNG DELIVERY

This first example concerns a recombinant protein originally developed for parenteral administration and subsequently considered for the local treatment of idiopathic pulmonary fibrosis. The intended patients may have had severely compromised

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inspiratory capacity, so the delivery platform needed to operate without demanding a high inspiratory flow. This requirement supported selection of a smart mesh nebuliser, such as the FOX™ Vibrating Mesh Nebuliser, which immediately connected the patient and device pillars of the framework.

The formulation was redesigned using excipients with a pulmonary precedent to support clinical readiness. Viscosity and surface tension were considered in the context of the selected nebuliser rather than as isolated formulation measurements. Once a suitable viscosity had been established, the surfactant used to support protein stability also reduced surface tension, increased output rate and offered the potential for a shorter treatment time (Figure 2).

The central technical question, however, was not simply whether an aerosol could be generated. It was whether the recombinant protein could retain its relevant quality attributes and biological function after passing through the device. Orthogonal testing before and after nebulisation showed that the monomer content remained largely unchanged. Some higher-molecular-weight and basic species were observed, but potency was maintained. In practical terms, the formulation supported protein stability and nebuliser performance while also offering the potential to reduce treatment time for the patient.

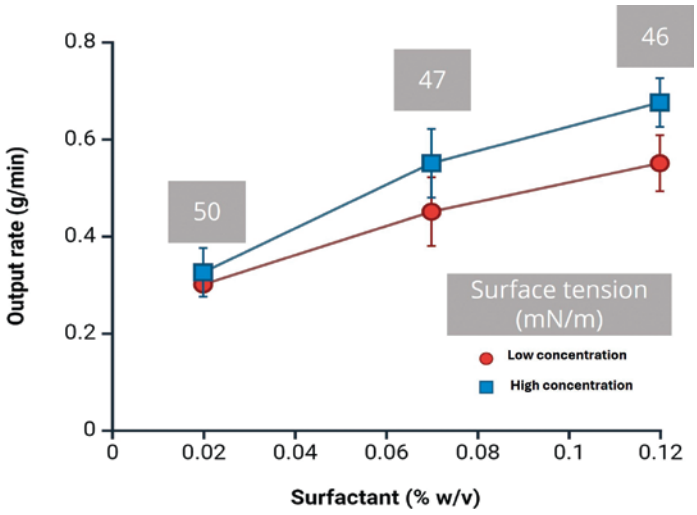


Figure 2: Parenteral-to-inhaled formulation optimisation of a recombinant protein – increasing surfactant concentration supported protein stability while reducing surface tension (mN/m) and increasing nebuliser output rate.

CASE STUDY 2: ENGINEERING INHALABLE DRY-POWDER LNPs

This second case considers spray-dried LNPs for pulmonary delivery. LNPs have become established vehicles for RNA delivery and offer a route to therapies in which the patient's own cells produce the therapeutic protein. Their potential extends beyond vaccination into areas such as protein replacement and cancer treatment. However, a conventional liquid LNP system can be constrained by the need for refrigeration or ultra-low-temperature storage and by the physical fragility of the nanoparticles. Converting an LNP into an inhalable powder could improve stability, reduce dependence on ultra-cold chain storage and, ultimately, broaden patient access, while enabling targeted respiratory delivery. However, drying introduces stresses that may alter the formulation's nanoparticle size, cargo retention and colloidal behaviour after reconstitution in lung fluid.

In an experiment to isolate the particle-engineering question, a surrogate cationic LNP containing polyadenylic acid was used. Formulations were spray dried with trehalose and either crystalline leucine or amorphous trileucine as shell-forming excipients. The distinction proved important. Leucine-containing powders were associated with marked LNP growth after reconstitution in water, whereas trileucine-containing formulations maintained LNP particle sizes below 155 nm. Shell-forming agents also improved aerosol performance, and the lead powders retained encapsulation of the cargo.

"CONVERTING AN LNP INTO AN INHALABLE POWDER COULD IMPROVE STABILITY, REDUCE DEPENDENCE ON ULTRA-COLD CHAIN STORAGE AND, ULTIMATELY, BROADEN PATIENT ACCESS, WHILE ENABLING TARGETED RESPIRATORY DELIVERY."

Device capacity formed part of the formulation strategy rather than being a later selection step. The powder was low density, low loading and the intended payload relatively high, so a high-payload dry powder inhaler (DPI) was selected. A single-dose disposable DPI concept device was then used to investigate dose escalation. Increasing blister fill weight raised the fine-particle dose without requiring reformulation, with an equivalent lung dose of up to 51 µg of surrogate cargo reported (Figure 3).

Work in this area continues to examine longer-term stability and more representative cargos. Even at this stage, the results show how formulation composition can protect the biotherapeutic nanoparticle and produce a readily dispersible powder, while device design provides a practical means of delivering a higher dose. Readers interested in the experimental design, aerosol data and mechanistic interpretation are directed to the full Drug Delivery to the Lungs (DDL) paper.[1]

CASE STUDY 3: MATCHING LNP COMPOSITION WITH NASAL DEPOSITION

This third case retains the LNP modality but changes the route to intranasal delivery as a model for mucosal vaccination. This change altered the target anatomy, spray analytics and deposition pattern. For mucosal vaccination, cationic lipids

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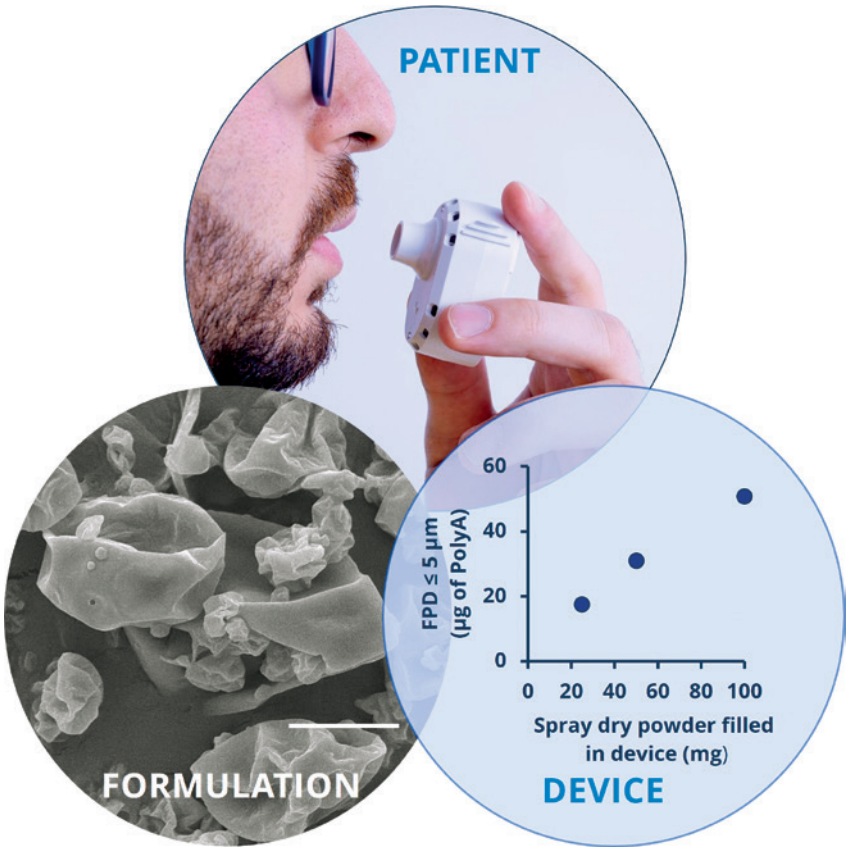


Figure 3: Spray-dried LNP case study illustrating the three-pillar framework – a single-dose disposable DPI concept device addresses convenient patient needs; a scanning electron image shows the LNP-containing spray-dried particles (white bar represents a 5 µm scale); and increasing fill weight enables dose escalation without reformulation.[1]

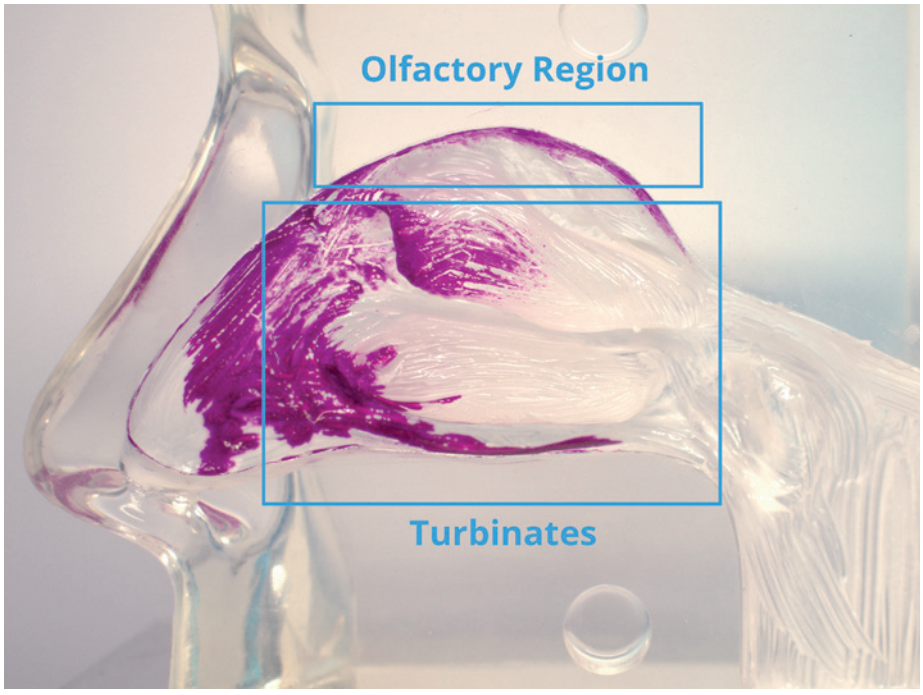


Figure 4: Intranasal LNP case study – deposition of an optimised LNP formulation in a KOKEN nasal cast as a model for mucosal vaccination.

may provide adjuvant-like properties that support immune responses, whereas ionisable lipids are associated with efficient nucleic acid delivery and improved tolerability. A future mucosal nasal vaccine may need to balance these behaviours rather than maximise either in isolation.

In this study, cationic and ionisable LNPs were prepared with different PEGylated lipid contents and tested using an off-the-shelf syringe fitted with a nasal nozzle. Increasing PEGylated lipid content generally improved post-actuation cargo recovery. Aerosol characterisation showed an appropriate spray pattern and plume geometry, with a low fraction of droplets below 10 µm, reducing the potential for unintended lung penetration.

Deposition was assessed using an anatomically representative KOKEN (Tokyo, Japan) nasal cast (Figure 4). The LNP-containing formulation deposited predominantly in the turbinate region, with lower deposition in the nasal vestibule and olfactory region. This pattern may be relevant to mucosal vaccination, as recent work has shown that IgA-secreting plasma cells accumulate in the turbinate region following nasal immunisation, identifying the turbinates as an important effector site for upper-airway immunity.[2] The complete formulation matrix of the case study, post-actuation characterisation and aerosol findings are available in the DDL publication,[3] which provides detailed data.

EARLY INTEGRATION CREATES BETTER DEVELOPMENT CHOICES

Across the three case studies, the pharmaceutical modalities, dosage forms and target anatomies were different, but the development logic consistently followed the respiratory framework. Patient needs defined what the system had to achieve. Formulation design protected the biologic and established the physical characteristics of the dose. Device selection and engineering converted that dose into the required aerosol or spray and supported its intended use. None of those activities would have been successful if pursued in isolation.

For increasingly complex respiratory medicines, particularly proteins, nucleic acid systems and biological modalities, this integrated approach is not simply a

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way to improve development efficiency; it is the foundation of a credible development strategy. It also leads to a more useful technical question: not whether the formulation and device work independently, but whether the complete product delivers the right biotherapeutic to the right region, in the right condition and for the intended patient.

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"THIS INTEGRATED APPROACH IS NOT SIMPLY A WAY TO IMPROVE DEVELOPMENT EFFICIENCY; IT IS THE FOUNDATION OF A CREDIBLE DEVELOPMENT STRATEGY."



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TUNING IN: A NEW ACOUSTIC PLATFORM FOR THE AGE OF INHALED BIOLOGICS

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Dr Ethan Miller of **Sanner** alongside **Andrea Cusack** and **Dr David Cottenden** of **Nebu~Flow** highlight the mismatch between the delivery requirements of emerging drugs and the design of existing inhalation devices, making the case for the Nebu~Flow platform, which can be combined with a wide range of therapies and is capable of tuning droplet formulation.

BIOLOGICS ARE READY: TODAY'S DEVICES ARE NOT

For most of their history, inhaled therapies have been instruments for symptom management. Chronic respiratory diseases represent a substantial and growing global burden – chronic obstructive pulmonary disease (COPD) and asthma alone affect more than half a billion people worldwide and cause almost four million deaths annually; lung cancer causes a further 1.8 million, with idiopathic pulmonary fibrosis adding to a rising toll of morbidity and mortality. Against this backdrop, the pharmacopoeia for inhaled drugs has been dominated by small molecules: bronchodilators that relax constricted airways and corticosteroids that suppress inflammation. These agents relieve the consequences of disease – and they do it well – but they rarely touch its origin. For decades, this has been the ceiling of what an inhaler or nebuliser has been asked to deliver (Figure 1).

That ceiling is now lifting. A new generation of therapeutics offers the prospect not of simply managing symptoms but of correcting the biology that produces them. For conditions such as cystic fibrosis and alpha-1 antitrypsin deficiency, where the molecular

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Figure 1: A standard nebuliser used for inhaled therapies.

cause is well characterised, inhaled gene-silencing agents, nucleic acid therapeutics and protein replacement strategies hold the potential to intervene at the level of the underlying defect. RNA-based medicines, monoclonal antibodies and gene-silencing oligonucleotides can be directed at pulmonary targets that small molecules cannot reach, delivering the drug precisely where it is needed most and reducing the systemic exposure and off-target effects that accompany oral or intravenous administration.

A second, parallel opportunity treats the lung not as the target but as the gateway. The alveolar region presents an enormous, thin and highly perfused absorptive surface – an ideal port for systemic delivery without needles. Administering a biologic by inhalation can bypass hepatic first-pass metabolism entirely, lower the required dose and open a non-invasive route for molecules that would otherwise demand injection. Whether the goal is to treat the airway itself or to use it as a conduit to the bloodstream, the direct respiratory route has never looked more attractive.

The obstacle is not the pharmacology; it is the device. The three established nebuliser classes (jet, vibrating mesh and ultrasonic) were engineered for small-molecule solutions, with each

"WHETHER THE GOAL IS TO TREAT THE AIRWAY ITSELF OR TO USE IT AS A CONDUIT TO THE BLOODSTREAM, THE DIRECT RESPIRATORY ROUTE HAS NEVER LOOKED MORE ATTRACTIVE."

imposing mechanical and physicochemical constraints that biologic candidates must routinely violate (Figure 2). Jet nebulisers subject formulations to repeated high-velocity Venturi passes, generating turbulent shear and interfacial stress that degrade fragile macromolecules and cause foaming in surfactant-containing formulations.

