

A FLEXIBLE APPROACH TO BIOANALYSIS

QPS is a global CRO with four advanced bioanalytical facilities in the US, Netherlands, Taiwan and India to serve the evolving needs of the Pharmaceutical and Biotech industries. Our staff has considerable experience with conventional matrices (plasma, serum, whole-blood, urine, feces), as well as various animal and human tissues.

At QPS, bioanalysis brings together leading-edge technologies focused on small molecules, protein biotherapeutics, vaccines and cell & gene therapies, and provides a full range of bioanalytical solutions to support drug development from drug discovery through clinical development.

METHOD DEVELOPMENT

A full method validation is typically described in a sponsor approved validation protocol and includes at least six assay runs to determine both inter- and intra-batch precision and accuracy, dilution linearity (hook effect tests), matrix selectivity, matrix effect ($n \geq 6$) and necessary stability tests including benchtop (ambient temperature), freeze-thaw and long-term storage.

- ▶ Lead optimization vs. Candidate Selection vs. Regulated Bioanalysis
- ▶ LC-MS/MS for small molecule drug candidates and their potential metabolites (since 2000)
- ▶ Ligand Binding Assay (LBA) or LC-MS/MS for proteins and peptides
- ▶ UHPLC-HRMS, hybridization-HPLC fluorescence or HPLC-ultraviolet (UV) or hybridization-LBA for oligonucleotides
- ▶ Reaction (RT-qPCR/qPCR) for mRNA (biotherapeutics and viral or plasmid vectors)
- ▶ ELISA for Immunogenicity and Neutralizing Antibodies



Pharmacokinetic (PK)



Pharmacodynamic (PD)



Immunogenicity Assessment



Pharmacogenomics (PGx)

VALIDATED ASSAYS FOR BIOTHERAPEUTICS, BIOMARKERS AND BIOLOGICS

- ▶ A portfolio of 800+ validated assays, bound to cover your global bioanalysis and clinical study needs.
- ▶ Cell and Gene Therapy – 45+ ASO/siRNA/aptamer and 20+ mRNA/vector programs (since 2003)
- ▶ Cell-based Assays – 50 cell-based assays supported (since 2002)

REGULATED BIOANALYSIS

- ▶ QPS incorporates global GLP principles and regulations for successful submissions, smoothing the way for regulatory acceptance.

A GLOBAL FULL SERVICE CRO ACROSS USA, EU, ASIA, AND AUSTRALIA

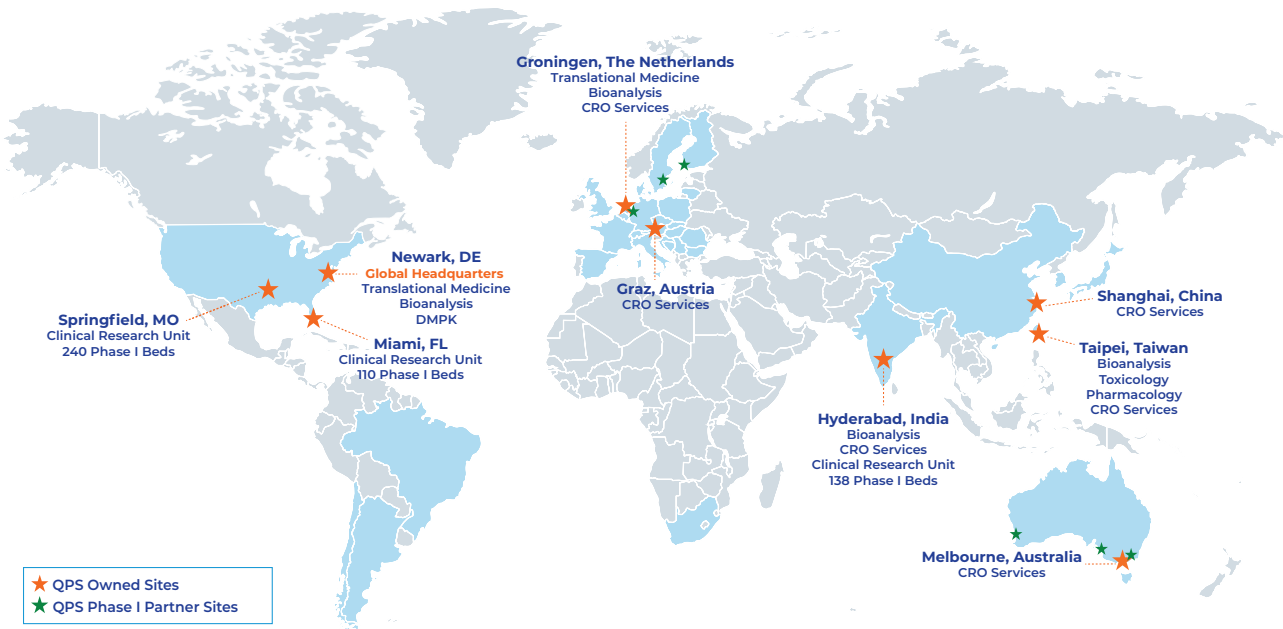
QPS BIOANALYTICAL CAPABILITIES

- ▶ Biotherapeutics
- ▶ Biomarkers
- ▶ Genomics
- ▶ Translational Medicine
- ▶ Mass Spectrometry
- ▶ Cell & Gene Therapy

QPS CLINICAL RESEARCH OPERATIONS SERVICES

- ▶ Project Management
- ▶ Site Selection & Monitoring
- ▶ Clinical & Medical Monitoring
- ▶ Data Management & Biostatistics
- ▶ Medical Writing
- ▶ Quality Assurance
- ▶ Regulatory & Medical Affairs
- ▶ Safety & Pharmacovigilance
- ▶ Clinical Program Management

QPS CLINICAL TRIAL SITES AND NETWORK LOCATIONS



NETWORK LOCATIONS USA / Austria / Australia / Argentina / Belgium / Bosnia / Brazil / Bulgaria / Chile / China / Croatia / Czech Republic / Denmark / France / Finland / Germany / Hungary / India / Italy / Lithuania / Netherlands / Poland / Romania / Serbia / Slovakia / South Africa / South Korea / Spain / Sweden / Taiwan / United Kingdom

Discover how QPS can accelerate your clinical research.

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