

POLYMERASE CHAIN REACTION (PCR) SERVICES

- ▶ High quality service across all phases of pre-clinical and clinical drug development in compliance with GLP and GCP regulations
- ▶ More than 10 years of experience to perform activities in regulated environment
- ▶ Extensive method development expertise to meet the most demanding and challenging client needs
- ▶ State-of-the-art labs and technologies
- ▶ Multidisciplinary collaboration to provide an integrated solution to accelerate drug development process

Method development and validation

Analysis for PK/TK studies

Biomarkers



Biodistribution

Viral shedding and viral persistence/clearance

PCR is the most useful technique for molecular biology research. Our regulated PCR services group, with state-of-the-art instrumentation and GxP compliant laboratories, has a track record of providing PCR support, for both preclinical and clinical phases of biotechnological products development including gene and cell therapies. We can meet the most demanding and challenging client needs thanks to our scientific expertise, operational experience, and up-to-date knowledge of the regulatory environment. We offer a suite of PCR, quantitative real time PCR (qPCR) and reverse transcription qPCR (RT-qPCR) applications, including copy number estimation assays, gene expression profiling and genotyping assays.

REGULATED PCR SERVICES

- ▶ Method development
- ▶ Method transfer of existing validated methods
- ▶ Cross-validation of method performance against existing laboratories
- ▶ Validation following EMA/FDA guidelines
- ▶ GxP analysis in support of preclinical and clinical Phase I–III studies
- ▶ Analysis of a wide range of sample matrices
- ▶ Full quality assurance of study plan and final reports

THERAPEUTIC MODALITIES

- ▶ Gene therapies (viral delivery systems i.e. AAV, lentivirus)
- ▶ Cell therapeutics (i.e. CAR-T and stem cell)
- ▶ RNA/oligonucleotide therapeutics
- ▶ Antibody-drug conjugates
- ▶ New chemical entities
- ▶ Liposomal products
- ▶ Peptides including peptides nucleic acid
- ▶ Proteins (mAb)

APPLICATIONS

- ▶ PK/TK studies
- ▶ Biodistribution
- ▶ Viral shedding and viral persistence/clearance
- ▶ Biomarkers, i.e. efficacy (PD) endpoints, exploratory endpoints, genotyping, immune response, liver damage, gene expression studies

SAMPLE MANAGEMENT

- ▶ Dedicated team
- ▶ Freezer rooms with controlled access
- ▶ Capacity to store about 300K samples at -20°C and -80°C
- ▶ Freezers connected with an alarm system and with a validated software for temperature monitoring
- ▶ Production and supply of sampling kits, labels, study manual for clinical trials