Cytovance® Biologics

Fill and Finish 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 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.

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 & Qualificaiton, Design-of-Experiments (DoE)

Process Validation
Process Validation Master Plan

Supporting Services
ICH Stability Studies, Regulatory, CMC Support & Project Management

coming soon

Fill and Finish

Cytovance® Biologics aseptic vial fill and finish line can suuport you with final product for your clinical supply needs. Partnering with Cytovance for your fill and finish will provide you with expertise and reliable personal attention.

Capabilities include:

- Vial sizes 2ml - 100ml
- Batch size 100 - 20,000 vials
- Manual and fully automated filling capability
- Qualified/Validated Facilities
- Compliant with FDA and European requirements
- Coordinated labeling and shipping to clinical sites

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