Clinical Support Services

Introduction

Two of the four recognised stages in the drug development process require the quantification of analytes extracted and separated from complex biological matrices.

Tepnel Pharma Services provides clients with fast, reliable, pre-clinical and clinical data in compliance with global guidelines. Our analytical method development and validation, sample analysis and GLP bioanalysis laboratories offer in-house assessment of your biological samples and test articles.

Our experienced team works independently of any associated animal house or bedded unit to help you deliver your pre-clinical or clinical package on time.

Our services include:

- **Bioanalysis of Small and Large Molecules**
- **Biomarker Validation**
- **Translational Services**

As an experienced provider of pre-clinical and clinical bioanalysis, we believe in developing and promoting a successful partnership with you so we become an extension of your own laboratory.

30 Years'
Experience in Developing Testing Methods for Numerous Drug Products

Pharmaceutical Quality System

We are committed to achieving high standards of reliability and quality as embodied in our Pharmaceutical Quality Management System. Our quality system draws together the requirements from ICH Q10 and regional GLP, GCP and cGMP regulations allowing us to perform work in compliance with these regulatory requirements under a unified quality approach.

Tepnel Pharma Services is an independent CRO that specialises in the provision of pharmaceutical testing and molecular genetic services in support of drug development. Tepnel Pharma Services is focused on providing accurate, robust and time-honoured services that enhance patient safety and provide a better standard of healthcare.

MOLECULAR GENETIC SERVICES • PRE-CLINICAL & CLINICAL SUPPORT SERVICES
cGMP DRUG DEVELOPMENT SUPPORT SERVICES

HOLOGIC® | GEN-PROBE

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Clinical Support Services
Established and Independent Provider
Quality Assured and Regulatory Compliant

TEPNEL
Pharma Services

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Small Molecule Support

Bioanalysis deals with complex biological samples that contain an analyte alongside a diverse range of chemicals that can have an adverse impact on the accurate and precise quantification of the analyte and its metabolites.

As an independent bioanalytical laboratory we provide a wide range of techniques – including UPLC chromatographic systems with LC-MS/MS detection and automated high-throughput sample preparation robotics – that can be applied to extract the analyte from its matrix for analysis in early discovery, pre-clinical and clinical phases of product development.

During our 30 years' experience in developing testing methods we have met the diverse needs of numerous drug products by offering:

- **A Wide Range of Chromatographic Resources:**
  - LC-MS/MS, UPLC-MS/MS, HPLC, GC, IC
- **Experience in Bioanalytical Testing Support for Pre-Clinical Toxicology:**
  - Rodents, dogs, primates
- **Extraction of Analytes and Metabolites from:**
  - Blood, urine, faeces, tissue
- **Bioanalysis of Samples from Human Clinical Trials for Safety, Efficacy, Kinetics and Metabolism**
- **Method Development, Validation and Transfer**

Large Molecule Support

Bioanalysis has traditionally been executed in terms of measuring small molecule drugs using Mass Spectrometry platforms. However, in recognition of the evolution of biotechnology in drug development we have embraced the new techniques and technologies that are required for the analysis and characterisation of today's biopharmaceuticals and therapeutic agents.

Our Immunochemistry services, including ELISA-based techniques, are used in conjunction with traditional chromatography platforms to enable large molecule bioanalysis built on a strong foundation of science and project managers grounded in Biologics.

Our GLP accredited laboratory and extensive experience in developing immunochemistry and conventional large molecule bioanalysis testing methods meets the diverse needs of protein, peptide and oligonucleotide based products:

- **Method Development – Feasibility Assessment, Establishing Methods and Development**
  - Maldi-TOF-MS, LC-MS/MS, size exclusion, affinity chromatography, UPLC-MS/MS, IC, ELISA
- **Sample Analysis of Biopharmaceutical Concentration or Anti-Drug Antibody (ADA) in Biological Matrices**
  - Pre-clinical toxicology from rodents, dogs and primates
  - Clinical trials for safety, efficacy, kinetics and metabolism
- **Method Validation in Accordance with Global GLP Regulations and Guidelines**

Biomarker Discovery & Validation

Biomarkers are now an integral part of industry efforts to streamline drug development.

They are increasingly important in helping "go/no-go" decisions in early phase pre-clinical and clinical development, either as indicators of safety or efficacy.

We offer biomarker services for discovery and validation from initial translational research into study design, through clinical trials support and onto the development of companion diagnostic tests.

- **Method Development – Feasibility assessment, establishing methods and development**
- **Validation of Biomarker Methods – Validation of both in-house and commercial biomarker methods to GCP/GLP standards**
- **Biomarker Quantification Experience in Performing Sample Analysis on both Human and Animal Samples:**
  - Enzyme Linked Immunosorbant Assays (ELISA)
  - Multiplexed assays (Luminex® xMap technology)
  - MRM mass spectrometry
- **Antibody Development and Validation of Antibodies**
- **Comprehensive Range of Genomic Technologies for the Development and Validation of Biomarkers in both Pre-Clinical and Clinical Studies:**
  - DNA and RNA extraction services
  - Invader® chemistry
  - Microarray services
  - qPCR
  - Sanger sequencing and fragment analysis
  - Ion Torrent® Next Generation Sequencing
  - Luminex multiplexing

Why Choose Us?

Over 30 years' experience in serving the pharma industry

Serving customers worldwide

Regulatory compliant analytics

Translational Services

Our Molecular Genetic Services team has extensive biomarker services experience and expertise supporting pre-clinical and clinical biomarker discovery and validation studies for the World's leading pharmaceutical companies. Our laboratories operate under GCP regulatory compliant conditions.

- **Biomarker Discovery and Validation.** The identification of prognostic, predictive or pharmacodynamic biomarkers can be carried out using a range of platforms. These studies can utilise samples from a number of sources including pre-clinical and clinical studies. Our biomarker services can support you through every aspect of your biomarker discovery and validation, from initial study design to data analysis
- **Assay Design and Validation.** Custom assay design and validation services are available to support clinical trials or the development of companion diagnostic tests
- **Regulatory Compliant Processing of Samples from Clinical Studies**
- **Rapid Response Services are Available to Support Clinical Studies (48 hour turn-around)**
- **We have significant experience working with FFPE Tissue in a wide range of Biomarker Discovery and Validation Studies.** Our biomarker services scientists have the expertise and know-how to ensure the data produced for your study is of unparalleled quality providing you with the maximum return on your valuable samples:
  - Sample sourcing
  - Expertise in handling a broad range of tissue types, including small biopsies
  - Extraction of miRNA, RNA or DNA using FFPE specific protocols

A wealth of experience across a wide range of technology platforms

Targeted ahead of time delivery through process optimisation

Effective two way communication