

MEETING THE DEMAND FOR PATIENT CENTRICITY WITH NASAL SPRAY REPOSITIONING

Eric Kaneps of Renaissance Lakewood discusses key emerging drug delivery trends poised to help the pharmaceutical industry meet the growing demand for patient-centric solutions, with a particular focus on nasal drug delivery, as the nasal spray repositioning of existing drugs offers a range of benefits, including rapid onset of action, improved bioavailability and ease of administration for patients.

"THERE IS NOW WIDESPREAD RECOGNITION THAT THE 'ONE-SIZE-FITS-ALL' APPROACH IS INADEQUATE, LEADING THE INDUSTRY TO MOVE TOWARD PERSONALISED MEDICINE, WITH TREATMENTS AND DELIVERY METHODS TAILORED TO INDIVIDUAL PATIENT NEEDS, PREFERENCES AND LIFESTYLES."

The pharmaceutical industry's growing focus on patient centricity has driven the development of drug delivery systems that prioritise not only therapeutic efficacy but also patient convenience and safety. In recent years, the emphasis on the patient experience has been at the forefront of many industry discussions, with regulatory agencies reinforcing the idea that patient-centric models should be at the centre of pharmaceutical companies' approaches.¹ Many organisations have adopted patient focus as a key strategic imperative at every stage of drug development, manufacturing and commercialisation.²

Patient-centric drug delivery systems are becoming increasingly vital for improving treatment outcomes and enhancing the overall patient experience. These systems prioritise convenience and safety, which, combined with therapeutic efficacy, result in improved outcomes. By offering user-friendly and convenient administration methods, these systems can significantly improve patients' adherence to treatment regimens, which is vital for chronic conditions requiring long-term treatment.

THE SHIFT FROM TREATING THE DISEASE TO TREATING THE PATIENT

The increasing emphasis on patient centricity is fundamentally reshaping the landscape of drug delivery systems. There is now widespread recognition that the "one-size-fits-all" approach is inadequate, leading the industry to move more towards personalised medicine, with treatments and delivery methods tailored to individual patient needs, preferences and lifestyles.

"FROM THE PATIENT-CENTRIC PERSPECTIVE, NASAL DELIVERY HAS PROVEN TO BE AN ATTRACTIVE OPTION FOR CONDITIONS REQUIRING SWIFT THERAPEUTIC ACTION AND DRUGS WHERE PATIENT CONVENIENCE AND ADHERENCE ARE CRITICAL."

Consequently, there is a push towards simplified administration and less frequent dosing with user-friendly devices that make it easier for patients to adhere to their prescribed medication regimens, resulting in more consistent drug levels and better therapeutic effects. This is especially important when treating chronic diseases, such as respiratory conditions, where long-term consistency is a necessity. Modern targeted drug delivery systems also ensure that medications reach the specific site of action, maximising their effectiveness while minimising systemic side effects.

From the patient-centric perspective, nasal delivery has proven to be an attractive option for conditions requiring swift therapeutic action and drugs where patient convenience and adherence are critical. Nasal products are often easy to use and can be readily self-administered. Importantly, nasal delivery enables rapid and efficient drug absorption into the bloodstream, preventing drugs from metabolising before reaching their target.

CURRENT AND FUTURE NASAL DRUG DELIVERY TRENDS

Several emerging trends in nasal drug delivery systems are helping the industry meet the demand for patient-centric solutions, significantly impacting the market and patient outcomes both now and in the near future. These trends are transforming how drugs are administered and addressing critical factors such as patient convenience, safety and therapeutic efficacy.

Nasal Spray Repositioning

This strategy involves reformulating existing drugs for intranasal delivery, unlocking a range of benefits for patients and potentially breathing new life into older therapies. One of the primary advantages of nasal sprays is improved patient comfort and compliance. These sprays offer a distinct advantage over other routes of administration, such as injections, due to their ease of use and convenience for self-administration. This enhanced convenience can promote better patient adherence to treatment regimens, ultimately improving overall therapeutic effectiveness and patient comfort.

Nasal drug delivery can also offer enhanced efficacy and safety. Drugs delivered orally typically pass through the digestive system and are extensively metabolised, limiting bioavailability. Intranasal delivery bypasses this first-pass metabolism, potentially enhancing therapeutic effects and lowering dosing requirements. The nasal mucosa allows for rapid drug absorption and, in some cases, direct drug delivery to the central nervous system, making it valuable for conditions requiring immediate relief, such as seizures, migraines or panic attacks.

Repositioning an existing drug as a nasal spray can open up expanded market opportunities. It can be particularly beneficial for patient populations who may have difficulty with other routes of administration, such as paediatric or geriatric patients, or those with conditions affecting the gastrointestinal tract.

