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# ONDrugDelivery

JUNE 22ND 2026

## ORAL DRUG DELIVERY

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# ORAL DRUG DELIVERY


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# Biologics and Manufacturing:
## On the Forefront of Oral Delivery

For many, the once-a-day pill remains the gold standard for drug delivery. However, achieving an efficacious and manufacturable oral solid dosage (OSD) form can be a daunting task in the face of the challenging and sensitive biologic therapies that are making up an increasing share of pharmaceutical pipelines. In this issue of ONdrugDelivery, we explore how the oral sector is rising to meet today's challenges, both in deliverability and in manufacturing.

Beginning the issue, **PCI Pharma Services** takes a look into dry granulation of powders during OSD manufacturing (Page 6). PCI goes into detail on how roller compaction has demonstrated itself to be the most preferable approach for this stage of production, particularly for heat- and moisture-sensitive APIs, as well as those that require stringent containment measures due to their high potency.

Continuing on the theme of powder technologies, **Catalent Pharma Services** puts the spotlight on micronisation technology (Page 14). Catalent describes how, by using the appropriate solid-state analytical techniques to characterise the API before and after micronisation, drug developers can gain a clearer understanding of how micronisation will affect the API's performance, stability and manufacturability.

Turning our attention to biologics, **Dr Sahab Babaee** investigates the potential of device-based technologies for delivering biologics via the oral route (Page 10). While biologics have earned significant notoriety for how sensitive they are to the harsh conditions of the gastrointestinal tract, Dr Babaee provides an overview of how some innovators are exploring novel device approaches to taking on this challenge, as well as the opportunities this space represents.

**Lonza Capsugel** further contributes to this discussion with a look into the formulation approaches for biologic deliverability (Page 20). Considering next-generation technologies, such as nanoparticles and ready-to-use enteric capsules, Lonza Capsugel examines the formulation strategies available to drug developers both for protecting biologics within the gastrointestinal tract and for improving their bioavailability.

Rounding out the issue, **ACG** returns us to the realm of OSD manufacturing, with a particular focus on advanced connectivity and integration (Page 24). Using its own progress on this front as an example, ACG highlights the benefits that an integrated, data-driven manufacturing can provide over the traditional, more siloed, fragmented approach, both in terms of flexibility and overall cost.

**James Arnold**
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# ROLLER COMPACTION IN MODERN ORAL SOLID DOSE DEVELOPMENT

**David O'Connell** of **PCI Pharma Services** delves into oral solid dosage production, highlighting the advantages of roller compaction for sensitive drugs as well as the possibilities for integration into existing manufacturing lines.

Roller compaction has become an increasingly important technology in oral solid dosage (OSD) development. It offers a robust dry granulation route for formulations that are difficult to process by direct compression and are unsuitable for wet granulation. This matters in a market where OSD products remain dominant – one recent market analysis valued global OSD manufacturing at US$599 billion (£445 billion) in 2025, rising to $623 billion in 2026.[1] Tablets alone are expected to account for approximately 70% of the market in 2026. Within this large OSD base, dry granulation is widely used as a practical enabling technology for formulations that are moisture-sensitive, heat-sensitive, poorly flowing or intended for continuous manufacture. Roller compaction represents the predominant dry granulation approach in modern pharmaceutical production.

For technical teams, the attraction of roller compaction is clear. It densifies powders without the addition of a liquid binder, creates granules with improved flow and handling properties, and removes the need for a drying step. This combination

"ROLLER COMPACTION REPRESENTS THE PREDOMINANT DRY GRANULATION APPROACH IN MODERN PHARMACEUTICAL PRODUCTION."

can reduce process complexity while supporting product stability, especially for APIs vulnerable to hydrolysis, thermal stress or unwanted solid-state change. It can also fit well with current development priorities, including quality by design (QbD), containment for highly potent compounds and a broader shift towards continuous manufacturing.[2]

## THE ROLLER COMPACTION METHOD

In simple terms, roller compaction converts a powder blend into a ribbon by feeding the material between two counter-rotating rollers under pressure (Figure 1). The ribbon is then milled into granules with controlled particle size distribution suitable for downstream tableting, encapsulation or sachet filling. Although the sequence appears to be simple, the process depends on careful control of feed consistency, compaction conditions and milling intensity, as each affects granule structure and therefore final dosage form performance.

The process starts with delivery of the powder blend to the compaction zone, usually through a hopper and screw-based feed system designed to provide consistent de-aerated powder flow (Figure 2). Good feeding is essential because fluctuations in powder supply directly influence ribbon density and thickness. At the nip point between the rollers, particles rearrange, deform and bond under stress to form a coherent, compact stream. This compacted ribbon is subsequently broken down using a controlled milling step, where mill screen size, rotor speed and mill geometry determine the balance between target granules and undesirable fines.

The dry route offers clear advantages over both slugging and wet granulation. Slugging, the older dry granulation method, depends on pre-compressing large slugs on a tablet press followed by milling, but it is typically less consistent and less scalable than roller compaction. Wet granulation remains highly useful, but it introduces liquid addition and drying, which can create issues for compounds that are water- or heat-sensitive. By removing those steps, roller compaction can simplify the process and reduce the risk of stability-related problems that arise during manufacture.

## CRITICAL PROCESS VARIABLES

From a development perspective, three variables dominate process behaviour: specific compaction force, roller gap and roller speed. Specific compaction force governs the degree of densification and the strength of the ribbon. If the applied force is too low, ribbons may be weak and generate excessive fines during milling; if it is too high, the material can become over-compacted, which may reduce tabletability and adversely affect downstream compression behaviour. Therefore, the optimal setting depends on formulation properties and must be established experimentally rather than assumed from prior product manufacture.

Roller gap and speed are equally important, as they affect dwell time, ribbon thickness and throughput. A narrow gap can promote higher densification, while higher roller speed may increase output but shorten the effective time under load. In practice,


Figure 1: A Gerteis (Jona, Switzerland) roller compactor in use at PCI Pharma Services.


Figure 2: High-potent granulation suite at PCI.

these variables interact strongly with feed rate and formulation compressibility; therefore, process understanding should rely on structured experimentation rather than one-factor-at-a-time studies. For this reason, roller compaction is well suited to QbD-based development, where design of experiments can be used to map the relationship between process settings, ribbon properties, granule attributes and final tablet performance.

The milling stage also deserves more attention than it sometimes receives. Once the ribbon has been formed, overly aggressive milling can remove the benefits achieved during compaction by generating too many fines or damaging granule structure. Gentle oscillating mills are often preferred because they can produce a narrower granule size distribution with less attrition than more aggressive approaches. This is not a minor downstream detail – granule size distribution affects die filling, segregation risk, blend uniformity and ultimately the robustness of tablet compression or capsule filling.

## EQUIPMENT AND CONTROL

Equipment architecture can materially affect process consistency. Broadly, pharmaceutical roller compactors are configured either as fixed-gap or floating-gap systems. In a fixed-gap system, the roller distance is held constant, so changes in feed characteristics or material behaviour can appear as variations in compaction force. In a floating-gap system, the gap adjusts dynamically in response to process conditions to maintain a more constant compaction force, helping to stabilise ribbon density and granule quality. For development and scale-up, this improved control can be valuable, particularly when dealing with blends that have variable flow, compressibility or air retention.

