



FACILITY SPOTLIGHT: UK-BASED CAPABILITIES IN INHALED AND NASAL DRUG-DEVICE PRODUCT DEVELOPMENT



Ross Errington of **Bespak** introduces the company's Holmes Chapel (UK) site, which is equipped to support device development programmes from early-stage formulation to large-scale manufacture.

The inhaled and nasal drug-device industry is undergoing rapid transformation, from the urgent shift to low-global-warming-potential (GWP) propellants in pressurised metered dose inhalers (pMDIs) to the development of next-generation novel therapies. Navigating this landscape means overcoming regulatory, environmental and supply chain challenges while still striving for innovative solutions that can enhance patient therapeutic outcomes.

To succeed, pharmaceutical developers need support across the development process, from analytical and formulation services to regulatory guidance and commercial supply. On top of that, these services and capabilities are needed across a wider range of platforms and drug types than ever before.

Bespak, a specialist inhalation CDMO, has established itself as a complete partner for developers navigating this changing industry. Following the consolidation of operations in North Carolina (US), the company's Holmes Chapel (UK) site is now equipped to support programmes from early-stage formulation to large-scale

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manufacture and sits proudly alongside Bespak's established device development and manufacturing site at King's Lynn (UK). With state-of-the-art laboratories, GMP manufacturing suites and access to advanced analytical capabilities, the facility plays a central role in Bespak's mission to drive innovation and lead the industry's transition to a more sustainable future.

A WALK THROUGH THE HOLMES CHAPEL SITE

Bespak's Holmes Chapel site is the company's headquarters, and supports customers from pilot- to large-scale supply of inhaled and nasal drug-device products. The facility brings together multiple functions under one roof, enabling a seamless transition to commercialisation. The site is dominated by its GMP manufacturing facilities, where finished pharmaceutical products are produced. This area is currently being expanded to encompass new manufacturing lines for pMDIs with next-generation low-GWP propellants.

Across the site, a product development area includes seven GMP suites, allowing Bespak to set up dedicated equipment to manufacture different types of inhaled or nasal products at clinical or commercial scale, depending on customer needs. In a third area, analytical laboratories enable the testing of raw materials, components and finished products. By consolidating capabilities previously spread across multiple sites, Holmes Chapel has increased efficiency and broadened the scope of services available to customers.

SUPPORTING MORE THAN pMDIs

Bespak is a leader in the green transition to low-GWP propellants, and its Holmes Chapel site is central to that work. The facility has seen significant investment in the form of new filling lines capable of manufacturing low-carbon pMDIs using HFO-1234ze and HFA-152a, the next-generation propellants currently at the forefront of the green transition. These lines have been, and continue to be, vital to the redevelopment of existing inhaler products, and the facility also has space for further planned expansion.

However, the Holmes Chapel site is not solely focused on pMDIs. The site also has proven expertise in dry powder and aqueous nasal formulations, supporting both existing therapies as well as next-generation therapeutic applications, including APIs capable of treatment via the central nervous system.

The Holmes Chapel team has recently collaborated on new molecules and novel APIs, helping customers to develop products that are ready for regulatory filing and commercial manufacturing. Since these new therapies often come with limited safety data, Bespak has established robust systems to handle them and ensure safe, compliant operations.

Furthermore, the Holmes Chapel site supports customers looking to reformulate existing therapies to take advantage of novel devices and administration routes that may improve ease of use or speed of onset. The facility can also provide technology transfer services for those looking for additional capacity. No matter the requirement, Holmes Chapel can provide bespoke solutions to meet each customer's unique needs, with Bespak's regulatory team on hand to support CMC filings and provide expert guidance to streamline the process from development through to market readiness.

EXPERTS IN ANALYTICS

Within the walls of the Holmes Chapel site, Bespak's formulation and analytical specialists have experience that spans suspensions, solutions and dry powders. The site's capabilities range from API characterisation and dosage form selection through to comprehensive aerosol and device performance testing. The facility also offers extractables and leachables studies, helping developers to understand how formulations interact with their container closure systems over time.

Stability testing is another service that Bespak offers to its customers. Products can be stored under controlled conditions, with GMP-compliant testing carried out to evaluate degradation, compatibility and performance across a product's lifespan. These services are particularly valuable for developers adapting to the transition to low-GWP propellants, where understanding

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the compatibility with their new formulations is essential. The Holmes Chapel site has already supported customers facing challenges when changing propellants, helping them to adjust device and componentry parameters to restore or optimise performance.

The Holmes Chapel site also has access to world-leading modelling capabilities offered as part of Bespak's overall development service offering. By simulating design and formulation changes virtually, developers can test hypotheses without needing to run large numbers of physical experiments. This allows them to identify critical parameters and predict large-scale performance with ease. This approach streamlines early development, cutting both time and cost, while reducing reliance on manual testing and minimising experimental waste. It also enables more intelligent design of experiments, improving efficiency and consistent quality to deliver faster, smarter outcomes for customers.

