

Intertek Pharmaceutical Services

MiBio – Stability of Biopharmaceuticals 21st October 2015, Cambridge Chris Vernall, Ashleigh Wake and John Todd



Intertek - A Leading Quality Solutions Provider



Intertek is a leading quality solutions provider to industries worldwide. From auditing and inspection, to testing, training, advisory, quality assurance and certification, Intertek adds value for its customers by helping improve the quality and safety of their products, assets and processes.

With a network of more than 1,000 laboratories and offices and over 38,000 people in more than 100 countries, Intertek supports companies' success in the global marketplace, by helping customers to meet end users' expectations for safety, sustainability, performance, integrity and desirability in virtually any market worldwide.

An extensive global network



Core capabilities



GMP Drug Development Support

- Drug Substance and Product Development
- Formal ICH Stability Studies/Shelf-Life Assessments
- Formulation and Clinical Manufacturing
- 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



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Stability Capabilities



Managing Stability Studies

- 20 year experience of running GMP stability studies.
- Consultancy services for all aspect 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 has just come on-line that will be a dedicated stability storage facility.
- This has quadrupled our total storage capacity to 190,000L



Biopharmaceutical Services



- Process development analytical support
- Formulation development analytical support
- cGMP Stability Services
- CMC Analytical Support
- Comparability Studies (biosimilars)
- cGMP Release testing
- Extractables / leachables
- Cell based potency assays (safety & efficacy)
- Cell Line / Cell bank characterisation

Services
Aligned
to the
ICHQ6B



Characterisation of a biotechnological or biological product includes:

- Physicochemical properties
- Biological activity
- Immunochemical properties
- Purity and impurities.

Intertek recently opened a new bioanalytical and biopharmaceutical characterisation facility

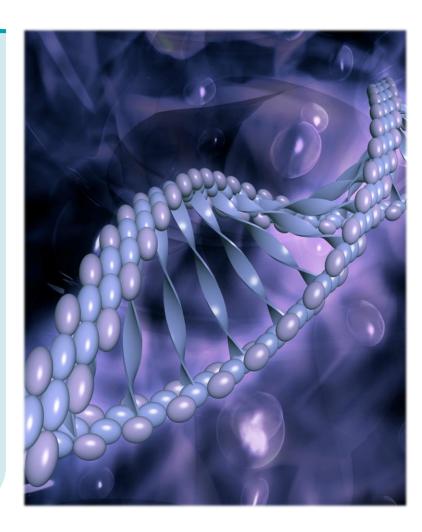
This brings expanded capacity of analytical and bioanalytical laboratories at our Manchester-based Centre of Excellence for Biologics.

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Experience



- Monoclonal antibodies
- Growth Factors
- Hormones
- Enzymes
- Toxin
- PEGylated proteins
- Proteins with amino acid modifications
- Biospecific antibodies
- Antibody Drug Conjugates
- Oligonucleotides



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