Q² Solutions®

Bioanalytical Immunoassay Services to Accelerate Biosimilar Development

Biosimilars have an important role in the global market for biologic medicines. To obtain regulatory approval, a biosimilar must demonstrate comparable safety and efficacy to the approved biological product. When bringing a biosimilar to market, a developer must meet the rigorous approval standards that apply to other pharmaceuticals, while recognizing the effects that a biosimilar product's molecular complexity may exert during development and manufacturing.

Navigating the challenges of developing a biosimilar through clinical trials while meeting regulatory guidelines requires an experienced partner. Q² Solutions offers tailored solutions that will help you make informed decisions and shape validated outcomes for your study, from research to commercialization.

Q² Solutions can partner with you to provide custom and appropriate bioanalytical biosimilar testing, including:

Tailored, Science-Based Solutions

A biosimilar must demonstrate that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product throughout the product's lifecycle. Q² Solutions' bioanalytical immunoassay services team has experience developing, transferring and validating nonclinical and clinical assays to support biosimilar studies, including quantitative, immunogenicity and biomarkers assays. Specific bioanalytical capabilities include:

Pharmacokinetic (PK) concentration assays – Q² Solutions has extensive experience developing or transferring quantitative immunoassays in a timely and efficient manner. Our veteran scientists have experience developing assays that span a range of molecule types, formats and instrument platforms. A single PK assay is recommended to be applied to demonstrate the bioanalytical similarity of the originator and biosimilar drugs.

Anti-drug antibody (ADA) or immunogenicity assays – A single assay also is recommended to be applied to demonstrate anti-drug antibody binding comparability in ADA assays. In addition, sensitivity and free drug tolerance are important characteristics to be optimized. Using techniques such as affinity capture elution, precipitation and acid dissociation, solid-phase extraction with acid dissociation and microparticle-based approaches, Q² Solutions can provide you with an optimized assay to mitigate interferences. In addition, Q² Solutions will label and characterize your drug and will calculate ADA cut points in-house applying the latest industry-accepted guidelines.

Neutralizing antibody (NAb) assays – Q² Solutions uses either plate-based competitive ligand binding assays or cell-based approaches that are specific to your drug's mode of action, immunogenicity risk assessment, technical feasibility and sponsor discussions with regulators to ensure an appropriate format is applied to support your program.

Project Management Team with Scientific Expertise

The Q² Solutions Project Management team, which includes Project Managers, Method Developers and Project Leaders, is experienced in bioanalytical methodologies and compliance. We understand the science behind the assays and will serve as trusted partners in decision making. Through formal scheduled updates, our Project Managers will keep you informed of progress and timelines while also leveraging our experience to accelerate decision making and assessing the impact of potential issues on the study. Q² Solutions' Project Managers strive to resolve issues through efficient, transparent collaboration, thereby assuring that assays run smoothly for the duration of the project.

An Efficient, Connected Workflow

From the earliest stages of development through validation and sample analysis, Q² Solutions offers full capabilities to bring efficiency and streamline channels of communication. In addition to testing, we provide cut point statistical analysis, protein conjugation services in-house, attention to critical reagent control and qualification, thereby ensuring assay performance, accelerating data turnaround time and supporting high-throughput projects. Our Q² Solutions bioanalytical laboratories integrate with central laboratory facilities, drawing on a depth of scientific expertise and providing flexibility as needed to navigate changes in the product development cycle.

A Proven History of Delivery Excellence

Our scientists are ready to partner with you to provide key insights into your biosimilar development program, regardless of the therapeutic area. Q² Solutions' bioanalytical laboratories have developed and tested thousands of samples for biosimilars and comparators that include:

- Adalimumab
- Ipilimumab
- Nivolumab
- Omalizumab
- Pembrolizumab
- Rituximab
- Bevacizumab
- Imiglucerase
- Filgrastim
- Pegfilgrastim

Our team of bioanalytical experts can collaborate with you at any step of the biosimilar testing process, from high-throughput assay development to navigating the evolving regulatory landscape. Quality is our priority throughout the bioanalytical development lifecycle – from method development to the delivery of the protocol final sample testing report, you can have confidence in the results. Contact us today to discuss how we can shorten timelines and increase the potential success of your product.

Contact us

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