

From Molecule to Market, Faster: Solving Nasal Drug Delivery's Biggest Development Bottlenecks

Formulation, device and manufacturing decisions need to work together, yet they are often made separately, with expertise spread across multiple suppliers. As a result, problems may only become clear once development is well underway: the chosen device may not suit the final formulation, late changes can lead to costly rework, or scale-up risks may not have been addressed early enough. For developers of complex nose-to-brain and systemic therapies delivered nasally, this can mean delays, added cost and regulatory uncertainty.

To address these challenges, Bepak®, along with Upperton, and Resyca®, have brought together their expertise in a new collaboration to provide a more connected approach from early feasibility and formulation development through to device engineering, clinical supply and commercial manufacture for liquid spray, soft mist and dry powder.

We sat down with Bepak CEO Chris Hirst, Upperton CEO Nikki Whitfield, and Resyca CEO Deborah Jones to discuss why this approach is needed and how it could help customers make better decisions earlier, reduce development risk and move promising CNS therapies towards the clinic faster.

What market need led you to form this strategic partnership, and what makes your combined offer different?

Chris Hirst: Interest in nose-to-brain and systemic delivery via the nasal route is growing because of the possibilities it could open up for patients. But these are complex products to develop, and molecule developers need the right support from early formulation work and device selection through to clinical supply and commercial manufacture.

Too often, those decisions are made in silos, with different suppliers responsible for different parts of the programme and no one looking across the whole pathway. That is when mismatches arise, rework causes

delays and scale-up risks are identified too late.

We formed this partnership to address that gap. By bringing formulation development, device selection and optimisation, fill-finish and product supply into one network, we can give customers a clearer, more connected route from molecule to market.

Deborah Jones: The nasal delivery landscape has changed significantly over the past decade. The focus has expanded beyond local conditions such as allergies and sinusitis towards systemic and CNS therapies. Nose-to-brain delivery could create new ways to treat serious conditions, including those where potentially effective medicines struggle to reach the target area.

At the same time, these therapies place much greater demands on the delivery system. For example, reaching specific regions of the nasal cavity requires precise control of deposition, while sensitive molecules such as biologics need to remain stable during delivery. At Resyca, our Ultra Soft Nasal™ platform was developed with these challenges in mind, but the device is only one part of the product.

That's why we formed this partnership which pools our respective expertise in soft

mist technology with formulation expertise, and advanced tools such as deposition modelling to help customers make informed decisions earlier in development and reduce risk in later program delivery. The partnership allows customers to work with a unified team that truly understands the complexity in the entire nasal development customer journey.

Nikki Whitfield: To echo Chris and Deborah, we are also seeing interest extend well beyond traditional local nasal products – into systemic delivery, peptides, biologics and CNS therapies, including those with potential for nose-to-brain delivery. That creates a real formulation challenge, because each molecule brings its own stability, solubility, dose, particle engineering and manufacturability considerations.

For nasal products, early formulation decisions have a major influence on device compatibility, deposition, scalability and ultimately clinical performance, so it is essential that formulation development is not treated in isolation.

By combining Upperton's formulation development and GMP clinical manufacturing expertise with Bepak's liquid and powder device capabilities and Resyca's soft mist technology, we can help customers make

Complex challenges from molecule to market

Turning breakthroughs into next-generation nasal drug-device products means navigating a complex interplay of factors including:

Formulation

- Managing stability, solubility and dose
- Optimising particle engineering and deposition
- Addressing manufacturability from the outset



Device

- Selecting a device compatible with the formulation
- Achieving consistent dose and delivery performance
- Designing for patient usability and real-world use



Anatomy

- Variable nasal anatomy and physiology
- Rapid mucociliary clearance limits nasal residence time
- Targeting the olfactory region or trigeminal nerve for nose-to-brain delivery



Regulation

- Generating the data needed to support regulatory submissions
- Navigating complex and evolving regulatory landscapes
- Managing drug-device combination product requirements



Manufacturing

- Handling complex molecules and sensitive formulations
- Identifying manufacturing complexities before commercialisation
- Maintaining product quality and stability through scale-up



the right decisions earlier and move more efficiently from feasibility through to clinical supply and commercialisation. For developers evaluating nasal delivery for complex and innovative molecules, that joined-up expertise can make a significant difference.

What expertise does each partner bring, and how does it come together as one offer?

