eurofins | CDMO

BIOLOGICS
Process development

EXPERTISE

- **Tailored solutions for manufacturing a diverse range of biologics:**
  Proteins (antibodies, fusion proteins, enzymes, viral particles and vaccines)
  Live/inactivated bacteria and spores
- **Strong track record on difficult-to-express and complex proteins**
- **High focus on efficiency, robustness, scalability with integrated product characterization, analytical support and formulation**

SERVICES

PROCESS DEVELOPMENT

Upstream process (USP)

- Optimization and selection of growth media
- Defining process parameters and feeding strategy at 1L scale (parallel bioreactor system)
- DOE with focus on quality and yield
- Development of harvest strategy (centrifugation, depth filtration, TFF)
- Scale-up and confirmation of process parameters

CAPABILITIES

	Stainless steel	Single-Use
UPSTREAM	• 20L Bioreactor • 100L Bioreactor	• 4x1L Parallel DASGIP® system • 10-50L SU Bioreactor • 200L SU Bioreactor • Wavebags up to 50L
DOWNSTREAM	• ÄKTA® Avant 25/150 • ÄKTA® Pure	• High pressure cell homogenizer • Tangential flow filtration (TFF) systems

Downstream process (DSP)

- Optimization of cell lysis by high-pressure cell disruption
- Isolation, solubilization and refolding of proteins expressed as inclusion bodies
- Protein purification using a broad array of (membrane) chromatography techniques
- Design of a robust process with viral clearance potential
- Technology and material transfer for viral clearance studies
- Development of protein formulation steps (TFF)
- Scale-up and process confirmation for easy transfer to GMP manufacturing

eurofins | CDMO

BIOLOGICS
Process development

ANALYTICAL & FORMULATION DEVELOPMENT

- Development of the analytical methods monitoring product CQA's during process development and productions (IPC analysis)
- Product characterization and non-GMP stability studies
- Quality by design (QbD) approach during the analytical life cycle
- Transfer to GMP QC
- Formulation platform for different administration routes
- DS and DP release

ANALYTICAL METHODS PORTFOLIO

BIOCHEMICAL ASSAYS	BIOPHYSICAL ASSAYS	BIO-ASSAYS
Gel electrophoresis (SDS-PAGE, WB) CE-SDS Chromatograpy (for product purity methods and for residuals testing methods) • Reverse Phase • Ion-exchange • Size-exclusion with UV or RI-MALS • Affinity • 2D-LC High resolution mass spectrometry - Intact mass & peptide mapping Glycosylation profiling DNA quantification ELISA assays Endotoxin (LAL) testing Enzymatic activity assays HCP testing	Interaction studies Spectroscopic methods • FT-IR • UV-VIS • Fluorescence Capillary electrophoresis cIEF Colorimetry pH Conductivity Osmometry Dynamic light scattering and zeta-potential DSF (Tm) Sub-visible particles (Flow imaging, LO) Protein aggregates and foreign particles (Flow imaging) Moisture (KF, water activity)	Cell-based assays for neutralizing antibody assays or relative potency assay: • Cell proliferation • Signal transduction • Enzyme activity Microbial assays • Plasmid retention • Purity / bioburden • Viability (CFU count) • Growth curves and survival studies

FACILITY

● Process development

YOUR DRUG DEVELOPMENT PARTNER

- Cell banking
- Process development
- Clinical manufacturing (DS/DP)
- Clinical supply (packaging & logistics)

OCT 2022

VISIT OUR WEBSITE

eurofins | CDMO

SEND US YOUR REQUEST
cdmo@eurofins.com
www.eurofins.com/cdmo