We are Catalent

To develop, manufacture and supply products that help people live better and healthier lives

Catalent®

Standalone and Integrated Biologics Analytical Services

95%+
On Time Delivery

- 90%+ Returning Customers
- 9+ out of 10 customers would recommend to others
- Dedicated PM & technical lead

30+
Years of Experience

- 40% of analysts has MS or PhD
- 300+ programs supported
- Avg. 30 audits performed annually
- Zero 483-form issued during last inspection

175+
Scientists

- 800+ assays and techniques
- 20,000+ ft^3 of lab space
- 31,000+ ft^3 stability storage
- Low turnover ~10%

We are **Catalent**

60+ GMP Trained Bioassay Experts

Cell-based assays: generation and qualification of analytical cell banks and critical reagents

Ligand binding by ELISA, SPR or BLI

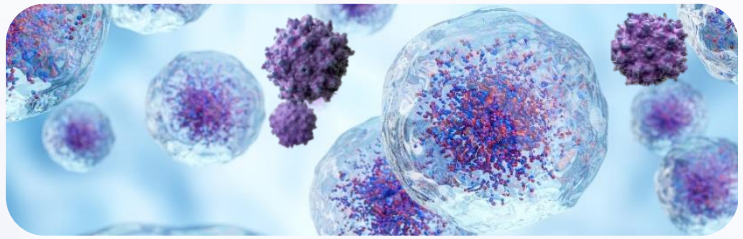
Traditional impurities such as residual HCP, DNA, Protein A, etc.

Validated 60+ cell-based potency methods

Method development with the mind set of best practices and quality by design

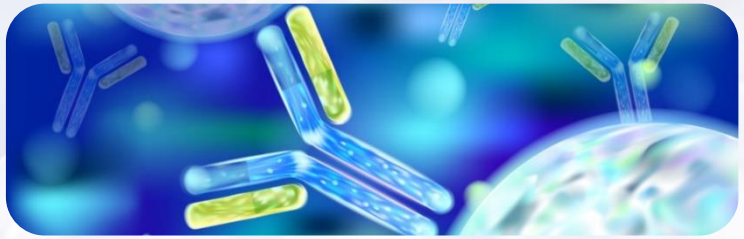
Uniquely Lab setups support efficiently and effectively multiple projects and workflows

Molecular Biology and Cell-Based Assays



Cell-Based Potency Assays
- Proliferation/Cytotoxicity
- Receptor Activation Assays (KIRA)
- mRNA Transcription Assays
- Master & Working Cell Bank Generation

Molecular Biology
- qPCR, dPCR and tdPCR Analyses
- Host Cell DNA Content
- Mycoplasma Determination
- Functional Assay



Binding Analysis
- Octet (BLI) & BiaCore (SPR)
- Kinetic Binding
- Quantitative Binding
- Relative Potency

Immunoassay
- Potency Assay
- Residual Impurities - Host Cell Protein/Residual DNA, Pro A, beta Glucan, rLongR3

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Case 1: Antagonist antibody to a biological ligand

Goal	To develop a phase III cell-based potency assay all the way from proof-of-concept to commercial
Challenge	The recapitulation of biological MoA of the client molecule required the use of endogenous complex signaling stimulation of a cell line that takes place in a relatively fast-signaling cellular event triggered by a biological ligand. Therefore, for the antagonistic methodology to consistently work requires numerous processes controls, including but not limited to ligand stability/dose response, cell response, critical reagent/steps identification, incubation times, etc.
Solution	The team designed a robust strategy based of best practices and experience throughout the years; any changes/optimization were carefully monitored based on data and verified through execution of more than one analyst with multiple lots from different client manufacturer sites and different instrument readers.
Impact	The quality and robustness of the assay was such that method was utilized for manufacturing process validation by the client. Due to the massive amount and quality of data generated, it was easy for client to set specifications. In fact, the laboratory PAI at Catalent KC was waived by the FDA due to the quality of the data.

Case 2: Fusion Protein Cell-Based Potency Bioassay Development

Goal	To develop a phase III cell-based potency assay all the way from proof-of-concept to commercial
Challenge	The *in vitro* recapitulation of biological MoA of the client fusion protein molecule, although involved direct interaction with a cell surface receptor, the interaction required activity of a co-receptor. The cell line of choice lost the response during earlier method evaluations.
Solution	The team designed a strategy to understand the biology of the fusion protein interaction with Receptor and co-Receptor. Utilizing cell surface immunoaffinity sorting and pull-down the team was able to rescue the responder cell-line phenotype, however, at the same time demonstrating that cells fate inevitable will lose their response at earlier cell passages. The team investigated the intrinsic biology driving the loss of cellular response, made drastic recommendations to client and these recommendations were accepted. Using an entirely new engineered cell line the team completed initial method PoC, optimization and Phase III validation successfully.
Impact	The quality and robustness of the assay was such that method was utilized for understanding charge variants activities by both binding and cell-based potency enabling a better understanding of structure-function. In addition, the bioassay method was essential for formulation development.

Catalent

Booth #6

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