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## STRATEGIES FOR SELECTING THE RIGHT CDMO FOR NASAL DRUG DELIVERY

In this article, Mark Ignaczak, Director of Innovation and Partnerships – Nasal Delivery at Catalent, explores the current nasal drug delivery landscape and outlines key considerations for choosing the right contract development and manufacturing organisation to ensure the success of nasal drug projects.

Nasal drug delivery systems have garnered significant attention in recent years, emerging as a versatile and effective method for administering a wide range of therapeutic agents. From treating localised nasal conditions to delivering systemic drugs and vaccines, nasal drug delivery offers numerous advantages, including rapid absorption, non-invasiveness and patient convenience. As the demand for innovative nasal drug products continues to grow, the role of contract development and manufacturing organisations (CDMOs) has become critical in bringing these products to market efficiently and cost effectively. Selecting the right CDMO is vital because the decision directly impacts product quality, supply chain reliability and the overall commercial success of the nasal programme.

### THE CURRENT NASAL DRUG DELIVERY LANDSCAPE

#### Market Dynamics and Growth Drivers

The nasal drug delivery market is expanding rapidly, driven by several key factors. Traditionally used for local treatments, such as decongestants and allergy medications, nasal delivery is now being explored for vaccines and systemic therapies, including pain management, anaphylaxis and disorders of the central nervous system (CNS).

One of the many advantages of the nasal route of administration is that it avoids the gastrointestinal tract, circumventing the first-pass metabolism by the liver, which plagues oral dosage forms, and promoting rapid absorption into the bloodstream

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and rapid effects. Furthermore, intranasal delivery can potentially offer direct access to the brain, bypassing the blood-brain barrier.

The increasing demand for patient-friendly, non-invasive delivery methods is also driving significant interest and growth in this area. Nasal drug delivery offers a convenient alternative to both oral and injectable routes and may be of particular benefit to patients who have difficulty swallowing pills, and those with needle phobias or who simply prefer to avoid injections. Through many device options, intranasal delivery provides patients with an easy-to-use alternative to other dose forms, and a metered dose can be self-administered without medical training, which can also promote adherence to a dosing regimen.

The ongoing development of nasal vaccines, particularly in response to the covid-19 pandemic, has further highlighted the potential of this delivery route. When pondering the worldwide vaccination effort during the pandemic, one must contemplate how an effective, self-administered and stable nasal product could have provided safe, self-administered, effective and rapid treatment, especially with healthcare systems under pressure to treat those already infected.



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## Technological Innovations

Technological advancements have been instrumental in expanding what can be achieved via nasal drug delivery. Innovations in formulation technologies have led to the development of new dosage forms, such as nasal powders, that offer extended stability and increased residence time compared with liquid formulations. Device technology has also evolved, with the introduction of advanced nasal spray pumps and breath-actuated inhalers, which more precisely target drug deposition in the nasal cavity and further enhance the potential of passing the blood-brain barrier.

Many emerging trends have served to promote nasal drug delivery. These include the development of preservative-free formulations, driven by patient preference for products with fewer additives, and highly potent APIs, which allow for lower dose sizes and reduced side effects. Such innovations are extending the boundaries of what can be achieved using the nasal route and offer new therapeutic possibilities for patients and healthcare providers.

Additionally, the success of rescue therapy applications – for example, to counter opioid overdose – has helped position nasal applications as both reliable and easily and consistently delivered in an emergency. The resulting effect has allowed for the expansion of treatment areas and mainstream acceptance of nasal drug delivery.

## Regulatory Environment

Navigating the regulatory landscape is one of the most challenging aspects of developing nasal drug products. Regulatory requirements vary across regions, with different agencies imposing specific standards for nasal formulations, devices and packaging. Ensuring compliance with these regulations is critical to avoid delays in product approval and market entry.

