



Process Development 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 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*





Process Development

Cytovance® Biologics develops processes de novo or transfers-in existing processes to be optimized or scaled-up to meet regulatory requirements. We take time to fully understand every client's short- and long-term technical and business needs and develop processes accordingly. We provide a full complement of development services critical to a complete and successful manufacturing project, including:

- Cell Line Development for mammalian and microbial systems
- Cell Culture Development with bench scale bioreactors
- Recovery and Purification Development
- Scale down modeling for viral validation studies
- Microbial Strain Construction and Expression feasibility studies
- Microbial Fermentation Development with bench scale fermenters
- Development and scale up of refold for inclusion bodies
- Development and scale up of Pegylation Technologies
- Pre-formulation development
- Analytical Method Development/Qualification and Validation
- Process Characterization

We strive to deliver processes that are cost effective, robust, scalable, compliant and transferable.



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