Preservative-Free Formulations

There is a growing demand for preservative-free formulations in nasal sprays. Although crucial for preventing microbial growth

in multidose pharmaceutical products, preservatives can sometimes cause allergic reactions, particularly in sensitive patients or with long-term use.³ Common preservatives, such as benzalkonium chloride, can cause nasal mucosal irritation, dryness and even damage to the cilia, which are crucial for the nasal cavity's natural clearance mechanisms.⁴ This irritation can exacerbate existing nasal conditions or lead to rhinitis medicamentosa, a rebound congestion effect that worsens symptoms.

Due to these side effects, patients are increasingly aware of the ingredients in their medications and actively seek preservative-free options for improved comfort and quality of life. Eliminating preservatives not only enhances patient comfort and safety but also addresses concerns about potential long-term effects and drug stability. This is because removing preservatives mitigates concerns about potential cumulative adverse effects of prolonged exposure, providing peace of mind and promoting better long-term health outcomes.

Advancements in aseptic manufacturing techniques and specialised container systems have enabled the production of safe and effective preservative-free nasal sprays. These innovations ensure that preservative-free products maintain sterility and stability throughout their shelf life. Strict aseptic manufacturing processes, including controlled environments and sterile filtration, minimise the risk of microbial contamination throughout production. Real-time monitoring and rigorous quality control standards have paved the way for producing safe and effective preservative-free nasal sprays.

Innovative Nasal Spray Devices

New nasal spray device technologies are constantly emerging, offering improved usability, dose accuracy and portability. These advancements can significantly impact patient adherence, particularly

for complex drug regimens or chronic conditions, which often require multiple medications to be taken at varying times, creating a complex daily routine. This complexity can lead to confusion and errors. User-friendly devices that are easy to handle, provide clear dosing instructions and minimise discomfort can empower patients to take control of their treatment and achieve better outcomes.

Selecting an appropriate nasal spray device is a pivotal decision in the development process, with far-reaching implications for patient experience and regulatory approval. Device compatibility with the drug's formulation, precise dosing, targeted delivery and user-friendliness are paramount to ensure optimal therapeutic outcomes and minimise side effects. Modern devices are engineered to produce finer, more consistent sprays, ensuring that the medication reaches the targeted areas within the nasal cavity, which helps to optimise drug absorption and efficacy. Innovations in nozzle design and spray pump technology allow for precise control over spray patterns, minimising medication waste and reducing the risk of it running down the throat.

Nasal spray developers must rely on experts who fully understand the interplay between device design, formulation characteristics and intended use to guide them in this critical selection. By harmonising these elements, specialists can ensure optimal drug delivery and efficacy, with patient safety being a particular focus. Their expertise is also crucial for navigating complex regulatory requirements and ensuring prompt product approval.

NASAL SPRAY REPOSITIONING CHALLENGES AND SOLUTIONS

Although nasal spray repositioning offers significant promise, it is not without its challenges. One key challenge is

"SELECTING AN APPROPRIATE NASAL SPRAY DEVICE IS A PIVOTAL DECISION IN THE DEVELOPMENT PROCESS, WITH FAR-REACHING IMPLICATIONS FOR PATIENT EXPERIENCE AND REGULATORY APPROVAL."

market competition. Unlike novel drugs with potential first-mover advantage, repositioned therapies typically compete with existing treatments for the same indication, including other nasal sprays. This competitive landscape intensifies the pressure to streamline development and manufacturing processes while ensuring that the product offers unique benefits.

Navigating the regulatory landscape for nasal spray repositioning requires a thorough understanding of the approval process and a keen awareness of potential pitfalls. A successful regulatory strategy requires efficiency and accuracy, while a well-prepared submission package helps expedite the review process and avoid delays that can hinder timely product approval.

Collaborating with a partner with a proven track record of successful submissions, particularly those with extensive experience with the 505(b)(2) pathway (Box 1), can be a significant advantage. Developing a stable and effective nasal spray formulation for a repositioned drug requires specialised knowledge and an understanding of the challenges involved to ensure that the final product meets the unique requirements of nasal drug delivery. Careful device selection is also a critical factor in the success of any nasal spray product, especially for repositioned therapies.

As the demand for patient-centric drug delivery options continues to expand, nasal spray repositioning is poised to become an increasingly vital tool for the pharmaceutical industry. Further development of nasal spray formulations is expected for a wide range of therapeutic areas. Advancements in formulation technologies, such as novel excipients and penetration enhancers, will continue to expand the possibilities for nasal spray repositioning, enabling the nasal delivery of a broader range of drugs.