In recent years, regulatory agencies have increasingly focused on the safety and efficacy of nasal drug products, particularly around the use of preservatives, device performance

and *in vitro* testing. Because the device and formulation are classed as combination products, the regulatory landscape becomes more complex – compliance with the appropriate sections of the US FDA’s 21CFR 210 and 211 (drug GMPs) and 21CFR 820 (medical device quality system regulation) depends on the approach the sponsor selects for its overarching quality system. Companies must demonstrate that their nasal drug products meet rigorous quality standards for many aspects of safe and efficacious delivery, including stability and dose consistency. A thorough understanding of these regulatory requirements is essential for successful product development and commercialisation.

## KEY CONSIDERATIONS WHEN SELECTING A CDMO FOR NASAL DRUG DEVELOPMENT

### Expertise in Nasal Formulation and Device Integration

The most important factors to consider when selecting a CDMO is its experience and expertise in nasal formulation and device integration. Nasal drug delivery requires specialised knowledge of formulation techniques, such as optimising particle size for nasal powders or ensuring the solubility and stability of APIs in liquid formulations. It is critical that a CDMO not only understands the upfront design of experiments requirements but also how they may directly impact downstream spray characterisation guidelines.

A CDMO with a proven track record in nasal drug development should be able to demonstrate the expertise necessary to address the unique challenges associated with this delivery route. This includes the ability to develop and optimise formulations that are compatible with different device technologies, as well as the experience necessary to enhance drug delivery to the desired areas of the nasal cavity, thus ensuring maximum therapeutic efficacy.

### Regulatory Compliance and Track Record

Regulatory compliance is non-negotiable in the pharmaceutical industry, and the stakes are even higher for combination drug products. It is critical to partner with a CDMO that has the expertise to navigate this landscape and quickly identify the critical quality attributes that will affect the process. When selecting a CDMO, it is essential to evaluate its track record in meeting regulatory requirements, inspection

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outcomes for the facility and the suitability of its quality management system. This includes its experience with international regulatory submissions, its success in passing regulatory audits and its ability to maintain compliance throughout the product development lifecycle.

A CDMO with a strong regulatory track record will have established processes for ensuring that all aspects of nasal drug development, from formulation to device selection, meet the required standards. This can help minimise the risk of regulatory delays and ensure a smoother path to commercialisation.

### Analytical Capabilities

Comprehensive analytical services are critical for the successful development of nasal drug products. Analytical testing ensures that products meet all necessary quality attributes, such as those for potency, purity and consistency. Key analytical techniques for nasal drug products include particle-size analysis, spray-pattern testing and droplet-size distribution.

When selecting a CDMO, it is important to assess its analytical capabilities and ensure that it has the necessary equipment and expertise to conduct tests that assess those attributes. A CDMO with strong analytical capabilities can provide valuable insights into formulation and device performance, helping to optimise the product and ensure that it meets all regulatory requirements.

### Scalability and Manufacturing Excellence

Scalability is another key consideration when selecting a CDMO. The ability to scale up production from small clinical batches to full-scale commercial manufacturing is essential for the successful commercialisation of nasal drug products. This requires a CDMO with flexible manufacturing capabilities able to handle various batch sizes and complexities.

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Manufacturing excellence is also critical, as it ensures consistent quality of the product throughout the production process. A CDMO with a strong track record in manufacturing can provide the assurance that the product will be manufactured to the required standards, reducing the risk of production issues and ensuring a reliable supply chain.

### Strategic Alignment and Risk Management

Cultural alignment and communication practices are often overlooked but are key to a successful partnership. Catalent has collaborative values and a communication style that helps foster a productive, collaborative relationship. Some key considerations include transparency and accountability, responsiveness, proven programme management capabilities and cultural alignment with the innovator. Additionally, transparency in timelines, costs and potential risks is essential to building trust. Evaluate the CDMO's responsiveness to queries and its ability to provide solutions when issues arise. Catalent proactively addresses challenges and provides critical thinking to deliver a smooth and efficient programme experience.