Roller compaction is also advantageous because it aligns naturally with continuous manufacturing. A 2021 review of small-molecule continuous manufacturing notes that dry granulation with a roller compactor is inherently continuous and sits comfortably within integrated feeder-blender-compactor-mill-tablet press lines.[2] The same review highlights the regulatory support for continuous approaches from agencies including the EMA, US FDA and MHRA, as well as the close alignment between continuous processing, advanced control strategies and QbD principles.

**"ROLLER COMPACTION IS NOT SIMPLY A BATCH ALTERNATIVE TO WET GRANULATION; IT IS ALSO A KEY BRIDGE TO MODERN INTEGRATED MANUFACTURING STRATEGIES."**

In other words, roller compaction is not simply a batch alternative to wet granulation; it is also a key bridge to modern integrated manufacturing strategies.

That said, the benefits are not automatic. Continuous roller compaction still requires a rigorous control strategy, including an understanding of the effects of residence time, disturbance handling, material traceability and, where relevant, real-time monitoring or feed-forward control. As with any advanced process, success depends on combining suitable equipment with a deep understanding of powder properties and process dynamics. When that understanding is built early, the same basic platform can support rapid transitions from development to commercial scale by adjusting run time rather than redesigning the process around entirely different unit operations.

## POTENT COMPOUNDS AND CONTAINMENT

Another reason roller compaction has gained strategic relevance is the increasing importance of highly potent APIs. Many newer small molecules require containment levels beyond what can be managed safely with procedural controls and personal protective equipment alone. At the same time, developers want efficient manufacturing routes that minimise open handling and unnecessary unit operations. Roller compaction can help on both counts because it is a dry, enclosed process and can be integrated with contained feeding, sealed transfer and milling solutions (Figure 3).

For a CDMO environment, this combination of dry processing and containment is particularly useful. Technical teams can evaluate wet and dry routes in parallel, then select the approach that best balances stability, manufacturability and occupational safety. In practice, roller compaction is often a strong candidate when the API is moisture-sensitive, when the formulation is poorly flowing or

Figure 3: Interior of a manned high-potent isolator.

when exposure control is a central design constraint. Its value is therefore not limited to one narrow class of products; it sits at the intersection of formulation science, process engineering and industrial hygiene.

## DEVELOPMENT IMPLICATIONS

From a formulation standpoint, one of the most important development questions is whether the material will tolerate the stress of densification without losing its ability to form a strong final tablet. Some excipients and APIs respond well to roller compaction, while others show strain hardening that can reduce compactibility upon recompression. This is why development work should not stop at making acceptable granules. Teams need to link ribbon density, granule size distribution and the proportion of fines to downstream tableting properties, such as hardness, friability, disintegration and dissolution. The roller compaction step has to be judged in terms of the final dosage form, not just the intermediate granule.

A technically sound development programme therefore begins with material characterisation and route selection. If direct compression is not viable and wet granulation carries unacceptable stability risks, roller compaction becomes an obvious route to evaluate. Initial studies should establish feasible ranges for compaction force, gap and speed, while also screening excipient systems that support both ribbon formation and downstream compression. As the process matures, the focus should shift towards defining a robust design space, supported where possible by in-process measurements and a control strategy proportionate to the product risk.

## LOOKING AHEAD

Against the scale of today's OSD market, even a modest proportion of products requiring dry granulation translates into a significant technical opportunity. Precise global penetration data for dry granulation are limited in the public domain, but the available technical literature consistently positions roller compaction as the predominant pharmaceutical dry granulation method and a preferred option for moisture- and heat-sensitive products, as well as products oriented towards continuous manufacturing. This makes it highly relevant not as a niche equipment option but as an advanced manufacturing capability within the much broader and still expanding OSD sector.

For pharmaceutical scientists and engineers, the significance of roller compaction lies in the combination of practicality and strategic fit. It improves powder handling, avoids liquid addition, supports containment and lends itself to continuous processing, which can be scaled successfully when appropriately developed. As OSD products continue to dominate the pharmaceutical landscape, roller compaction is likely to remain an essential option in the development toolkit, particularly for formulations that challenge conventional wet processing routes.

"AS OSD PRODUCTS CONTINUE TO DOMINATE THE PHARMACEUTICAL LANDSCAPE, ROLLER COMPACTION IS LIKELY TO REMAIN AN ESSENTIAL OPTION IN THE DEVELOPMENT TOOLKIT, PARTICULARLY FOR FORMULATIONS THAT CHALLENGE CONVENTIONAL WET PROCESSING ROUTES."

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# Expert View

# ORAL DELIVERY OF MACROMOLECULES: CHALLENGES AND OPPORTUNITIES FOR DEVICE-ENABLED GI DELIVERY

**Dr Sahab Babaee** discusses the potential of device-based approaches to enable the delivery of macromolecules via the gastrointestinal tract, considering the constraints and possibilities of mucosal delivery devices, as well as the technologies currently being investigated to make this potential a reality.

Macromolecules, including biologics such as peptides, proteins and nucleic acids, are large, complex molecules that represent a major segment of the pharmaceutical market. Over the last several years, there has been growth in biologics license applications (BLAs) and approvals (Figure 1), with a market valuation around US$450 billion (£335 billion) in 2025 and projected to more than double to over $1 trillion by 2035, growing at a compound annual growth rate of about 8–10%.[1–3]

This growth is driven by rising demand across major therapeutic areas, including oncology, immunology, rare diseases and haematology, along with continued expansion into infectious disease, metabolic and cardiovascular indications. Currently, biologics are primarily administered via subcutaneous or intravenous routes, which present barriers to compliance, patient preference and accessibility. Oral gastrointestinal (GI) delivery represents a viable alternative to improve patient convenience and potentially reduce treatment burden.

