Biologics Analytical Services

Stand-Alone / Integrated

Sonya Banks

2026 CASSS Bioassays Symposium

Catalent
Pharma Services™

Biologics Analytical Center of Excellence

30+ Years of Experience

- 300+ Programs Supported
- 30 Audits per year

High-Client Satisfaction

- 90%+ returning clients
- 9+ out of 10 would recommend
- Dedicated Project Manager & Technical lead

800+ assays and techniques

- 175+ scientists (<10% turnover)
- 47,000+ ft^2 Facility
- 31,000+ ft^3 stability storage

Catalent Pharma Services

Mexico Ministry of Health

Drug Enforcement Administration

Republic of Turkey Ministry of Health

Pharmaceuticals and Medical Devices Agency (Japan)

Food and Drug Administration

Medicines and Healthcare products Regulatory Agency (UK)

Jordan Food and Drug Administration

Brazilian Health Regulatory Agency (Anvisa)

Medicines and Healthcare products Regulatory Agency

Ministry of Health Canda

Ministry of Healthcare of the Republic of Kazakhstan

Ministry of Health of the Russian Federation

With the help of our experienced scientific team and range of capabilities, our goal is to serve as your strategic partner to support all your biologics analytical development and testing needs under a rigorous cGMP environment.

190+ Scientists | 30+ Years Experience | 11+ Regulatory Agencies

Catalent Pharma Services

Contract Biologics Analytical

From traditional to emerging modalities, and from discovery to commercial

MABS & BISPECIFIC ANTIBODIES

PEGYLATED PEPTIDES

BIOCONJUGATES & ADCS

RECOMBINANT FUSION PROTEINS

CELL & GENE THERAPIES

OLIGONUCLEOTIDES, NUCLEIC ACIDS

Supports All Modalities

DISCOVERY | PRE-CLINICAL | PHASE 1 | PHASE 2 | PHASE 3 | COMMERCIAL

- Developability & pre-formulation studies
- Comparability studies
- Extended molecule and product characterization
- Method development
- Phase-appropriate method qualification
- Phase-appropriate method validation
- Compendial method verification
- Stability studies
- Material and impurity characterization and identification
- GMP release testing

Catalent®

Biologics Analytical Services Center of Excellence (Kansas City)

Accelerate your biologics' path to patients

Developability & Early Risk Assessment
- In-Silico Modeling
- Colloidal & confirmational Stability
- Forced Degradation Study
- Binding Kinetics Determination
- Early CQA Risk Identification

Formulation & Pre-Formulation Development
- Predictive Stability Studies
- Pre-Formulation DOE screening
- Formulation Definition Studies
- Lead & Back-Up Formula
- Formulation Change Risk Assessment

Analytical Method Development & Validation
- De Novo Method Development
- Method Qualification & Validation
- Phase-Appropriate Analytical Strategy
- Method Transfer and re-establishment

Structural, Molecular & Variant Characterization
- Variant & Isoform Analysis
- Molecule Profiling and Mapping
- Structural Conformation & Stability
- Product-Related Variant Characterization
- Higher-Order Structure Assessment
- Aggregation Analysis

Mass Spectrometry-Enabled CQA & Comparability
- CQA characterization by MS
- Product-related variant analysis
- Impurity identification and confirmation
- Comparability studies (process, scale, or site changes)
- Structural mapping and peptide analysis

Impurity & Degradation Analysis
- Process-related impurity analysis (host cell proteins, residuals, reagents)
- Product-related impurities (aggregates, fragments, variants)
- Degradation product identification
- Forced degradation impurity profiling
- Impurity trending and risk assessment

Potency, Bioassays & Functional Characterization
- Cell-Based Bioassays
- Binding & Relative Potency
- Analytical Cell Bank Generation
- Assay Control and Reference Standard Strategy
- Molecular DNA & RNA Analysis

