

# Intertek Pharmaceutical Services

## MiBio – Stability of Biopharmaceuticals

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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



## 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



## 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



- 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.**

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