Chris Hirst: Bepak has decades of experience manufacturing nasal drug-device combination products, from multi dose aqueous sprays to powder systems. That expertise spans our sites too, combining established nasal spray and powder fill-finish capabilities at Holmes Chapel with novel device development at King's Lynn.

We apply this experience to help partners move through development more efficiently. For example, our modelling and virtual simulation capabilities help us identify potential design issues early, while rapid prototyping allows us to test and refine solutions quickly.

The partnership adds Resyca's soft-mist technology to Bepak's liquid and dry powder portfolio, encompassing both unit dose and multi dose formats. This means we can recommend a platform based on the needs of the molecule, formulation and patient, rather than asking customers to commit to a device before the science is settled.

The real value lies in connecting these choices to the wider development pathway. Customers can access connected support from pre-formulation through to clinical and commercial manufacture, wherever they are in their programme.

Deborah Jones: As Chris says, bringing these capabilities together gives customers a much broader choice of nasal delivery platforms. Resyca adds specialist expertise in soft-mist delivery, aerosol science, device development and regulatory support.

At the heart of our Ultra Soft Nasal™ technology is a proprietary spray nozzle that generates a slow-moving, low-shear aerosol. This can help protect sensitive molecules, including biologics, while supporting targeted deposition within the nasal cavity. The platform is also designed to reduce sensitivity to differences in insertion angle and depth. Combined with its slower, more controlled actuation, this can support more consistent delivery in real-world use.

Our role is to help determine when soft mist is the right approach and tailor its performance to the needs of the product. By bringing deposition science and device performance into the conversation early, we can help customers make better-informed development decisions.

Nikki Whitfield: At Upperton, we support customers by bringing deep expertise in the formulation development of nasal products across the full development pathway, from early pre-clinical feasibility through to late-stage GMP manufacture.

One of the ways we help overcome early obstacles is through our UpperNose™ platform, which enables rapid formulation screening and assessment of nasal product performance at an early stage. This helps customers make better-informed decisions around formulation strategy, device compatibility and manufacturability before significant time and cost have been committed.

A major benefit of this collaboration is that customers do not have to manage multiple disconnected vendors or navigate time-consuming and costly transfers between organisations. Instead, they work with a closely aligned, integrated team from start to finish. That continuity improves decision-making, reduces development risk and ultimately helps accelerate innovative nasal medicines towards the market and into the hands of patients.

From start to finish, what does the process look like for a customer, and what's actually different about it?

Nikki Whitfield: The vision for the collaboration is to offer customers a breadth and depth of knowledge that would be difficult to access through a fragmented development model. By bringing together Upperton's formulation development, analytical, stability and GMP manufacturing expertise with Bepak's device capabilities and Resyca's soft mist technology, we can help ensure each product is developed using scientifically robust approaches and with a clear pathway to the clinic and beyond.

Deborah Jones: Successful CNS nasal therapies need an integrated approach from day one, because the physiology of the nose creates challenges at every stage:

- Spray droplets need to sit within a specific size range to reach the trigeminal

nerve or olfactory region rather than being inhaled

- Rapid mucociliary clearance limits how long a drug stays in contact with nasal surfaces
- Large biological molecules are often unstable once delivered

We start by evaluating the molecule, therapeutic objective and patient population to define a clear target product profile, including which regions of the nasal cavity need to be targeted, so formulation, device performance and usability requirements are aligned from the outset rather than reconciled later.

As programmes move through pre-clinical and clinical development, we generate the performance data needed for regulatory submissions while refining the product for patient use, then shift focus to manufacturability, scale-up and commercial readiness once clinical proof of concept is established.

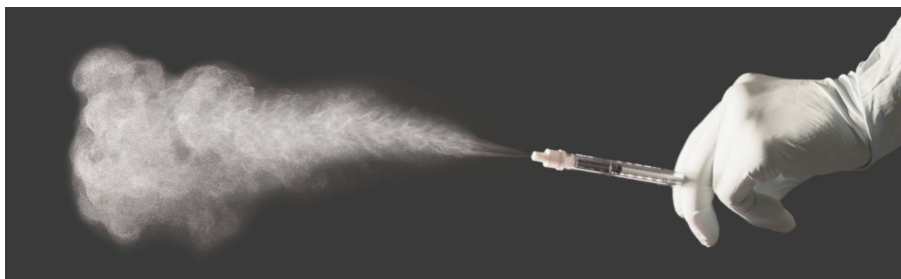
The benefit for customers is a single team that understands the entire journey from early-stage development through to commercial supply, fewer handovers, fewer gaps for things to fall through, and a faster route to a clinic-ready product.

