

## Facility Spotlight: Device design and development at King's Lynn

The inhalation industry is evolving. Advances in *in silico* and AI-based technologies, sustainability drivers, and a changing regulatory landscape are collectively moving the goalposts for device design and development. Against this backdrop, specialist contract development and manufacturing organisations (CDMOs) such as Bespak are in a unique position to get ahead of the curve by adopting the latest technologies to support their customers.

We sat down with key thought leaders at Bespak to discuss inhalation device design and development capabilities at Bespak's King's Lynn site in Norfolk, UK and how these have evolved to meet industry needs. In this deep dive, we gathered insights from: Shaun Williams, Product Engineering Manager, Karl Bass, Principal Model-Based Systems Engineer, Tony Mallett, Platform Development Group Manager, and Thomas Daly, Development Engineer, at Bespak.

### Please can you tell us about your services at King's Lynn?

**Tony Mallett (TM):** At King's Lynn, we are a one stop shop for holistic device design and development. From early-stage testing to quality assurance (QA), our engineers can rapidly progress inhalation devices toward commercialisation in our validated development lab. Meanwhile, Bespak's polymer lab provides an excellent understanding of material characterisation that can feed into rapid prototyping. But it's not just about capabilities; it's about how you use them. A major focus for us right now is cutting down on the amount of time needed to get from, say, "stage A" to "stage C" or "D". That's where concept feasibility comes in, leveraging device design understanding to allow products to progress to clinical trials more quickly and with reduced testing needs.

**Shaun Williams (SW):** We also offer cutting-edge in-house simulation capabilities, which are supported by a high-performance

computer cluster that can run simulations rapidly. Our team offers rapid prototyping, functional testing, toolroom manufacturing, QC, and analytical labs. At the same time, our award-winning Injection Moulding Academy helps to keep standards high in device manufacturing. Here, we offer unique apprenticeships for polymer technicians and in-depth training programmes for engineers transitioning from other industries. Sharing skills in-house in this way enables the business to quickly adapt to new industry demands and trends, ensuring Bespak remains at the forefront.

### Which key industry trends have impacted your device design & development work at King's Lynn?

**TM:** The biggest industry trend from a pressurised Metered Dose Inhaler (pMDI) point of view is ensuring effectiveness as the industry transitions to next-generation propellants with a lower Global Warming Potential (GWP). Materials innovation, such as the use of greener materials in inhalation devices, is another area that I am excited about.

**Karl Bass (KB):** From my perspective, model-based systems engineering, which involves using digital models as the primary source of truth for designing, analysing, and verifying complex systems, is an important and growing trend. In a similar vein, virtual simulation is something that I believe holds enormous promise. While this technology has been used predominantly in product development, at Bespak we are working to expand the use of virtual simulation into other areas as well – such as formulation development and *in silico* clinical trials.

**Thomas Daly (TD):** Simulation is certainly at the forefront of the industry. There is a clear movement toward more *in silico* simulation-driven approaches to solve challenging engineering problems and identify optimal solutions, which are then supported with validated experimental data.

**SW:** I would also say that sustainability is another key driver in the industry right now. Environmental awareness and regulatory changes are fuelling the transition to low

carbon pMDIs as well as efforts to reduce waste and enhance material selection. As part of that, we are seeing a need to optimise or develop tools that can allow us and our customers to become more sustainable. Advances in *in silico* technology are making an impact here too, supporting fewer clinical trials, reduced API usage, improved material selection, and an increased use of digital engineering that can reduce the reliance on physical experimentation.

### Can you tell us more about how Bespak is making use of AI, digitalisation and virtual simulation technologies at King's Lynn?

**KB:** There are many opportunities to use the latest virtual simulation technologies. At Bespak, we are looking for ways to leverage these to both improve efficiency in device design and reduce waste from prototype testing. We have already completed a proof-of-concept study on the use of advanced modelling and virtual simulation to map the entire design space for a pMDI valve. This allowed us to easily identify the impact of changes to design parameters and ascertain when components have deviated too far from critical-to-quality attributes and need to be rejected. A similar process can be applied to other pMDI components or to existing devices that we are considering design tweaks for, cutting down the amount of manual testing needed and offering the potential to reduce the cost and time taken on projects while improving quality and sustainability.

