

Molecular Genetic Services

Introduction

Tepnel Pharma Services offers a comprehensive range of services for biomarker discovery, assay development, assay validation and companion diagnostic development to support your pre-clinical, clinical and translational studies.

Our Services Include:

- ✓ Companion Diagnostic Development
- ✓ Clinical Services
- ✓ Research Services

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.

**Seamless Path
to Companion Diagnostic
Development**

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

Molecular Genetic Services

Established and Independent Service Provider
Quality Assured and Regulatory Compliant



Europe

Appleton Place, Appleton Parkway,
Livingston, West Lothian,
EH54 7EZ, UK.

T: +44 (0)1506 424270

E: pharma@hologic.com

www.tepnelpharmaservices.com

Heron House, Oaks Business Park
Crewe Road, Wythenshawe
Manchester, M23 9HZ, UK.

T: +44 (0)161 946 2200

E: pharma@hologic.com

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TEPNEL
Pharma Services



Clinical Services

Our team has extensive biomarker experience and expertise supporting clinical and pre-clinical biomarker discovery and validation studies. Operating under GCP regulatory compliant conditions we offer:

- **Biomarker Discovery and Validation**
 - Prognostic, predictive or pharmacodynamic biomarkers can be identified using a variety of platforms. We can support you through every aspect of your project, from initial study design to data analysis using a wide range of sample sources including pre-clinical and clinical studies.
- **Assay Design and Validation for both RUO and GCP Projects**
- **Regulatory Compliant Processing of Samples from Clinical Studies**
- **Rapid Response Services to Support Clinical Studies (48 hour turn-around)**
- **FFPE** - We have significant experience working with FFPE tissue in a wide range of biomarker discovery and validation studies 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

Companion Diagnostic Development

With all the major pharmaceutical companies adopting new programs to develop companion diagnostic products, Tepnel Pharma Services is uniquely placed to provide a front-to-end service. We can support companion diagnostic development from early pre-clinical research and biomarker discovery through to the development, manufacture and regulatory approval of a companion diagnostic test.

We support all stages of the companion diagnostic development process including design control, kit manufacture, validation studies, production of Investigational Use Only assays for use in clinical trials and regulatory approval.

Our design process includes:



Our companion diagnostic development process aims to optimise the value of your drugs in the marketplace.

Research Services

Our portfolio offers researchers access to a broad range of technologies in support of a variety of research applications. Our dedicated and experienced team will guide you through every aspect of your project, from initial study design to data analysis.

In partnership with Fios Genomics we can offer a wide range of bespoke data analysis solutions for a variety of application areas. Capabilities range from data QC and basic statistics to advanced informatics such as network and pathway based analysis, clustering techniques and data mining/integration methods to produce a comprehensive picture of the underlying biology of your experiment.

Services include:

- **Gene Expression and RNA Seq**
- **Genotyping (from single-plex up to GWAS studies)**
- **Copy Number Analysis**
- **Methylation and Epigenetics**
- **Metagenomics and Small Genome Sequencing**
- **FFPE Analysis**
- **AgBio – Full range of genotyping solutions**
- **Drug Metabolism Studies**
- **Custom Assay Design and Validation is Available on a Wide Range of Platforms (e.g. qPCR genotyping and microarray gene expression)**
- **Data Analysis**

Why Choose Us?



Over 30 years' experience in serving the pharma industry



Serving customers worldwide



Regulatory compliant analytics

Our Technologies

We offer an established and comprehensive portfolio of genomic technologies including nucleic acid extraction, gene expression, genotyping, copy number and epigenetic analysis using microarrays, qPCR, Sanger sequencing, fragment analysis and next generation sequencing. All our services can be run as "research use only" or as a regulatory compliant offering:

- **DNA and RNA Extraction Services**
- **Invader® Chemistry**
- **Affymetrix® Microarray Services**
- **Illumina® Microarray Services**
- **qPCR**
- **Sanger Sequencing and Fragment Analysis**
- **Ion Torrent® Next Generation Sequencing**
- **Luminex® Multiplexing**
- **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