A FLEXIBLE APPROACH TO BIOMARKERS

AT QPS, TRANSLATIONAL MEDICINE BRINGS TOGETHER LEADING-EDGE

technologies and pharmaceutical research & development experience to create a business service unit that works efficiently to advance your drug development program.

QPS BIOMARKERS AND TRANSLATIONAL MEDICINE OVERVIEW

At QPS, translational medicine brings together leading-edge technologies and pharmaceutical research and development (R&D) experience to create a business service unit that works efficiently to advance your drug discovery and development program.

Pharmacokinetic (PK)

Immunogenicity Assessment

Pharmacodynamic (PD)

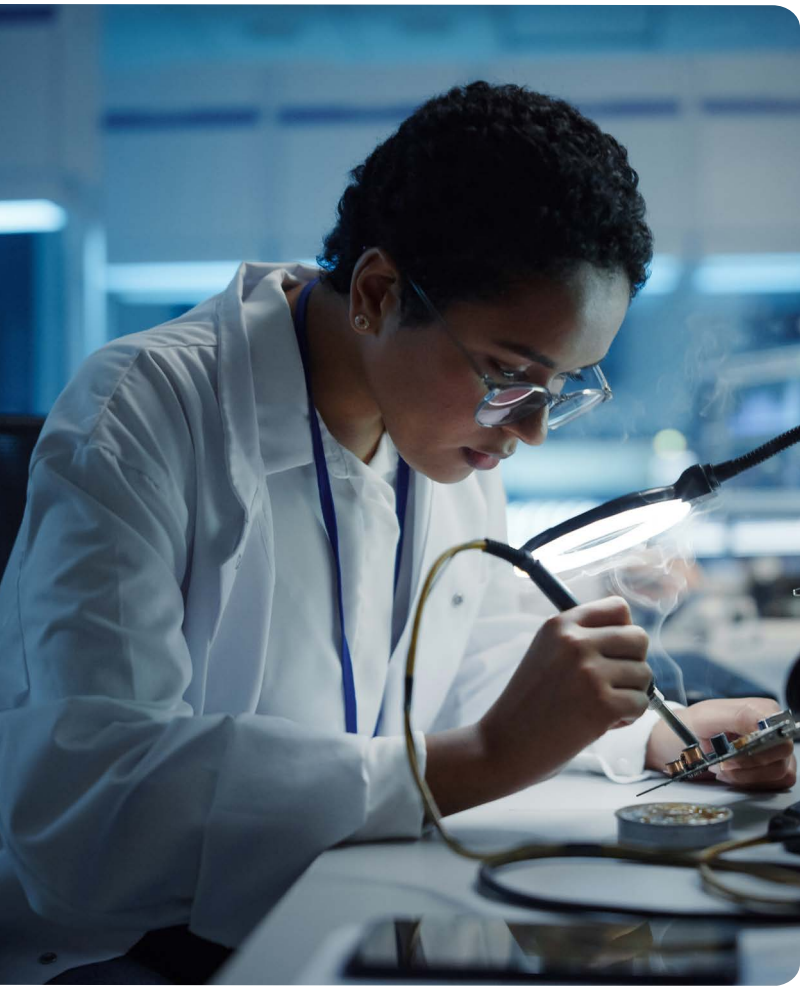
Pharmacogenomics (PGx)

TRANSLATIONAL MEDICINE OVERVIEW

Projects in translational medicine include qualification/validation of commercially available kits, method transfer of assays originating from the Sponsor's lab, or a collaborative effort between the QPS team and the Sponsor's lab for custom assays. We also develop assays independently without help from the Sponsor. In addition to immunoassays for PK and immunogenicity assessment, QPS develops cell-based assays for neutralizing antibody activity and biomarker evaluation in support of your drug development programs.

VALIDATION & QUALIFICATION

We work diligently with clients to determine best practices for conducting biomarker or other pharmacodynamic studies to support both preclinical studies and clinical trials. As pharmacodynamics assays are often for explorative use only, we have adopted a "fit-for-purpose" to qualify and validate assays. QPS can plan a "fit-for-purpose" method qualification or validation that identifies the key tests needed to ensure the suitability of an assay method on an individual basis.



We can provide a shorter method qualification, usually performed with a vendor-qualified assay kit. A qualification typically includes 3 or more precision and accuracy runs and matrix testing. In this case, assay specifications including more extensive validation tests are provided by the assay vendor. As a “fit-for-purpose” qualification, additional tests may be added based on the nature of the assay and specific study considerations. In some cases, an inter-laboratory cross validation may be performed for data comparison, using 20-30 samples provided by the sponsor.

In a “fit-for-purpose” method validation, the individual biomarker characteristics and the study specifics are used to determine which of these tests are appropriate. Some tests may be eliminated on an individual basis if they are not applicable to the particular biomarker, not useful for a specific type of assay (e.g. activity assay) or if they are not relevant to the clinical or preclinical study our method is supporting. Additional tests may be added given the same considerations.

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 ≥6) and necessary stability tests including benchtop (ambient temperature), freeze-thaw and long-term storage.

SCIENTIFIC LEADERSHIP AND PROVEN RESULTS

Our dedicated, experienced team ensures that bioanalysis studies meet all timelines and regulatory requirements. QPS provides high quality data along with direct access to our technical staff, regularly scheduled updates in a format that works for you, and prompt and courteous answers to your inquiries at a fair and competitive price.

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

QPS
CUSTOM-BUILT RESEARCH™

QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

BENEFIT FROM THE WORLDWIDE RESOURCES THAT A GLOBAL CONTRACT RESEARCH ORGANIZATION BRINGS

Whether your focus is small molecules, protein biotherapeutics, vaccines, gene therapy or cell therapy, QPS provides a full range of bioanalytical services to support all drug development needs from discovery, through clinical development and regulatory filing.

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TIME IS OF THE ESSENCE IN DRUG DEVELOPMENT.
CONTACT THE QPS BUSINESS DEVELOPMENT TEAM TODAY!

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