2nd
Novel Nasal Formulation & Delivery Summit

March 12-14, 2024 I San Diego, CA

EXPERTISE PARTNER

Aptar pharma

Reenal Gandhi
Director Business Development
Aptar Pharma

Check out the Summit here: www.nasal-formulation-delivery.com

Given the recent promising results and FDA approvals in the intranasal drug delivery, what key technological and therapeutic advancements are driving the progress in 2024 and beyond? Are you driving the progress in 2024 and beyond?

The fact that naloxone has proven to the market that a life saving product can be delivered intranasally and can be used by both HCP and untrained people is the pivoting point. It brings ***intranasal to the main stage and proves there is untapped potential for intranasal****. This route can be used for CNS diseases, which has unmet market needs.*
This is bringing more research and understanding to the space and the industry is learning more about the routes of delivery and formulation techniques to help with systemic delivery and then looking at routes from olfactory and trigeminal pathways.
There are projects testing beyond small molecules, such as biologics in clinical trials, and even intranasal stem cells, mAbs, and exosomes. There are animal trials on-going that shows products being transported into target areas of the brain - which is exciting.

How have factors such as patient preferences, the development of new devices, and molecules influenced the potential of nasal drug delivery?

The products are considered combination products and have human factor requirements; therefore, patient preference is considered from the conception of the device and throughout the development process.

We've completed ***user studies on our side to consider factors that influence the use of nasal sprays and worked around specific disease cases like Parkinson's, Alzheimer's patients or First Responders for emergencies.***

In the cases where are considering a targeted delivery to maximize deposition of the drug into a given area, we've furthered the industry understanding of how to control that and alignment within the nasal cavity. I'll be speaking about that further at the conference.

User studies provide key insights as to how to improve the ergonomy and to accommodate patients' needs has provided valuable feedback on the usability of a device for a specific disease population.

With the heightened focus on antiviral therapeutics post-COVID-19, do you see a role for nasal drug delivery in creating self-administered drugs for infectious and respiratory diseases?

We definitely see the potential of ***self-administration on the vaccine front****. Many COVID-19 vaccine programs have been in the last 3 years, which have now broadened the scope. While* ***looking at COVID and Influenza platforms,*** *we can imagine a multi-dose antiviral option to protect against these viruses.*

How does Aptar Pharma support biopharma companies in optimizing both device and formulation in nasal drug products to achieve controlled, targeted, and reliable dose delivery? What can the audience expect as the key takeaway from your presentation?

With nasal being such a niche space, there is years of experience with managing combination product requirements, user needs, and regulatory. Supporting formulation to patient, we've focused on building ***expertise from numerous marketed products that we've supported over the years and expertise in formulation development, combination products, and helping to prepare for filings.*** *Getting through that initial pre-IND stage can be tough, so now thinking of how to smooth that process with experience. With product launches, thinking about how patients will be on-boarded and how therapies can be managed better. I'm excited to see so much new interest in the space so I look forward to seeing what comes next.*

As the use of nasal drug delivery for CNS and neurological conditions gains traction, what are some key hurdles to passing the blood-brain barrier?

The BBB is meant to shield the brain from harmful substances, but ***new developments are looking at the nasal pathway as a route to bypass that barrier of entry****. However, it comes with its challenges, it is difficult to measure the pathways, and likely only a small amount of drug product can travel through to the CNS. Every nose is different, and it is difficult to target the olfactory zone (~10% area), but there are now devices looking to tackle that problem. And there needs to be established regulatory pathways; it's clearly an interesting space, but more research is needed.*

If achieved, it ***could meet many unmet medical needs in the CNS field (a holy grail),*** *bypass the BBB and avoid injections, metabolised API degradation; it could target the CNS directly and minimize systemic side effects.*