



## Capabilities Overview

RESPONSIVE. RELIABLE. RESOURCEFUL.

**Cytovance® Biologics** is a leading contract development and manufacturing provider of both mammalian and microbial service offerings to the biopharmaceutical industry.



**R&D Services** include cell line development using Freedom® CHO-S® (Life Technologies), microbial strain development using GeneGPS™ Codon Optimization Technology (DNA2.0) and Cytovance® Biologics' Keystone™ Expression System, research cell bank production, process development, process optimization using statistical Design-of-Experiments (DoE), technology transfer, scaled-down model development and process characterization using a QbD framework.

Each customers' project is customized to match the required scope and clinical phase. In-house mammalian and microbial platform processes enable efficient movement from development to commercialization.

A strong **Analytical Development** team is integrated into R&D Services and ensures a seamless transition into Quality Control for in-process and release testing. Core competencies include method development, method transfer, method optimization, method qualification, preformulation development, and product characterization. For early phase customer needs Cytovance offers Manufacturability Assessments for antibodies, other mammalian expressed proteins and Expression Feasibility Studies for microbial expressed proteins.

Since its inception 10 years ago in Oklahoma City Cytovance® Biologics has successfully manufactured a wide array of biological products for our customers in the U.S., European, and Asian markets.

**Cytovance® Biologics** are your partners for mammalian and microbial process development and cGMP biopharmaceutical manufacturing from the bench to commercialization.

### **Our Mission**

*Cytovance® Biologics' mission is to become a value-added partner to our clients by providing an integral pathway in converting today's novel protein discoveries into future life saving therapies and diagnostics.*





### Product Types

Monoclonal Antibodies, Recombinant Proteins, Enzymes, Transgenics, Fragment Antibodies, Fusion Proteins, Scaffold Molecules, Vaccines, and PEGylated Proteins

### Expression Systems

Keystone™ Expression System (microbial)  
Freedom® CHO-S® (mammalian)

### Cell Line Development

Transfection, Clone Screening & Selection

### Microbial Strain Selection

Bacterial and Yeast Cell Lines  
Strain Screening & Selection

### Upstream Process Development

Media Screening and Optimization  
Batch/Fed Batch Development  
Platform Processes Available

### Downstream Process Development

Harvest/Clarification  
Resin Screening and Selection  
Development of Orthogonal Processes  
Viral Clearance  
Development of Refold for Inclusion Bodies  
Development and Scale-Up of Pegylation Technologies

### Analytical Development Services

- Endotoxin
- HPLC (IEX, SEC, RP-HPLC, Peptide mapping)
- Bio-layer interferometry using Octet® RED96 System
- BCA/Bradford protein assay
- SDS-PAGE/CGE
- Western blot
- IEF/cIEF/icIEF
- Bioburden
- ELISA
- Cell based assays
- UV/VIS spectroscopy
- Fluorescence activity assays
- qPCR based residual DNA
- Glycan analysis and glycoprofiling

### cGMP Cell Banking

Microbial & Mammalian

### cGMP Manufacturing

Mammalian Production  
100L Mammalian Bioreactor Suite  
500L Mammalian Bioreactor Suite  
1000L Mammalian Bioreactor Suite  
5000L Mammalian Bioreactor Suite\*  
50L, 200L, 250L & 1000L SUBS  
Flex cGMP Suites

### Microbial Production

10L Microbial Fermentation Suite  
200L Microbial Fermentation Suite  
1000L Microbial Fermentation Suite

### GMP Fill/Finish

Automated Liquid Vial Filling

### Process Characterization Studies

Process Characterization Master Plan  
Risk Assessment  
Scaled-down Model Development & Qualification  
Design-of-Experiments (DoE)

### Process Validation Studies

Validation Master Plan  
Process Validation Batches  
Resin Reuse Studies

### Supporting Services

ICH Stability Studies  
Regulatory  
CMC Support  
Project Management

*\*coming soon*



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