

# A FLEXIBLE APPROACH TO IMMUNOGENICITY

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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.





## IMMUNOGENICITY

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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  $\geq 700$  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

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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      | ▶ Specificity |
| ▶ Target interference | ▶ Precision   |
| ▶ Sensitivity         |               |



## IMMUNOGENICITY MONITORING ADA & NAB

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### 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

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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.

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

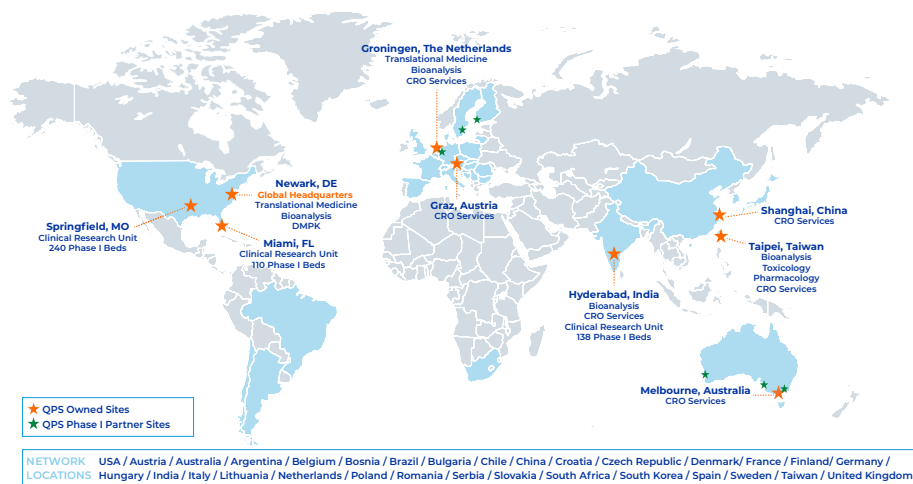


## QPS IS A GLOBAL CRO WITH LOCATIONS AROUND THE WORLD

### 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 drug development needs from discovery, through clinical development and regulatory filing.



CUSTOM-BUILT RESEARCH™

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

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