

Biopharmaceutical development services

Custom bioassay development and management

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 biologic development cycle that fast-tracks your commercial objectives—not a bottleneck brought about by imprecise science or regulatory inexperience.

At Catalent, we have the clinical expertise and technological resources to custom design the right bioassay for your product. We solve assay development challenges pertinent to every conceivable indication and every type of biologic product. 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 facilities.

Experience with biologics

We have developed and validated bioassays for:

- Proteins and peptides
- Therapeutic viruses
- Attenuated bacterial vaccines
- Aptamers

Breadth of service

We'll help you demonstrate that your biopharmaceutical product is active by testing it in a system that appropriately reflects its clinical indication. Our assays 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



The right protocol produces the right results

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

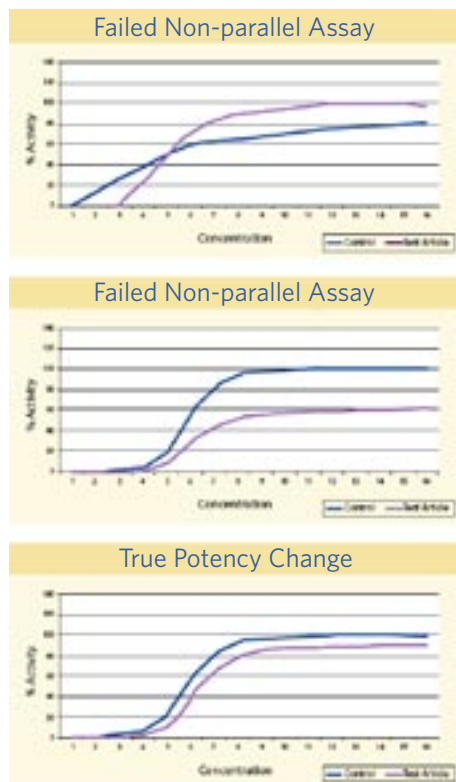
Our services include:

- 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 cell number
- Optimize preassay conditions (i.e., cell density and time of stock preparation used for testing)
- 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 on results
- Write a detailed final standard operating procedure

Bioassay evaluation: IC₅₀ data is not enough!

Which method do you use to evaluate the results of your bioassay—parallelism or linearity? Choosing a single data point to interpret your findings may offer false indications about product performance and hide data that are critically important to your product's development.

Catalent scientists use their experience and specialty training to develop bioassays that adhere to prescribed specifications. Our intellectual capital includes data-interpretation skills that allow us to streamline the validation of your bioassay.



The people behind the science

The Catalent team can provide fast and reliable answers to your bioassay questions. We are committed to helping you clear the scientific and regulatory hurdles that stand in the way of your product's development.

We maintain a superior quality systems infrastructure, state-of-the-art equipment and an excellent FDA audit history. Such unique attributes expedite development time and result in a fundamentally better product.

Our team prides itself on its accessibility and attention to detail. We have expertise not only in scientific protocol and regulatory guidelines but also in provider-to-client interaction. We put a face behind the science—and our responsiveness and dedication ensure that you'll get the service you need from someone you can trust.

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Lit. No. PD-BA (09/07)
Printed by Catalent Pharma Solutions, Moorestown, NJ.



All indications covered

Catalent scientists have developed assays for numerous compounds across many therapeutic targets, including:

- Oncology (ADCC, apoptosis)
- Cardiovascular (angiogenesis)
- Immunology (cytokine induction)
- Infectious diseases (bacterial lysis, viral plaques, bacterial immunoassay)

Quality systems and infrastructure

Our facility in Research Triangle Park, North Carolina, has undergone numerous FDA inspections and is a proven world-class operation. In fact, our scientific practices are so well validated that the facility serves as an FDA training center.

To learn more about our Bioassay Development Services, contact us today.

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