

A flexible approach to

# Biotherapeutics and Vaccines

**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.

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

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## Quantitation of Biologics Using Ligand Binding Assays (LBAS)

QPS is at the forefront of a wide range of LBA technology platforms including ELISA using colorimetric, fluorescent and chemiluminescent detection as well as Gyrolab®, electrochemiluminescence (ECL) on the MSD® platform and Quanterix® platform. Our in-depth technical expertise enables us to offer cost-effective services for pharmacokinetics (PK) and immunogenicity – both anti-drug antibody (ADA) and neutralizing antibodies (NAb) assessments – in various biological matrices.

## Quantitation of Biologics Using UPLC-MS/MS

QPS has analyzed polypeptides and proteins using LC-MS/MS since 2000. The direct approach combines sample extraction from the biological matrix, followed by sample clean-up, concentration and UPLC-MS/MS analysis. We also offer a more elegant approach starting with immunoaffinity capture followed by enzymatic digestion and LC-MS/MS. Essentially, this method uses an immunoaffinity column or beads to selectively enrich the target peptide(s) and / or protein(s) prior to analysis, resulting in lower total signal complexity and higher specific peptide(s) signal by LC-MS/MS. The decision on what methodology to use depends on the individual protein target. Both approaches are non-trivial and utilize the skills of our highly experienced bioanalytical chemists.

## Cell-Based Assays

Since 2002, QPS has supported more than 50 cell-based studies for numerous sponsors.

### Capabilities include:

- ▶ Endotoxin Stimulation (Cytokine Production)
- ▶ Compound Toxicity on Monocytes (Cytokine Induction)
- ▶ Uptake Study ( $^{33}\text{P}$ ) Using Primary Cells
- ▶ Toxin Neutralizing Assay (Cell Proliferation)
- ▶ Neutralizing Antibody (NAb) Assay (Cell Viability)
- ▶ Custom Functional Assay

## Immunogenicity & Neutralizing Antibodies

### Capabilities include:

- ▶ Preparation of antigen-protein conjugates for plate coating
- ▶ Method development and validation using ELISA format
- ▶ 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
- ▶ Detection and determination of various classes of antibodies
- ▶ Neutralizing antibody assays

## QPS is a Global CRO with locations around the world