Vibrating mesh nebulisers force fluid through 2–5 µm apertures under high-frequency mechanical stress, fragmenting delicate payloads and disrupting lipid nanoparticle (LNP) carriers.[1] When surface tension falls below approximately 35 mN/m, surfactant-induced flooding becomes more likely,[2] and viscous, concentrated or buffered LNP formulations accelerate aperture clogging and fouling in ways that are difficult to mitigate without reformulation.[3]

Ultrasonic nebulisers generate acoustic cavitation alongside the accompanying temperature rises that denature thermolabile proteins and nucleic acids. These nebulisers struggle with complex formulations, unable to aerosolise suspensions effectively, as the dispersed phase sediments in the reservoir. Elevated viscosity, inherent to many concentrated biologics, compounds these problems across all three nebuliser classes, reducing throughput and shifting aerosol particle size unpredictably.[4] The sophisticated medicines now entering development are, quite simply, not supported by current devices intended to deliver them.

This exposes a fundamental design dilemma. The formulation characteristics needed to maximise the potency, stability and manufacturability of a biologic are frequently the very ones that degrade nebuliser performance. Faced with this conflict, the instinct of industry has been to adapt the medicine to survive

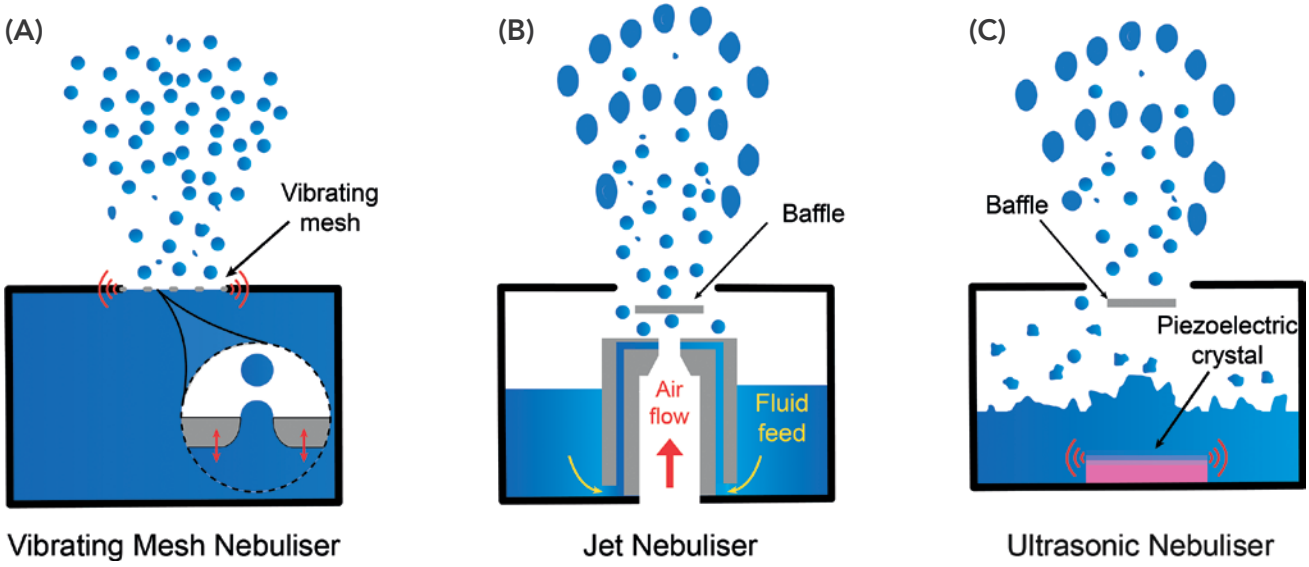


Figure 2: The mechanisms of vibrating mesh, jet and ultrasonic nebulisers.

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the physics of the device, sometimes compromising the formulation until it can withstand the shear, heat and apertures it needs to pass through. That instinct is the wrong way round. If the device is the limiting factor, then the device is what should change. Rather than engineering the drug to tolerate the nebuliser, the more logical, and ultimately more powerful, approach is to re-engineer the nebuliser around the drug.

A DIFFERENT KIND OF NEBULISER

Nebu~Flow's platform takes a mechanistically distinct approach to the physics and aerosol generation: the use of piezoelectric transducers to create a controlled acoustic field in the liquid loaded at the surface (Figure 3). The interaction of the generated acoustic waves and the liquid is tailored to create a soft aerosol plume. By manipulating the acoustic wave characteristics, the surface acoustic wave can be modulated to create an aerosol with minimal shear stresses, low thermal content and a desirable particle distribution. In this surface acoustic nebuliser design, acoustic energy is transferred to the liquid surface in a distributed manner along the propagation path of the wave.

There is no constrained orifice through which the formulation must be forced, meaning that shear stresses during aerosol generation are substantially lower and that there is minimal cavitation, the process responsible for the thermal and mechanical damage associated with conventional ultrasonic devices. Importantly, these characteristics can be precisely modulated through drive electronics. It is the tunability of this acoustic engine, rather than any fixed physical geometry, that governs droplet formation.

This innovation has consequences for the success of therapeutic delivery. Nebu~Flow's patented technology resulted in approximately 1% loss of large molecular weight species; a comparable vibrating mesh nebuliser caused greater than 3% loss under equivalent conditions, and an increase of over 10% in mid-size fragment populations, indicating substantially greater strand scission.[5,6]

Beyond its compatibility with biologics, the Nebu~Flow transducer architecture offers a capability without equivalent in current commercial devices: the controlled tuning of aerosol droplet size from a single hardware configuration. Changing drive parameters, such as the frequency ratio, phase relationship or delivered power to the transducers, changes the mass median aerodynamic diameter (MMAD) of the output aerosol. This tuning is achieved entirely through electronics, without any tooling change or hardware modification. MMADs in the range of 1–3 µm are achievable using the same device, allowing the same device to deliver a range of formulations effectively.

> "THE NEBU~FLOW TRANSDUCER ARCHITECTURE OFFERS A CAPABILITY WITHOUT EQUIVALENT IN CURRENT COMMERCIAL DEVICES: THE CONTROLLED TUNING OF AEROSOL DROPLET SIZE FROM A SINGLE HARDWARE CONFIGURATION."

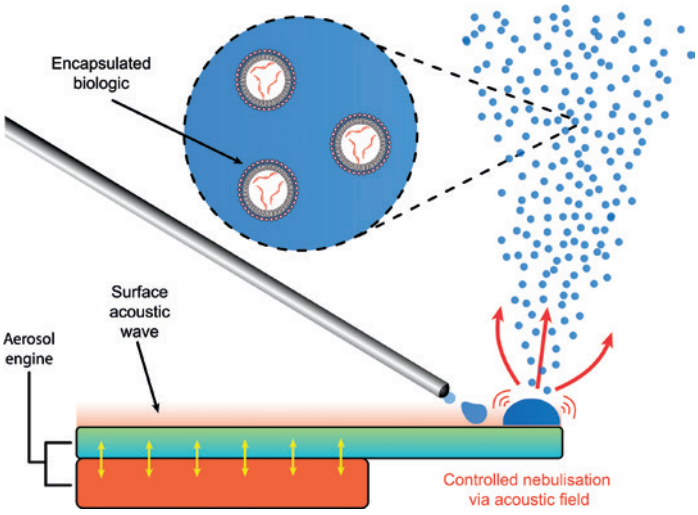


Figure 3: Aerosol generation using Nebu~Flow.

There is no mesh to block, no aperture to foul and no cleaning procedure constrained by fragile micron-scale geometry. Additionally, the absence of a coupling layer between the transducers and the liquid simplifies the architecture.

FREEING THE FORMULATION

Coupling therapeutics and inhalation devices typically leads to severe constraints on both formulation and device characteristics in order to achieve successful delivery. Reformulation to meet differing device constraints can add months to a development timeline, may require the sacrifice of bioavailability-enhancing excipients and introduces uncertainty into stability and manufacturability programmes. Similarly, adapting device parameters can lead to a total re-design, re-tooling and new manufacturing processes, which are far from trivial in cost or time required. An adaptable acoustic platform reverses this conventional drug-device compromise.

The versatility of the Nebu~Flow platform is beneficial for pharmaceutical development at several stages. During early discovery, candidate RNA sequences evaluated across a range of concentrations and chemical modification patterns can be assessed using the same device, reducing the instrument variability that complicates head-to-head comparisons between candidates. As programmes progress into lead optimisation, LNP and lipid-carrier formulations are refined iteratively for stability and potency. As their physicochemical properties change accordingly, an adaptable platform accommodates this evolution without triggering full aerosol re-characterisation campaigns each time the formulation is adjusted.

During dose ranging, changes in dose concentration alter formulation viscosity and surface tension, but a parametrically tuneable nebuliser can compensate electronically to maintain consistent aerosol output across the range studied in Phase I/II trials, removing a source of variability that would otherwise complicate

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"EARLY AND DELIBERATE SELECTION OF A DEVICE PLATFORM CAPABLE OF REMAINING COMPATIBLE WITH THE FORMULATION ACROSS THE FULL PRODUCT DEVELOPMENT CYCLE REDUCES ONE OF THE MOST SIGNIFICANT LATE-STAGE RISKS IN INHALED BIOLOGIC DEVELOPMENT."

pharmacokinetic and pharmacodynamic modelling. Finally, at the stage of indication selection, the optimal pulmonary deposition target may differ substantially between disease areas: a bronchial target for airway epithelial knockdown in cystic fibrosis or asthma demands a different MMAD to an alveolar target for systemic delivery or distal lung disease. Yet, the same hardware serves both, requiring only appropriately validated drive parameter sets rather than a different device entirely.

Nebu~Flow's acoustic platform also provides a potential route to formulation phenotyping and drug-device data generation. Measurements including compressibility, attenuation and phase velocity could generate formulation-specific acoustic fingerprints that can be correlated with nebulisation performance. Combined with breath sensing and digital connectivity, these data could ultimately support dose verification and longitudinal monitoring of drug-device and dosing performance to improve patient outcomes.

FROM BENCH TO BEDSIDE, FASTER

One factor that should not be underestimated when viewing the development of inhalation therapies is the regulatory landscape. Under the US FDA combination product framework (21 CFR Part 3) and the equivalent EMA requirements, a drug-nebuliser combination product receives market authorisation for administration using only the specific device validated in pivotal trials. A device switch post-Phase II requires a full bridging comparability package and, in many cases, additional clinical data. This can add 12–24 months to the development timeline, along with the associated costs and resources. Early and deliberate selection of a device platform capable of remaining compatible with the formulation across the full product development cycle reduces one of the most significant late-stage risks in inhaled biologic development.

The intellectual property dimension reinforces this case. The main patents protecting major vibrating mesh nebuliser platforms are maturing, limiting the commercial exclusivity through drug-device combination product strategies with those devices. A novel platform with active, broad patent protection that covers both the acoustic generation mechanism and specific drive parameter configurations for different formulations offers pharmaceutical partners a combination product with meaningful runway on product lifetime that may extend further than that of the drug substance alone.

Ultimately, the Nebu~Flow platform represents more than a device upgrade and acts as a development enabler. Removing the constraints on the formulation imposed by conventional nebulisers and shortening the iterative cycles that consume time and resource in early development results in a clearer, faster path through the regulatory landscape to the patients who need these therapies most.

THE NEXT WAVE IN INHALED THERAPIES

Nebu~Flow's partnership with Sanner brings together acoustic technology with established device development, electromechanical systems integration and regulated manufacture under ISO 13485. Sanner's experience in inhalation systems provides the engineering and quality infrastructure needed to translate Nebu~Flow's acoustic engine into a prototype and a consistently manufacturable, market-ready product.

That technical rigour has been matched by an equal commitment to user-centric design. Sanner's human factors and industrial design teams have applied formative research grounded in ISO 62366 to ensure that the platform's sophistication is expressed through an experience that is intuitive and accessible across the intended patient populations – from elderly patients with COPD to clinical trial participants receiving novel RNA therapeutics. This enables usability requirements, device architecture and manufacturing constraints to be developed together rather than sequentially, supporting a product suitable for its intended users and clinical environments.

This approach is particularly important because Nebu~Flow is intended as a platform to be used for a broad range of inhaled medicines, small molecules and emerging biologics, including nucleic acid formulations. Rather than requiring a new hardware configuration for every formulation, the development programme involves an evaluation of how aerosol performance can be adjusted through the device's operating parameters. This creates the potential to accommodate different formulation characteristics while preserving a common product architecture. Working within this framework allows engineering, design-for-manufacture, supply-chain and quality requirements to be considered early, reducing the risk of costly re-design as the platform progresses towards verification, regulatory approval and scale-up.

For pharmaceutical and development partners, the value is therefore not simply in device performance, but a more efficient drug-device development pathway. Early formulation testing can inform device settings and product requirements before significant engineering investment is committed, while Sanner's involvement ensures that manufacturability and industrialisation are considered alongside performance. Together, this is intended to reduce technical

"FOR PHARMACEUTICAL AND DEVELOPMENT PARTNERS, THE VALUE IS THEREFORE NOT SIMPLY IN DEVICE PERFORMANCE, BUT A MORE EFFICIENT DRUG-DEVICE DEVELOPMENT PATHWAY."

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and scale-up risk, shorten development iterations and provide a clearer and potentially faster route from formulation feasibility, through beta development, to clinical and commercial manufacture.

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Andrea Cusack, Chief Executive Officer of Nebu~Flow, brings more than 25 years of pharmaceutical and drug delivery experience spanning GSK, Catalent, West and LEON. Her experience includes scaling small- and medium-size enterprises, securing investment, and developing licensing and strategic partnerships. At Nebu~Flow, Ms Cusack leads commercial strategy, pharmaceutical and investor engagement, ensuring that the company's technology development remains closely aligned with customer needs and its ambitions for growth and future investment.

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David Cottenden, PhD, Chief Technical Officer of Nebu~Flow, has spent over 15 years developing medical and drug delivery devices, from product definition through architecture development and technical concept creation to manufacturing support. In his current role, he draws on his experience in technical and project leadership as well as product and project strategy for effective management of risk. Dr Cottenden has Bachelors, Masters, and Doctoral degrees in Physics, Maths and Bioengineering from the University of Cambridge (UK) and University College London (UK).