ACCELERATING NASAL PRODUCT DEVELOPMENT

Nasal spray product development and manufacturing require extensive experience and expertise to navigate effectively. The ability to anticipate and address challenges proactively helps companies

BOX 1: THE 505(b)(2) PATHWAY

The growing demand for patient-centric drug delivery options and the unique advantages of intranasal administration have positioned nasal sprays as a key area of focus in pharmaceutical development. Using regulatory pathways such as the 505(b)(2) pathway in the US, pharmaceutical companies can efficiently reposition existing drugs as nasal sprays, capitalising on this market opportunity and bringing new therapies to patients.

By allowing companies to draw on existing safety data, the 505(b)(2) pathway can bring improved formulations to market more quickly, enhancing patient comfort and reducing potential irritation or allergic reactions. This regulatory pathway can encourage developing and adopting innovative nasal spray devices by providing a streamlined approval process. Used correctly, it can be a valuable tool for pharmaceutical companies seeking to bring patient-centric nasal spray solutions and novel nasal spray devices to the market more efficiently.

to maintain momentum and avoid costly delays as the project progresses to clinical phases and towards commercialisation. Partnering with an experienced contract development and manufacturing organisation (CDMO) can offer several benefits in developing and manufacturing nasal spray products.

CDMOs with expertise in nasal spray development can help expedite products to clinical phases. They achieve this by employing various strategic approaches and specialised capabilities. Experienced CDMOs are also well-equipped to navigate the complexities and challenges of nasal spray development – their expertise allows them to proactively anticipate and address potential issues, reducing the risk of costly delays and setbacks.

Crucially, CDMOs with a deep understanding of regulatory guidelines and established relationships with regulatory bodies can help ensure compliance with stringent regulatory requirements. This is particularly important as products move toward commercial stages. In-house regulatory support can provide clients

with direct access to experts who are well-versed in the intricacies of nasal drug development regulations. A range of strategic approaches, dedicated equipment and processes for clinical manufacturing and transparent communication across various disciplines help to accelerate timelines and get treatments to patients fast.

By prioritising patient needs and preferences, the pharmaceutical industry can continue to advance drug delivery systems that enhance therapeutic efficacy and improve patient convenience, safety and overall treatment experiences. Collaboration between pharmaceutical companies, specialised contract partners and regulatory bodies will be essential to navigate these complexities and bring novel, patient-centric solutions to market.

ABOUT THE COMPANY

Renaissance Lakewood is a US-based global contract development and manufacturing organisation (CDMO) for pharmaceutical and biotech companies. With more than

“CRUCIALLY, CDMOs WITH A DEEP UNDERSTANDING OF REGULATORY GUIDELINES AND ESTABLISHED RELATIONSHIPS WITH REGULATORY BODIES CAN HELP ENSURE COMPLIANCE WITH STRINGENT REGULATORY REQUIREMENTS.”

20 years of experience in nasal sprays and sterile injectable dosage forms, Renaissance has an unparalleled track record of providing exceptional service and resources to clients from the development stage through commercial launch.

REFERENCES

1. Kerfoot H, "Recent trends in the pharmaceutical industry: Patient-focus". *Pharmora*, Jan 2025.
2. Paul V, Bickley S, "Evolution of Patient-centricity in the Multi-indication Pharmaceutical Era". *IQVIA*, Mar 2025.
3. Díaz MV et al, "New Challenges in Drug Allergy: the Resurgence of Excipients". *Curr Treat Options*, 2022, Vol 9(3), pp 273–291.
4. Riechelmann H et al, "Nasal toxicity of benzalkonium chloride". *Am J Rhinol*, 2004, Vol 18(5), pp 291–299.



Eric Kaneps

Eric Kaneps is the Vice-President of Sales & Marketing at Renaissance Lakewood. He has more than 25 years of experience in sales, business development, and account management in the pharmaceutical industry. Mr Kaneps worked at DPT Laboratories as the Director of Business Development from 2001–2016. In this role, he transitioned the over-the-counter (OTC)/consumer health business towards pharmaceutical-based nasal and injectable products, which became the foundation for the new, renamed entity Renaissance Lakewood. In between his roles at the Lakewood site, Mr Kaneps was Senior Vice-President of Business Development for Pharma-Tech Industries, a contract manufacturing organisation that specialises in prescription and OTC ingestible and topical products. Mr Kaneps holds a BS BA in International Business & Economics from The Ohio State University (OH, US).

E: info@renpharm.com

Renaissance Lakewood LLC

1200 Paco Way, Lakewood, NJ 08701, United States
www.renpharm.com



Drive Your Science Forward

Combination Products Summit 2025

12-13 May

Philadelphia PA



**Next-generation Product Development, Quality
Control & Regulatory Compliance**

Featured Speakers Include:

- **Khaudeja Bano, Genentech**
- **Heather Guerin, Novartis**
- **Alie Jahangir, Biogen**
- **Subhi Saadeh, Gilead Sciences**
- **Rumi Young, Novo Nordisk**

www.pharmaedresources.com

Contact: 217.721.5774; khubbard@pharmaedresources.com