CAPABILITIES OVERVIEW

WHO WE ARE

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

Since our inception 15 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. We have a compelling track record in molecules developed demonstrated by our global customer base and our impressive number of clinical trials that we support.

OUR COMMITMENT

Each customers' project is customized to match the required scope and clinical phase. We have a commitment to a modern, phase appropriate lifecycle management approach. We further our commitment to workforce development with industry leading training programs. Lastly, we are committed to innovation and continuous improvement in all that we do. Cytovance® has industry and academic collaborations in order to further enhance our capabilities

SERVICES

R&D Services include cell line development using Freedom® CHO-S® (Life Technologies) & Horizon™ CHO-GS®-/-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 , process characterization using a QbD framework and with our newest pDNA services.

Analytical Development 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.

CGMP Process Development and Manufacturing is a core competence for mammalian and microbial products from the clinic to commercialization. Our manufacturing success rate exceeds 95%

Program Management is our highly efficient, centralized, and responsive team that coordinates all critical chemistry, manufacturing and controls (CMC) activities for each client program around raw materials management, QC testing, ICH stability studies, and regulatory support.

Quality is the bedrock our business is built upon. Our regulatory compliance group strives to be among the best in the industry. All of our client's products are manufactured to the highest standards.

People are what make us successful. We employ the best and brightest and commit to their success.

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)
Horizon™ CHO-GS®-/- (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

pDNA & Viral Vectors
R&D Grade
Critical Reagent Grade
CGMP Grade

CGMP Cell Banking
Microbial & Mammalian

CGMP Manufacturing – Clinical and Commercial

Mammalian Production
500L Mammalian Bioreactor Suite
250L, 1000L, & 2000L SUBs

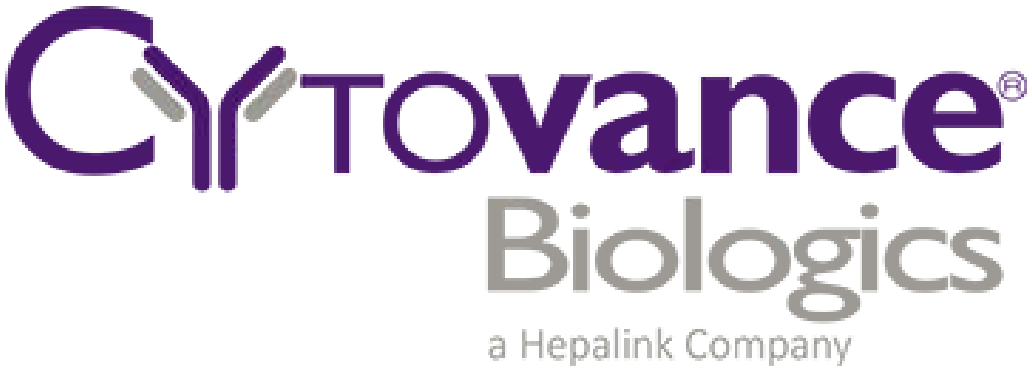
Flex CGMP Suites

Microbial Production
10L Microbial Fermentation Suite
200L Microbial Fermentation Suite
1000L Microbial Fermentation Suite
30L & 300L SUFs
2 x 5000L Protein Refolding

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

Value Added Services
ICH Stability Studies Regulatory
CMC Support
Project Management



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