Guide

Nasal Drug Product Development for Oligonucleotide or mRNA Therapeutics

Key Considerations for Developing Intranasal Nucleic Acid Therapies for CNS Targets

Our experts provide a concise overview of the key challenges and emerging opportunities in developing intranasal delivery strategies for mRNA and oligonucleotide therapeutics targeting the central nervous system.

Challenges in Nose-to-Brain Delivery of mRNA and Oligonucleotide Therapeutics

Delivering mRNA and oligonucleotide therapeutics to the brain remains challenging due to biological barriers such as enzymatic degradation, mucociliary clearance, and the limited permeability of the nasal epithelium. In addition, the large size and instability of nucleic acids complicate efficient uptake, distribution, and consistent dosing. Overcoming these hurdles is critical to unlocking the full therapeutic potential of nucleic acid medicines for central nervous system disorders.

Why Nose-to-Brain Delivery Is a Promising Strategy

Nasal delivery offers a compelling approach for advancing RNA and oligonucleotide therapeutics, enabling rapid uptake, localized expression, and potential direct access to the central nervous system through a simple, non-invasive route. Key advantages include:

- Rapid absorption through the highly vascularised nasal mucosa.
- Potential nose-to-brain transport, supporting CNS-targeted therapeutics.
- Localized delivery and expression, reducing systemic exposure and potential side effects.
- Non-invasive administration, improving patient convenience and compliance.
- Protection from gastrointestinal degradation, preserving nucleic acid stability.
- Compatibility with nanoparticle and advanced delivery systems for enhanced targeting and uptake.
- Potential to stimulate both mucosal and systemic immune responses, supporting RNA-based vaccines and immunotherapies.

Partnering to Advance CNS Nucleic Acid Therapies

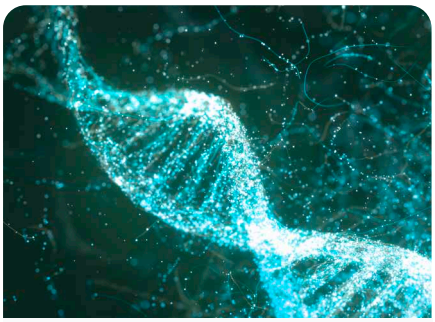
Developing intranasal RNA and oligonucleotide therapeutics for CNS delivery requires specialised expertise across formulation, device compatibility, analytical testing, and regulatory strategy. With more than 35 years of experience in respiratory and nasal drug development, our scientists support innovators worldwide in advancing both novel and generic inhaled and nasal drug products.

As an independent partner with no proprietary IP constraints, we collaborate closely with clients to design and optimise delivery approaches using the most appropriate formulation and device technologies for each therapeutic program.

Our capabilities include:

- **Formulation development** – Designing and optimising nasal formulations suitable for nucleic acid therapeutics and advanced delivery systems.
- **Performance and delivery testing** – Evaluating Spray Content Uniformity, Device Delivery, Spray Pattern, Plume Geometry, droplet size, and device compatibility to ensure consistent and effective nasal administration.
- **Clinical manufacturing support** – Providing integrated solutions for clinical supply of nasal and inhaled drug products.
- **Regulatory and CMC expertise** – Delivering comprehensive analytical and CMC support for regulatory submissions, including NDA and ANDA programs.

Together, these capabilities help accelerate the development of innovative nasal delivery strategies for next-generation CNS therapeutics.



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