

With expertise based on years of experience, ImQuest BioSciences will design, optimize, and validate your immunoassay in a GLP-compliant manner to support the evaluation of your new biologic – either biotherapeutic or vaccine – in preclinical and clinical development.

Our extensive experience with tissue culture and assay development is essential for the development of ELISA-based technology used to provide highly sensitive and robust detection of biomolecules in animals and humans.

ImQuest scientists develop a wide variety of immunoassays for use in support of toxicology and clinical trial programs. Immunoassays can be performed utilizing EISA, ELISpot and flow cytometry, as well as other cell-based and bio-assays.

### Our Methodology

Our initial step in immunoassay development is the **transfer of the assay methodology** allowing our scientists to define the critical steps and reagents used in your study assay.

ImQuest scientists conduct a **feasibility study** to replicate your assay, determine its robustness and sensitivity, and define required development steps.

We **optimize** the existing methodology to define the most appropriate, sensitive, and robust assay for validation. ImQuest scientists will also modify an assay to detect biologic vaccine product and perform immunogenicity and neutralization studies sequentially in three species as required.

The assay is **validated** according to GLP-compliant standards. Parameters assessed include accuracy and precision, selectivity and reproducibility, and sensitivity. Stability issues such as freeze/thaw effects and long- and short-term stability at a range of temperatures are also assessed.

Once your samples are submitted, ImQuest's team of scientists analyzes them in a GLP-compliant manner and prepares a report.

Technology  
Transfer

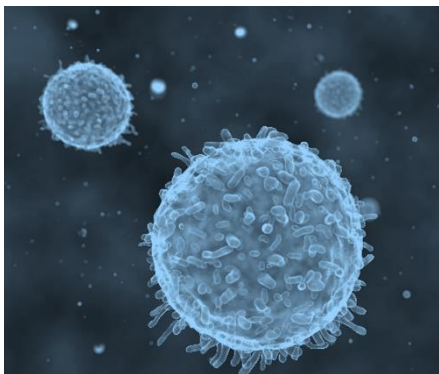
Feasibility

Optimization

Validation

Sample  
Analysis

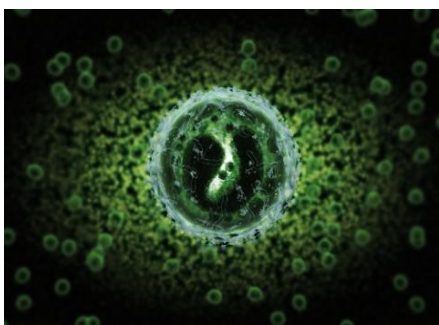
### Immunotoxicology Studies



Take advantage of ImQuest's immunoassay development services for your immunotoxicology studies. Our expertise in immunology and assay development provides a platform for the rapid development, optimization and validation of assays to evaluate the immunomodulatory effects of drugs and biologics targeted at infectious disease, cancer, and inflammatory disease. Assays include:

- Immunophenotyping
- Colony-Forming Cell (CFC) Assays
- Cytotoxic T Lymphocyte Function
- NK Cell Assays
- KLH ELISA for T-Dependent Antigen Response (TDAR)
- Cytokine Assays
- Host Resistance Assays

### Immunogenicity Studies



Let ImQuest develop, optimize and validate immunoassays in suitable formats for your immunogenicity studies. We offer time tested immuno- and cell-based assays using GLP-compliant standards to evaluate the immunogenicity of potential new biotherapeutic agents and vaccines. Assays include:

- ELISA Screening and Confirmatory Assays
- Neutralization Assays (cell based & competitive)
- Anti-Drug Antibody Assays
- Antigen-specific B-cell ELISpot Assays
- CD4 Antigen-driven Proliferation Assays
- Cytokine Assays

### Applications

ImQuest GLP-compliant immunoassays, are key tools in the preclinical and clinical phases of biologic development. These assays are typically used to:

- Define the pharmacokinetic profile of biologics.
- Evaluate the immunogenicity of biotherapeutic agents and determine if the antibodies produced neutralize the immunogenic antigen. During clinical trials, immunogenicity assays are used to monitor the immune response to the molecule with screening and confirmatory immunoassays as well as neutralization assays. For vaccines in development, immunogenicity studies are used to measure the efficacy of vaccine antigens and the effects of the vaccine on the immune system.
- Examine the immunotoxicological effects of potential new biologics on the immune system. Some assays assess the overall effect on the immune system, whereas others evaluate more specific effects.

Move your drug or biologic development program forward more efficiently and expeditiously with ImQuest Immunoassay Services. ImQuest BioSciences, a preclinical CRO, specializes in the development of drugs, vaccines and biologics for the treatment and prevention of infectious disease, cancer and inflammatory disease.

[Contact ImQuest BioSciences to learn more.](#)