QPS

CUSTOM-BUILT RESEARCH™

A flexible approach to

Biomarkers & Translational Medicine

AT QPS, TRANSLATIONAL MEDICINE BRINGS TOGETHER LEADING-EDGE TECHNOLOGIES AND pharmaceutical research and development experience to create a business service unit that works efficiently to advance your drug development program.

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

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Translational Medicine Overview

Projects in translational medicine include qualification/validation of commercially available kits, method transfer of assays originated 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 pre-clinical 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.

QPS is a Global CRO with locations around the world