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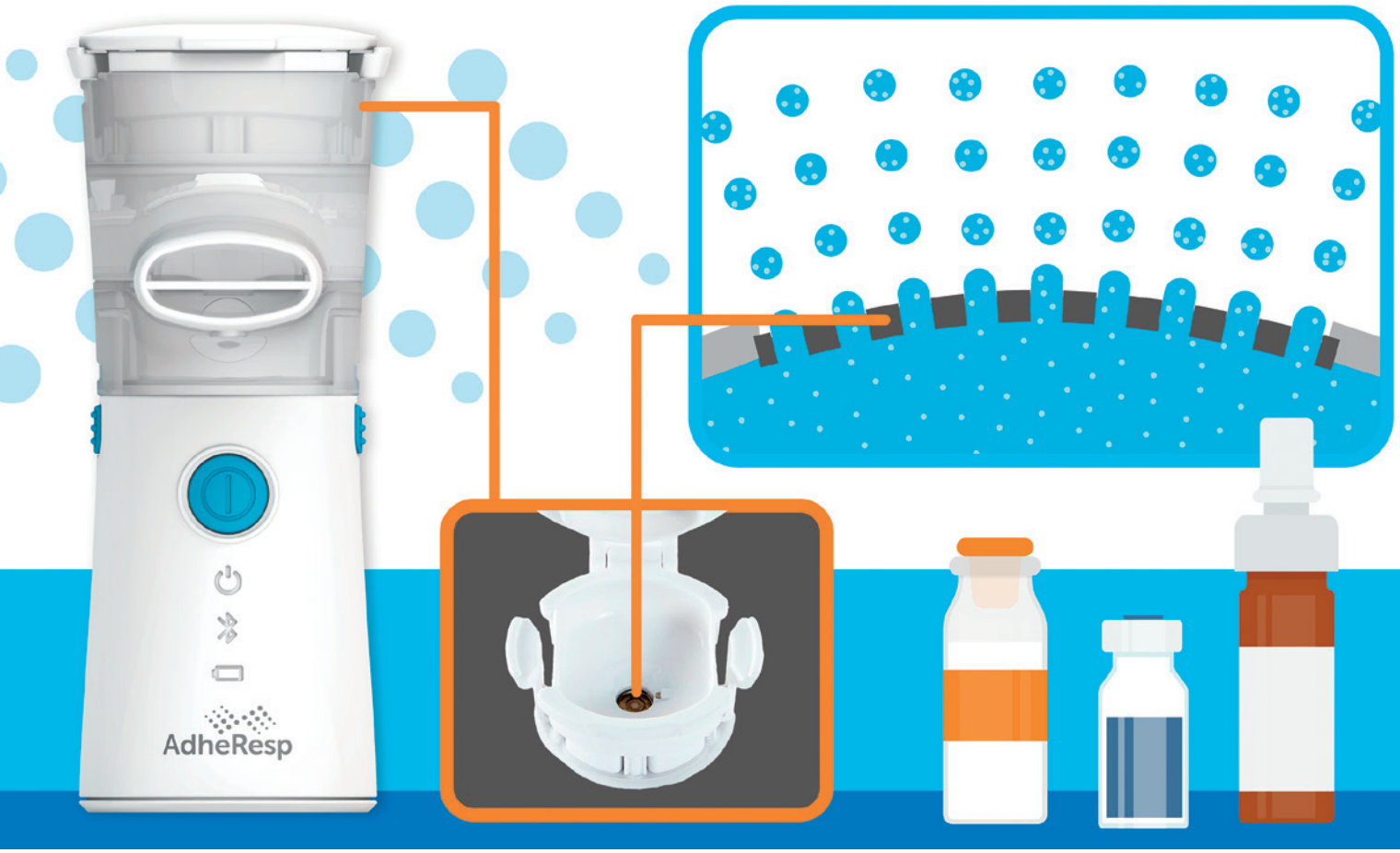


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TUNING THE AdheResp BREATH-ACTUATED MESH NEBULISER FOR CHALLENGING DELIVERY TO THE LUNGS

Chris Vernall of **HCmed Innovations** presents an overview of the AdheResp® breath-actuated mesh nebuliser platform, alongside several studies conducted to optimise mesh nebuliser features to achieve ideal aerosol generation, particle size and delivery time.

The development of inhaled medicines is creating exciting opportunities to treat respiratory diseases with increasingly complex molecules. Proteins, antibodies and nucleic acids offer new therapeutic possibilities, but their formulations can introduce challenges that require closer integration between drug and device development.

For pharmaceutical developers, generating an aerosol is only part of the requirement – the delivery system must preserve the formulation's critical attributes, generate an appropriate aerosol size distribution and deliver the intended dose within an acceptable treatment time (TT). Achieving this balance requires an understanding of how the formulation interacts with the device and the flexibility to adjust that interaction.

HCmed's AdheResp® breath-actuated mesh nebuliser provides a highly customisable platform for this approach. Studies with

"PROTEINS, ANTIBODIES AND NUCLEIC ACIDS OFFER NEW THERAPEUTIC POSSIBILITIES, BUT THEIR FORMULATIONS CAN INTRODUCE CHALLENGES THAT REQUIRE CLOSER INTEGRATION BETWEEN DRUG AND DEVICE DEVELOPMENT."

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viscous model solutions and fragile lipid nanoparticle (LNP) formulations illustrate how different challenges can be addressed through formulation-specific device selection.

A PLATFORM DESIGNED FOR CUSTOMISATION

AdheResp received US FDA 510(k) clearance in June 2025 across several different configurations.[1] The platform combines aerosol generated by a vibrating mesh with breath actuation, synchronising aerosol delivery with inspiration to reduce drug loss during exhalation. Bluetooth connectivity supports transmission of treatment data, while a lock-and-key activation system enables pairing with a specific medication.[2]

For combination product development, AdheResp's flexibility encompasses hardware and firmware configurations, mesh pore size and driving power. These provide developers with options for balancing aerosol characteristics, output and delivery efficiency.

This flexibility is particularly relevant when two formulations require different approaches to aerosolisation. A viscous solution may require greater driving energy to initiate and sustain output, whereas a fragile LNP formulation may benefit from conditions that minimise the stress experienced during delivery (Figure 1).

DIFFERENT FORMULATIONS, DIFFERENT PRIORITIES

Elevated viscosity, including values above approximately 2.5 cP, can substantially restrict a liquid's movement through a vibrating mesh. This is a practical development challenge rather than a universal threshold – performance also depends on surface tension, composition and mesh design. Reduced output can extend TT and, in some cases, prevent effective aerosol generation.

Higher driving power can help to overcome viscous resistance, while larger pores can facilitate liquid passage. However, these adjustments must also respect the integrity of the API. For sensitive biologics, improved output is valuable only if post-nebulisation quality and activity remain acceptable.



Figure 1: A lipid nanoparticle.

LNP-encapsulated messenger RNA (mRNA) presents a different challenge. Mechanical and interfacial stresses during aerosolisation can disrupt nanoparticle structure or alter cargo retention. Lower-energy delivery conditions may help to preserve sensitive formulations, but electrical power alone does not alleviate the stresses placed on LNPs.[3] Mesh design, formulation composition and exposure duration also matter. The objective is therefore to identify operating conditions that preserve formulation quality while providing useful aerosol performance.

BALANCING AEROSOL SIZE, OUTPUT AND TREATMENT TIME

Alongside formulation integrity, developers often aim for a specific mass median aerodynamic diameter (MMAD) or aerodynamic particle size distribution to support delivery to the intended lung region (Figure 2). Mesh pore size and device power can influence both aerosol size and output rate (OR). Increasing OR can reduce TT, but larger pores may also generate larger droplets.

For breath-actuated operation, elapsed TT also depends on the breathing cycle. Consequently, continuous-mode OR should not be used directly to predict breath-actuated TT. Device screening should assess these parameters together, with laser diffraction characterising droplet size and cascade impaction establishing aerodynamic performance where required.



Figure 2: Delivery to the optimal lung region.

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CASE STUDY 1: ADAPTING DELIVERY FOR ELEVATED VISCOSITY

An HCmed study evaluated three investigational AdheResp configurations operating at high power (HP) with a standard mesh, S03, and two larger-pore meshes, C01 and C02.[4] Model formulations contained 0.1% albuterol sulphate and 10%, 20% or 30% sucrose in normal saline, providing viscosities spanning 1.26–2.86 cP. Tables 1 and 2 describe the resulting variations in treatment time and delivered dose.

Droplet size was measured by laser diffraction. Treatment time and delivered dose were assessed using a 1.5 mL fill and a standard adult breathing pattern (500 mL tidal volume, 15 breaths per minute and equal inspiratory and expiratory durations). Testing was performed in triplicate.

With the lowest-viscosity formulation, S03 produced a volume median droplet diameter (Dv50) of 4.03 µm, with a TT of 4 minutes 55 seconds and approximately 80% of the nominal loaded dose collected on the inhalation filter. At the highest viscosity, however, TT with S03 increased to 18 minutes 53 seconds.

Pairing the 2.86 cP formulation with the C02 mesh reduced TT to 5 minutes 57 seconds, while retaining approximately 83% delivered dose. The Dv50 was 4.31 µm, with approximately 62% of aerosol volume below 5 µm. These laser diffraction results describe droplet size, rather than MMAD or an aerodynamic fine particle fraction (FPF).

The results also demonstrate why the largest pore is not automatically the best option. With the lowest-viscosity formulation, C02 shortened TT to 2 minutes 13 seconds, but increased Dv50 to 6.52 µm and reduced the delivered dose to approximately 54%. Therefore, the appropriate configuration depends on the formulation and the required balance between speed, aerosol size and dose.

An additional exploratory run used an ultra-high-power (UHP) unit with C02 and a 30% sucrose formulation. Here, TT decreased from 5 minutes 57 seconds to 4 minutes 57 seconds, approximately 17% shorter than the original HP/C02 configuration.

However, the Dv50 increased from 4.31 µm to 4.86 µm, while the aerosol volume below 5 µm decreased from approximately 62% to 52%. Compared with the original data, this illustrates a potential trade-off between shorter treatment time, delivered dose and droplet size. More work is required before drawing firm conclusions about the benefits of increasing power.

Sucrose solutions provide useful models of elevated viscosity, but do not establish the stability of a complex biologic under equivalent conditions. Molecule-specific integrity and activity testing remain essential. Since completing this study, HCmed has also investigated biologic formulations with viscosities exceeding 3.2 cP, achieving good results with the HP base unit.

Sucrose (% w/w)	Mesh	Power	TT (min)	Delivered dose (mg)	Delivered rate (mg/min)
10	S03	HP	04:55 ± 00:23	1.21 ± 0.04	0.25 ± 0.01
10	C01	HP	02:50 ± 00:13	0.95 ± 0.04	0.34 ± 0.01
10	C02	HP	02:13 ± 00:05	0.81 ± 0.07	0.37 ± 0.02
20	S03	HP	05:59 ± 00:00	1.30 ± 0.02	0.22 ± 0.00
20	C01	HP	03:35 ± 00:30	1.07 ± 0.09	0.30 ± 0.02
20	C02	HP	03:11 ± 00:04	1.00 ± 0.04	0.32 ± 0.02
30	S03	HP	18:53 ± 02:35	1.35 ± 0.02	0.07 ± 0.01
30	C01	HP	06:06 ± 01:32	1.26 ± 0.04	0.21 ± 0.04
30	C02	HP	05:57 ± 00:11	1.24 ± 0.04	0.21 ± 0.00
30	C02	UHP	04:57	1.06	0.21

Table 1: Mesh and power selection: treatment time and delivered dose.

Sucrose (% w/w)	Mesh	Power	Dv50 (µm)	Volume fraction <5 µm (%)	Geometric standard deviation
10	S03	HP	4.03 ± 0.08	64.01 ± 1.58	1.73 ± 0.01
10	C01	HP	5.73 ± 0.28	41.68 ± 2.93	1.80 ± 0.02
10	C02	HP	6.52 ± 0.70	34.39 ± 6.37	1.80 ± 0.02
20	S03	HP	3.66 ± 0.20	71.21 ± 4.27	1.59 ± 0.08
20	C01	HP	4.70 ± 0.24	54.04 ± 3.33	1.72 ± 0.02
20	C02	HP	5.09 ± 0.39	48.98 ± 5.02	1.72 ± 0.02
30	S03	HP	2.97 ± 0.07	89.20 ± 4.29	1.48 ± 0.07
30	C01	HP	3.97 ± 0.43	67.76 ± 8.49	1.59 ± 0.04
30	C02	HP	4.31 ± 0.60	61.98 ± 11.36	1.59 ± 0.05
30	C02	UHP	4.86	52.05	1.68

Table 2: Mesh and power selection: droplet size distribution.

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CASE STUDY 2: PRESERVING LNP CHARACTERISTICS DURING AEROSOLISATION

A study conducted by InhaTarget Therapeutics (Gosselies, Belgium), in collaboration with HCmed, examined AdheResp with empty LNPs, followed by an mRNA-loaded LNP formulation. These experiments used the standard-power (SP) unit in continuous operation, providing an initial assessment of mesh compatibility before subsequent breath-actuated evaluation. Tables 3 and 4 display these results.

For empty LNPs at 1.30 mg/mL total lipid concentration, gravimetric OR increased from 0.30 to 0.41 and 0.52 mL/min across the small to medium and large meshes. Larger meshes also shifted the droplet size distribution towards larger diameters, as expected. Across three lipid concentrations, the volume fraction below 5 µm was approximately 65–68% with the small mesh and 52–55% with the large mesh.

Measurements of LNP size, dispersity and surface charge supported progression with the small mesh and SP base unit. The subsequent mRNA-LNP formulation contained 230 µg/mL mRNA and 5.29 mg/mL total lipid. It generated a Dv50 of 4.1 µm, with 66% of the aerosol volume below 5 µm.

After one minute of nebulisation, encapsulation efficiency was 99.4% in the collected aerosol, compared with 99.5% before nebulisation. The mean hydrodynamic diameter decreased from 213.5 nm to 192.7 nm. These observations support retention of encapsulation under the tested conditions, while highlighting the need to further investigate material recovery and compositional changes.

Aerodynamic testing used a cooled next-generation impactor (NGI) at 15 L/min, with a phospholipid tracer quantified by liquid chromatography–electrospray ionisation–mass spectrometry. Across three runs, MMAD was 3.8–3.9 µm and the reported FPF below 5 µm was 63.3–65.5%. These findings support the need for further development, including direct assessment of mRNA recovery, functional activity and performance during breath-actuated delivery.

HCmed has developed a low-power base unit, which is being studied with InhaTarget on different LNP compositions, with data to be shared next year.

Mesh	OR (mL/min)	Volume fraction <5 µm (%)		
		1.30 mg/mL lipid concentration	3.25 mg/mL lipid concentration	6.50 mg/mL lipid concentration
Small	0.30	68	65	65
Medium	0.41	60	59	59
Large	0.52	54	52	55

Table 3: Empty-LNP mesh screening with SP base unit and different LNP volumes.

