



BIOASSAY DEVELOPMENT

Turn your hurdle into an achieved milestone

Fast-track to commercialization At Catalent, we understand bioassay development and validation are visible components of a product's path to market. The process of designing, optimizing, validating and implementing your bioassay should be a transparent part of the development cycle that fast-tracks your commercial objectives—not a bottleneck.

Broadest bioassay development experience Catalent's strength is in our proven history of solving the toughest bioassay development challenges pertinent to virtually every indication and type of biologic product. This experience, combined with our expert staff and technical resources, provides you the tools to overcome the bottleneck created by imprecise science and regulatory inexperience for:

- Oncology (ADCC, apoptosis)
- Cardiovascular (angiogenesis)
- Immunology (cytokine induction)
- Infectious diseases (bacterial lysis, viral plaques, bacterial immunoassay)
- Proteins and peptides (ELISA, MSD)
- Therapeutic viruses
- Attenuated bacterial vaccines
- Aptamers
- Cellular therapies (flow cytometry)

Robust assays for complete testing needs We'll help you demonstrate that your product is active by testing it in a system that appropriately reflects its clinical indication. Our bioassays are robust in all applications, including:

- Lot-release testing of biologic material
- Stability-point testing
- Verification of stress-point testing
- Process or formulation change support

Cost effective end-to-end solutions Our product-tailored protocols and industry know-how save you time, money, and the disappointment of a failed or improperly documented bioassay. And once development and validation are completed, we can transfer your bioassay to your site or continue to run it in our cGMP facilities.



DEVELOPMENT



DELIVERY



SUPPLY

Quality you can depend on Our facilities have undergone numerous FDA inspections and are proven world-class operations. In fact, the scientific practices at our Research Triangle Park, NC facility are so well validated that the facility serves as an FDA training center!

The Right Protocol Produces the Right Results

Catalent applies a time-tested approach to bioassay optimization. We realize that all live cells are not created equal – so we adhere to an assay protocol that maximizes the potential of each biologic product.

Our Protocol Services include:

- Evaluate the existing assay under non-cGMP conditions at a selected end point
- Confirm the negative control (product)
- Prepare and validate Master or Working Cell Bank
- Optimize preassay conditions (i.e., cell density and time of stock preparation used for testing)
- Optimize 'in assay' cell number
- Optimize exposure time
- Define the parallelism region
- Run under cGMP conditions
- Test a minimum of 2 serum / media lots, along with other required biological reagents
- Identify passages that are suitable for validation
- Define specifications for qualification/validation protocol based results
- Write a detailed final standard operating procedure

Our Services at Work

	CLIENT A	CLIENT B
SITUATION	<ul style="list-style-type: none"> • The client had an existing potency bioassay that could not successfully measure the bioactivity of clinical samples 	<ul style="list-style-type: none"> • The client's current non-radioactive method for assessing bioactivity of their biosimilar was not yielding consistent results.
SOLUTION	<ul style="list-style-type: none"> • The assay was redeveloped as a pharmacokinetic assay so that the bioactivity of the clinical serum samples could be measured. • The redesigned assay provided a cost effective method to gain accurate measurement keeping the project on schedule. 	<ul style="list-style-type: none"> • Non-radioactive and radioactive methods were compared with cells lines A and B and the radioactive method demonstrated robust results with cell line B. • The Catalent investigation and solution resulted in significant cost and time savings to the client—moving the project forward past this major hurdle.

Contact Catalent today and let our expert team tailor a bioassay program to fit your needs.

more products.
better treatments.
reliably supplied.™

www.catalent.com

Catalent Pharma Solutions

14 Schoolhouse Road
Somerset, NJ 08873
T + 1 732 537 6200
F + 1 732 537 6480
solutions@catalent.com

Catalent Pharma Solutions

160 Pharma Drive
Morrisville, NC 27560
T + 1 919 465 8155
F + 1 919 481 4908
solutions@catalent.com