## KEY CHALLENGES IN ORAL DELIVERY OF MACROMOLECULES

The main barriers to oral delivery of biologics, which contribute to their

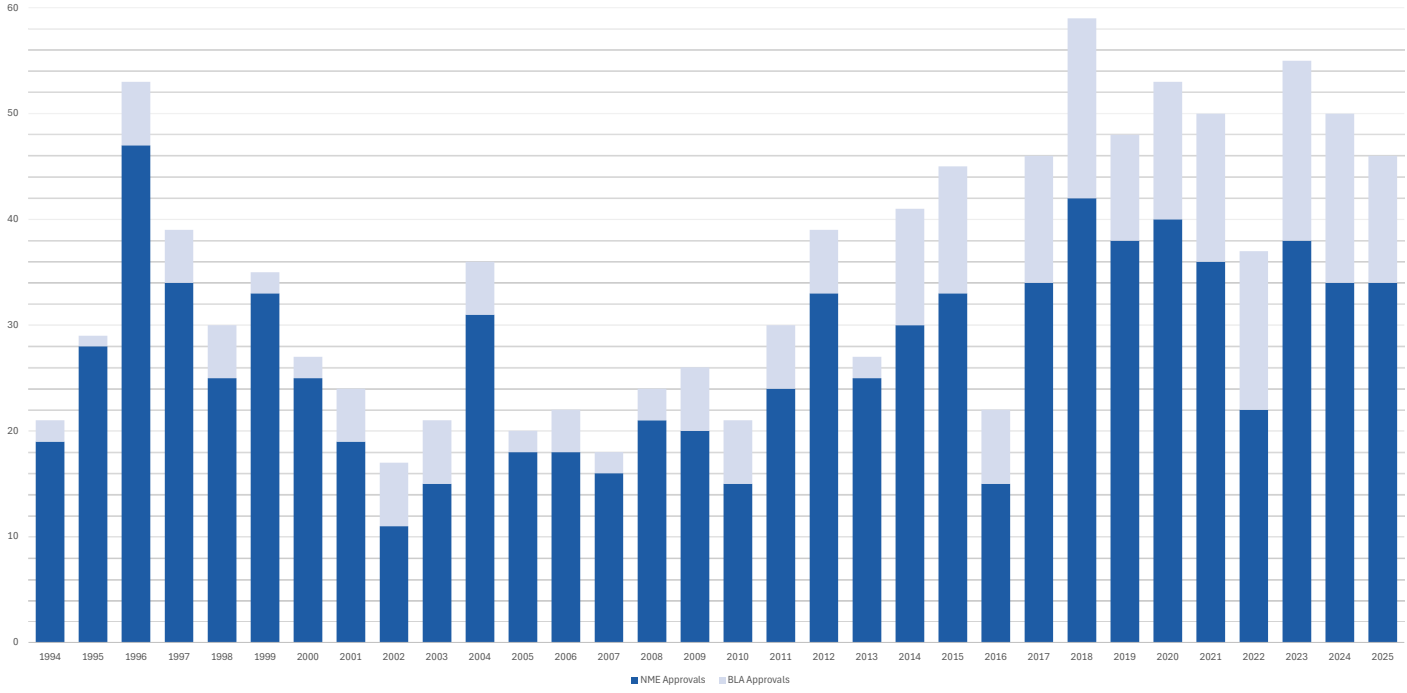


Figure 1: Paradigm shift from small molecules to biologics. Annual numbers of new molecular entities (NMEs) and BLAs approved by the US FDA's Center for Drug Evaluation and Research since 1994.[3]

poor efficacy, are:

1. **Poor Stability:** Biologics exhibit poor stability due to their complex structures and large molecular sizes
2. **Rapid Degradation:** Large molecules undergo rapid degradation when exposed to gastric acid and GI enzymes, making them inactive
3. **Poor Absorption:** Absorption is limited due to the poor permeability of biologic drugs across the GI epithelium (i.e. inability to effectively cross mucosal barriers and overcome first-pass metabolism)
4. **Low Bioavailability:** Due to rapid degradation and poor absorption, orally administered biologics typically have very low bioavailability – often less than 2%.

To address these challenges, device-based strategies have been developed to bypass epithelial barriers and inject drugs directly into the GI submucosa, referred to as oral local mucosal delivery. This approach results in significantly higher bioavailability compared with conventional non-mucosal oral delivery, such as oral suspensions, and can achieve bioavailability comparable with or exceeding subcutaneous injection. Mucosal targeting GI delivery also offers a range of advantages over parenteral routes, which include:

- Non-invasive, painless delivery without the use of needles
- The ability for self-administration and improved patient convenience
- Higher rates of patient adherence
- Increased bioavailability through enhanced local and/or systemic drug exposure.

In addition, mucosal delivery enables the administration of macromolecules or highly sensitive pharmacologic agents that are challenging to deliver via a non-mucosal oral route and mitigates first-pass hepatic metabolism.[4]

"TO ADDRESS THESE CHALLENGES, DEVICE-BASED STRATEGIES HAVE BEEN DEVELOPED TO BYPASS EPITHELIAL BARRIERS AND INJECT DRUGS DIRECTLY INTO THE GI SUBMUCOSA, REFERRED TO AS ORAL LOCAL MUCOSAL DELIVERY."

## DESIGN REQUIREMENTS FOR GI MUCOSAL DELIVERY

### Oral Delivery and Transit

The device needs to have an appropriate size and morphology to allow safe ingestion (e.g. a standard size 00 ingestible capsule) and passage through narrow orifices of the GI tract, such as the oesophagus, to reach the intended target site (e.g. stomach or intestines) without the need for endoscopy. Common design approaches include shape-shifting mesoscale devices and micro-architectures embedded within capsule platforms via non-endoscopic delivery.

### Deployment and Positioning

The device must be capable of adopting the correct configuration, position and orientation at the target site to perform its intended function. Deployment may be self-actuated or triggered by internal or external stimuli. Considerations include whether deployment is targeted or random, and whether positioning is independent or dependent on local anatomy or physiological forces.

### Activation and Drug Delivery

The device must reliably perform its intended therapeutic or diagnostic function. Functional modalities may include therapeutic interventions (e.g. drug delivery), diagnostic capabilities (e.g. sensing, monitoring, gripping, wireless communication, etc.) or combined functions. Devices may operate as sensors and/or actuators and may be passive or active (i.e. pre-programmed or capable of real-time interaction). Long-term retention within the GI tract is generally challenging and often undesirable due to the risk of obstruction, particularly at the pylorus, except for small-molecule therapies.

### Safe Removal and Exit

The device must ensure safe passage through the GI tract and, ultimately, exit the body without risk of obstruction or perforation. Removal strategies may include dissociable or biodegradable designs, as well as "ingest and recover" approaches, in which the ingestible device is naturally excreted and retrieved from stool (e.g. capsule endoscopy). Manual removal via endoscopic retrieval by a GI specialist is generally undesirable.

### Safety Considerations

Safety plays a key role in the design and development of GI technologies, with two primary factors governing the safety of ingestible devices in the GI tract. First, device size and shape must allow safe passage through the narrow anatomical regions of the GI tract without presenting sharp features. Devices exceeding critical size thresholds (typically > 3 cm) pose an obstruction risk and may require surgical removal. Current constraints on electronics and battery miniaturisation can limit size reduction and increase this risk. Second, depth of penetration and interaction with the GI wall must be carefully controlled to avoid perforation, injury or bleeding. The gastric cavity provides a greater safety margin due to its thicker wall (about 4–8 mm) compared with the intestine (about 0.5–2 mm), resulting in more restrictive allowable penetration depths in intestinal applications.[5–7]

"VARIOUS DEVICE-BASED TECHNOLOGIES HAVE BEEN DEVELOPED AND INVESTIGATED TO OVERCOME THE EPITHELIAL CELL LAYER OF THE GI TRACT IN ORDER TO DELIVER THERAPEUTIC PAYLOADS TO THE GI SUBMUCOSA."

