

# Promoting Patient Safety and the Development of Future Medicines



## Tepnel Pharma Services

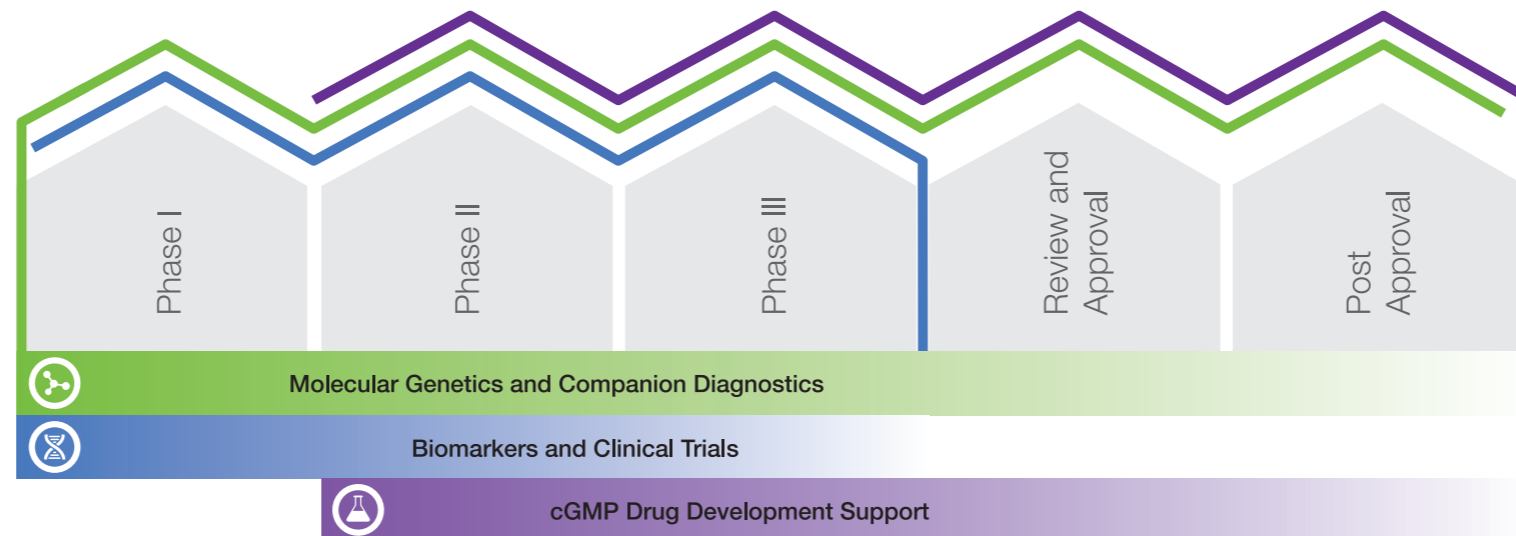
Tepnel Pharma Services is an independent Contract Research Organisation which supports the drug development pipeline at the Rx/Dx interface.

With over 30 years of experience in supporting pharmaceutical, biopharmaceutical and biotechnology companies through the provision of outsourced cGMP compliant Chemistry, Manufacturing and Control (CMC) and human genetics testing, Tepnel Pharma Services is positioned to provide CMC support for drug development, whilst also providing a companion diagnostic solution which addresses the requirements of personalised and stratified medicines.

## Specialties

Research & Clinical Services, CDx Development, Batch & Product Release, Stability/Raw Materials Testing, Method Development & Validation, DNA & RNA Extraction, Microarray Services, qPCR, Invader, Next Generation Sequencing, RX/DX Partnership, Small & Large Molecules, Translational and Biomarkers.

## Pharmaceuticals, Biopharmaceuticals, Biologics and Diagnostics



Services and Capabilities						
LabWare® Laboratory Information System	<b>Research and Clinical Genomics</b> Nucleic Acid Extraction (DNA, RNA and miRNA) Gene Expression and RNA Seq Genotyping, (single-plex up to GWAS) Copy Number Analysis Epigenetics Small Genome Sequencing Metagenomics Drug Metabolism studies Bioinformatics	<b>Method Development and Validation</b> ICH Q2 (R1) Experience Stability Indicating Assay Related Substances HPLC Immunoassay Cleaning Validation Dissolution Analytical Method Transfer	<b>Raw Materials and Compendial Testing</b> USP/NF, Ph.Eur, JP, BP, UV, FT/IR, ELISA, SDS-Page, IEF, Western Blot, Disintegration, Dissolution, Particulate Size Distribution, SEC, IEX, Peptide Mapping, Physical and Physicochemical Methods, Moisture Determination, Raw Materials and In-Process Analysis	<b>ICH Stability Testing</b> ICH Q1 Stability ICH Stability Storage In-Use Studies Forced Degradation Photo Stability API and DP program management and analysis Clinical stability programs FUST Stability Programs Retained Sample Storage	<b>Global Batch Release</b> Pharmaceuticals BioPharmaceuticals IMP batch release testing and re-test Method transfer and analyst exchange	<b>Companion Diagnostic Development</b> Concept and feasibility Product definition and planning Development and verification Product validation and launch Post launch support
	<b>Tools and Technologies</b>					
	<b>Genomic Analysis</b> Nucleon® Chemistry Invader® Chemistry Affymetrix® and Illumina® Microarray Services qPCR Sanger Sequencing and Fragment Analysis Next Generation Sequencing, Ion Torrent Luminex® Multiplexing	<b>Chromatographic platforms</b> Waters Alliance® HPLC (UV, PDA, Flu, ELSD, RI) Waters UPLC® (TUV, PDA and SQD) Waters® H-Class (Method Development Platform and high sample volume analysis) ABI Sciex 4000™ Mass Specs Agilent® and Shimadzu® GCs	<b>Microbiology Services</b> Sterility Isolators LAL Testing Bioburden Analysis Absence of Pathogens Antibiotic Assay Preservative Efficacy Testing Microbial Identification	<b>Inhalation Support</b> Next Generation Impaction Delivered Dose Apparatus Content Uniformity Assay/Degradation Moisture Analysis Controlled Temperature and Humidity Cabinets		
Project Enablers - Integrity – Customer Focus – Accountability – Experience – Innovation – Delivery						
Quality Enablers: Pharmaceutical Quality System – cGMP/GLP/GCP/ISO9001 – MHRA/FDA						

## Formulation Experience

Inhalation (MDI, DPI & Nebulised), Topical, Enteral, Parenteral, Lyophilised, Monoclonal Antibodies, Proteins/Peptides, Vaccines, Medical Devices, Powders for Oral Solutions and Controlled Drugs.

## Therapeutic Experience

Infectious Diseases, Oncology, Autoimmune, Respiratory, Cardiovascular, Erectile Dysfunction, Immunotherapy and Vaccines.

## Quality First and Foremost

Tepnel Pharma Services is fully committed to operating a GxP system which is wholly and continuously compliant with current Good Manufacturing Practices (cGMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) accreditation as defined in the relevant statutory instruments and current regulatory guidance.

Tepnel Pharma Services is proud to be a part of the Scottish Life Sciences Community. Together, this community has developed a vision that by 2020 Scotland will have:

“A globally focused, sustainable life sciences sector built on a fully connected national strategy that exploits strengths in scientific excellence, financial services and innovative business models, and that develops, retains and builds upon Scotland’s talents.”

The Life Sciences Scotland identity exists to unify the community and to broadcast Scotland’s depth of expertise in Life Sciences across the world.

**TEPNEL**  
Pharma Services

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