Assessment	Parameter	Reported result
LNP quality after 1 min	Encapsulation efficiency	Before: 99.5%; reservoir: 99.5%; collected aerosol: 99.4%
LNP quality after 1 min	Hydrodynamic diameter (Z-average)	Before: 213.5 nm; reservoir: 195.6 nm; collected aerosol: 192.7 nm
LNP quality after 1 min	Derived scattering count rate	Approximately 15% reduction reported; not a direct particle count
Laser diffraction	Dv50/volume below 5 µm	4.1 µm/66%
NGI: 30 s	MMAD/FPF below 5 µm	3.8 µm/65.5%
NGI: 60 s	MMAD/FPF below 5 µm	3.8 µm/64.3%

Table 4: mRNA-LNP quality and aerosol performance with SP base unit.

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BUILDING THE FORMULATION-DEVICE PAIRING EARLY

Together, these studies illustrate the value of treating device configurations as an active development variable. For viscous formulations, mesh selection and sufficient driving power can make a substantial difference to aerosolisation effectiveness and treatment time. For LNP formulations, useful aerosol characteristics must be achieved alongside acceptable nanoparticle and cargo quality.

A practical development programme should screen mesh and power combinations against predefined targets for aerosol size, delivered dose, treatment time and post-nebulisation integrity. Promising configurations can then progress to testing under representative breathing conditions.

AdheResp's customisable platform offers a means of exploring this balance early. As inhaled therapies become more complex, close collaboration between formulation and device teams will be central to translating promising molecules into practical treatments for patients.

"TOGETHER, THESE STUDIES ILLUSTRATE THE VALUE OF TREATING DEVICE CONFIGURATIONS AS AN ACTIVE DEVELOPMENT VARIABLE. FOR VISCOUS FORMULATIONS, MESH SELECTION AND SUFFICIENT DRIVING POWER CAN MAKE A SUBSTANTIAL DIFFERENCE TO AEROSOLISATION EFFECTIVENESS AND TREATMENT TIME."



Chris Vernall

Chris Vernall is the Executive Vice President of Business Development at HCmed, UK, supporting customers worldwide in advancing inhaled medicines using HCmed's proprietary mesh nebuliser technologies. A chemist by training, he holds Master's degrees in Medicinal and Pharmaceutical Chemistry and Executive Leadership. With extensive experience across respiratory-focused CROs and drug delivery companies, Mr Vernall is passionate about inhaled drug development and actively advises on technical and commercial strategy, also leading industry forums and committees in inhaled biologics.

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INVESTING IN INHALATION INNOVATION: A FUNDING GUIDE FOR RESPIRATORY START-UPS

DDL2026
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Here, the **DDL Incubator Committee** reviews the challenges, considerations and opportunities associated with the funding routes available to early-stage and start-up respiratory companies, ahead of the conference's novel DDL Incubator Hub titled "Investing in Inhalation Innovation".

THE CURRENT FUNDING CLIMATE

At a time of geopolitical unrest, market unease and investment uncertainty, understanding and sourcing the right finance to move a novel respiratory technology from bench to market can be a daunting task. Whether developing a novel inhaled therapy, a smarter dry powder inhaler or a connected nebuliser, the question for respiratory start-ups is the same: "Which money, when, and at what cost?"

The good news is that respiratory innovators can still raise capital. However, the particular challenge the sector faces today is that the funding environment is more selective, more concentrated and more politically uncertain than it was a few years ago, and that makes access uneven, especially for earlier-stage projects or start-ups.

Macro Headwinds

Economic volatility and higher interest rates throughout 2025 made investors more cautious about long-duration, high-risk assets such as life science R&D. Fundraising cycles have lengthened and some planned funding rounds were derailed. Even though overall biotech financing was relatively strong in dollar terms, capital has not flowed evenly – indeed commentators often refer to tightened financing and liquidity traps.

A Narrowing IPO Window

US biotech initial public offering (IPO) activity dropped sharply in 2025, with only

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a handful of companies raising more than US$50 million (£37 million). In the UK and Europe, public markets are an even clearer weak spot, with reports of three consecutive years without a UK biotech IPO. That means, specifically for UK respiratory start-ups, companies cannot count on a public listing to refinance their pipelines; instead, they will need to stretch private capital further and think creatively about structure. Meanwhile biotech IPO activity across the Asia-Pacific region has experienced a notable rebound, driven heavily by Hong Kong's market leadership. This rebound has been characterised by a strong first half of fiscal year 2026–27, followed by an environment where investors have been increasingly selective.

The Rising Gap Between Haves and Have-Nots

Capital is concentrating into fewer, larger mega-rounds for later stage, clinically validated assets, which is resulting in a widening gap between those and early- and mid-stage companies. Companies or projects with strong validation still attract oversubscribed rounds while less proven platforms can struggle to secure any institutional funding at all.

Policy Uncertainty and Competition for Capital

Proposed cuts to the US FDA's budget, and therefore staff, and contentious drug-pricing initiatives have been cited as major obstacles to financing confidence. Meanwhile, the industry is also competing with artificial intelligence, which recently absorbed an estimated 80% of global venture capital in just a single quarter. Add to that the reductions in public research funding, and fundraising is becoming a full-time job for biotech founders, with investors wanting more third-party validation before they commit.

FUNDING OPTIONS AT A GLANCE

Table 1 provides a practical overview of the funding options available to early-stage respiratory companies and start-ups. Of those, the five options highlighted here are most often the key ones to focus on.

Bootstrapping: Buy Time and Keep Control

Bootstrapping means growing a business with personal savings, consulting income and early revenue. It keeps the founders in full control, but capital is limited and scaling is slow. Many companies bootstrap in a broader sense, stitching together grants, small contracts, and shared lab or incubator space to delay dilution. This works best when capital burn is low, such as a virtual model using contract research organisations, or when working on a narrow device or diagnostic proof-of-concept.

Funding route	What it is	Positives	Negatives
Bootstrapping	Self-funding through personal resources or early revenue	Full control; no dilution; fast decisions	Limited capital; personal financial risk; slower scaling
Friends & family	Early money from personal contacts	Quick access; flexible terms; early validation	Relationship risk; limited strategic input
Grants & public funding	Non-dilutive funding from public or institutional bodies	Non-dilutive; credibility; supports R&D	Slow processes; reporting and admin burden
Angel investors	Individuals backing early-stage companies with capital and advice	Mentorship; networks; early-stage expertise	Equity dilution; investor quality varies
Seed funds & venture capital	Professional investors funding high-growth start-ups for equity	Large capital; scale quickly; strong signalling	Significant dilution; growth pressure; reduced control
Accelerators & incubators	Structured programmes offering mentorship and small funding for equity	Mentorship; investor access; credibility	Equity for small capital; time-intensive
Revenue-based financing	Non-equity funding repaid as a percentage of revenue	No dilution; repayments scale with revenue	Requires revenue; cash-flow impact
Debt/loans	Borrowed capital repaid with interest	No equity loss; predictable cost	Repayment risk; personal guarantees often required
Corporate/strategic investment	Investment from established companies seeking strategic alignment	Market access; industry knowledge; partnerships	Strategic constraints; slower decisions
Crowdfunding	Raising from many individuals via online platforms	Validation; marketing exposure; community	Admin complexity; disclosure risk; investor management

Table 1: Funding options for respiratory start-ups, kindly provided by DDL speaker Chris Hall of Shallcross Partners (Norfolk, UK). Routes highlighted in bold will be discussed in detail during the DDL Incubator Hub.

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Grants: De-Risk the Science Without Giving Away Equity

Grants do not need repaying and usually do not cost equity. The trade-off is slow processes, deliverables, audits and reporting, so companies need clear workplans and endpoints. Used well, grants can validate the science and de-risk early milestones before a larger equity round.

Angel Investors: Smart Money at the Early Stage

Angels and family offices, often experienced entrepreneurs or industry executives, bring capital plus networks and domain expertise. For respiratory start-ups, an angel investor with inhalation, device or regulatory experience can be worth far more than the cheque. The caveat is that bringing investors onboard requires giving away equity. Also note that investor quality varies, so it is critical to choose angel investors carefully.

Seed and Venture Capital: Fuel to Scale

Venture capital is typically the main source of scale capital once initial technical risk is mitigated, and the company needs to fund preclinical packages, clinical trials and manufacturing. It offers large sums and strong market signalling, but it is expensive – significant equity dilution, board oversight, milestone pressure and an expectation of a high-value exit all come with venture capital investment. Furthermore, the timing really matters, as raising capital after grants and early data have cleared key inflection points regularly results in a higher valuation and stronger negotiating position.

Corporate and Strategic Investment: Capital Plus Muscle

In standard industry practice, pharma and device companies invest in smaller biotech firms through corporate venture arms, option-to-license and co-development deals, sponsored research and early distribution agreements. For inhalation innovators, a strategic partner can bring formulation, device, regulatory and manufacturing capability that would be costly to build alone. The downside is strategic constraint, slower decision-making and careful management of intellectual property (IP) and exclusivity.

Stage	Main Investor Type	Typical Raise
Idea/prototype	Bootstrapping	£0–30k
MVP and traction	Friends and family	£30–100k
Early growth	Grants and angel investors	£100–250k
Scale-up	Seed funding and series A venture capital	£250k–1m
Expansion	Series B+ venture capital and strategic investors	£1m+

Table 2: A typical funding journey.

THE TYPICAL FUNDING JOURNEY

Funding routes are rarely chosen once – they stack up over time. A typical path is shown in Table 2. As a start-up progresses through its journey, founder ownership can fall from 100% to as little as 10%. Therefore, two questions matter at every stage – first, "How can development and scale-up costs be minimised while maximising income, thereby reducing the need for external funding?", and second, "What is needed to be credible to investors when moving to the next step?"

WHAT "INVESTOR READY" REALLY MEANS

Investor readiness is not just having a presentation deck and a good idea. It means that a company can withstand professional scrutiny and justify the capital it is asking for, which, in practice, means fulfilling the following criteria:

- **Science and IP De-Risking:** Robust data, not just hypotheses, plus a clear IP and freedom-to-operate position.
- **A Value Inflection Map:** Milestones such as proof-of-concept, safety packages, device verification and clinical readouts, with each injection of capital tied to a point where risk drops and value rises.
- **A Coherent Narrative:** Connecting an unmet respiratory need, a novel solution, the competitive landscape, the regulatory path and commercial potential.
- **Structured Operations and Governance:** A functioning team with defined roles, ready for board oversight and reporting.
- **Financial Clarity:** A realistic capital burn rate, use of funds, timelines and valuation logic, including dilution and capitalisation table.
- **External Validation:** Grants won, accelerator places, key opinion leader support and early partnerships (i.e. evidence that others have already tested the company's claims).

THE BOTTOM LINE

The funding environment is tougher than it has been for a while, but it is not closed. Respiratory start-ups that combine the right routes in the right order – bootstrapping and grants to prove the science, angel investors to build momentum, venture capital to scale and strategic partners to reach patients – will be best placed to secure the capital they need. To achieve success, companies should start with credibility, protect their equity for as long as they can and make every funding round count.

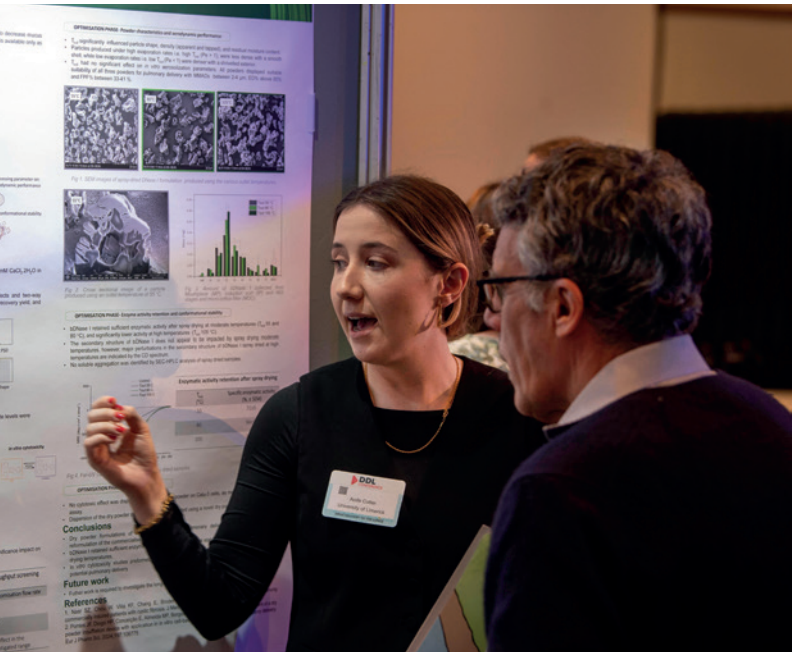
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The Drug Delivery to the Lungs Conference (DDL) is a not-for-profit conference dedicated to advancing the science and technology of pulmonary and nasal drug delivery. Held annually in Edinburgh, DDL brings together scientists, researchers, clinicians and industry professionals from across the world to share the latest research, exchange knowledge and explore developments in inhaled and nasal drug delivery. Established as a leading international meeting in the field, the conference provides a valuable forum for scientific discussion, collaboration and networking across academia and industry.

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Expert View

CONNECTED INHALER TESTING: STRENGTHENING CONTROL, CONSISTENCY AND TRACEABILITY

Paul Martin and **James Taylor**, both of Copley Scientific, explore how fragmented inhaler testing workflows can compromise consistency, data integrity and traceability, and how greater connectivity between equipment, software and data can strengthen control, scalability and productivity.

Inhaler test methods and set-ups have advanced considerably in recent decades. Innovations in impactors, interfaces, flow control and breathing simulators have transformed testing practices and enhanced clinical relevance. The inclusion of realistic aerodynamic particle size distribution (rAPSD) within evolving US FDA Product-Specific Guidances (PSGs) illustrates the growing role of more advanced *in vitro* testing in bioequivalence (BE) assessments and the potential of *in vitro* methods to reduce reliance on clinical studies.

However, inhaler testing workflows have changed far less and remain heavily reliant on manual interventions, manual inputs and manual recording. The result is operational risk and underlying variability that can erode data integrity, control and auditability. To realise the full value of *in vitro* data, these limitations in established practice need to be addressed. Digitalising inhaler testing workflows could help laboratories reduce variability and operational risk by improving the consistency, transferability and scalability of inhaler testing.

"DIGITALISING INHALER TESTING WORKFLOWS COULD HELP LABORATORIES REDUCE VARIABILITY AND OPERATIONAL RISK BY IMPROVING THE CONSISTENCY, TRANSFERABILITY AND SCALABILITY OF INHALER TESTING."

WHERE FRAGMENTATION REMAINS IN CURRENT WORKFLOWS

Inhaler testing workflows typically combine multiple standalone instruments, manual set-up and parameter entry, analyst-dependent interventions and separate systems for recording and processing data. While automation has already reduced operator-dependent variability and improved efficiency in key steps, connectivity between individual workflow elements often remains limited. As a result, equipment, test parameters, analyst actions and data may still need to be brought together manually to create the complete test record.