## GI DEVICE DEVELOPMENT: PHYSICAL MODES OF DELIVERY

GI drug-device combination technologies have been adapted from principles originally developed for transdermal drug delivery systems.[7] Various device-based technologies have been developed and investigated to overcome the epithelial cell layer of the GI tract to deliver therapeutic payloads to the GI submucosa. These devices use physical modes of drug delivery that include, but are not limited to:[6–8]

- **Needle-Free (Jet) Injection:** A high-pressure fluid jet penetrates the GI mucosa to deliver macromolecules through a nozzle orifice, achieving robust bioavailability and immune responses. This approach represents the leading device-based strategy for oral GI drug delivery devices.[9–11]
- **Needle-Based Injection:** Ingestible capsules deploy a solid or soluble needle to inject macromolecules into GI tissue without requiring endoscopy.[12]
- **Iontophoresis:** An electrically assisted delivery method that enhances transport of charged therapeutics or macromolecules across GI epithelial barriers using low-intensity electric currents.[13]
- **Low-Frequency and Focused Ultrasound:** Acoustic energy is used to transiently enhance GI epithelial permeability and local transport via induced oscillation or collapse of microbubble cavitation, enabling rapid and targeted delivery of large molecules.[14,15]
- **Thermally Triggered Delivery:** Heat-assisted delivery strategies are employed to modulate drug release or act as absorption enhancers by increasing mucosal transport and epithelial permeability, such as thermo-responsive hydrogels.[16]
- **Magnetic:** External magnetic fields have been explored as a means of enhancing the targeting of macromolecules within the GI tract via the use of magnetically responsive nanoparticles.[17,18]

## SUMMARY & OUTLOOK

Despite advances in the development of new GI technologies over recent years, oral mucosal delivery of macromolecules via the GI tract remains challenging due to several key constraints, including the rapid degradation and poor absorption of large molecules, as well as technical and safety challenges associated with the design of ingestible devices. This article has reviewed device-driven strategies, which employ a device to physically perturb the GI epithelium and deposit drug depots directly into the submucosa. Many of these technologies are currently being explored in preclinical or early clinical studies and have demonstrated promising results. However, except for a limited number of devices, their safety and efficacy have yet to be fully established in late-stage clinical trials.

As such, this field represents a promising yet challenging target space for innovation and a key opportunity for continued investment, with the potential to deliver substantial therapeutic benefits to patients and significant value to the biopharmaceutical sector. It is also worth noting that non-device-based strategies aimed at enhancing the stability and/or absorption of oral GI biologics are also attracting increasing interest and advancing rapidly in parallel with drug-device combination approaches, paving the way for the development of novel GI-based drug delivery platforms.

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"THIS FIELD REPRESENTS A PROMISING YET CHALLENGING TARGET SPACE FOR INNOVATION AND A KEY OPPORTUNITY FOR CONTINUED INVESTMENT, WITH THE POTENTIAL TO DELIVER SUBSTANTIAL THERAPEUTIC BENEFITS TO PATIENTS AND SIGNIFICANT VALUE TO THE BIOPHARMACEUTICAL SECTOR."

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# MICRONISATION SUCCESS STARTS WITH SOLID-STATE UNDERSTANDING

**Dr Derek Beauchamp** and **John Kusnierz**, both of **Catalent**, explain how solid-state characterisation underpins the behaviour of a drug substance under processing conditions, and consider the importance of micronisation in improving bioavailability and drug product performance.

As molecules become more complex and solubility challenges more common, particle engineering, particularly micronisation, has become a core strategy to enhance bioavailability and optimise drug product performance. For BCS Class II compounds, reducing mean particle diameter to the low-micron range increases specific surface area and accelerates dissolution kinetics, consistent with the Noyes–Whitney relationship.[1,2] In highly potent API programmes, micronisation also enables precise dosing and content uniformity when API loading is minimal.

However, micronisation is not a neutral unit operation. The mechanical energy introduced during size reduction can alter the solid-state form of the API by way of polymorphic transitions, partial amorphisation and surface disorder.[3,4] These changes may not be immediately visible, but they can directly impact stability, dissolution behaviour and downstream manufacturability.

> "THE MECHANICAL ENERGY INTRODUCED DURING SIZE REDUCTION CAN ALTER THE SOLID-STATE FORM OF THE API BY WAY OF POLYMORPHIC TRANSITIONS, PARTIAL AMORPHISATION AND SURFACE DISORDER."

Solid-state characterisation is therefore not a downstream confirmation step. It is the foundation for understanding how a drug substance behaves under processing conditions. When integrated early and applied consistently, it can reduce development risk, support scale-up and aid micronisation in delivering the intended performance without unintended consequences.

## WHY MICRONISATION INTRODUCES RISK WITHOUT SOLID-STATE CONTROL

Micronisation is often approached as a mechanical step. In practice, it is a material-sensitive process where particle collisions, shear forces and localised temperature increases can disrupt and change crystal structure. These process-induced effects may include:

- Partial amorphisation not fully captured by bulk measurements
- Polymorphic conversion triggered by stress or humidity exposure
- Surface disorder that alters dissolution kinetics
- Recrystallisation during storage or downstream processing.

Figure 1 shows a goniometer being used for powder X-ray diffraction (PXRD), a high-precision mechanical technique that is used to accurately position and rotate the sample, X-ray source and detector to measure diffraction angles and provide an output used to confirm crystalline form.

Mechanical activation during milling has been shown to have the potential to generate disordered regions that can later recrystallise, leading to variability in product performance.[3,4] Without a defined solid-state strategy, these risks often emerge later, during scale-up or stability studies, when mitigation is more complex and costly.

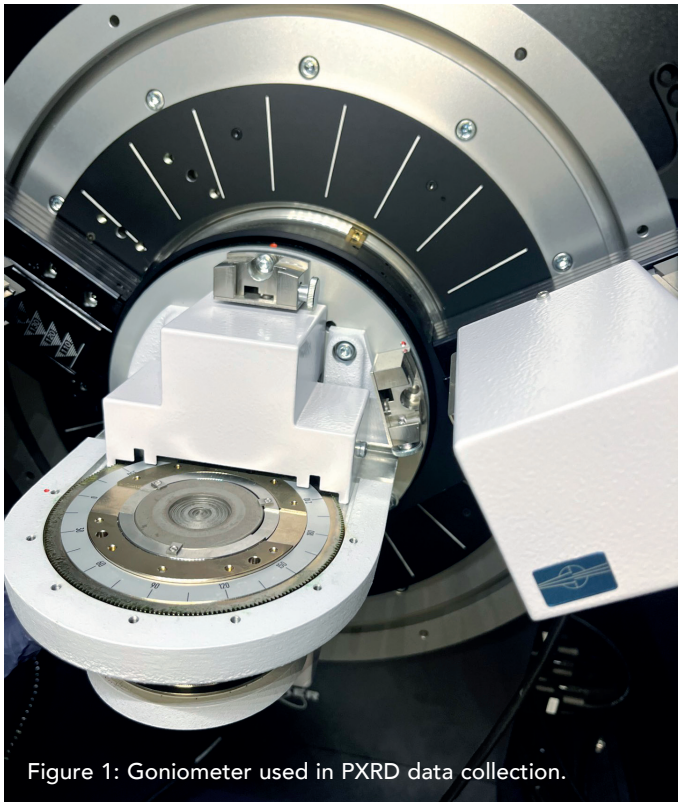

Figure 1: Goniometer used in PXRD data collection.

