

COVID-19 VACCINE AND THERAPEUTIC TESTING AND DEVELOPMENT OUTSOURCING SOLUTIONS

SUPPORTING CRITICAL RESOURCE AND TESTING NEEDS

We understand the pressures placed on your business to maintain the supply of critical medicines or to accelerate development of safe, effective and high-quality drugs for patients in need or vaccines to safeguard lives. Making these goals a reality comes with many challenges for your business. Our global team of scientists, regulatory consultants and auditors are ready to help you innovate and progress the fight against COVID-19.



The sheer, unprecedented, impact of COVID-19 is accelerating the development of next-generation vaccines and therapies around the world to help prevent infection and to aid patient recovery. In parallel, supply chains are experiencing a strain on resources, inhibiting their capacity to not only develop viable COVID-19 solutions, but in maintaining their existing medicine supply chains.

Accelerating Development

There is a global drive to develop safe and effective COVID-19 vaccines and therapies. There are many different categories of products in development – all of these are complex. Development needs to be rapid in order to get these products through the clinical phases to market whilst ensuring the highest levels of safety and efficacy, which can only be achieved through application of validated analytical methods. With the complexity of the technology platforms involved, the need for specialist, bespoke analytical approaches in order to understand all critical attributes and build strategic quality control programs has never been more important.

To bring critical methodology into a GXP regulatory environment, we leverage our experience in method development and validation to provide strategies for clients. We offer solutions which are built on our 30+ years' experience of working in regulatory-analytical science and experience which encompasses multiple modes of therapeutics and vaccines. We provide solutions for the design and implementation of characterisation, release testing and quality

control, ensuring that the data generated is robust and accurate to guide both clinical development and support CMC requirements.

>60,000 ft²

Centre of Excellence for Biologics Characterisation, Manchester, UK

GLP/GCP/GMP

Global Laboratory Network

Complex Technology Platforms

The range of the COVID-19 therapy technology platforms currently being evaluated is astounding, with products based on everything from nucleic acid (DNA and RNA), antibodies to small molecules. The vaccine landscape is equally diverse, including peptides, virus like particles, live attenuated or inactivated virus. In addition, many products have specialist delivery requirements such as inhaled or intranasal or through lipid nanoparticle or liposome encapsulation.

Regardless of the complexity or modality of the vaccine, therapeutic or delivery technology, Intertek can design and deliver the highest quality, phase appropriate characterisation and QC/release testing solutions. With proven scientists who have contributed to the development of existing flu vaccines, our solutions are built on experience, from early stage formulation development, clinical trials to manufacturing and beyond.

Repurposing Products for Inhaled Delivery

To treat COVID-19, inhaled delivery of therapies to the lung offers speed and precision of treatment. When designing new therapeutic candidates, it is important to evaluate the suitability of the formulation for the delivery platform and suitability for local delivery in the lung. To rapidly and safely develop a treatment that could save lives, repurposing for inhaled delivery demands a strategic approach that is tailored to the product and where it has reached in the development pipeline.

Our team have worked on over 5000 unique OINDP projects over the past 10 years with over 200 of these focused on repurposing for inhaled or intranasal delivery. Based on this significant foundation of experience, our rapid response strategies for inhaled delivery include efficient pathways for repurposing formulations for targeted delivery directly to the lungs in a safe, effective, and expeditious way.

>5000

We have performed over 5000 unique OINDP projects over the past 10 years alone

>200

Repurposing projects for delivery to the lungs

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Contingency and Risk Mitigation in Maintaining Medicine Supply Chains

With increasing demand on your internal resources, maintaining existing medicine supply chains becomes a more pressing challenge for both R&D and general medicine release. We can provide the necessary support to alleviate your current resource challenges providing flexible analytical resource to maintain existing product production including requirements where specialist knowledge and technologies are needed (including Biologics or OINDP). Our network of GMP, GCP and GLP laboratories can provide, at minimal notice, short- or long-term solutions for quality control testing (batch release testing) or R&D support. Our flexibility provides viable alternative solutions when your existing testing capacity is stretched, and our experienced scientists are mobilized to assist you every step of the way from bench to patient.

Bioanalytical Support

The first COVID-19 vaccine candidate entered clinical testing on 16 March 2020 signalling a rapid drive to evaluate candidates for safety and efficacy. Intertek are experienced in delivering accurate and efficient bioanalysis services supporting preclinical and clinical studies for vaccines and therapeutics including immunoassays, PK, ADA and assessment of specific antibody, biomarkers. With expertise in assay development and validation we ensure bespoke methods are robust to meet the requirements of preclinical and clinical phases.

Rapid Response Strategies

Intertek provides mission-critical quality assurance solutions to ensure production and operations continue to function smoothly in rapidly changing situations. Our priority is always health and safety while delivering outstanding service to our customers. From reformulation and re-purposing drug products to delivering accurate insight from clinical studies, we understand the critical steps and strategic approaches that can accelerate your development programs efficiently. We work across many modalities including small molecule, viral vector products, oligonucleotides, mRNA, recombinant and natural proteins, inhaled or nasal drugs, lipid nanoparticle or liposome encapsulated products and so whatever your modality, we have the expertise ready to assist you.

- Vaccine or Therapeutic Development Support
- Repurposing Products for Inhaled Delivery
- GLP/GCP Bioanalytical Support
- Characterisation for Biologics
- mRNA Characterisation and Development Support
- GMP and CMC Laboratory Services Outsourcing
- Method Development and Validation
- GMP Stability Programs
- Extractables/Leachables
- Quality Control Testing
- GXP Audit Report Purchase or Shared Audit solutions
- GXP Bioanalytical Services
- GMP Potency Testing

About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 46,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enables our customers to power ahead safely.

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