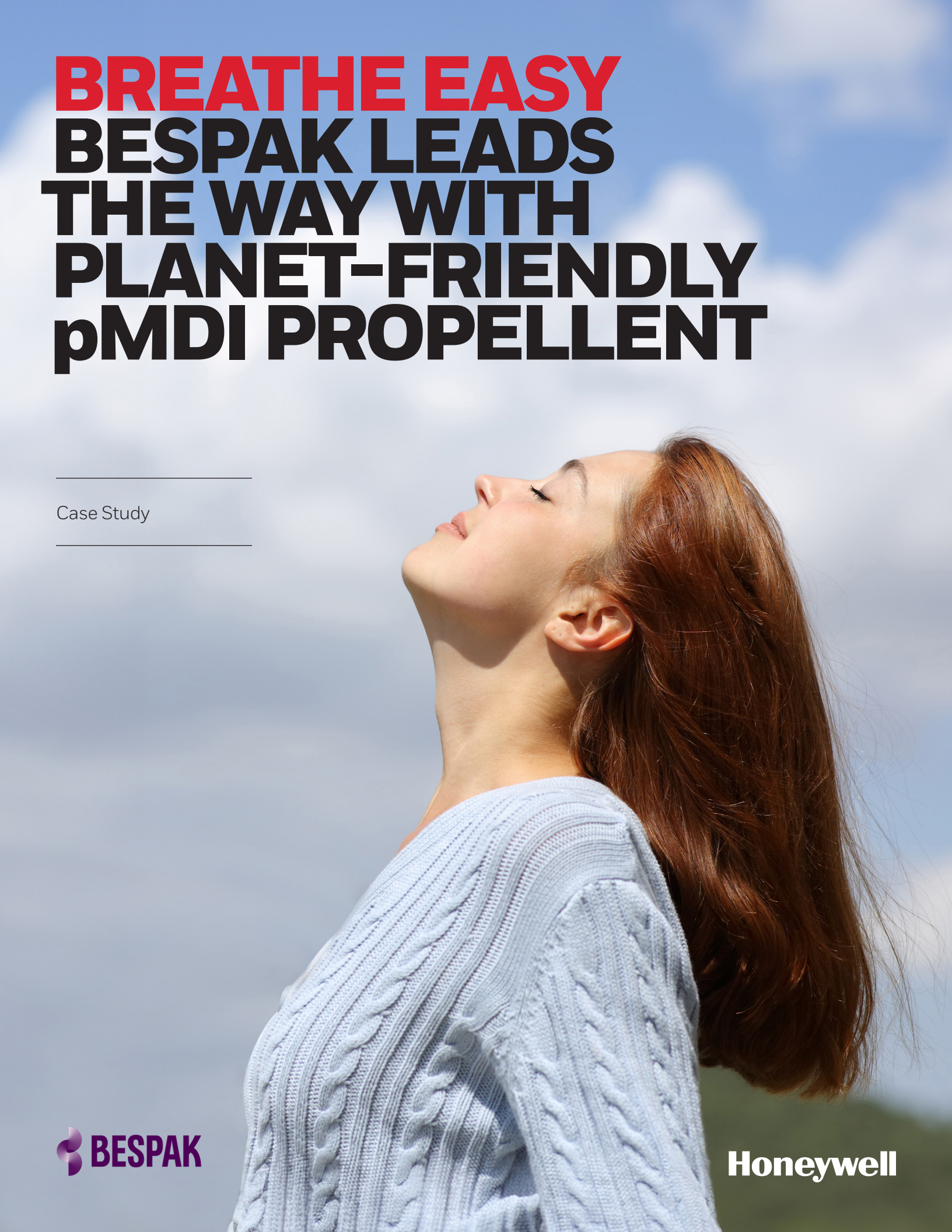
BREATHE EASY
BESPAK LEADS THE WAY WITH PLANET-FRIENDLY pMDI PROPELLENT

Case Study



BESPAK

Honeywell

Bespak broke new ground as the first contract development and manufacturing organization (CDMO) to use Honeywell's low global warming potential (GWP) Solstice® Air propellant in the pressurized Metered Dose Inhalers (pMDIs) it produces for leading pharmaceutical companies.

