

## A solution provider for your biopharmaceutical outsourcing requirements.

The proportion of biologics in new drug approvals has risen by over 30% during the last decade, and with the current pipeline containing more than 500 protein and 50 peptide developmental drugs, this trend is set to continue. With specialist knowledge in the development, manufacturing and testing of biopharmaceuticals Tepnel can offer outsourcing solutions at all stages of the product development pipeline.

### Experience

Tepnel is experienced in handling a wide range of sample types, including production intermediates, final products, pre-clinical and clinical samples. Tepnel has expertise in protein analysis methods such as SDS-PAGE and Immunoblotting, Size Exclusion Chromatography, Ion-Exchange Chromatography, Reverse-Phase-HPLC, LC-MS/MS coupled with 20 years experience in custom ELISA/ELISPOT development.

### Quality Assurance

Tepnel is a GLP accredited company, operating a fully auditable Quality Management System ensuring an excellent service with full documentation and traceability. All stages of the bioanalysis service are audited including the study plan, sample receipt and storage, operational activities, data analysis, data derivation, draft/final reports and archive. Our QA personnel are fully conversant with GLP/GCP regulations and provide an independent and fully accountable inspection and auditing service.

### Stability testing

Tepnel can provide analytical testing and quality control support for Stability Studies in accordance with the International Conference on Harmonisation (ICH) guidance documents under current Good Manufacturing Practices. All our stability facility conditions are mapped, qualified and validated. We take a multi-faceted approach to stability testing of proteins, using multiple methods to ensure that physical and chemical integrity; and very importantly biological activity has been maintained.

### Custom ELISA

This service offers the development and validation of regulatory compliant monoclonal and polyclonal bioassays that can be routinely used to support pre-clinical and clinical studies. With over 20 years experience in the development of technically challenging and sensitive ELISA assays, we can provide testing solutions for biopharmaceutical drug products and support for biomarker identification, elucidation and anti-drug information.

## Testing Capabilities

### API Development

- Characterisation
- Storage stability studies
- Development/validation of purity assays

### Pre-clinical

- Drug substance analysis using sensitive and specific ELISA
- Custom ELISA development and validation
- Animal study support

### Clinical studies

- PI-III human
- Pharmacokinetics
- DNA extraction
- Stability

### Clinical Product Development

- Development/validation of stability indicating assays
- Release testing

### Finished Product Development

- Batch release testing
- Post Marketing Surveillance
- Manufacturing Support



## Other Services from Tepnel

**Tepnel Research Products & Services offers a broad range of additional services to the pharmaceutical, biotechnology and healthcare sectors including:**

### Microbiology Services:

- Sterility Testing
- TVC/Abs of Pathogens
- Preservative Efficacy
- Disinfectant Testing
- Bacterial Endotoxin
- Environmental Monitoring
- Bioanalytical Services

### Pharmaceutical Services:

- ICH Stability Testing
- Batch Release
- Raw Materials Testing
- Method Development & Validation
- IMP Testing/Release

### Molecular Services:

- DNA/RNA Extraction
- Sample Quantification & Normalisation
- Whole Genome Amplification
- SNP Genotyping
- ELISA/ELISPOT Assay Development

### Bioanalytical Services:

- Pre-clinical Support
- Phase I-III Support
- Pharmacokinetics
- Non-proprietary Assays

**Tepnel Research Products & Services** specialises in the provision of regulatory services and analytical solutions in the areas of analytical chemistry, microbiology, bioanalysis and molecular services under inspection and approval of the MHRA and FDA

## Contact Details

### Tepnel Research Products & Services

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## Our Approach & Services

### Discovery Support:

With extensive experience in the development of biologics we offer support for product characterisation and process development. We have the ability to generate monoclonal or polyclonal antibodies to customer-defined specificities which can be used in immunochemical tests.

### Method Development:

- Full method development, feasibility and validation for NCE's, pre-clinical and Phase I-III clinical trials
- Biomarker identification, elucidation and anti-drug information
- Specialists in ELISA/ELISPOT development

### Method Validation:

- Study plans based on current regulatory guidelines and latest recommendations for ligand-binding assays.
- Methods validated in accordance with ICH Q2 (R1) (CPMP/ICH/381/95 and addendum CPMP/ICH281/95) and the FDA Guidance for Industry on Bioanalytical Method Validation
- The following validation parameters are routinely tested:
  - Accuracy/Recovery
  - Precision (Repeatability and Intermediate Precision)
  - Calibration/Standard curve
  - Specificity/Selectivity
  - Quantitation/Detection Limit
  - Linearity
  - Range
  - Stability of samples in matrix (including freeze-thaw, short and long-term stability)
  - Stability of standard stock solution/s

### Method Transfer:

- Where reliable and robust methods are in place we offer a rapid, quality assured method transfer service

### Sample Analysis:

- Sample analysis for a full range of sample types from drug substance to pre-clinical/clinical samples in mammalian species
- Experience in a wide variety of product types including recombinant proteins, monoclonal and polyclonal antibodies, vaccines, peptides and blood products.
- Drug substance and batch release testing using USP, EP, JP, BP and client-supplied methods
- Clinical support from Phase I through to Bioequivalence
- High throughput sample analysis
- IT support using LIMS software ensures data integrity and facilitates fast turnaround of analysis and report preparation
- Efficient delivery of QA audited reports tailored to client/sponsor's specification