Intertek Melbourn Company Presentation

MIBio 2016

November 2016

Intertek

Valued Quality. Delivered.

Global Leader in quality solutions across all industries

Innovative and bespoke quality solutions for our clients 24/7

FTSE 100 company in the support services sector

Market capitalization of over £4 billion

Revenue generation of over £2 billion in 2015

With more than 100 countries, 1000 locations & 41,000 employees

Bringing quality and safety to life

Intertek Pharmaceutical Sites Globally

Intertek Pharma Core Capabilities

GMP Analytical Support

- Drug Substance and Product Development
- Full CMC Analytical Support
- Process development and evaluation
- Extractables & Leachables
- QC/batch release testing

Bioanalytical Services:

Immunochemistry & LC/MS/MS

- Method development & validation of assays for preclinical and clinical
- Immunogenicity evaluations (ELISA, MSD®, BEAD, cell based assays)
- Biomarker assays, including multiplex
- Ocular and tissue bioanalysis
- State of the art capability in structure elucidation and characterization

Intertek Pharma Core Capabilities

Formulation / Product Development

- Excipient Compatibility Studies
- Accelerated Feasibility Studies
- NCE and Generic Development

Toxicology & Regulatory Consultancy

- Strategic Planning, Programme Management
- Regulatory Affairs Interaction

Shared Auditing Service

- Global network of auditors
- API / Excipient manufacturers
- Online system for joining audits

Clinical Research Services

- In-house clinic supporting consumer healthcare products
- Wide network of volunteers
- Claims testing

Intertek Melbourn

Founded in 1989 to provide fee-for-service analytical support to the Pharmaceutical Industry. Joined Intertek July 2013

Focus on analytical, formulation and development manufacturing services to the Pharmaceutical, Biotech and Consumer Healthcare markets.

Particular expertise and experience in working with complex drug delivery systems (inhaled, nasal, controlled release SOD, parenteral)

Vast stability storage and testing capabilities – New, dedicated facility opened in 2015 to provide over 225,000L of storage space across ICH and bespoke conditions.

Currently over 115 people across two sites, with continued growth of 10-15% this year.

Intertek Melbourn – Accreditations & Inspections

FDA
GMP PAI
July 2012

MHRA
GMP Test facility
March 2014

MHRA
MAA (IMP)
March 2014

MHRA
MAA (Import release)
March 2014

Managing Stability Studies

- 20 year experience of running GMP stability studies.
- Consultancy services for all aspects of stability assessment such as protocol design.
- Dedicated stability team.
- All ICH conditions provided, as well as fridges, freezers (conventional and -80˚ C), photo-stability and temperature cycling.
- Second site provides dedicated stability storage
- Total storage capacity of over 225,000L.
- Contingency / Disaster Recovery Storage

Intertek Melbourn – Pharmaceutical Analysis

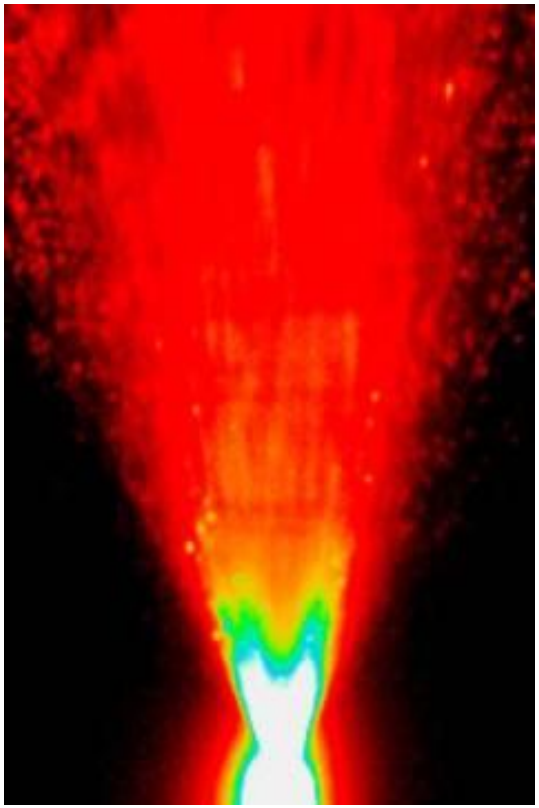
- Experience of testing numerous product types
  - Tablets, Capsules, Parenterals, Transdermals,Topical Creams/Gels, Liquids
- Experts in Chromatography
  - HPLC, uPLC, LC/MS, GC, IC,
  - Assay, Impurities, Method development/validation
- Physical/Chemical Testing
  - pH, Moisture Content, Dissolution, Viscosity, Osmolality, Microscopy, Powder Rheometry
  - Particle/Droplet Sizing and Particulate Characterisation
  - Sub-vis Particulates
- Pharmacopeia Testing
- Work typically supports CMC/Stability and developmental studies or Batch Release (QP on-site)

Inhaled Product Testing

- Largest CRO in Europe for Inhaled Product Testing
- Experience of all Inhaled Product types;
  - pMDI, DPI, Nebuliser, Soft Mist Products
  - Small and Large Molecules
- Key product performance parameters routinely assessed
  - Aerodynamic Particle Size Distribution (APSD) by Cascade Impaction, Delivered Dose, Particle / Droplet Size by Laser Diffraction, Spray Pattern & Plume Geometry
- Temperature & Humidity Controlled Laboratories
- Full Product Development Service, including Formulation and Clinical Manufacture
- CMC Support
- Bioequivalence Testing and Formal Statistical Analysis for Generic Products
- GMP Release Testing
- Consultancy Services

Nasal Product Testing

- Experience of all nasal product types
  - Solutions, Suspensions, Dry Powder Formulations
- Laser Particle Sizing with automated actuators (Proveris and Innova systems)
  - Measures particle/droplet size (non aerodynamic)
- Spray Pattern/Plume Geometry – Proveris SprayView system
- Impaction Testing & Delivered Dose
- Full Product Development Service
- CMC Support
- GMP Release Testing
- Bioequivalence Testing for Generic Products, including Statistical Analysis



Formulation Capabilities

- Experience of many different product types
- No IP so all formulation development based on core platforms
  - Essential for early stage where projects are dynamic
  - Clients not tied in to ‘novel’ technologies when projects progress
- Proof of concept
  - Formulation Feasibility
  - Accelerated Stability & Excipient Compatibility
- Blending/Formulation studies
  - Identify best routes for formulation (potentially avoiding IP/Patents)
  - Stability studies
  - Scale up support & Process Transfer
- Variety of projects from NCE to Generic, small and large molecules

Clinical Manufacturing

- Suite of rooms available for the preparation of Investigational Medicinal Products (IMP)
- Main Cleanroom is Class C (ISO 7)
- Suitable for the preparation of dry powders, liquid solutions/suspensions (non-sterile), topical creams and gels
- Experience of manufacturing clinical material up to Ph.IIb
- Excellent relationships with sterile manufacturers and CMOs
- Experience of method and process transfer
- QP on-site
- Range of equipment including turbula blenders, high shear mixers, liquid dispensers, capsule fillers and blistering capability

Summary

- Dedicated 225,000L Stability Storage facility
- Proven experts in pharmaceutical testing and product development
- GMP accredited
- Experience with small and large molecules
- High class formulation and manufacturing services compliment testing capabilities
- Faster and Easier route to market