



## Mammalian GMP Manufacturing 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 customer's 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 Services

### Product Types

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

### Expression Systems

Mammalian, Microbial

### Expression Platforms

Freedom® CHO-S® (Life Technologies), Keystone™ Expression System

### Mammalian Cell Line Development

Transfection, Clone Screening & Selection

### Microbial Cell Lines

Bacterial & Yeast Cell Lines  
Strain Screening & Selection

### Process Development

Batch/Fed-Batch Development, Scale Up & Harvest Optimization, Purification Development

### Analytical Method Development

Impurity Testing, In-process testing, Assay development/Transfer, Qualification

### cGMP Cell Banking

Microbial & Mammalian

### cGMP Manufacturing for Mammalian Production

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

### cGMP Manufacturing for Microbial Production

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

### cGMP Fill/Finish

Automated Liquid Vial Filling

### Process Characterization

Process Characterization Master Plan, Risk Assessment, Scale-Down Model Development & Qualification, Design-of-Experiments (DoE)

### Process Validation

Process Validation Master Plan

### Supporting Services

ICH Stability Studies, Regulatory, CMC Support & Project Management

*\*coming soon*





## Mammalian cGMP Manufacturing

**Cytovance® Biologics** provides a state-of-the-art full service manufacturing solution. Our cGMP manufacturing services include:

- cGMP Cell Banking
- Cell Culture (Stainless Steel and Single Use Bioreactor Systems)
- Purification
- Fill/Finish

Cytovance has considerable experience in transferring processes into and out of its facilities. We have very successfully demonstrated our ability to develop and transfer full processes or drop in process optimization steps to our customers or third party facilities.

Cytovance operates out of four facilities encompassing over 100,000 sq.ft. of cGMP manufacturing cleanrooms, development laboratories, QC laboratories, cGMP warehousing, and applicable support services.



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