"MECHANICAL ACTIVATION DURING MILLING HAS BEEN SHOWN TO HAVE THE POTENTIAL TO GENERATE DISORDERED REGIONS THAT CAN LATER RECRYSTALLISE, LEADING TO VARIABILITY IN PRODUCT PERFORMANCE."

## DESIGNING A MICRONISATION STRATEGY

A successful micronisation strategy begins with the material, not the equipment. The key considerations include:

- Crystallinity, polymorphic form and thermal behaviour
- Sensitivity to moisture and mechanical stress
- Likelihood of phase transitions under process conditions
- Impact of downstream unit operations such as blending and tableting.

Materials that appear stable under ambient conditions may respond differently under high-energy milling environments. Solid-state transformations under stress are well established and can directly affect dissolution, stability and manufacturability.[4]

A risk-based approach requires linking material attributes to process parameters early in development. This includes defining critical quality attributes (CQAs), understanding process sensitivities and building data that translate at scale.

This approach aligns with quality-by-design principles, where material understanding drives process design rather than trial-and-error optimisation.[5]

## MAINTAINING CONTROL OF SOLID-STATE PROPERTIES ACROSS THE PRODUCT LIFECYCLE

Solid-state risk does not disappear after micronisation. It evolves across the entire development lifecycle:

### Early Development

Early development defines the foundation for success. The key questions include:

- Which polymorph, hydrate or solvate is most stable under process-relevant conditions?
- How does the material respond to thermal, mechanical and humidity stress?
- What particle size is required to achieve the target dissolution profile?

The selected solid-state form directly influences dissolution rate, stability and manufacturability.[6] Decisions made at this stage determine the robustness of the micronisation strategy.

| Analytical Technique | What It Measures | Why It Matters |
|---|---|---|
| **X-ray Diffraction** | Crystal structure, polymorph identity, amorphous content | Verifies solid-state form and crystalline structure of product |
| **Differential Scanning Calorimetry** | Thermal transitions (melting point, glass transition, recrystallisation) | Detects polymorphic changes and amorphisation introduced during processing |
| **Thermogravimetric Analysis** | Weight changes from moisture loss, decomposition or solvent evaporation | Assesses thermal stability and drying behaviour |
| **Dynamic Vapour Sorption** | Moisture or solvent uptake profiles under controlled humidity | Evaluates hygroscopicity and supports formulation and storage strategy |
| **Specific Surface Area** | Surface area per unit mass | Links surface properties to dissolution, flow and particle interactions |
| **Particle Size Distribution** | Distribution of particle sizes (e.g. via laser diffraction, dynamic light scattering) | Defines a critical quality attribute impacting dissolution and content uniformity |
| **Scanning Electron Microscopy** | Particle morphology, surface texture, agglomeration | Correlates physical structure with processing behaviour and performance |

Table 1: Overview of key solid-state analytical techniques used to characterise APIs before and after micronisation.

> "AS DEVELOPMENT PROGRESSES, CONSISTENCY BECOMES CRITICAL. VARIABILITY IN PARTICLE SIZE OR SOLID-STATE FORM CAN LEAD TO MEASURABLE DIFFERENCES IN DISSOLUTION AND BIOAVAILABILITY."

### Clinical Development

As development progresses, consistency becomes critical. Variability in particle size or solid-state form can lead to measurable differences in dissolution and bioavailability. Solid-state characterisation during clinical development can assist:

- Stability of the selected polymorph during micronisation
- Control of process-induced amorphous content
- Consistent particle size distribution (PSD) across batches and scales
- Reproducible material performance.

These controls are essential to maintain alignment between clinical and commercial material.[6]

### Process Validation

During validation, the focus shifts from understanding to control. Solid-state characterisation can support this by:

- Confirming equivalence between input and micronised material
- Establishing acceptable process ranges
- Linking material attributes to product performance
- Supporting regulatory submissions.

Polymorphic form and solid-state properties are recognised as CQAs due to their direct impact on drug product performance.[6]

### Commercial Supply

Even after process validation, solid-state risks remain. Changes in raw materials, environment or equipment can introduce variability that affects product quality. Ongoing monitoring can ensure:

- Long-term polymorphic stability
- Control of amorphous content
- Consistency in PSD and morphology
- Early detection of process drift.

Maintaining this control is essential for attaining consistent product performance and patient safety.

## BUILDING A MULTI-TECHNIQUE ANALYTICAL STRATEGY

No single analytical method can fully characterise solid-state behaviour. A combination of orthogonal techniques is required to build confidence in form and stability. Table 1 provides an overview of key solid-state analytical techniques used to characterise APIs before and after micronisation.

An example of the dynamic vapour sorption (DVS) sample vessel used to determine mass changes in real time under varying humidity is shown in Figure 2.

Each technique contributes a different perspective. Together, they provide a complete understanding of how the material responds to micronisation and subsequent processing.

Figure 2: A DVS sample vessel used to determine mass changes in real time under varying humidity levels.

### Applying Solid-State Thinking Beyond the API

Solid-state considerations extend beyond the API to intermediates and finished dosage forms.

**API Evaluation**

- Confirm polymorphic form and crystallinity
- Assess stability and moisture sensitivity
- Define PSD and morphology.

**Intermediate Evaluation**

- Monitor transformations during processing
- Evaluate API–excipient compatibility
- Detect amorphous content.

**Final Product Evaluation**

- Confirm API form within the formulation
- Verify stability over shelf life
- Link solid-state properties to dissolution and bioavailability.

"SOLID-STATE CONSIDERATIONS EXTEND BEYOND THE API TO INTERMEDIATES AND FINISHED DOSAGE FORMS."

This integrated approach ensures continuity in characterisation from raw materials to final product and reduces the risk of late-stage surprises.[6]

"THE UNDERLYING SOLID-STATE PROPERTIES OF THE MATERIAL ULTIMATELY DETERMINE STABILITY, PERFORMANCE AND MANUFACTURABILITY."

## CONCLUSION

Micronisation and particle engineering are powerful tools, but their success depends on more than achieving a target particle size. The underlying solid-state properties of the material ultimately determine stability, performance and manufacturability.

A development strategy that integrates solid-state characterisation before and after micronisation, supported by process understanding and lifecycle control, reduces risk and enables predictable scale-up.

For sponsors, the ability to combine particle engineering expertise with deep solid-state knowledge is critical. It enables informed decision-making, reduces development uncertainty and supports consistent product quality from early development through to commercialisation.

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# ADVANCING ORAL BIOLOGIC DELIVERY: OVERCOMING BARRIERS TO ENABLE INNOVATION AND ACCESS

Capsugel®

Lonza

**Dr Vincent Jannin** of **Lonza Capsugel** considers the advantages of delivering biologic medications, including glucagon-like peptide-1s, via oral delivery and discusses the technological strides being made towards enabling biologics to shift away from parenteral delivery.

Biological therapies, more commonly referred to as biologics, have redefined the treatment landscape across multiple disease areas, from metabolic disorders to oncology. However, despite their clinical impact, the vast majority of biologics remain constrained to parenteral administration.[1] This reliance on injection not only contributes to patient burden but also creates inefficiencies across healthcare delivery.

