Accelerating Life-Enhancing Pharmaceutical Products to Market

BROUGHTON

Testing • Consulting • Compliance

Pharmaceutical Product Development

As experts in the design and execution of product development programs, we support our partners in bringing innovative, life-enhancing drugs and devices to market for better patient outcomes. Our services cover different stages of the pharmaceutical product lifecycle to ensure our partners receive the data and insight necessary to inform go/no-go decisions at every stage of their project reducing risk, increasing efficiency, and maximizing success.

Drawing on our experience in laboratory support services and regulatory consultancy, Broughton is your outsourcing partner of choice across formulation consultancy, analytical services, product development and regulatory support. Our scientific experience and technological capabilities, supported by bespoke quality and data management software, help accelerate development times and ensure better investment choices. Broughton's scientists and regulatory consultants bring a wealth of knowledge and expertise to individual projects. We offer support both as a wholly outsourced unit or as an ongoing extension of your in-house team.

We focus on helping small to medium-sized pharmaceutical companies with product development and have a special interest in novel inhalation and smart delivery systems. We offer support on the following stages of the pharmaceutical product lifecycle.

- Formulation consulting
- Analytical services
- Product development services
- Commercialization
- Regulatory and compliance consulting

Outline of product support areas

FORMULATION CONSULTANCY

» Consultancy
» Regulatory Advice
» Project Management
» Analytical Services

ANALYTICAL SERVICES

» Extractables and Leachables
» Genotox Consultancy
» Genotox Experimentation
» Toxicity Consultation
» Microbiology Consultancy
» Stability Testing
» Analytical Method Development

We know that navigating regulatory approval pathways and reaching key milestone moments in product development can be a complex and costly process. Creating a cross-functional integrated plan with an eye towards later stages of development enhances project efficiency and helps reduce cost. Our regulatory experts specialize in the strategic planning and alignment of registration goals to help de-risk a project at later stages. Our scientists will help design and plan efficient transitions between the formulation, analytical, product development and commercial stages of your project.

We understand that each customer has unique needs and focus on building customized solutions across different stages of the product development life cycle to meet the bespoke needs of your project. Our mission is to support our partners with high quality drug and device development services to help them bring innovative, life-enhancing pharmaceutical products to market and deliver better health outcomes for patients.

PRODUCT DEVELOPMENT

» Technical Due Diligence
» Comparative Analysis
» Product Optimization

COMMERCIALIZATION

» Stability Testing
» QC Batch Release Testing

REGULATION AND COMPLIANCE

» Regulation and Compliance Advisory
» MA Report Writing and Submission
» Pharmacovigilance

About us

Broughton is an independent life sciences contract research organization serving a global roster of clients from Europe, North America, the Middle East, Asia, and Australia. We offer high quality drug and device development services across all stages of the pharmaceutical product lifecycle. Our in-house laboratory testing facilities are GMP and GLP compliant and regularly inspected by the Medicines and Healthcare products Regulatory Agency (MHRA), US Food and Drug Administration (FDA) and United Kingdom Accreditation Service (UKAS). With over 15 years of scientific experience and a world-leading team of scientific and regulatory consultants we support our partners in bringing innovative products to market to deliver better health outcomes for patients. Our aim is to help our partners accelerate their product to market and ensure its on-going success.

Introducing some of our subject matter experts:

DR NVEED CHAUDHARY

Chief Scientific and Regulatory Officer

Nveed joined Broughton having previously directed several regulatory applications for global multinational companies. His goal has always been to reduce the burden that lung disease has on patients, society, and public health.

- Over 20 years' experience in lung disease with a focus on chronic obstructive pulmonary disease (COPD), asthma and Pulmonary Fibrosis across the biotechnology, pharmaceutical and nicotine industries.
- Multi-disciplinary background in pre-clinical and clinical assessment of novel products culminating in regulatory applications.
- A true pioneer for Next Generation Nicotine Delivery Products (NGPs) and has worked collaboratively with FDA in the submission of both PMTAs and MRTPs as well as having heavy involvement in PMTAs for both e-vapor and heated tobacco products.
- Has a passion for storytelling around the improvement of the benefit to risk ratio across a range of active substances.

PAUL HARDMAN

Managing Consultant Chemistry and Manufacturing Controls

Paul leads a team of consultants specializing in understanding product chemistry across pharmaceuticals and consumer products. He has experience in developing inhaled pharmaceuticals and conducting characterization projects for e-cigarettes, nicotine pouches, and medicinal products.

- He started his career at Vectura, where he gained experience in developing dry powder inhaled medicines and co-invented a novel powder dispersion engine design for a passive dry powder inhaler, with potential for use across a range of API and with a range of inhalers.
- He then led the Quality Control laboratory at one of Perrigo's manufacturing sites before overseeing product characterization at Nerudia and Imperial Brands, focusing on the assessment of Next Generation Nicotine Products (NGPs).
- He currently leads the European Committee for Standardization working group on extractable and leachable compounds in vaping products.

LIBBY CLARKE

Managing Consultant Toxicology

Libby joined Broughton in 2021 with over 13 years of experience in the field of toxicology.

- She is a European-registered toxicologist specializing in the design and execution of non-clinical strategies to support product stewardship and regulatory applications for nicotine and cannabis-based products.
- She began her career as a toxicologist at the Forensic Science Service in London where she directed case strategy for the detection of drugs using a broad range of analytical techniques and provided testimony as an expert witness in over 100 court cases.
- She subsequently joined Imperial Brands with roles in product stewardship toxicology, post-market surveillance, regulatory affairs, and cannabis science.
- She is a skilled communicator, able to explain highly complex scientific data in clear key messages positioned according to regulatory guidance.

Let's Collaborate

www.broughton-group.com