BACKGROUND

Pressurized Metered Dose Inhalers are vital lifelines for hundreds of millions of people suffering from respiratory ailments like asthma and chronic obstructive pulmonary disease (COPD). As the most-prescribed inhaler type globally, it is critical to maintain the pMDI option for patients and prescribers who rely upon them to manage these life-threatening conditions.

Today, pMDIs use hydrofluoroalkane (HFA) propellants HFA-134a or HFA-227ea, which contribute to global warming. In fact, these propellants are powerful greenhouse gases that can trap 1,500 to 3,600 times as much heat as carbon dioxide over 100 years, according to the Intergovernmental Panel on Climate Change.

HFAs are being phased down, and will eventually be phased out worldwide, and replaced with low global warming potential propellants including hydrofluroolefins (HFOs). The combination of strengthened environmental regulations and corporate environmental, social and governance (ESG) strategies are leading pharmaceutical companies to convert to lower GWP propellants, with many aiming to launch pMDIs with a minimal carbon footprint by as early as 2025.

"Climate-friendly propellants are vital to lowering our industry's environmental footprint. In 2023, we introduced Honeywell's Solstice Air propellant at our Holmes Chapel, UK, manufacturing site to meet the needs of customers who want to replace the high global warming potential (GWP) propellants they are using today with a near-zero GWP alternative without sacrificing patient performance."

– NICK ATKINSON
HEAD OF PROJECT MANAGEMENT BESPAK

Bespak, a leading pharmaceutical CDMO, has commissioned a fully operational plant in the United Kingdom to produce pMDIs using Solstice Air from Honeywell. In 2023, the plant became the first CDMO to use ultra-low GWP Solstice Air, which reduces GHG emissions by up to 99.9% compared to current-generation HFA propellants.

"Demand is accelerating rapidly for the lowest GWP pMDI propellant, Solstice Air. As pharma companies set ambitious greenhouse gas reduction targets, Solstice Air is safe, nonflammable and much better for the environment. It's also a near drop-in replacement so producers like Bespak don't have to change processes or equipment as they transition from high-GWP gases to planet-friendly Solstice Air."