Chris Hirst: Our goal is to reveal that complexity early, rather than let it surface once a programme is already underway, allowing life-changing CNS-targeted products to have a clearer run to market. With that in mind, we have set out to make our partnership as simple for our customers as possible.

In practice, every customer is assigned a single commercial lead as their touchpoint from early pre-formulation through to scale-up and manufacture. Whichever partner they approach first, they get access to the full network. As such, decisions about target device, scalability, and regulatory and manufacturing requirements are made together and early, not bolted on after the fact. By aligning the formulation and device thinking from day one, we can avoid potential hurdles six months down the line.

What does this actually mean for customers and the wider industry, what's the tangible benefit?

Chris Hirst: In practice, this means that when formulating a nasal therapy, a framework is in place to make sure this is being done with a view toward the target nasal device,



scalability, regulatory and manufacturing requirements, and so on. By engineering our recommendations and process specifically around our customer's specific drug molecule, we are able to improve efficiency and the speed a programme progresses towards the market.

For customers, this translates into faster decisions, because there's no back-and-forth between disconnected suppliers, and reduced risk because the same team that helped shape the formulation is still there at scale-up. It means fewer surprises late in development, less rework, and a faster, more predictable route to a clinic-ready product.

But underneath that, what we're really offering is a partner committed to getting a molecule to patients, not just a supplier for one part of the journey.

Nikki Whitfield: For customers, the ultimate goal of the collaboration is to provide expertise and programme delivery across all of the individual aspects of nasal product development within one integrated project team. A CNS or nose-to-brain therapy does not move through development in a simple linear sequence; formulation, device selection, analytical methods, stability testing, manufacturability, regulatory strategy and clinical

supply all influence one another. Our role is to ensure those workstreams are connected from the outset.

The value of working through this helps customers avoid the silos that can slow programmes down or introduce unnecessary risk. In a fragmented model, a product can move from one vendor to another several times, creating complex technical transfers, potential gaps in product knowledge and, in some cases, the need to repeat work at a new site. That can add time, cost and uncertainty.

By contrast, our collaboration provides a closely aligned team that manages the programme from start to finish. Product knowledge is retained, decisions are made with the full development pathway in mind, and each stage builds on the work that came before it. That integrated approach helps customers move more efficiently from early formulation thinking through to clinical development and ultimately commercialisation.

Deborah Jones: As Nikki says, customers increasingly want integrated solutions that reduce complexity and development risk, rather than having to coordinate multiple suppliers themselves. Through this partnership, customers get access to the Ultra Soft Nasal™ technology, specialist soft mist

device expertise, formulation capability and established regulatory support, alongside manufacturing and commercialisation pathways, with the flexibility to choose whichever delivery technology actually fits their molecule. The aim is a seamless journey that gets therapies to patients faster.



Nikki Whitfield

Nikki, CEO of Upperton, brings 30 years of pharmaceutical and CDMO leadership experience across small molecules and biologics. She has led drug development programmes from early formulation through to late-stage development and pre-launch, overseeing technical strategy, manufacturing, scale-up, regulatory submissions and clinical supply. Her senior leadership roles span biotech, pharma and CDMO organisations.



Chris Hirst

Chris, CEO of Bepak, brings 25 years of experience in the pharmaceutical sector. Previously a member of Recipharm's Executive Committee and Head of its Advanced Delivery Systems business unit, he has led the development and commercialisation of pMDI, DPI and nasal drug delivery technologies, with a strong focus on innovation and sustainability.



Deborah Jones

Deborah Jones, Ph.D., CEO of Resyca, brings more than 20 years of executive leadership experience in life sciences technology. She specialises in commercial growth, international expansion and strategic partnerships, with particular expertise in inhalation and nasal drug development. She has a strong track record of advancing innovative aerosol and spray technologies to enable more patient-focused drug delivery.

An accelerated route to commercialisation: Engineered around you

Bringing complementary expertise together across the value chain to support your nasal drug-device programme.



Device platforms, device engineering, product development and commercialisation capabilities



Formulation, analytical and clinical manufacturing expertise



Specialist delivery technologies provided by device partners, including Resyca's innovative soft mist technology

One integrated pathway, from early feasibility to commercial supply

Formulation development

Device screening and optimisation

Device development

Modelling and rapid prototyping

Clinical supply

Commercialisation

Regulatory support