Expert View

CHOOSING THE RIGHT PROPELLANT IS ONLY THE FIRST STEP TOWARDS LOW-GWP pMDI SUCCESS

Darren Bromley-Davenport of Orbia Fluor & Energy Materials considers the pressures being placed on pressurised metered dose inhaler developers and manufacturers by tightening regulations regarding fluorinated gases and the transition to lower global warming potential propellants, and lays out how those that invest in partnerships with industry experts are set to de-risk their development programmes and decrease their time to market.

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As EU medical quotas under fluorinated gas (F-gas) regulations continue to phase down towards 2030, the strain on pressurised metered dose inhaler (pMDI) manufacturers has never been greater. Across the industry, development programmes focused on transitioning to lower global warming potential (GWP) propellants are accelerating. However, while significant attention has been placed on identifying an alternative propellant, the reality is that successful transition programmes will depend on much more than propellant selection alone.

The manufacturers reaching the market first are likely to have already combined technical expertise, specialist testing capabilities, manufacturing infrastructure and regulatory support into a seamless development pathway. As regulatory deadlines approach and more manufacturers move rapidly towards low-GWP submissions, the industry's biggest challenge is how quickly and efficiently that transition can be achieved.

PREVIOUS PROPELLANT TRANSITIONS

The industry has experienced a major propellant transition before. The move from chlorofluorocarbon (CFC) propellants to hydrofluoroalkane (HFA) alternatives was ultimately successful, but it was far from straightforward. Many manufacturers encountered unforeseen formulation challenges, longer-than-anticipated development timelines and supply constraints. Products often required extensive reformulation work, while seemingly minor changes in propellant behaviour had significant downstream implications for device performance, stability and manufacturability.

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Today, low-GWP propellants offer promising pathways towards compliance with evolving environmental regulations. However, the physical and chemical properties of these alternatives differ from those of HFA-134a, a propellant currently used in pMDIs. As a result, developers cannot simply substitute one propellant for another and expect equivalent performance. Instead, every aspect of the product must be carefully evaluated to ensure that patients continue to receive the same therapeutic outcomes.

CRITICAL DEVELOPMENT CONSIDERATIONS

Successful low-GWP development begins with understanding how a new propellant behaves within the entire formulation system. A change in propellant can affect API compatibility, suspension behaviour, solubility, moisture sensitivity and long-term stability. These factors can introduce development risks that may not become apparent until later stages of testing. This is why formulation expertise is becoming increasingly important. Development teams must assess not only how the propellant performs independently, but how it interacts with the formulation as a whole.

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Compatibility testing is also essential. It provides confidence that products will continue to perform effectively throughout their entire lifecycle and helps to identify potential issues before they emerge in clinical studies or commercial manufacturing. This includes evaluating interactions between the propellant and elastomers, valves, canisters and other device materials.

Manufacturers must also demonstrate product equivalence following reformulation through evaluations such as single actuation content, aerodynamic particle size distribution (APSD) and realistic APSD testing, while also assessing the impact of any changes throughout the product's stability period. The organisations most likely to progress quickly are those capable of identifying and mitigating formulation risks early through industry partnerships. Investing in expertise and accuracy upfront can significantly reduce the likelihood of costly delays later in the development programme.

MANUFACTURING PARTNERSHIPS ARE ESSENTIAL FOR SUCCESS

Clinical manufacturing that follows GMP guidelines is a fundamental requirement for advancing low-GWP inhalers, yet development infrastructure across the market remains limited. Facilities that can accommodate formulation development, analytical testing, stability studies and clinical manufacturing are in high demand (Figure 1).

For many companies, building this capability internally is neither practical nor economical. Establishing specialist facilities requires substantial investment, highly trained personnel and significant lead times.

As a result, partnerships with organisations that already possess the necessary infrastructure are becoming a key component of the low-GWP propellant transition. Access to integrated facilities can enable developers to move more seamlessly from formulation development through testing and into clinical manufacturing. In the race to commercialisation, efficiency and continuity are major competitive advantages.



Figure 1: Five litre bulk suspension solution manufactured with HFA-152a in ATEX-rated equipment.

COMPLIANCE MUST BE PART OF THE DEVELOPMENT STRATEGY

The evolving F-gas landscape presents manufacturers with further considerations around quota allocation, security of supply and long-term commercial planning. As regulations tighten and available quotas become increasingly complex, manufacturers must ensure compliance strategies are developed alongside product development programmes.

Delaying these considerations can create unnecessary risk and uncertainty. However, working with organisations that can support quota management can help manufacturers to navigate an increasingly complex regulatory landscape. By building compliance into development plans from the outset, manufacturers can reduce regulatory hurdles and avoid delays to programme timelines.

BUILDING THE FASTEST PATH TO MARKET

As the 2030 deadline approaches, manufacturers are facing an increasingly limited window to bring new products to market, while navigating a complex range of technical, regulatory and commercial challenges. Companies that partner with industry specialists that can provide

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support in critical areas, from formulation development to quota management, will be best placed to de-risk programmes, minimise delays, accelerate the path from concept to commercialisation and ensure continued supply of essential respiratory healthcare.

ABOUT THE COMPANY

Orbia's Fluor & Energy Materials (F&EM) business is a global developer, manufacturer and supplier of fluoroproducts used in a vast range of applications, including energy storage, infrastructure, indoor climate management, refrigeration and low-GWP propellants for pMDIs. Orbia F&EM has 1,700 employees and eight manufacturing facilities worldwide, serving 60 countries through a global sales and distribution network.



Darren Bromley-Davenport

Darren Bromley-Davenport, Technical Manager at Orbia Fluor & Energy Materials, has more than 30 years' experience in medical and pharmaceutical device markets, specialising in new product introduction, process development and regulatory compliance. He holds over 50 global patents and has developed and commercialised numerous products, including pioneering nanocoating technology designed to prevent drug adhesion in asthma inhaler canisters. In his current role, Mr Bromley-Davenport draws upon his extensive industry expertise to provide authoritative insights into the technical workings of respiratory propellants, their interactions with medicines and the implications for patient care.

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