Recent advances in formulation and delivery technologies are fundamentally challenging this paradigm. Oral delivery of biologics is now emerging as a viable and increasingly scalable approach to unlock new opportunities to expand access to these critical medications and improve patient adherence. However, significant scientific and manufacturing challenges must still be addressed to further advance oral biologics in clinical pipelines.

**"RECENT SURVEYS DEMONSTRATED A STRONG INCLINATION TOWARD ORAL DELIVERY, WITH THE MAJORITY OF PATIENTS – APPROXIMATELY 91% IN ONE SURVEY – FAVOURING ORAL DELIVERY OVER INJECTABLE ALTERNATIVES."**

"TRADITIONALLY, PEPTIDES AND PROTEINS WERE CONSIDERED UNSUITABLE FOR ORAL ADMINISTRATION DUE TO INSTABILITY AND POOR ABSORPTION IN THE GASTROINTESTINAL TRACT. HOWEVER, ORAL SEMAGLUTIDE HAS FUNDAMENTALLY CHALLENGED THIS ASSUMPTION."

## PATIENT PREFERENCE AND SYSTEM-LEVEL PRESSURES

The momentum behind development of oral biologics is driven by both patient demand and structural pressures within healthcare systems. Injectable therapies, particularly in chronic disease, are associated with a range of barriers, including administration complexity, reliance on healthcare professionals and reduced patient adherence.

Patient preference data are unequivocal. Recent surveys demonstrated a strong inclination toward oral delivery, with the majority of patients – approximately 91% in one survey – favouring oral delivery over injectable alternatives. One survey reported that 55% of patients with twice-yearly injections would prefer daily oral administration if given the choice.[2] This preference reflects both the reduced convenience of regular injections and well-documented aversion to needles, which remain a significant barrier to treatment initiation and persistence.

From the perspective of healthcare systems, these challenges are amplified by capacity constraints, workforce shortages and the rising prevalence of chronic diseases. The need to transition appropriate therapies towards self-administration is therefore not only patient-driven but also operationally imperative. Thus, oral biologics offer a dual advantage: improving patient adherence and alleviating the burden on healthcare systems. Nowhere is this shift more evident than in the rapid emergence of oral glucagon-like peptide-1 receptor agonists (GLP-1 RAs).

## THE RISE OF ORAL GLP-1 RECEPTOR AGONISTS

The clinical and commercial success of oral GLP-1 RAs represents a pivotal demonstration of feasibility in oral biologic delivery. Traditionally, peptides and proteins were considered unsuitable for oral administration due to instability and poor absorption in the gastrointestinal tract. However, oral semaglutide has fundamentally challenged this assumption.

The clinical and commercial performance of oral semaglutide has illustrated that biologic efficacy can be preserved in an oral format when supported by appropriate formulation strategies. The use of absorption enhancers, such as salcaprozate sodium, can enable protection from gastric degradation and facilitate transcellular uptake across the gastric epithelium.

Importantly, this success is not merely product-specific; it has catalysed broader interest in oral delivery platforms. GLP-1 RAs have provided a validated proof-of-concept that is now informing development pipelines across peptides, proteins and emerging biologic classes.

## BARRIERS TO ORAL DELIVERY

Historically, three interconnected challenges have limited the development of oral biologics:

- Protecting molecules from degradation
- Enabling absorption across the intestinal barrier
- Achieving sufficient bioavailability for therapeutic effect.

First, biologics, particularly proteins and peptides, are highly sensitive to degradation. The acidic environment of the stomach and the presence of proteolytic enzymes can rapidly break these molecules down, rendering them inactive before absorption occurs. Biologics also suffer from poor permeability across the intestinal lining. Even when intact, the mucus layer acts as a protective barrier, preventing large molecules from reaching epithelial cells, while tight junctions between cells restrict passive diffusion.

Furthermore, bioavailability remains a major constraint. It has been estimated that the vast majority of orally administered proteins are digested before systemic uptake, posing a significant challenge to achieving therapeutic efficacy. In addition to those hurdles, manufacturing considerations also play a role. Biologics can be sensitive to heat, solvents and processing conditions, making scale-up and commercialisation of oral formulations particularly demanding. Collectively, these challenges have driven innovation across the industry, spurring the development of new solutions in formulation and delivery strategies to overcome these barriers.

## ADVANCING FORMULATION STRATEGIES

New formulation approaches have emerged that can enable oral biologic delivery by addressing both stability and absorption challenges. However, each strategy ultimately depends on the properties of the biological agent in question.

One of the most important innovations in this regard is enteric protection. Enteric coatings or capsules are designed

"NEXT-GENERATION CAPSULE TECHNOLOGIES, SUCH AS READY-TO-USE ENTERIC CAPSULES, HAVE FURTHER STREAMLINED THIS APPROACH. BY ELIMINATING THE NEED FOR POST-FILLING COATING STEPS, THESE SYSTEMS REDUCE THE EXPOSURE TO HEAT AND SOLVENTS, WHICH CAN DAMAGE SENSITIVE APIs."

to remain intact in the acidic stomach environment and dissolve in the more neutral pH of the intestine, protecting sensitive biologics from degradation. Next-generation capsule technologies, such as ready-to-use enteric capsules, have further streamlined this approach. By eliminating the need for post-filling coating steps, these systems reduce the exposure to heat and solvents, which can damage sensitive APIs. This also improves manufacturing efficiency and scalability. Critically, these innovations open the door to more patient-centric therapies by enabling reliable oral delivery without adding complexity to production processes.[3–5]

Beyond protecting biologic APIs, improving bioavailability is key. Several strategies have emerged to address these challenges, including:

- Permeation enhancers, which work by destabilising the integrity of lipid membranes and opening tight junctions to enhance transcellular and paracellular permeability[6,7]
- Lipid-based formulations (LBFs) can support the absorption of drugs by keeping drugs solubilised in lipid systems or colloids to protect against enzymatic degradation, while enabling hydrophilic compound solubility via hydrophobic ion pairing (HIP) with surfactants[8,9]
- Nanoparticles are used as a versatile tool to address multiple barriers to biologic absorption and have the potential to increase biologic uptake either through activation of non-specific uptake channels or by targeting specific receptors.[6]

In some cases, a single strategy can be sufficient for several biological agents, while in others, combining multiple approaches has proven particularly effective. For example, alternative models of GLP-1 administration have used a combination of enteric protection, LBFs, HIP and permeation enhancers. Also, preclinical models of monoclonal antibodies and RNA-based therapies have also shown promising results with combination strategies.[6,9–11] These integrated delivery platforms represent a scalable model for improving oral bioavailability and expanding the range of biologics that can be delivered orally.

## IMPLICATIONS FOR PATIENT ACCESS

The successful translation of oral biologics has implications that extend beyond formulation science – by enabling self-administration, oral therapies can reduce dependence on healthcare infrastructure and remove key barriers associated with injectable delivery. This is particularly relevant for chronic disease management, where long-term adherence is critical for maintaining therapeutic efficacy. Oral delivery also has the potential to support earlier healthcare interventions, improve patient persistence and broaden access to treatment across diverse populations. From a health-economic perspective, the shift towards oral administration may also reduce the costs associated with clinical administration, hospital visits and resource use.

