INHALED & INTRANASAL BIOLOGIC DRUG DEVELOPMENT

Contract drug development expertise to accelerate your inhaled biomolecule to market

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Total Quality. Assured.

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Complex challenges

Respiratory administration of biomolecules presents opportunities for less invasive targeted and systemic delivery routes when compared to the more traditional intravenous administration. This route also opens up potential new therapeutic pathways for diseases such as cystic fibrosis, asthma and lung cancer.

These new modalities present complex challenges for successful development. Characterisation in line with ICH Q6B Guidelines is an increasingly well-established approach for biologics but this relies on a broader portfolio of complimentary tests to understand the overall product quality. OINDP testing is similarly complex with a need to characterise the products performance in terms of particle size and dose which is not normally a factor for simple parenteral formulations. Device technologies, which are often poorly compatible with biopharmaceuticals, means that established small molecule approaches need to be challenged, improved, or reinvented.

While regulation and guidance are also well established for OINDP developments, combining this with the regulatory expectations and unique challenges of these novel active substances can be especially demanding.

> We have experience across all formulation and device technologies for both orally inhaled and nasal drug products

Inhaled biologic expertise

We have over 30 years of experience in biologics characterisation, from small peptides and oligonucleotides through to larger proteins, mRNA and monoclonal antibodies. This is in combination with the same depth of experience in orally inhaled & nasal drug product development, from early-stage development to QC batch release testing.

Our Intertek Centre of Excellence for Inhaled Biologics deploys a strategic program of formulation, analytical testing and clinical manufacturing services. Our orthogonal analytical approach aims to fully characterise the biologic drug substance whilst identifying formulation and delivery options for delivering a well performing, stable and scalable inhaled or nasal drug product. Services include:

- CMC Development & Analytical Support
- Biologics Characterisation (Q6B)
- Formulation Development
- Method Development/Validation
- Device Screening/Selection
- ICH & Accelerated Stability Studies
- Product Characterisation Studies

Biologics characterisation

Biologic drugs have complex structures including higher-order structures fundamental to their function, safety and efficacy, and are susceptible to a wide range of degradation routes such as aggregation, fragmentation, deamidation, hydrolysis, oxidation, deglycosylation and disulphide bond formation/breakage. Sophisticated formulation development and device selection are key to avoiding these pathways, to ensure a stable, efficacious product. In parallel, a wide suite of robust biologics characterisation tools is essential to meet the requirements of the ICH Q6B Guidance.

Our characterisation teams routinely design programs to include potency, structural characterisation and confirmation, establish physicochemical properties, post-translational modifications (PTM), and assessment of product-related impurities and process-related residuals.

Strategic formulation

With integrated formulation, method development/validation and stability teams, we can design and deliver bespoke development approaches to drive maximum insight into the design, function and stability of the formulation and device. Biologics can be expensive to produce, and strategic design of these studies is vital to maximise the return on material investment.

We have experience across all formulation and device technologies, including solutions, suspensions and dry powders for both orally inhaled and nasal drug products offering comprehensive CMC support and clinical manufacturing capabilities. Intertek are well placed at the leading edge of delivering novel solutions to this important and powerful new class of products.

Total Quality Assurance

With a heritage of supporting advanced pharmaceutical product development coupled with a comprehensive range of state-of-the-art analytical technology, our experts offer Total Quality Assurance to help you ensure the safety, efficacy, and quality of your inhaled biologic product.

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30+ years' experience in inhaled product development and experts in rapid development strategies

We have the largest GMP facility in Europe for OINDP development support with extensive experience across both biologics and small molecules


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