A LOCAL PARTNERSHIP NETWORK

Collaboration is crucial in an industry undergoing rapid transformation, and the Holmes Chapel site does not operate in isolation. Not only does the team work

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in lockstep with Bespak’s device and componentry experts at the King’s Lynn site, the facility is also part of a broader network across the north west of England that creates a collaborative hub for inhaled and nasal innovation. Component manufacturers, propellant suppliers, clinical trial centres and formulation experts all work in close co-ordination to accelerate product development while minimising environmental impact.

As the industry transitions to low-GWP propellants, limited manufacturing capacity poses a significant bottleneck. Bespak’s partnerships address this gap, creating an end-to-end service that encompasses formulation development through to commercialisation of low-GWP pMDIs. Strategic relationships with H&T Presspart (Blackburn, UK) and Orbia Fluor & Energy Materials (Runcorn, UK), as well as Solstice Advanced Materials (Morris Plains, NJ, US),

formerly Honeywell Advanced Materials, help to ensure access to GMP-grade materials and propellants. Early-stage formulation development is also supported through collaboration with OzUK (Chippenham, UK), using the latest developments in metering valve technology from Bespak’s King’s Lynn site.

Clinical trials are another essential component of taking a product to market. Bespak collaborates with experts at the Medicines Evaluation Unit (Manchester, UK) in designing and managing clinical trials for inhalation therapies to help streamline this process for customers.

As well as offering reassurance around confidentiality and intellectual property, these partnerships provide immediate access to critical capabilities. With many partners based locally, and its team of device and componentry experts at King’s Lynn on call, Holmes Chapel can bring expert advisors on site within

hours – speeding up decision-making, keeping development timelines on track and decarbonising the supply chain to support Bespak’s wider environmental commitments.

SUSTAINABILITY IN ACTION

Sustainability is central to Bespak’s operations in Holmes Chapel. The site integrates renewable energy, waste reduction and efficient operations to minimise its environmental impact. The facility is also thoughtfully integrated into its natural surroundings through on-site biodiversity assessments and action plans. A supply chain biodiversity footprint assessment was conducted to evaluate the environmental impact of every stage of operations, from raw material sourcing to transportation and logistics.¹

The adoption of low-GWP propellants is a huge step forward in improving the carbon footprint of the industry, and the Holmes Chapel site has played a significant part in this shift. Even so, propellants can be lost to the atmosphere unnecessarily during manufacturing. As such, Bespak has put waste and capture systems in place that allow for the appropriate disposal or recycling of these propellants.

Packaging design is another area where sustainability has been considered.

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By optimising commercial packaging processes, Bespak can reduce both material loss and environmental impact. For instance, careful design ensures that only a minimal number of units are discarded during unexpected line stops, conserving aluminium and propellant, along with the associated costs. Automated filling and testing processes reduce the need for on-site staff, further decreasing the facility's carbon footprint.

These factors all support Bespak's ambitious net-zero and emission reduction targets, which are validated by the Science Based Targets initiative (London, UK), a corporate climate action organisation. This includes a long-term target of reducing greenhouse gas emission intensity by 97% by 2050. This validation marks a significant step in Bespak's climate journey and reinforces its commitment to taking science-aligned climate action to reduce its carbon footprint.²

THE FUTURE OF HOLMES CHAPEL

Bespak is actively investing in expanding its Holmes Chapel facility. Following the installation of the first manufacturing line to produce pMDIs with a low-GWP propellant in 2025, additional construction is already underway, with additional filling lines in both the design and build phases to support the growing demand for production. Capacity is projected to grow exponentially as Bespak continues to lead the transition to next-generation low-carbon inhalers. These investments

are not limited to manufacturing equipment, as they also include new operational space and infrastructure to support staff and warehousing.

The industry-wide shift towards low-GWP propellants remains a dominant trend and, as such, Bespak is continuing to invest in equipment capable of handling both HFO-1234ze and HFA-152a at its Holmes Chapel site. Manufacturing with these next-generation propellants requires capacity that meets evolving safety requirements, such as flammability risks, as well as regulatory and performance needs. Rising costs and legislative pressures around existing propellants further underscore the urgency for the industry to transition, and Bespak's expanding capacity and integrated network allows developers to move rapidly from development through to regulatory approval and large-scale production.

Alongside the transition to low-GWP propellants, the future of inhaled and nasal drug delivery is being shaped by next-generation therapies and device innovations, and the Holmes Chapel facility is ready to support customers with bespoke, end-to-end solutions.

A TRUSTED PARTNER

Bespak represents a new era in inhaled and nasal drug-device development. By integrating analytical, formulation, manufacturing and regulatory capabilities at one site, supported by device and componentry expertise at a second site,

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the company provides end-to-end support for developers navigating this evolving landscape. Its leadership in low-GWP propellant adoption, expertise in novel therapies and commitment to sustainability position Bespak as a trusted partner in the delivery of life-changing treatments.

Through strategic partnerships and ongoing investment in capacity and technology, Bespak continues to strengthen its position as a leader in innovation, collaboration and environmental stewardship. The company brings together advanced manufacturing and formulation expertise in Holmes Chapel with device and component design and modelling capabilities in King's Lynn, creating an integrated offering. For developers, this means access to an efficient and sustainable path from early-stage formulation through to commercial-scale production, ensuring that patients continue to receive the therapies they need in a rapidly changing world.

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