## DEFINING INNOVATION FOR FUTURE SUCCESS

The emergence of oral biologics reflects the convergence of formulation innovation, patient-centric design and market demand. While significant challenges remain, the field has moved beyond proof-of-concept towards early-stage commercialisation and platform development. The success of GLP-1 RAs has demonstrated that oral delivery of biologics is not only achievable, but scalable when supported by appropriate technologies. Meanwhile, advances in enteric protection, bioavailability and manufacturing processes are expanding the range of biologics that can be delivered orally.

**"THE SUCCESS OF GLP-1 RAS HAS DEMONSTRATED THAT ORAL DELIVERY OF BIOLOGICS IS NOT ONLY ACHIEVABLE BUT SCALABLE WHEN SUPPORTED BY APPROPRIATE TECHNOLOGIES."**

Looking ahead, this progress is expected to continue. As technologies mature and more products reach the market, oral biologics have the potential to move from the exception to the expectation, reshaping treatment paradigms across multiple disease areas. This reflects a fundamental shift towards therapies that are designed around patient needs, improving adherence, enabling earlier interventions and expanding access to life-changing treatments.

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# INTELLIGENT INTEGRATION: WHY CONNECTED OSD ECOSYSTEMS ARE RESHAPING PHARMACEUTICAL MANUFACTURING

ACG

Make it better.

**Borja Guerra** of **ACG** delves into how the oral solid dosage manufacturing industry is being reshaped by connected machinery, advanced digital systems and integrated supplier ecosystems across the production process.

The oral solid dosage (OSD) manufacturing environment is becoming increasingly complex. Factors such as rising stock-keeping unit variability, shorter production timelines, growing regulatory expectations and pressure to maximise operational efficiency are changing how pharmaceutical manufacturers approach production infrastructure and their supplier strategy.

Historically, many OSD manufacturing operations have evolved through fragmented supplier ecosystems. Tablet compression systems, encapsulation machinery, packaging lines, inspection technologies and track-and-trace solutions have often been sourced independently, integrated retrospectively and managed across multiple vendors. And, while this has long been accepted as standard industry practice, it has increasingly created hidden inefficiencies within many modern manufacturing environments.

As pharmaceutical production becomes more agile, digitised and data-driven, manufacturers are beginning to recognise that one of their greatest operational challenges comes from the gaps that have been created across the different systems in use. Equally, fragmented supplier relationships can create real integration challenges, misaligned accountability and, ultimately, performance losses. As a result, demand is increasing for more integrated end-to-end production ecosystems capable of delivering greater operational consistency, flexibility and long-term scalability across the entire OSD value chain.

## THE HIDDEN COST OF FRAGMENTED OSD MANUFACTURING

The growing complexity of modern OSD manufacturing can place real strain on traditional production models. Pharmaceutical manufacturers today are managing a number of areas, including:

- Increasing product portfolios
- Greater batch variability
- Shorter product lifecycles
- More personalised therapies
- Stricter compliance expectations
- Faster time-to-market pressures.

This operational breadth has significant implications across production environments. Each of the above requirements demands manufacturing systems capable of operating with far greater agility than has been seen in previous decades.

Where disconnected machinery ecosystems exist, operational inefficiencies can rapidly accumulate. These may include:

- Prolonged line integration
- Inconsistent communication between machines
- Duplicated validation processes
- Fragmented operational data
- Greater downtime exposure
- Increased or varied maintenance requirements.

In many environments, even relatively minor integration misalignments between systems can create downstream productivity losses across an entire manufacturing line.

This operational burden becomes particularly pronounced when manufacturers rely on multiple suppliers operating independently of each other across machinery, packaging materials, inspection technologies and digital systems. In these scenarios, accountability can become fragmented, troubleshooting harder and overall system optimisation significantly more difficult.


Figure 1: The ACG team presenting the company's integrated OSD manufacturing systems at Interpack 2026.

As such, pharmaceutical manufacturers are increasingly shifting away from isolated equipment purchasing decisions towards more connected manufacturing strategies focused on ecosystem-level optimisation. According to ISPE's Pharma 4.0™ survey, manufacturing, quality and engineering teams now account for approximately 75% of digital transformation activity across the pharmaceutical value chain, reflecting the industry's accelerating focus on connected and integrated manufacturing environments.

## INTEGRATION: A MANUFACTURING STRATEGY

The next phase of OSD manufacturing is likely to be increasingly centred around intelligent integration. Rather than treating machinery, packaging and digital systems as separate operational functions, manufacturers are beginning to view them as interconnected components within a unified production ecosystem.

For example, at Interpack 2026, ACG demonstrated this approach through its fully-integrated OSD manufacturing systems, including capsules, tablet compression, packaging machinery, packaging materials, visual inspection and track-and-trace technologies (Figure 1).

The principle behind the company's approach is relatively straightforward: systems that have been designed to work together from the outset can achieve significantly higher operational efficiency than systems that are integrated retrospectively from multiple independent vendors. This is particularly important within high-speed OSD environments.

ACG's Blister X system, for example, has been engineered specifically for seamless integration within broader OSD production lines. It has been designed to support high-speed blister packaging while maintaining precision, consistency and rapid adaptability across increasingly variable product requirements.

As another example, ACG's ProTab 700 helps manufacturers to address the challenge of production flexibility. As dosage requirements continue to evolve, manufacturers increasingly require tablet

> "RATHER THAN TREATING MACHINERY, PACKAGING AND DIGITAL SYSTEMS AS SEPARATE OPERATIONAL FUNCTIONS, MANUFACTURERS ARE BEGINNING TO VIEW THEM AS INTERCONNECTED COMPONENTS WITHIN A UNIFIED PRODUCTION ECOSYSTEM."

compression systems capable of rapidly switching between monolayer and bilayer applications without compromising productivity or product quality. At the end of the day, ACG is focused on delivering flexibility and operational resilience at scale.

## PACKAGING MATERIALS AND MACHINERY MUST WORK TOGETHER

Within OSD manufacturing, packaging materials and packaging machinery are intrinsically linked, yet, historically, they have often been developed independently. This has frequently created operational mismatches across production environments, impacting line efficiency, changeover performance and overall product consistency.

However, as pharmaceutical manufacturing environments have become increasingly complex, manufacturers have begun placing far greater emphasis on ensuring reliability, precision and flexibility in production, as variations in substrate behaviour, forming characteristics, sealing properties and machine compatibility can all significantly influence operational performance across the packaging line.

At the same time, the rise of lightweight structures, recyclable materials, enhanced barrier requirements and broader sustainability expectations is introducing further complexity into OSD packaging operations. As a result, a far more collaborative approach between material science and machinery engineering is becoming essential.

Manufacturers are recognising that packaging efficiency depends on both the individual performance of materials or machines and how effectively they are designed to work together as part of a connected production ecosystem.

## DIGITALISATION AND INTELLIGENCE-LED MANUFACTURING

The rise of integrated OSD ecosystems is closely connected to the broader acceleration of Industry 4.0 technologies across pharmaceutical manufacturing. Today's connected manufacturing environments are increasingly enabled by technologies such as the industrial internet of things (IIoT), machine learning, generative artificial intelligence (AI), digital twins and real-time monitoring systems. Independently and together these technologies are fundamentally changing how production lines are managed, optimised and maintained.

