A FLEXIBLE APPROACH TO **IMMUNOGENICITY**

WHEN YOUR FOCUS IS BIOTHERAPEUTICS,
QPS' global laboratories provide a full range of bioanalytical solutions to support immunogenicity evaluations during drug development from discovery through clinical development and filing.

QPS
CUSTOM-BUILT RESEARCH™

IMMUNOGENICITY

While biotherapeutic drugs such as monoclonal antibodies (mAbs), recombinant proteins and oligonucleotides are emerging treatments for diseases, they may illicit an immune response in the form of anti-drug antibodies (ADAs) resulting in potential reductions in efficacy, and sometimes, safety concerns. As such, immunogenic potential needs to be assessed.

QPS is a global CRO with state-of-the-art bioanalytical facilities and immunogenicity testing laboratories strategically located in the United States (Delaware) and Europe (The Netherlands).

QPS first implemented ADA analysis for proteins and mAbs in 2003 and for oligonucleotides as early as 2013. Since that time our laboratories have performed ≥700 regulated ADA studies supporting over 150 biologic drug development programs.

QPS is an expert in nAb testing and since 2002 we have applied our extensive knowledge and application of new assay technologies to over 60 programs.

METHOD DEVELOPMENT AND OPTIMIZATION

With the knowledge that the evaluation of ADAs is often a multi-step analytical approach with differing assay formats and platforms, QPS offers custom-built method development and optimization.

Method development at QPS can involve antibody enrichment and sample pretreatment techniques to improve assay sensitivity and drug tolerance or to reduce target interference:

- Affinity capture elution (ACE)
- Solid-phase extraction with acid dissociation (SPEAD)
- Critical reagent labeling (biotin and sulfo-tag, etc.)

Assay Optimization:

- Drug tolerance
- Target interference
- Sensitivity
- Specificity
- Precision

IMMUNOGENICITY MONITORING ADA & NAB

ADA Capabilities:

- Screening, confirmation and titering by ELISA or MSD Electrochemiluminescence (MESO SECTOR S 600)
  - Screening for positive responses in study samples
  - Confirmation test for samples displaying positive responses during screening
- Titering of confirmed positive samples to determine the relative degree of antigenicity
- On staff statistician for cut-point analysis
- Domain confirmation to bispecific therapeutic drugs

nAb Capabilities:

- Screening
- Titer assessment (quasi-quantification)
- Competitive ligand binding assay or cell-based neutralizing antibody detection
- Cell banking and maintenance

DATA QUALITY IS KEY

Our bioanalysis laboratories have been Good Laboratory Practice (GLP) compliant/certified since 2002. Across our clinical divisions, Good Clinical Practice (GCP) standards are embedded within our GLP quality systems. Our robust methods are fully validated in compliance with the FDA and EMA guidelines.

Our Experts at the QPS Labs in Delaware, USA and Groningen, The Netherlands are Ready to Support Your Next ADA & nAb Projects!

QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

BENEFIT FROM THE RESOURCES OF A GLOBAL CRO

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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