



Process Development Overview

**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 Designof-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 it's 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)

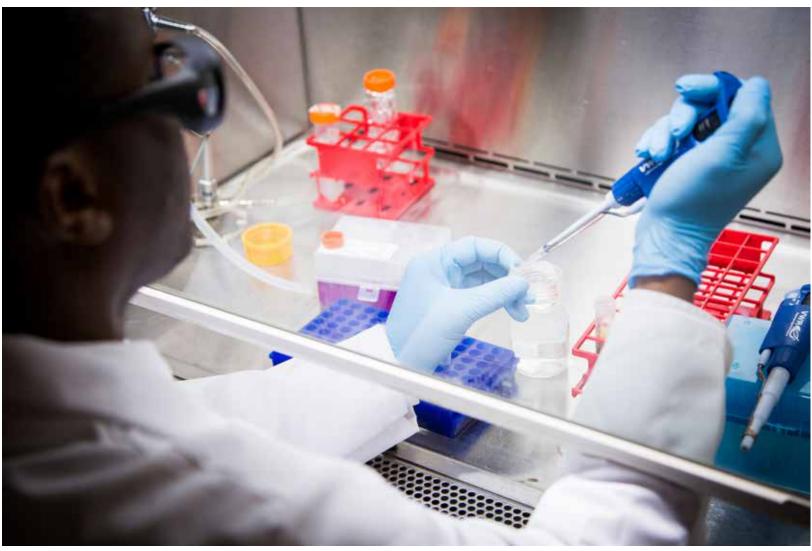
# **Process Validation**

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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