Laboratory workflows often combine product-specific test procedures with separate processes for recording, calculating and storing results. Moving data between these steps can require manual transcription or export, adding time to the analytical process, and opportunities for error.

Some laboratories, typically larger organisations, have a laboratory information management system in place, but these systems are not specifically designed for inhaler testing and may not readily bring together methods, equipment information and test data across the full testing workflow. This creates an important role for dedicated inhaler testing software that interfaces effectively with inhaler testing equipment.

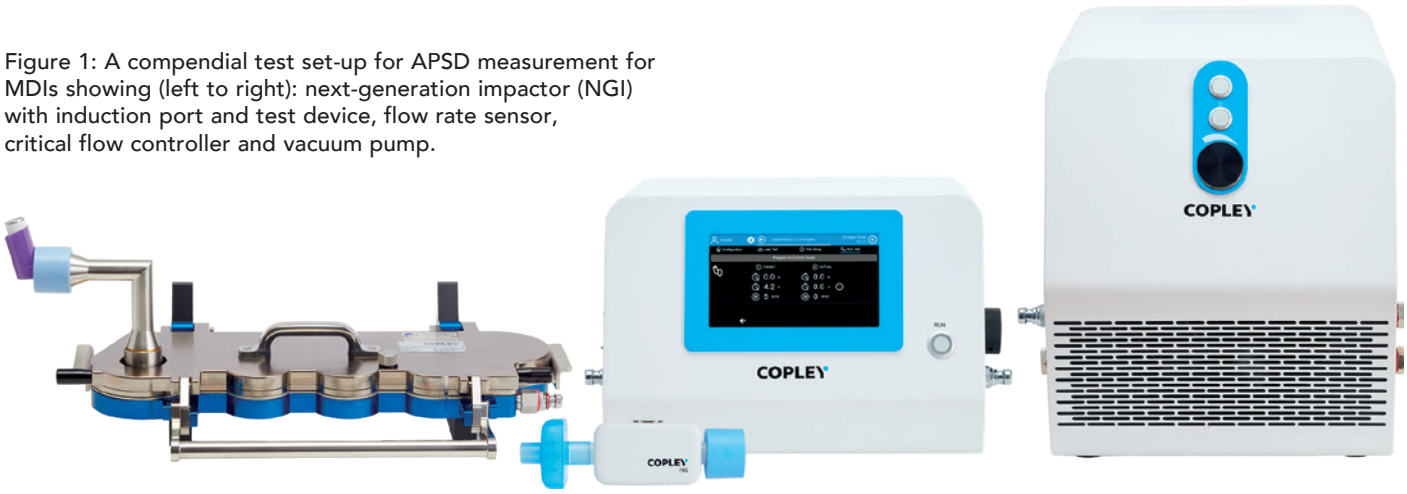
In the absence of this level of integration, workflows tend to be fragmented, with multiple points of potential for operational error, variability and compliance risk. Every point at which information is transferred between equipment, software, records or locations creates an opportunity for inconsistency or loss of traceability. If information control is weak, reproducibility can suffer and investigating unexpected or out-of-specification results becomes more difficult.

Focusing on Cascade Impaction

Closer examination of the workflow and information handled in APSD measurement highlights the limitations of current routine practice. APSD is a critical quality attribute for all orally inhaled products (OIPs), providing information relevant to likely *in vivo* deposition. Cascade impaction

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Figure 1: A compendial test set-up for APSD measurement for MDIs showing (left to right): next-generation impactor (NGI) with induction port and test device, flow rate sensor, critical flow controller and vacuum pump.



is the established technique for APSD measurement, providing aerodynamic particle sizing of the drug in the respirable size range.

Figure 1 shows a compendial cascade impactor test set-up for measuring the APSD of metered dose inhalers (MDIs). Key points to note about this set-up are:

- It comprises multiple standalone items that must be correctly configured and connected
- Equipment suitability, calibration/maintenance status and operating parameters must all be associated with the test
- Drug recovery from the cascade impactor can generate up to ten samples for assay, typically by high-performance liquid chromatography (HPLC)
- Each assay must be correctly linked to the corresponding impactor stage/component and stored within the test record for APSD calculation and reporting.

To summarise, each APSD measurement depends on multiple equipment records, operating parameters, analyst actions and data sources. The information necessarily recorded for each individual measurement ranges from results confirming the suitability and performance of the chosen equipment through experimental and environmental parameters, such as flow rate, humidity and temperature, to sample assays. All of it must be correctly linked to the same test to create a complete record.

Delivered dose uniformity testing, which also quantifies a critical quality attribute, is closely similar in many respects, albeit simpler. In both cases, the extent of manual input can make consistent method execution, documentation and transfer difficult, both between sites and when working with external partners.

> "THE SCOPE FOR VARIABILITY IS ESPECIALLY IMPORTANT BECAUSE EVEN RELATIVELY SMALL DEPARTURES FROM A DEFINED METHOD CAN IMPACT MEASURED VALUES."

EXAMINING THE DRAWBACKS AND RISKS OF CURRENT PRACTICE

These limitations become clearer when considering what inhaler testing needs to achieve. The goals are to produce reliable, reproducible data as efficiently as possible while maintaining complete, traceable records that support data integrity in line with ALCOA+ principles and applicable regulatory requirements.

Fragmented and highly manual workflows can make these goals harder to achieve by:

- Introducing potential for inconsistency and error at multiple steps
- Embedding time-consuming manual actions and processes within the workflow
- Requiring extensive training/re-training with individual analysts to achieve and maintain high levels of consistency
- Making it difficult to maintain an integrated, complete, auditable data record that is fully compliant and easy to interrogate.

The scope for variability is especially important because even relatively small departures from a defined method can impact measured values. These deviations can occur more easily than might be expected, for instance, when assembling an impactor, pipetting defined solvent volumes during drug recovery or transcribing data. In each case, the issue is not only preventing the deviation but being able to establish the cause and impact quickly and confidently during an investigation. On a larger scale, this scope for variability can make precise method transfer and scale-up major challenges for commercialisation and global manufacture.

Recognising or tracking down an error that has entered the data chain can often be both difficult and time-consuming. Disparate, manually linked data sources make auditing any individual measurement extremely complex and, in the worst-case scenario, critical information may simply go unrecorded. Investigating out-of-specification results can therefore become lengthy and costly, potentially delaying development or submission activities.

THE PROMISE OF DIGITALISATION

Across the pharmaceutical industry, the potential benefits of digitalisation are well-rehearsed. Automated, connected

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"AUTOMATED, CONNECTED AND DIGITALISED EQUIPMENT, COMBINED WITH CENTRALISED SOFTWARE, CAN GENERATE DATA THAT FLOW WITHOUT MANUAL INTERVENTION."

and digitalised equipment, combined with centralised software, can generate data that flow without manual intervention. Cited gains typically include:

- More consistent execution of defined methods
- Reduced reliance on manual transcription and data transfer
- Stronger links between equipment, operating parameters, samples and results
- Faster reconstruction of events during investigations
- Easier adherence to controlled, compliant laboratory practices
- A more complete and readily audited data trail well-matched to regulatory requirements.

In this context, connectivity is not simply moving data between systems. Its value lies in creating a more controlled workflow and a more complete and accessible record of what happened during a test. For many laboratories, full digitalisation will not be an immediate or practical objective, which reinforces the case for a progressive rather than wholesale approach to connected testing.

At the same time, several converging pressures are increasing the demands placed on inhaler laboratory workflows, creating motivation to act. More specifically:

- Continued growth and geographical diversification in the inhaled product market, increasing testing volumes and the need to reproduce methods consistently across laboratories, sites and external partners
- Ongoing MDI reformulation with new low global warming potential propellants, to aggressive timescales
- The introduction of revised FDA PSGs for certain OIPs with BE pathways that eliminate the need for comparative clinical endpoint studies, increasing the importance of robust and discriminatory *in vitro* evidence
- The delivery of inhaled biologics and other increasingly complex products, which can introduce more demanding *in vitro* testing requirements and additional workflow complexity
- Continued regulatory pressure around data integrity, traceability and demonstrable information control across analytical workflows and data chains.

The combined effect is an increase in not only the volume of inhaler testing but also in its complexity and the demands placed on laboratories to demonstrate consistent information control. Whether laboratories respond by increasing productivity, scaling operations across multiple sites or outsourcing elements of testing, the ability to reproduce methods consistently and maintain complete, traceable records becomes increasingly important. Greater connectivity, digital records and automation can all play a role in realising the necessary information control.

BUILDING TOWARDS CONNECTED TESTING

Moving towards connected testing does not require laboratories to digitalise or automate an entire workflow at once. A practical starting point is to examine existing processes, identify where manual hand-offs, disconnected records or repetitive analyst interventions create the greatest risk or burden, and prioritise those areas. A pragmatic strategy might involve:

- Introducing automation tools (Box 1) where repetitive or operator-dependent steps create unnecessary variability or burden
- Improving the connectivity between test equipment and software
- Bringing equipment identity, calibration and maintenance information into the test record, including for purely mechanical equipment, such as cascade impactors
- Using specialist software to centralise methods, equipment records, analytical data and test information, supporting more consistent execution and easier review.

BOX 1: AUTOMATION – A COMPLEMENTARY STRATEGY FOR VARIABILITY REDUCTION

Connected testing and automation are distinct but complementary. Connectivity can strengthen how test information is captured, stored and accessed, while automation can reduce the number of repetitive or operator-dependent interventions within the workflow.

Manual steps may remain within a connected workflow, but each intervention introduces another point that must be controlled and documented. Where appropriate, automation can reduce operator-related variability, while also making it easier to capture process information within the overall test record.

Consider the process of drug recovery from an NGI. Manually dispensing solvent into each collection cup, agitating the cups to dissolve the drug and transferring samples into HPLC vials for assay all depend on consistent analyst execution. The associated process information may also need to be recorded manually, creating additional opportunities for error or incomplete records.

In contrast, using an automated tool for solvent dispensing, agitation and sample extraction can improve the consistency of all these steps, minimising the risk of variability in drug recovery. Where automation is connected to centralised software, relevant process information can also transfer directly into the test record.

In summary, automation can deliver benefits in its own right while also supporting the development of more connected and traceable workflows.

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The appropriate starting point will vary between laboratories. For some, greater control of methods and equipment records may deliver the greatest immediate benefit; for others, reducing manual data transfer or automating a particularly operator-dependent step may be the priority. The important point is that connected capability can be built progressively around the areas of greatest need.

"CONNECTED CAPABILITY CAN BE BUILT PROGRESSIVELY AROUND THE AREAS OF GREATEST NEED."

The pace and extent of digitalisation will vary between laboratories. Progress can be incremental, starting with manual inputs, disconnected records or operator-dependent steps that create the biggest risk or burden.

For laboratory managers, the key question is therefore not how quickly to create a fully digital laboratory but where greater control would make the biggest difference today.

ABOUT THE COMPANY

Founded in 1946, Copley Scientific helps scientists improve people's lives by supporting the development of safe and effective medicines through specialist pharmaceutical testing solutions. With extensive expertise in orally inhaled and nasal drug product testing, Copley combines equipment, software, automation and services to help R&D and QC laboratories overcome testing challenges, streamline workflows and achieve consistent, reproducible results.



Paul Martin

Paul Martin is Head of Business Development at Copley Scientific. With more than a decade of experience in the inhaled drug delivery sector, he has a strong understanding of compendial testing requirements for OINDPs. He works closely with pharmaceutical and development teams to support complex programmes, with expertise in delivered dose uniformity and APSD measurement. Mr Martin supports organisations in interpreting evolving regulatory expectations and implementing robust, compliant OINDP test strategies. His approach centres on helping customers refine test set-ups to improve clinical relevance, strengthen *in vitro-in vivo* correlations, and gain deeper insight from their data, ensuring they derive maximum value from their analytical equipment and development activities.

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James Taylor is Product Support Specialist at Copley Scientific, where he provides practical guidance and technical support to customers working with OINDPs. With hands-on experience in pharmaceutical laboratory testing, Mr Taylor has worked across a broad range of quality control activities within GMP-compliant environments, including commercial and stability testing. His background includes a particular focus on delivered dose uniformity and APSD measurement, as well as crossover and ruggedness studies. This laboratory experience gives him a strong understanding of the practical challenges involved in OINDP testing. At Copley, Mr Taylor works closely with customers to provide technical guidance and training across a range of OINDP testing activities, helping laboratories apply testing methods effectively and navigate relevant regulatory requirements.

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Expert View

ELECTRONICS IN INHALATION DEVICES ARE TRANSFORMING DRUG DELIVERY, DOSE ACCURACY AND PATIENT ADVOCACY

Tom Oakley of Sanner provides an overview of how electronics can be successfully incorporated into inhalation devices, contributing to improved dosing accuracy, more consistent aerosolisation and, ultimately, better outcomes for patients, while also highlighting how these technologies can achieve smoother commercialisation when distinct development teams collaborate closely.

Respiratory drug delivery has evolved far beyond the familiar "puffer" inhaler.[1] Today, electronics are robust, mature and cheap enough to optimise how inhalation devices generate aerosols, deliver medication accurately, monitor patient technique and support adherence. From vibrating mesh nebulisers to breath-actuated smart inhalers, the integration of electronics is redefining what inhaled therapies can achieve (Figures 1 & 2).

"TODAY, ELECTRONICS ARE ROBUST, MATURE AND CHEAP ENOUGH TO OPTIMISE HOW INHALATION DEVICES GENERATE AEROSOLS, DELIVER MEDICATION ACCURATELY, MONITOR PATIENT TECHNIQUE AND SUPPORT ADHERENCE."

This shift is not simply about adding technology for technology's sake – it is about improving therapeutic outcomes, reducing dosing errors, empowering patients and giving clinicians better insight into real-world medication use.

Modern inhalation systems sit at the intersection of several highly specialised fields:

- Aerosol science and fluid dynamics
- Mechanical engineering
- Electronics and embedded systems
- Human factors engineering
- Pharmaceutical formulation science
- Regulatory compliance.

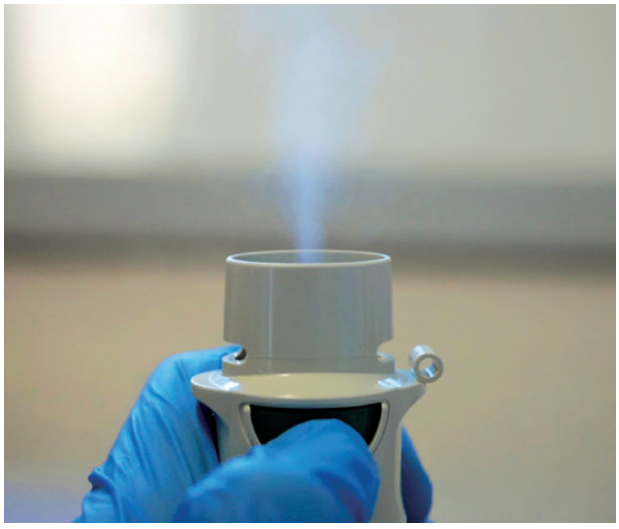


Figure 1: Soft mist plume testing for an inhaler.