Rather than relying solely on static operational data, connected manufacturing ecosystems can now provide:

- Predictive maintenance insights
- Live production monitoring
- Automated process optimisation
- Far greater operational visibility across manufacturing workflows.

Importantly, digitalisation is no longer simply being deployed for productivity improvement alone. Manufacturers are using connected systems to improve in areas from traceability to sustainability and resilience.

ACG has witnessed the real success of this convergence of operational intelligence and manufacturing performance first-hand at its Shirwal facility in India. It was recently recognised by the World Economic Forum's Global Lighthouse Network (GLN),[1] making ACG the world's first pharmaceutical packaging company to achieve Lighthouse recognition twice.

The Shirwal transformation programme spans end-to-end manufacturing operations and integrates generative AI, machine learning, deep learning, IIoT and digital twin technologies. The objective was the creation of a connected manufacturing environment capable of sensing, analysing and responding more intelligently across operational workflows. The results have been substantial:

- A 40% reduction in lead times
- A 71% reduction in defects
- A 31% reduction in energy consumption
- A 34% improvement in on-time delivery in full.

Operational integration increasingly supports multiple manufacturing objectives simultaneously to help support improvements in productivity, quality, sustainability and – importantly – customer performance.

## FLEXIBILITY AS A COMPETITIVE REQUIREMENT

Today's production environments must accommodate factors such as fluctuating demand, shorter manufacturing windows, increasingly diverse product portfolios and evolving therapeutic requirements. This means that manufacturing flexibility is no longer simply desirable – it has become operationally essential.

Importantly, integrated manufacturing ecosystems support this flexibility in several ways, as pharmaceutical companies seek to reduce operational risk while simultaneously improving manufacturing responsiveness.

Firstly, unified systems enable faster and more efficient changeovers. Where machinery, packaging materials and digital controls are designed to operate cohesively, manufacturers can reduce transition complexity between products and dosage formats.

Secondly, integrated data visibility improves production planning and responsiveness. Connected systems enable manufacturers to monitor performance across the entire production environment rather than as isolated operational silos.

Thirdly, integrated ecosystems simplify scalability. As pharmaceutical manufacturers expand capacity, introduce new products or enter new markets, connected production architectures can support more efficient

**"OPERATIONAL INTEGRATION INCREASINGLY SUPPORTS MULTIPLE MANUFACTURING OBJECTIVES SIMULTANEOUSLY TO HELP SUPPORT IMPROVEMENTS IN PRODUCTIVITY, QUALITY, SUSTAINABILITY AND – IMPORTANTLY – CUSTOMER PERFORMANCE."**

replication and standardisation across facilities. This is becoming increasingly important as manufacturers seek to scale operational excellence consistently across global operations, as evidenced by ACG's two World Economic Forum GLN recognitions, where connected manufacturing, operational intelligence and integrated systems have been successfully replicated across multiple facilities.

## LOWERING THE TOTAL COST OF OWNERSHIP

While integrated systems may initially appear to require greater strategic co-ordination, they frequently reduce total cost of ownership over time. In fragmented environments, hidden operational costs often emerge through areas such as integration complexity, downtime, duplicated training and reduced overall line efficiency.

By contrast, connected manufacturing ecosystems set out to simplify operational management and create clearer accountability across the production line. They can help manufacturers to achieve lower downtime exposure, simplified maintenance and improved machine usage. And as production pressures intensify, these operational advantages become increasingly commercially significant.

## THE FUTURE OF OSD MANUFACTURING

The pharmaceutical manufacturing sector is entering a new phase of operational evolution. Historically, manufacturing excellence was often measured primarily through machine-level performance. Today's competitive advantage is being shaped by how effectively entire production ecosystems operate together. Ultimately, it is about driving technology-led transformation across the manufacturing value chain, enabling smart manufacturing, connected products and services and creating new business models.

The future belongs to integrated, intelligent manufacturing environments capable of delivering flexibility, consistency, scalability, sustainability and operational resilience. The convergence of connected machinery, advanced digital systems and integrated supplier ecosystems across the entire production lifecycle is now reshaping how pharmaceutical products are manufactured, packaged and delivered globally.

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Make it better.

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**www.acg-world.com**

**ACG** is an integrated provider of oral dosage products and services, producing capsules, barrier packaging materials, manufacturing machinery and visual inspection and traceability solutions, fully compliant with international standards. ACG fosters long-term collaborative partnerships with customers in 138 countries across six continents.

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**Dr Vincent Jannin**
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**Lonza Capsugel** is an oral dosage solutions partner serving pharmaceutical and nutraceutical customers worldwide. With more than a century of expertise, Lonza Capsugel combines advanced capsule technologies, oral dosage form solutions, specialised CDMO capabilities and science-backed health ingredients to help customers turn ideas into scalable, market-ready products.

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Catalent™
Pharma Services

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**www.catalent.com**

**Catalent** champions the missions that matter to help people live better and healthier lives. Every medicine, therapy and product that the company helps develop, manufacture and deliver is part of its commitment to put patients first. Catalent is a trusted partner because it is committed to an exceptional, high-quality experience. Its customers turn to Catalent for tailored solutions to meet their needs as they work together to transform lives.

To learn more, see **Page 14**

# 2026/27 Editorial Calendar



Each issue of ONdrugDelivery focuses 100% on one specific topic *within* drug delivery.

| | | |
|---|---|---|
| **JUL**<br>Industrialising Drug Delivery<br>DEADLINE PASSED | **SEP**<br>Wearable Injectors<br>DEADLINE: **Aug 6, 2026** | **SEP/OCT**<br>Dual Chamber Delivery Systems<br>DEADLINE: **Aug 20, 2026** |
| **OCT**<br>Prefilled Syringes & Injection Devices<br>DEADLINE: **Sep 3, 2026** | **OCT/NOV**<br>Sustainability in Drug Delivery<br>DEADLINE: **Sep 17, 2026** | **NOV**<br>Pulmonary & Nasal Drug Delivery<br>DEADLINE: **Oct 1, 2026** |
| **DEC**<br>Delivering Gene & Cell Therapeutics<br>DEADLINE: **Nov 5, 2026** | **JAN 2027**<br>Prefilled Syringes & Injection Devices<br>DEADLINE: **Dec 10, 2026** | **FEB**<br>Oral Drug Delivery<br>DEADLINE: **Jan 7, 2027** |
| **MAR**<br>Ophthalmic Drug Delivery<br>DEADLINE: **Feb 4, 2027** | **APR**<br>Pulmonary & Nasal Drug Delivery<br>DEADLINE: **Mar 4, 2027** | **APR/MAY**<br>Sustainability in Drug Delivery<br>DEADLINE: **Mar 18, 2027** |
| **MAY**<br>Delivering Injectables: Devices & Formulations<br>DEADLINE: **Apr 1, 2027** | **MAY/JUN**<br>Dermal, Transdermal & Microneedles<br>DEADLINE: **Apr 15, 2027** | **JUN**<br>Industrialising Drug Delivery<br>DEADLINE: **May 6, 2027** |

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