Risk management is another critical aspect that must be evaluated. The development of nasal drug products involves inherent risks, such as formulation challenges, device compatibility issues and regulatory hurdles. A CDMO with a proactive approach to risk management can help identify potential issues early in the development process and implement strategies to mitigate these risks, ensuring a smoother path to market.

### FUTURE OUTLOOK AND EVOLVING TRENDS

#### Emerging Technologies and Innovations

Looking ahead, the nasal drug delivery landscape is poised for continued innovation. Emerging technological trends, such as the increasing use of artificial intelligence (AI) and digital health tools, have the potential to revolutionise nasal drug delivery. AI can be used to optimise formulation development, while digital health tools can enhance the patient experience and adherence, helping to monitor the effectiveness of a drug being delivered in real time.

The regulatory landscape for nasal drug products is also expected to evolve. As new technologies and formulations are developed, regulatory agencies may introduce new guidelines and standards to ensure the safety

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and efficacy of these products. CDMOs will need to stay ahead of these changes and ensure their processes are aligned with the latest regulatory requirements.

Finally, strategic partnerships will continue to play a critical role in driving innovation and market success in the nasal drug delivery space. Collaborating with the right CDMO can provide the expertise and resources needed to navigate the complex landscape of nasal drug development, ensuring the successful commercialisation of innovative new products.

### CONCLUSION

The nasal drug delivery landscape is evolving rapidly, with the advent of new technologies and market demands driving innovation. Selecting the right CDMO is a critical decision that requires holistic evaluation of technical expertise, regulatory compliance, financial stability, customer service and cultural alignment. By defining their needs, thoroughly assessing potential partners and negotiating clear contract terms, innovators can forge a productive, long-term partnership that accelerates their product's path to market while maintaining standards of quality and compliance. As the industry continues to evolve, the role of CDMOs will become increasingly important in helping companies navigate the complexities of nasal drug delivery.

Catalent is committed to excellence at every stage of inhalation drug development and manufacturing, bringing a deep expertise in navigating the complexities surrounding combination product regulatory pathways. Its client-centric approach ensures clear communication, transparency and flexibility, allowing it to tailor its services to meet its partners' specific needs while maintaining the highest standards of compliance and quality. Catalent brings innovation, scalability and seamless execution to every project, from formulation and clinical production to commercial manufacturing. With a history of success in regulatory

strategy for combination products, and strategic partnerships with industry leaders, the company is uniquely positioned to deliver comprehensive, multi-tiered support to help its partners achieve their goals. Let Catalent be your CDMO partner that drives your nasal programme from concept towards long-term success.

### ABOUT THE COMPANY

Catalent is a global leader in enabling pharma, biotech and consumer health partners to optimise product development, launch and full lifecycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies and multi-modality manufacturing, Catalent is an industry partner for personalised medicines, consumer health brand extensions and blockbuster drugs. Catalent helps accelerate over 1,500 partner development programmes and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply approximately 70 billion unit doses of nearly 8,000 products annually. Catalent's expert workforce of approximately 17,000 includes more than 3,000 scientists and technicians. The company generated approximately US\$4.4 billion (£3.3 billion) in revenue in its 2024 fiscal year.

### ABOUT THE AUTHOR

**Mark Ignaczak** is Director of Innovation and Partnerships – Nasal Delivery at Catalent, with an extensive background in nasal spray product development and commercialisation. He has 19 years of pharmaceutical experience and over 16 years of direct experience with nasal spray products. In that time, he has worked on over 75 nasal programmes in varying stages within the project lifecycle, ultimately launching more than 10 NDAs – some considered first-of-their-kind, best-in-class therapies. Throughout his career, Mr Ignaczak has fulfilled various roles within bioprocessing engineering, product development, supply chain and all aspects of nasal delivery programme management and strategy. He holds a BS in Biochemical Engineering from Rutgers–New Brunswick (NJ, US).



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