Figure 2: A smart inhaler, accompanied with an app giving reminders and instructions to the user.

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A device may contain advanced electronics, but the therapy can still fail if the droplet size distribution, plume geometry or delivered dose is wrong, or if the patient cannot inhale correctly or the mechanics fail under real-world use conditions (Figure 1).

ELECTRONICS AS AN ENABLER OF PARTICLE GENERATION AND DELIVERY

Electronics can provide features such as reminders and real-time feedback to solve the largest problem with inhaler use – adherence to the therapy regime (Figure 2). In addition, electronics can assist the generation of aerosolised drug particles.

Traditional inhalers typically rely on gas propellants or the inspiratory force of the patient. However, modern electronic systems can precisely control how a drug becomes airborne, improving consistency and enabling entirely new delivery mechanisms.

Ultrasonic Nebulisers

Ultrasonic nebulisers were among the first electronically powered inhalation devices to reach widespread clinical use. They generate aerosols using a piezoelectric crystal that vibrates at ultrasonic frequencies, creating standing waves on the surface of a liquid formulation. These waves form droplets that are released as an inhalable aerosol.

Compared with jet nebulisers, which tend not to have electronics, ultrasonic systems can offer:

- Faster aerosol generation rates
- Quieter operation
- Improved portability
- Reduced dependence on compressed air sources.

The aerosol characteristics are influenced by the frequency and power of the ultrasonic transducer, allowing for electronic control over droplet generation. However, ultrasonic nebulisers also have significant limitations. For example, the medication can warm during operation, potentially affecting temperature-sensitive drugs such as peptides, proteins and biologics because energy is transferred directly into the liquid formulation. In addition, some formulations may not aerosolise efficiently, and the droplet size distribution is generally less precisely controlled than in modern vibrating mesh nebulisers.

For these reasons, ultrasonic nebulisers have largely been superseded by vibrating mesh technologies for many pharmaceutical applications. Nevertheless, they remain an important example of how electronics have enabled active aerosol generation and helped to pave the way for more sophisticated electronically controlled inhalation systems today.

Vibrating Mesh Nebulisers

Vibrating mesh nebulisers use electronically driven piezoelectric elements to push liquid formulations through microscopic mesh apertures. This creates highly uniform aerosol droplets with a controlled particle size distribution.

Compared with conventional jet nebulisers, vibrating mesh systems can offer:

- More efficient drug delivery
- Reduced residual drug waste
- Quieter operation
- Portable and battery-powered designs
- Improved patient convenience.

These devices can achieve tighter reproducibility of particle generation and potentially improve lung deposition efficiency. However, they can damage biologic drugs during the aerosolisation process.

Acoustic Wave Aerosolisation

An emerging device category may avoid damage to biologics during aerosolisation. For example, the Nebu~Flow device (Acu-Flow, Glasgow, Scotland) uses surface acoustic waves and precise liquid wells to aerosolise droplet sizes optimised for inhalation into the deep lung where the surface area is greatest.[2] The timing and intensity of aerosol generation can be precisely controlled electronically.

Flash Evaporation Systems

In flash evaporation platforms, such as the Staccato system by Nova Pneuma (Fremont, CA, US),[3] a thin layer of drug formulation is deposited onto a heating plate powered by a battery, which heats the substrate and flash-vaporises the drug. The evaporated liquid then cools and condenses into aerosol particles suitable for inhalation.

This approach can create reproducible aerosols without requiring propellants or bulky nebulisation systems. Electronic control of the heating profile is critical because it determines particle formation, drug stability and dose reproducibility.

SMART SENSORS AND CONNECTED INHALERS

Electronics can enable inhalers to become intelligent monitoring systems rather than passive drug delivery devices. This is particularly important because lack of adherence and poor inhaler technique remain the largest contributors to treatment failure in respiratory medicine.[4]

Monitoring Inhalation Technique

Modern sensors in inhalers can monitor multiple aspects of device usage, including:

- Inspiratory flow rate
- Inhaled volume
- Device orientation
- Triggered actuation timing
- Duration of inhalation
- Time and date of each dose.

"ELECTRONICS CAN ENABLE INHALERS TO BECOME INTELLIGENT MONITORING SYSTEMS RATHER THAN PASSIVE DRUG DELIVERY DEVICES. THIS IS PARTICULARLY IMPORTANT BECAUSE LACK OF ADHERENCE AND POOR INHALER TECHNIQUE REMAIN THE LARGEST CONTRIBUTORS TO TREATMENT FAILURE IN RESPIRATORY MEDICINE."

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These measurements allow the device to detect whether a patient has co-ordinated inhalation properly with drug release. For example, when using pressurised metered dose inhalers, many patients actuate the device either too early or too late relative to inhalation. Electronic sensing systems can detect this mismatch and provide feedback to improve technique.

Platforms such as Hailie by Adherium (Melbourne, Australia), previously known as Smartinhaler,[5] and Propeller by Propeller Health (withdrawn from the market and company disbanded) incorporate sensors and adherence tracking into inhaler systems. Teva (Tel Aviv, Israel) launched three digital inhalers, but discontinued them in 2024.[6]

Early smart inhaler initiatives have tended to struggle to achieve commercial success, but this could change if they can demonstrate compelling benefits to users, clinicians, pharmaceutical companies, payers and/or regulatory authorities that outweigh the cost, use steps, technical complexity and environmental impact of their use.

Breath Actuation and Intelligent Drug Release

Dry powder inhalers are breath-actuated by default. Breath-actuation mechanisms for propellant-based inhalers have existed for several decades, with examples including AutoHaler by Kindeva (Woodbury, MN, US) and the discontinued k-haler by Napp Pharmaceuticals (Cambridge, UK). Breath-actuation mechanisms have had limited success, presumably due to their manufacturing cost and complexity.

However, if an inhaler already uses electronics, then adding breath actuation could provide the following advantages:

- Improved lung deposition
- Reduced oropharyngeal loss
- Greater dose consistency
- Reduced co-ordination burden for patients
- Better usability for elderly or paediatric populations.

Electronic breath actuation could tailor the rate of drug release to the inspiratory flow rate rather than being limited to a binary "on or off" (full drug aerosolisation or none).

Dose Counters are Becoming Smarter

Mechanical dose counters have existed for years, but have challenges with tolerances, cost and manufacturing complexity. Therefore, dose counters are another area where electronics can add value. Electronic counters can:

- Record dose timestamps
- Track remaining doses accurately
- Detect missed doses
- Monitor overuse
- Synchronise with digital health platforms
- Send reminders to patients.

This information supports both patients and clinicians by improving visibility of medication adherence.

For chronic diseases such as asthma or chronic obstructive pulmonary disease, timestamped dose data can reveal important behavioural patterns, including:

- Frequent rescue inhaler usage
- Poor adherence to maintenance therapy
- Incorrect dosing intervals
- Potential disease deterioration.

The ability to digitally track medication use transforms inhalers into valuable sources of real-world clinical data.

SUPPORTING PATIENT ADVOCACY THROUGH MORE RELIABLE DATA

The integration of electronics into inhalation devices also has important implications for patient advocacy. Historically, clinicians have relied heavily on patient self-reporting when assessing adherence and inhaler usage. This could create uncertainty as to whether poor outcomes were caused by ineffective drugs, poor technique or inconsistent usage.

"SMART INHALATION SYSTEMS CAN PROVIDE OBJECTIVE EVIDENCE OF WHEN THE MEDICATION WAS LAST TAKEN, IF A PATIENT'S TECHNIQUE WAS CORRECT AND IF A FULL DOSE WAS DELIVERED."

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Smart inhalation systems can provide objective evidence of when the medication was last taken, if a patient's technique was correct and if a full dose was delivered.

INTEGRATING MECHANICS AND ELECTRONICS FOR RELIABLE PERFORMANCE

Sensors must operate reliably under variable conditions, including moisture exposure, temperature fluctuations, repeated mechanical actuation, condensation, vibrations and impact during daily use. A sensor that performs well on a bench may behave differently once integrated into a compact inhaler subjected to thousands of use cycles. This means mechanical engineers, electronics engineers, firmware developers and manufacturing teams must collaborate closely throughout development rather than working independently on isolated design and manufacturing stages. This is where partnering with a CDMO is ideal to enable seamless connections between teams.

DESIGNING FOR MANUFACTURABILITY AND SCALABILITY

Another key benefit of multidisciplinary teams is ensuring that advanced inhalation technologies can be manufactured consistently at scale. Manufacturing engineers therefore play a major role in translating innovative concepts into reliable medical products.

"IN INHALATION DEVICES, EVEN SMALL MANUFACTURING VARIATIONS CAN SIGNIFICANTLY AFFECT AEROSOL GENERATION AND DOSE DELIVERY, MAKING COLLABORATION ACROSS DISCIPLINES ESSENTIAL."

In inhalation devices, even small manufacturing variations can significantly affect aerosol generation and dose delivery, making collaboration across disciplines essential.

CONCLUSION

Electronics can significantly extend the capabilities of inhalation devices. Inhalers could evolve into intelligent therapeutic platforms capable of generating highly controlled aerosols, monitoring patient technique, improving dose accuracy and supporting adherence.

As inhalation devices become more sophisticated, successful product development increasingly depends on multidisciplinary engineering teams that understand not only the electronics but also the pharmaceutical science, mechanical behaviour and patient interaction involved in the therapy.

ABOUT THE COMPANY

Sanner is a global German manufacturing company that develops and produces plastic packaging and drug delivery systems for pharmaceutical, medical and healthcare customers.

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Tom Oakley

Tom Oakley, Vice-President Strategic Partnerships at Sanner Group (previously Springboard), leads engineering and scientific teams developing new injection devices, pumps and inhalers. He has been the named inventor on dozens of patents throughout his 25 years' experience in the drug delivery industry. His most recent work focuses on developing robust device strategies and plans for a wide range of clients from the largest multinationals to the most dynamic start-ups. Mr Oakley is a regular speaker at various international conferences on innovation and medical device development. He read Engineering at Cambridge University (UK) before becoming the Choate Fellow in Human Physiology and Pathology at Harvard University (MA, US).

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WHAT IT TAKES TO DELIVER TWO SPRAYS: LESSONS FROM COMMERCIAL BIDOSE™ PRODUCT DEVELOPMENT

Aptar pharma

Reenal Gandhi of **Aptar Pharma** discusses the company's dual-dose intranasal delivery device, BiDose™, explains how an integrated development approach is particularly relevant to dual-dose nasal delivery and presents two case studies showcasing how BiDose can be applied for different therapeutic applications.

Systemic nasal drug delivery is entering a new phase. Over the past decade, the intranasal route has expanded beyond its traditional role in local nasal therapies and emergency-use applications. Pharmaceutical companies are now evaluating intranasal drug delivery across central nervous system (CNS) disorders, psychiatric conditions, cardiovascular indications and an increasingly diverse range of acute and episodic treatment settings.

As these opportunities have expanded, so too have the demands placed on delivery systems. For many development programmes, the question is no longer simply whether a drug can be delivered via the nose – it is whether the resulting combination product can progress successfully through development, manufacturing and commercialisation.

At first glance, dual-dose nasal delivery can appear relatively straightforward: a delivery system provides two sprays rather than one. In practice, however, those two actuations introduce interconnected formulation, performance, usability, regulatory and manufacturing requirements.[1]

The delivery system must provide consistent performance across both actuations. The formulation must remain protected during storage and transportation. Users must understand the intended administration sequence. Regulatory submissions must include appropriate evidence for the finished combination product. Manufacturing processes must maintain the required performance as production scales up.

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"SUCCESSFUL DUAL-DOSE INTRANASAL DELIVERY PRODUCTS SHOULD THEREFORE BE DEVELOPED AS COMPLETE COMBINATION PRODUCTS RATHER THAN AS FORMULATIONS PAIRED WITH DELIVERY SYSTEMS LATER ON IN THE PROGRAMME."

Successful dual-dose intranasal delivery products should therefore be developed as complete combination products rather than as formulations paired with delivery systems later on in the programme. Formulation compatibility, analytical performance, product protection, administration clarity, manufacturing readiness and commercial considerations can all influence how a programme progresses.

Aptar Pharma's BiDose™ System (BDS) was developed within this broader context. The established platform combines ready-to-use, primeless operation with two successive metered sprays, one-handed actuation and position-independent operation.[2]

Today, the platform continues to evolve. The latest BDS variant incorporates dose-status feedback and ergonomic refinements while building on the established foundation of the platform. This evolution reflects an important principle in drug delivery – experience should not simply validate a platform, it should inform its continued improvement.

The value of BiDose therefore extends beyond the physical delivery of two sprays. It draws on the technical knowledge, product-development insights and industrial experience accumulated through work on commercial programmes (Figure 1).

DEVELOPING THE FORMULATION AND DELIVERY SYSTEM AS ONE PRODUCT

Combination product success rarely depends on the delivery system alone. A formulation may demonstrate promising characteristics during development yet behave differently once integrated with the selected delivery device. Delivered dose, spray pattern, plume geometry, droplet-size distribution, formulation stability and material compatibility can all influence the performance of the final drug product.

For this reason, Aptar Pharma approaches development from the perspective of the complete combination product, rather than considering the formulation and delivery system as independent workstreams. The company's development capabilities include delivered-dose assessment, spray-characterisation studies, droplet-size analysis, nasal-cast investigations, compatibility assessments and development-scale filling.

These activities are not only intended to generate performance data but also to help identify the factors driving the observed results. When differences emerge during development, the objective is to understand the relationships between the formulation, delivery system and manufacturing process.