Stability Programs & Sample Management
- Stability Indicating Method Development
- Full ICH Q1 Stability Studies (Drug Substance & Drug Product)
- Custom and Accelerated Stability Conditions
- Cycling and Stress Study Support
- GMP Material aliquoting, Inventory, and Chain-of-Custody Management

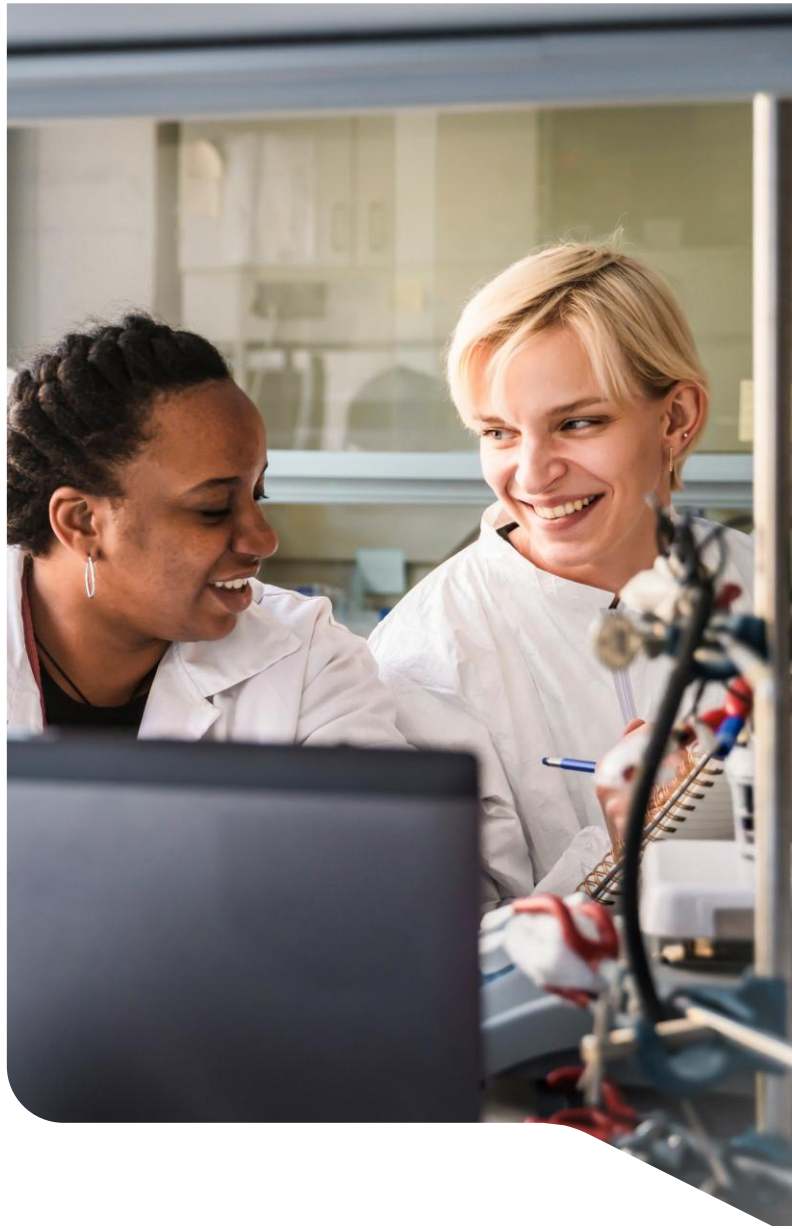
Regulatory, Lifecycle, GMP Readiness Support
- IND / CTA-enabling analytical packages
- Phase-appropriate method and stability strategies
- Lifecycle and change-management analytics
- Comparability strategy and execution support
- GMP release and stability testing support

Catalent Pharma Services™

40+ GMP Trained Bioassay Experts

Expertise & experience to solve unique problems and meet your needs

- **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**
- **Unique lab setups support workflows of multiple projects efficiently and effectively**



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Championing the missions that matter™

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