**TD:** We have also used Computational Fluid Dynamics (CFD) simulations to take a closer look at the filling of the pMDI metering valve, which is understudied despite playing a key role in ensuring dose consistency. We explored this across both traditional and next-generation, low GWP propellants, including HFA-134a, HFA-227ea, HFA-152a, and HFO-1234ze(E). Using this technique, it is possible to predict what happens inside the metering chamber during the refill event with a high level of spatial and temporal resolution. Differences in refill behaviour for the different propellants were identified, which can be compensated for by adjusting metering valve geometry to ensure rapid refill and consistent dosing. This really serves to highlight the exciting potential of simulation



technologies for streamlining the transition to low carbon pMDIs.

**Can you tell us about any future project you have planned that you're particularly excited about?**

**KB:** Beyond models for drug and device product development, we've started looking into the potential for *in silico* clinical trials for respiratory drug delivery with some early-stage collaboration and support from UK-CEiRSI. In essence, this would involve developing models of airways and evaluating the transport of aerosols through the respiratory tract with a computer simulation. CT scans would be used for the models initially and can be supplemented with generative AI to expand the dataset to support the scale of a clinical trial. When the aerosol reaches the lower airways, simplified models can be efficiently utilised in more distal regions of the lungs. Once the aerosol is deposited in the airways, it is then possible to model absorption and dissolution of the active pharmaceutical ingredient into the bloodstream to determine pharmaceutical effects with physiologically-based pharmacokinetic (PBPK) models. All of that can be repeated and combined thousands of times to augment real-world clinical data.

**SW:** Just to add to that, with this early work assessing the potential for *in silico* clinical trials, we are taking a step closer to bringing both device and drug together as a combination that can be modelled from start to finish. This is the future goal of our team here at Bespak and something that I am very excited about.

**What do you wish more people knew about your work at King's Lynn?**

**TM:** I am really proud of the depth of knowledge and flexibility we offer at King's Lynn. When it comes to building and testing our products, we can offer customised bespoke fixturing, low volume line production, high volume line support – all in-house. This allows us to design, build and test manufacturing equipment for low volume devices and development work if needed. It is the fact that all of those different areas intersect at King's Lynn that gives you that one-stop shop. What this means for our customers is that they can dip in and out as needed, whether it's just early-stage work or also scale up and manufacture that's on the cards.

**SW:** We don't rest on our laurels at King's Lynn but are constantly evolving. Our use of the latest virtual simulation technologies is one example of that, but is not the only way in which we are working to stay at the forefront of the sector. Our Injection Moulding Academy has garnered widespread praise and awards for providing much-needed upskilling to the UK manufacturing industry, and we are expanding the training on offer in 2026. We developed a hybrid BK357 pMDI metering valve for next-generation propellants and completed a Life Cycle Assessment on the BK357 valve to identify further ways to improve sustainability. The skill and experience of our team make these leaps possible, and our commitment to staying at the cutting edge helps us to push the envelope even further.



**Karl Bass**

Karl Bass is Principal Model-Based Systems Engineer at Bespak with over 10 years' experience in pharmaceutical and medical device development. A Chartered Engineer with a PhD in Mechanical Engineering.

Email: [karl.bass@bespak.com](mailto:karl.bass@bespak.com)



**Thomas Daly**

Thomas Daly is a Development Engineer at Bespak, specialising in pMDI metering valve development. He holds a BEng (Hons) in Mechanical Engineering and is completing a PhD focused on modelling next-generation low-GWP propellant systems.

Email: [thomas.daly@bespak.com](mailto:thomas.daly@bespak.com)



**Tony Mallett**

Tony Mallett is Platform Development Group Manager at Bespak with over 23 years' experience in medical device CDMO. He leads New Product Introduction across pMDIs, DPIs and nasal devices from concept to commercialisation.

Email: [tony.mallett@bespak.com](mailto:tony.mallett@bespak.com)



**Shaun Williams**

Shaun Williams is Product Engineering Manager at Bespak and a Chartered Mechanical Engineer with nearly 20 years' experience. He specialises in DPI, and SMI device development, supporting design, lifecycle management, and global commercial launch.

Email: [shaun.williams@bespak.com](mailto:shaun.williams@bespak.com)