This integrated approach is particularly relevant to dual-dose nasal delivery. Two consecutive actuations create specific expectations around consistency and reproducibility across the intended

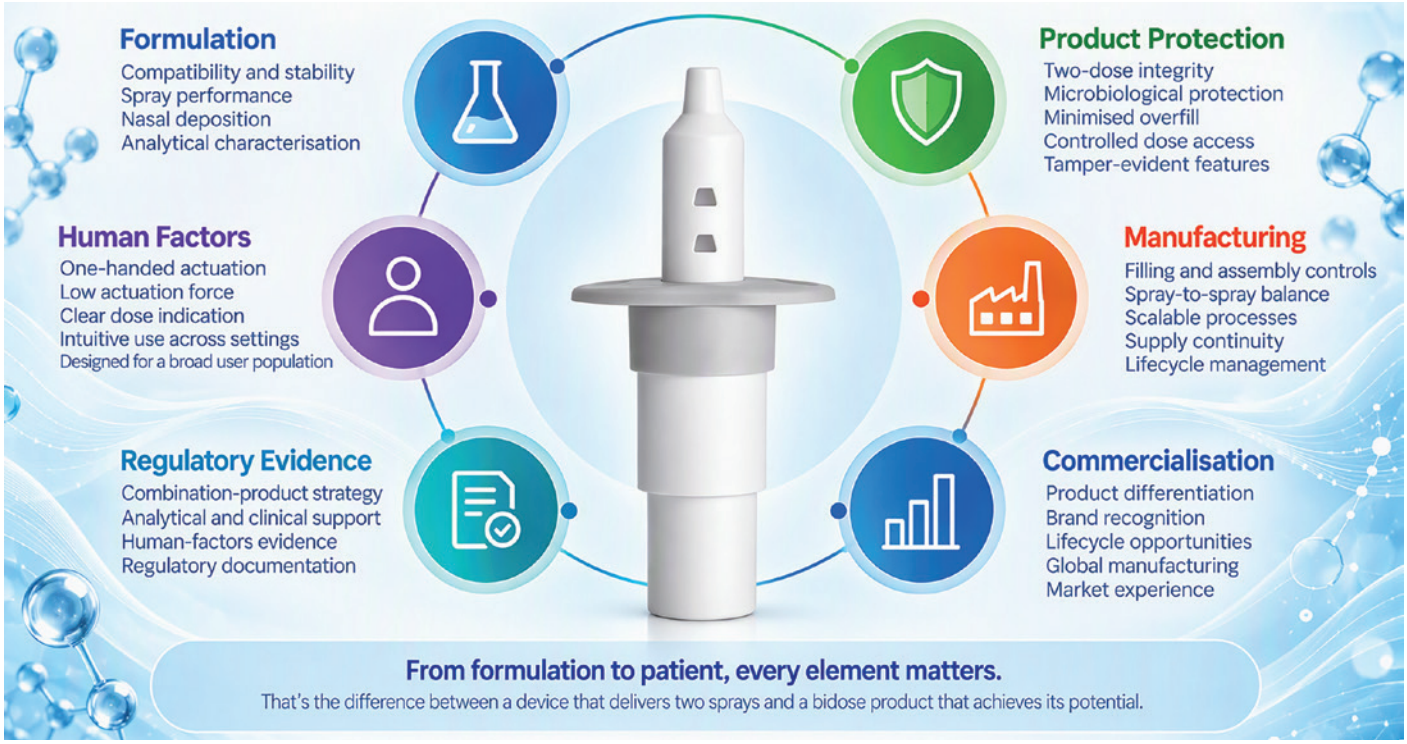


Figure 1: Delivering two sprays is only one part of dual-dose intranasal product development. Formulation, product protection, human factors, manufacturing, regulatory evidence and commercialisation must be considered as connected elements of the finished combination product.

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administration sequence. Development programmes may therefore benefit from examining how formulation–system interactions could influence finished product performance before regulatory submission and commercialisation.

For programmes evaluating BiDose, this means considering the formulation, platform and associated processes together from an early stage. This can help teams to develop a more complete understanding of the finished combination product as the programme advances.

Some formulation challenges originate outside the delivery mechanism itself. Moisture sensitivity, oxygen exposure and long-term stability can influence product performance well before administration. Through its Active Material Science division, Aptar Pharma can help development teams investigate potential sources of product instability and evaluate appropriate product-protection strategies, including technologies such as Activ-Vial™, which is designed to help protect sensitive formulations from moisture and oxygen during storage. This creates a broader framework in which the formulation, protection technologies and delivery system can be considered together.

PROTECTING THE FORMULATION, DOSE BY DOSE

As pharmaceutical pipelines increasingly include peptides, biologics, oligonucleotides and other high-value compounds, the conversation around intranasal delivery is expanding beyond dose administration alone. Development teams are therefore paying closer attention to how efficiently valuable formulation is used during development, clinical manufacture and commercial supply.

One frequently overlooked consideration is overfill. Formulation retained within a delivery system beyond the intended administered dose must still be manufactured, filled, tested and supplied. As API value increases, the significance of this additional volume may also grow.

BiDose was designed with this consideration in mind. The system delivers two metered 100 µL actuations while limiting the amount of formulation that remains undelivered.[2] For high-value or difficult-to-manufacture APIs, minimising non-delivered formulation can help to reduce unnecessary API consumption across development, clinical manufacture and commercial supply.

Where APIs are valuable or complex to produce, reducing the quantity committed to non-delivered volume may become an important consideration within the broader product strategy. In such cases, both the delivered dose and the volume that remains within the system warrant careful attention.

Product protection extends beyond API conservation. BiDose is designed to support formulation protection during storage and preserve the integrity of both doses until the point of use, an approach Aptar Pharma describes as two-dose integrity.

Another aspect of product protection concerns access to the formulation itself. Unlike multidose products that may contain larger volumes, BiDose was designed for applications in which one or two therapies are required for treatment. By limiting the quantity available within the delivery system to the intended treatment paradigm, the platform restricts access to excess drug product. By limiting the quantity of formulation available and helping to restrict direct access to the contained drug product, the BiDose design may be relevant to treatment strategies in which controlled access is an important consideration.

> "AS PHARMACEUTICAL PIPELINES INCREASINGLY INCLUDE PEPTIDES, BIOLOGICS, OLIGONUCLEOTIDES AND OTHER HIGH-VALUE COMPOUNDS, THE CONVERSATION AROUND INTRANASAL DELIVERY IS EXPANDING BEYOND DOSE ADMINISTRATION ALONE."

Aptar Pharma also highlights the relevance of this approach for compounds with abuse potential or products characterised by a narrow therapeutic index. By limiting the quantity of formulation available within the delivery system, the BiDose design may be appropriate for treatment strategies for which controlling access is essential. Its relevance is necessarily therapy-specific, but it reflects a broader principle: product protection involves both preserving formulation quality and aligning access to the drug product with the intended treatment strategy.

PLATFORM EXPERIENCE DRIVES CONTINUED EVOLUTION

The most significant aspect of the latest variant of the BDS is not any single feature but what the refinements collectively represent. The platform now incorporates an integrated status-indication system, which has been designed to provide clearer visibility of system status during use and can help healthcare professionals to understand the actuation status of the system.

Two visual windows provide dose-by-dose status feedback during administration. After each actuation, the corresponding indicator changes colour, helping the user recognise that an actuation has occurred and see whether the second spray remains available.

This focus on administration clarity reflects the environments in which many nasal products may be used – patients may manage symptoms outside the clinic, caregivers may need to administer treatment to another person and healthcare professionals may have limited time for instruction. In these situations, clear information about the status of the delivery system can become an important part of the product experience.

Following the first actuation, the button automatically releases, leaving the system ready for the second spray. Both actuations follow a similar administration sequence, with no initial or intermediate priming required. The actuation force for both sprays is intended to support use across a broad user population. Additional refinements include an enlarged finger flange, a narrower nasal tip and a coloured container-holder element supporting the

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status-indication system. These changes were introduced while maintaining targeted specifications for shot weight, spray pattern, droplet-size distribution and trigger force consistent with previous platform generations (Figure 2).

Together, these user-interface, ergonomic, design and process refinements build on the established BiDose platform rather than introducing a new two-spray concept. They are intended to support administration clarity, a consistent user interaction and reliable operation across the two-actuation sequence, illustrating how an established platform can evolve as development, manufacturing and commercial knowledge accumulates.

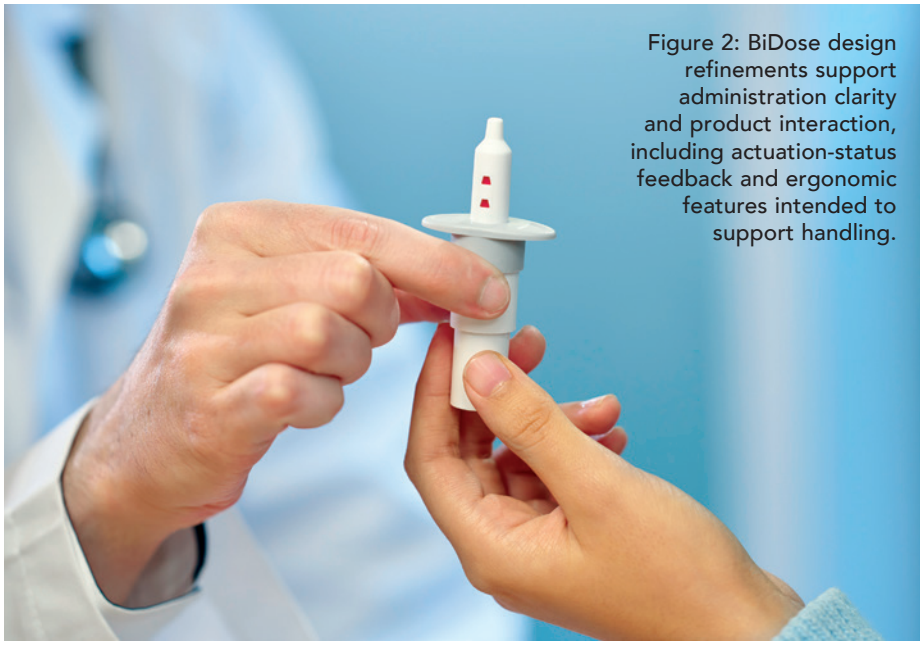


Figure 2: BiDose design refinements support administration clarity and product interaction, including actuation-status feedback and ergonomic features intended to support handling.

MANUFACTURING INSIGHT BUILT THROUGH COMMERCIAL EXPERIENCE

BiDose has supported marketed intranasal delivery devices across distinct therapeutic settings. This commercial presence provides practical insight into the requirements that emerge as a dual-dose intranasal device progresses from development through scale-up and commercial manufacture.

Experience across commercial programmes has shown that delivering two sprays with the intended performance profile is only one part of the challenge. Manufacturing readiness also requires reproducibility, appropriate filling and assembly controls, supply continuity and lifecycle planning. These considerations must be addressed alongside formulation and delivery system performance as part of the finished combination product.

A two-spray delivery platform must be integrated into production processes designed to maintain the required performance across manufacturing campaigns and throughout the commercial life of the product. As production scales, filling parameters, component assembly and process controls can all influence the performance of the finished product.

Aptar Pharma's experience in supporting commercial nasal drug delivery devices has shown that performance across two sprays depends not only on delivery-system architecture but also formulation filling, component assembly and manufacturing process controls. Although BiDose is designed to support consistency between actuations, variability can create challenges during development and performance evaluation. By evaluating the formulation, delivery system and filling process together, development teams can better understand potential sources of variability and establish a more informed control strategy for filling and assembly.

This helps to explain why Aptar Pharma's contribution can extend beyond supplying the delivery system. Development-scale filling, spray-performance testing, compatibility investigations and root-cause analysis can help teams to examine the interactions between formulation, process and device performance.

Through internal expertise and collaboration with service providers, including CDMOs and CMOs, Aptar Pharma can support programmes from early development and clinical manufacture through to commercial production. This framework gives developers access to BiDose alongside broader development and manufacturing support as their development programmes advance.

APTAR PHARMA'S BDS PLATFORM IN PRACTICE

The following examples illustrate two distinct applications: a customised BiDose configuration for a CNS therapy and the integration of the BDS platform into a broader product solution for cardiovascular care. Together, they demonstrate how the same underlying platform can be configured and supported around different product profiles, although each programme requires its own development and supporting evidence.

From a Two-Dose Requirement to Commercial Reality

The development of a marketed esketamine nasal spray provides a practical example of how a specific set of dosing and use requirements was addressed through a customised BiDose configuration. The programme called for two accurate, sequential doses, with one administered into each nostril and no initial or intermediate priming. The product also needed to support self-administration with minimal training.[3] In the US, the marketed product is self-administered under the supervision of a healthcare professional.

Meeting these requirements involved more than selecting a two-spray delivery system. Dose accuracy, plume projection and droplet size were evaluated and optimised as part of the development programme, which combined the customised BiDose liquid configuration, the formulation and the requirements of the finished combination product.[3]

Aptar Pharma's contribution extended across several areas documented in the published case study, including product development, pharmacokinetic studies,

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regulatory support, operational excellence, continuous improvement, lifecycle management and risk management. The programme also drew on Aptar Pharma's analytical laboratories, research facilities and manufacturing capabilities.[3]

Manufacturing considerations were incorporated from the outset. One programme objective was to develop a configuration optimised for high-volume production, bringing manufacturing requirements into the customised BiDose configuration alongside dose delivery, spray performance and intended-use requirements.[3]

The programme provides a practical example of how two-dose administration, drug-product performance, supervised self-administration and high-volume production requirements can be addressed around a customised BiDose configuration.

Experience from one programme does not replace the product-specific evidence required for another. It can, however, provide a more informed basis for identifying the formulation, performance, use and manufacturing questions that need to be addressed.

Extending BiDose into Cardiovascular Care

More recently, BDS has supported a product in a distinctly different therapeutic setting: cardiovascular care. Milestone Pharmaceuticals' (Montreal, Canada) CARDAMYST™ (etripamil) uses Aptar Pharma's BDS platform. The product received US FDA approval for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia to sinus rhythm in adults. This commercial milestone extended Aptar Pharma's BiDose experience into cardiovascular care.[4]

The clinical development programme evaluated self-administered intranasal etripamil using a symptom-prompted repeat-dose regimen for atrioventricular-nodal-dependent paroxysmal supraventricular tachycardia.[5] Separate clinical pharmacology studies characterised the pharmacokinetic and pharmacodynamic profile of intranasally administered etripamil and reported rapid absorption under the study conditions.[6]

Aptar Pharma's Active Material Science division collaborated with Milestone Pharmaceuticals to develop the customised polypropylene dual-container closure system used for CARDAMYST. The solution incorporates Activ-Vial technology to help protect the product from moisture and oxygen during storage. The protective presentation securely houses two BiDose units and includes an integrated cap, with features intended to help prevent accidental activation or the devices from falling out of the container while supporting reliable access when treatment is required.[4]

The CARDAMYST programme therefore illustrates how BiDose, Activ-Vial technology and a customised protective presentation can be brought together within a wider product solution, with delivery, product protection and the intended-use environment considered as connected elements.

FROM FEASIBILITY TO COMMERCIAL REQUIREMENTS

Experience across these programmes shows how the questions change as development advances. During feasibility, the central question may be whether two doses can be delivered with the required spray characteristics. As a programme progresses, the focus broadens. Teams must consider:

- How formulation and delivery-system performance will be maintained
- Which filling and assembly controls may be required
- How the administration sequence will be communicated
- How the system will be protected within the finished product presentation
- What analytical, human factors and regulatory evidence will be needed
- How production and scale-up requirements will be addressed.

These are not secondary considerations. They are part of the work required to progress a two-dose intranasal concept towards a commercial combination product.

The esketamine and CARDAMYST programmes illustrate different dimensions of this journey. One demonstrates the depth of development behind a customised two-dose CNS product intended for high-volume manufacture, while the other shows BiDose entering a cardiovascular setting as part of a broader protective product solution.