– LAURA REINHARD
VICE PRESIDENT & GENERAL MANAGER
HONEYWELL ADVANCED MATERIALS
INDUSTRIAL PRODUCTS, AEROSOL & SOLVENTS

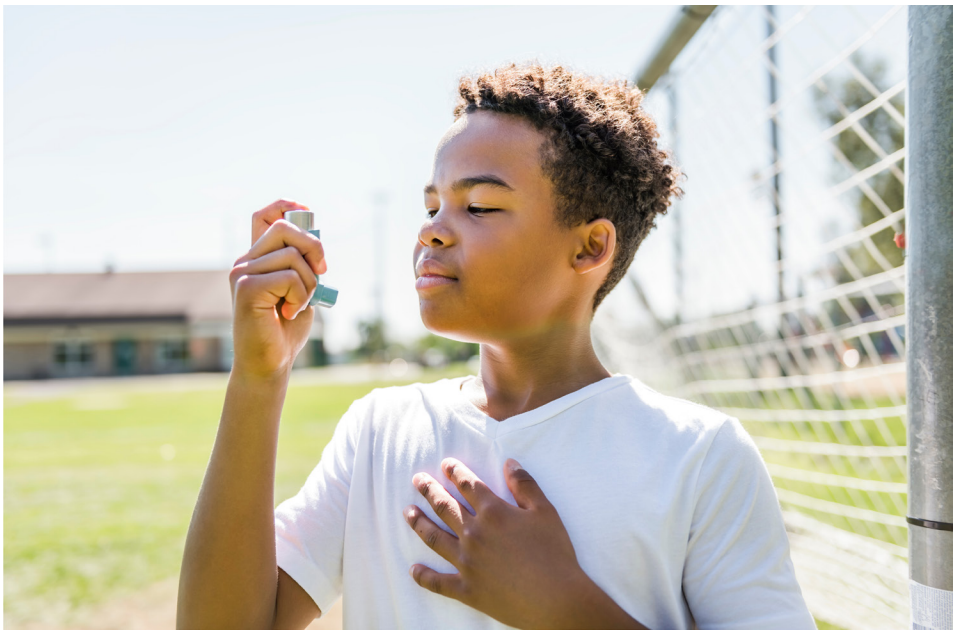
CHALLENGE

Bespak's success depends upon building strong and enduring partnerships with its customers, which include many of the pharmaceutical industry's most successful respiratory companies. As the industry faces the global HFA phase-down and pursues ambitious ESG goals, leading pharmaceutical players are turning to Bespak for climate-friendly solutions to deliver life-saving medicines to patients the world over.

To meet customer needs, the Bespak team needed to embrace low GWP propellants and quickly determine how to integrate the ultra-low GWP propellant Solstice Air with existing manufacturing equipment and processes with minimal cost and operational disruption.

SOLUTION

In 2022, after considering a number of options, Bespak's customer selected Honeywell as its partner and Solstice Air as the ultra-low GWP alternative to its current propellants. Bespak and Honeywell began working



"We are committed to leading the transition to low GWP propellants in pMDIs. With our broad range of services and team of experts enabling us to develop and commercialize pMDIs, combined with our market-leading position in pMDI valves and actuators, our customers can be confident they are in safe hands as they make the transition to sustainable inhalers."

– NICK ATKINSON
HEAD OF PROJECT MANAGEMENT BESPAK

together to integrate Solstice Air, known chemically as HFO-1234ze(E), into manufacturing processes at the Bespak pMDI manufacturing facility in Holmes Chapel, UK.

Solstice Air is a breakthrough medical propellant for pMDIs with the ability to reduce greenhouse gas emissions of propellant by up to 99.9% compared to current HFA propellants. In addition, Solstice Air is non-flammable, non-ozone-depleting and volatile organic compound (VOC)-exempt under U.S. federal and state guidelines.

Following pharmaceutical industry GxP good practice and safety protocols, Bespak conducted a comprehensive review of guidance and studies concluding that HFO-1234ze(E) is classified by multiple authorities as a nonflammable gas. The Bespak team followed up with a thorough risk assessment to ensure that the new propellent could be safely introduced at the factory level.

Bespak completed manufacturing process design verification, including using computer simulations, to determine how the new chemical would behave in the company's current manufacturing systems. Working with Honeywell, Bespak determined that minimal changes to manufacturing systems would be required. This assertion has since been validated during real-world operations.

RESULTS

Bespak reached a significant milestone in 2023 by becoming the second site in the world to manufacture a batch of pMDIs at commercial scale with Solstice Air propellant.

Since then, process validation batches have been successfully produced and further development batches have been manufactured at commercial scale to support additional customers with their product transition to Solstice Air.

ABOUT BESPAK

Bespak is a global CDMO focused on inhaled and nasal drug delivery devices and drug-device combination products. The company's service offering spans early-stage feasibility, analytical services and product development, from pilot-scale, through to clinical supply and commercial-scale drug product fill-finish, device and component manufacturing. With a long history in the development and commercial supply of pMDIs, Bespak supplies a major proportion of the world's pMDI dosing valves and actuators and has made significant investments in commercial-scale and pilot-scale filling equipment for the manufacture of pMDIs using low GWP propellants. Bespak also specializes in the industrialization and high-volume manufacture of complex dry powder inhaler (DPI) devices.

More information: www.bespak.com

ABOUT HONEYWELL

Honeywell is an integrated operating company serving a broad range of industries and geographies around the world. Our business is aligned with three powerful megatrends – automation, the future of aviation and energy transition – underpinned by our Honeywell Accelerator operating system and Honeywell Connected Enterprise integrated software platform. As a trusted partner, we help organizations solve the world's toughest, most complex challenges, providing actionable solutions and innovations through our Aerospace Technologies, Industrial Automation, Building Automation and Energy and Sustainability Solutions business segments that help make the world smarter, safer and more sustainable.

For more information on Solstice Air: Breathe Easy Solstice® Air (honeywell.com)

For More Information visit
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