# Promoting Patient Safety and the Development of Future Medicines

TEPNEL Pharma Services

HOLOGIC®

## Tepnel Pharma Services

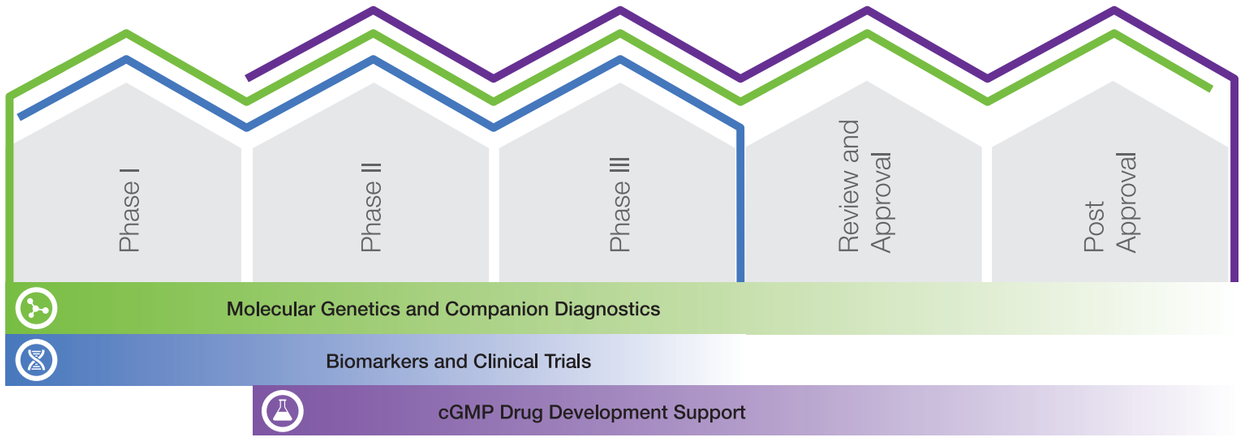
Tepnel Pharma Services is an independent Contract Research Organisation which supports the drug development pipeline at the Rx/Dx interface.

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




LabWare® Laboratory Information System

### Services and Capabilities

| Research and Clinical Genomics | Method Development and Validation | Raw Materials and Compendial Testing | ICH Stability Testing | Global Batch Release | Companion Diagnostic Development |
|---|---|---|---|---|---|
| Nucleic Acid Extraction (DNA, RNA and miRNA) | ICH Q2 (R1) Experience | USP/NF, Ph.Eur, JP, BP, | ICH Q1 Stability | Pharmaceuticals | Concept and feasibility |
| Gene Expression and RNA Seq Genotyping, | Stability Indicating Assay | UV, FT/IR, ELISA, SDS-Page, | ICH Stability Storage | BioPharmaceuticals | Product definition and planning |
| (single-plex up to GWAS) | Related Substances | IEF, Western Blot, | In-Use Studies | IMP batch release testing and re-test | Development and verification |
| Copy Number Analysis | HPLC | Disintegration, Dissolution, | Forced Degradation | Method transfer and analyst exchange | Product validation and launch |
| Epigenetics | Immunoassay | Particulate Size Distribution, | Photo Stability | | Post launch support |
| Small Genome Sequencing | Cleaning Validation | SEC, IEX, Peptide Mapping, | API and DP program management and analysis | | |
| Metagenomics | Dissolution | Physical and Physiochemical | Clinical stability programs | | |
| Drug Metabolism studies | Analytical Method Transfer | Methods, Moisture Determination, | FUST Stability Programs | | |
| Bioinformatics | | Raw Materials and In-Process Analysis | Retained Sample Storage | | |

### Tools and Technologies

| Genomic Analysis | Chromatographic platforms | Microbiology Services | Inhalation Support |
|---|---|---|---|
| Nucleon® Chemistry | Waters Alliance® HPLC (UV, PDA, Flu, ELSD, RI) | Sterility Isolators | Next Generation Impaction |
| Invader® Chemistry | Waters UPLC® (TUV, PDA and SQD) | LAL Testing | Delivered Dose Apparatus |
| Affymetrix® and Illumina® Microarray Services | Waters® H-Class (Method Development | Bioburden Analysis | Content Uniformity |
| qPCR | Platform and high sample volume analysis) | Absence of Pathogens | Assay/Degradation |
| Sanger Sequencing and Fragment Analysis | ABI Sciex 4000™ Mass Specs | Antibiotic Assay | Moisture Analysis |
| Next Generation Sequencing, Ion Torrent | Agilent® and Shimadzu® GCs | Preservative Efficacy Testing | Controlled Temperature and Humidity |
| Luminex® Multiplexing | | Microbial Identification | 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, Lyophalised, 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.

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