Together, they provide important evidence for the continued evolution of BDS. New variants are not intended to redefine dual-dose nasal delivery – they represent the evolution of an established Aptar Pharma platform, incorporating refinements informed by product development, manufacturing and commercial programmes.

DIFFERENTIATION THROUGH THE COMPLETE PRODUCT EXPERIENCE

In competitive pharmaceutical markets, differentiation rarely comes from the drug product alone. It can also emerge from how the formulation, delivery system, packaging, usability and product presentation are brought together into a coherent experience.

For dual-dose intranasal delivery systems, this broader perspective is particularly relevant. Two-spray delivery creates opportunities to reconsider how a product is configured, presented and administered. Rather than treating the delivery system as a standalone component, developers can evaluate how it contributes to the overall product proposition.

BiDose offers opportunities for customised configurations, ergonomic adaptation and differentiated product configurations. Recent platform enhancements continue this evolution through visible actuation-status feedback and ergonomic refinements intended to support the user experience.

"BIDOSE OFFERS OPPORTUNITIES FOR CUSTOMISED CONFIGURATIONS, ERGONOMIC ADAPTATION AND DIFFERENTIATED PRODUCT CONFIGURATIONS."

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Differentiation, however, extends beyond the appearance of the delivery system. Products sharing similar APIs, therapeutic targets or mechanisms of action may also be distinguished through their overall configuration and the way users interact with them. In this context, customisation may contribute to product recognition and a more distinctive experience for patients and healthcare professionals (Figure 3).

This approach may be particularly relevant to lifecycle-management programmes, repurposed molecules and when seeking a differentiated product position. Reformulation, changes to the route of administration and delivery platform selection can all contribute to a new product proposition.

Aptar Pharma supports these efforts through drug-repositioning and lifecycle-management expertise intended to help developers explore additional opportunities for existing assets. Innovation is not limited to discovering a new molecule – it can also involve reconsidering how an established molecule is formulated, delivered and experienced.

The use of a proprietary delivery platform may also contribute to the intellectual property strategy surrounding the finished drug product. The implications are necessarily programme-specific, but platform differentiation and intellectual property considerations may introduce an additional dimension when evaluating long-term commercial strategy.

Differentiation should therefore not be regarded solely as an aesthetic exercise. The value of a dual-dose intranasal delivery platform should be considered in the context of the complete product experience and the wider development and commercial strategy.

COMMERCIALLY ESTABLISHED, CONTINUING TO EVOLVE

Intranasal drug delivery continues to expand across therapeutic areas, molecule classes and treatment paradigms.



Figure 3: The interaction between the user and the delivery system forms part of the overall product experience.

As these opportunities develop, expectations of dual-dose intranasal delivery platforms are also evolving.

Aptar Pharma's BDS platform has progressed through experience spanning marketed products, combination product development and commercial manufacture. Its latest variant represents the next stage in that progression, incorporating actuation-status feedback and ergonomic refinements while building on the established platform foundation.

Discussions around dual-spray delivery often begin with the actuations themselves. Commercial combination products, however, are shaped by everything surrounding them, including formulation compatibility, product protection, usability, manufacturing processes, evidence generation and commercial execution.

Ultimately, the future of dual-dose intranasal delivery will not be shaped by delivery systems alone. It will depend on how effectively developers bring together formulation, delivery-system performance, patient and user needs, manufacturing strategy, regulatory planning and commercial objectives.

For programmes where two-spray delivery aligns with the intended product profile, Aptar Pharma's BDS brings together an established platform, commercial experience and integrated development capabilities. While delivering two sprays is only the starting point, the real value lies in the knowledge required to help translate a dual-dose strategy into a finished combination product.

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MY STERINITY NASAL: ADVANCING PHARMACEUTICAL GLASS PACKAGING FOR NEXT-GENERATION INTRANASAL THERAPIES

SGD Pharma introduces the company's dedicated ready-to-use Type I glass vial platform, My Sterinity Nasal, which is designed to address the sterility, compatibility, stability and manufacturing demands of preservative-free nasal medicines, as primary packaging increasingly becomes a strategic part of drug development as intranasal drug delivery expands into chronic, high-value and sensitive therapeutic applications.

Intranasal drug delivery is moving beyond its established role in emergency treatment and into a broader range of chronic and high-value applications, such as formulations targeting the central nervous system (CNS), vaccines and systemic therapies, which place increasingly demanding requirements on the primary container. For these products, the vial is not simply a vessel – it must help protect sterility, maintain compatibility with the formulation and support product stability over its intended shelf life.

These requirements are especially relevant for preservative-free products and sensitive formulations. Where a medicine is intended for repeated or long-term administration, the chemical behaviour of the container, its barrier performance and the cleanliness of the supplied packaging become important elements of the overall product strategy.

A DEDICATED READY-TO-USE PLATFORM

To address these needs, SGD Pharma has expanded its ready-to-use (RTU) platform with My Sterinity Nasal, a range of Type I pharmaceutical glass vials developed specifically for

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"SGD PHARMA HAS EXPANDED ITS RTU PLATFORM WITH MY STERINITY NASAL, A RANGE OF TYPE I PHARMACEUTICAL GLASS VIALS DEVELOPED SPECIFICALLY FOR PRESERVATIVE-FREE NASAL DRUG DELIVERY AND SENSITIVE FORMULATIONS."

preservative-free nasal drug delivery and sensitive formulations. The platform brings together the characteristics of pharmaceutical glass with validated preparation and sterilisation steps, providing vials that can be introduced into filling operations and eliminating the need for the manufacturer to perform the conventional container washing and preparation sequence.

My Sterinity Nasal is the first product resulting from a strategic collaboration between SGD Pharma and Prince Sterilization Services (Montville, NJ, US). SGD Pharma brings its pharmaceutical glass manufacturing expertise, while Prince provides capabilities in validated washing, depyrogenation and sterilisation for the North American market. The resulting device is intended to combine container performance with a robust, validated supply chain.

FORMATS AND PRESENTATION

The range is available in 3.5, 7.5 and 10 mL formats, with both clear and amber glass options. The vials are designed for compatibility with standard preservative-free nasal pump systems and are supplied in double-bagged trays. This RTU format is intended to simplify filling operations and reduce the number of container-preparation steps required at the pharmaceutical manufacturing site through the following:

- Controlled particulate and endotoxin levels
- Validated sterility assurance
- Compatibility with standard preservative-free nasal pump systems
- Double-bagged tray presentation for RTU filling.

WHY TYPE I GLASS MATTERS

For advanced nasal therapies, container-product interaction can be a critical consideration. Type I glass offers strong chemical resistance, helping to minimise interactions between the primary container and the drug product. This is particularly significant for formulations intended for repeated or long-term use, where maintaining formulation stability throughout the product lifecycle is essential.

Glass also provides excellent barrier properties and long-term biocompatibility. Together, these attributes support the integrity of sensitive formulations while providing a well-established pharmaceutical packaging material for developers working on increasingly sophisticated intranasal products.

PRODUCT RECOVERY FOR HIGH-VALUE FORMULATIONS

My Sterinity Nasal incorporates SGD Pharma's U-Save vial design, which was developed to maximise product recovery. This feature is particularly relevant for high-value formulations, where residual drug left in the container can represent both an economic loss and an efficiency issue.

By reducing residual volume and improving recoverability, the vial design can help manufacturers make more effective use of the filled drug product. In applications involving costly APIs or limited clinical material, this can become a practical consideration alongside more familiar packaging requirements, such as sterility and compatibility.

STERILITY, CLEANLINESS AND MANUFACTURING EFFICIENCY

The demands placed on primary packaging extend beyond the intrinsic properties of the glass. The condition in which the container arrives at the filling line also matters. The specifications for My Sterinity Nasal include controlled particulate and endotoxin levels and validated sterility assurance, reflecting the needs of preservative-free and sensitive nasal formulations.

The RTU approach is designed to simplify pharmaceutical filling operations. By receiving prepared vials in double-bagged trays, manufacturers can avoid the need to carry out the full conventional sequence of vial washing, depyrogenation and sterilisation in their own facility. This can reduce operational complexity while providing a defined, validated packaging input for development and production.

A SUPPLY CHAIN DESIGNED FROM CLINICAL DEVELOPMENT TO COMMERCIAL PRODUCTION

Packaging decisions made during development need to remain practical as programmes advance towards larger production volumes. My Sterinity Nasal is supported by a supply chain that is intended to serve pharmaceutical companies from clinical development through commercial production.

The glass vials are manufactured at SGD Pharma's Saint-Quentin-La-Motte facility in France. This established manufacturing capability is complemented by sterilisation services provided by Prince in North America. The collaboration therefore combines pharmaceutical glass production with dedicated sterilisation capabilities for the North American market.

"THE SPECIFICATIONS FOR MY STERINITY NASAL INCLUDE CONTROLLED PARTICULATE AND ENDOTOXIN LEVELS AND VALIDATED STERILITY ASSURANCE, REFLECTING THE NEEDS OF PRESERVATIVE-FREE AND SENSITIVE NASAL FORMULATIONS."

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"BY COMBINING HIGH-QUALITY TYPE I GLASS WITH VALIDATED RTU PROCESSING, MY STERINITY NASAL OFFERS A DEDICATED PACKAGING SOLUTION FOR PRESERVATIVE-FREE NASAL PRODUCTS AND SENSITIVE FORMULATIONS."

PRIMARY PACKAGING AS PART OF THE DRUG-DEVELOPMENT STRATEGY

The growth of intranasal delivery for treating neurological disorders via the CNS, as well as delivering vaccines, biologics and other high-value therapeutics, is increasing the importance of selecting the right primary packaging. As formulations become more valuable and increasingly sensitive, drug developers must consider how the container supports product quality, manufacturing efficiency and long-term stability rather than treating packaging as a late-stage commodity decision.

My Sterinity Nasal has been developed around this shift. Its combination of Type I glass, controlled cleanliness, validated RTU processing, pump compatibility and improved product recovery addresses several of the practical requirements associated with advanced nasal formulations in a single packaging platform.

SUPPORTING THE NEXT GENERATION OF NASAL MEDICINES

Intranasal delivery offers new opportunities for medicines that require rapid, convenient or non-invasive administration, while the expansion into CNS therapies, vaccines and other high-value applications raises the technical expectations placed on every component of the drug-device system. Primary packaging must be capable of protecting the formulation while also fitting efficiently into pharmaceutical manufacturing processes.

By combining high-quality Type I glass with validated RTU processing, My Sterinity Nasal offers a dedicated packaging solution for preservative-free nasal products and sensitive formulations. For developers seeking to move intranasal products from clinical programmes towards commercial manufacture, the platform is positioned to provide a consistent container solution focused on safety, product integrity, product recoverability and operational efficiency.

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DCA is a product design consultancy with a wealth of experience developing leading drug delivery devices for global markets, including all types of injection, infusion, inhalation, intranasal, oral and topical devices. DCA provides comprehensive, expert support for device design and development, including strategy, usability, connectivity, engineering, electronics, medical device software and industrialisation.

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Nanopharm, an Aptar Pharma company, is a provider of tailored analytical and drug development services, with a focus on OINDPs. Its unique processing technologies and formulation development tools enable seamless translation of preclinical development through to clinical manufacturing. Nanopharm's integrated development services aid successful product development by understanding how material properties and processing conditions influence product functionality.

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Nebu~Flow is a start-up medical device company transforming inhaled drug delivery with a new class of nebuliser technology. Nebu~Flow aerosolises a wider range of drug formulations than conventional devices, including novel therapies such as biologics, peptides and RNA therapeutics, that lack effective routes to the lung. Nebu~Flow is currently developing the product and seeking collaborators for product development.

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SGD Pharma produces primary glass packaging for the pharmaceutical and beauty industries at its ten ISO 15378-certified production sites in Europe and Asia, offering a wide range of Type I, II and III glass vials, ampoules and dropper bottles, in both amber and clear glass. It has a robust global supply chain and a network of more than 90 agents and distributors, ensuring performance and continuity for its customers.

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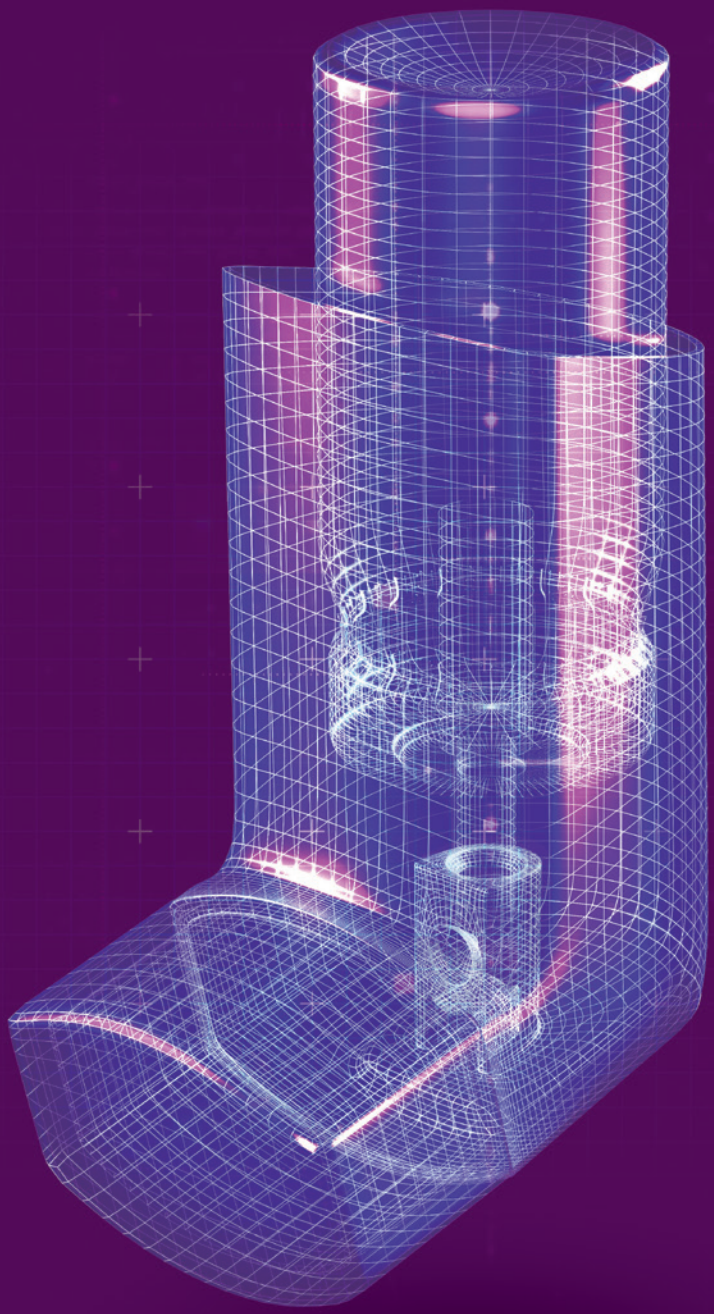
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