patheon
by **Thermo Fisher Scientific**

St. Louis, MO USA

Facility Facts:

Workforce:	>600
Regulatory Approval:	FDA, EMA, MHLW, ANVISA, Health Canada, KFDA, MoH
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Specialized Capabilities:

- Scale up and cGMP manufacturing for early and late clinical and commercial supply, including process validation and PPQ
- In house analytical expertise, QC and QA
- Expertise in Fed Batch, Perfusion, and n-1 Perfusion processes
- In house and partnered cell line development – CHO
- GMP cell banking
- Single use technologies and highly flexible facility design
- Upstream and downstream process development expertise

Analytical Offerings

Analytical Laboratory Capabilities	
Chromatography: affinity, IEX, SEC, HIC, RP, peptide mapping	MW determination by mass spectrometry
Capillary electrophoresis (CE-SDS, cIEF, CE-LIF)	Sequence confirmation and PTM/degradation by LC-MS/MS
Electrophoresis: SDS-PAGE densitometry, Western blotting, 2D gel analysis, & IEF	Aggregates by SEC-MALS
Potency: binding ELISA, enzymatic activity assays,cell-based potency assay	Subvisible particles by LO
Impurity: residual Protein A, HCP, residual DNA	Amino Acid Analysis by UPLC
Quantity: protein A/G HPLC, ELISA titer assay, A280	N-Glycan profiling by fluorescence-labeling and normal phase HPLC or CE
DOE for method development and method validation	Sialic acid content and NANA/NAGA ratio measurement
Protein conformation characterization using capillary DSF (uncle), and DLS	Monosaccharide Analysis
High throughput CE-SDS and glycan profiling with microfluidic instrument	Force degradation study
Charged Aerosol Detector (CAD) used to test Polysorbate, Anti-foam, Pluronic	Isolation and characterization of impurities

St Louis Key Equipment List

Process			Equipment
Process Development	Upstream	Fed-Batch	TAP Biosystems ambr® 15 and 250 Systems
			2L, 10/20L WAVE Single-Use Bioreactors
			3L Sartorius Glass Bioreactors
			10L, 50L and 200L Xcellerex Single-Use Bioreactors
		Perfusion	3L Glass Bioreactors
			10L 50L Xcellerex Single-Use Bioreactors
			50L Stainless Steel Bioreactor
			ATF, BioSep and Settling Cone Cell Separation Devices
		Cell Counting	ViCell Cell Counting System, Guava easyCyte Flow Cytometer, and BioProfile Flex2 Analyzer
		Gas Analysis	NOVA PHox
		Metabolite Analysis	Nova BioProfile 400 and FLEX2
	Downstream	Clarification	Small-scale depth filtration
			Pilot scale Millipore POD Harvest Clarification Pilot System (0.11 to 2.2 m^2)
			Pall Stax Pilot Holder (0.25 to 2.0 m^2)
		Chromatography	AKTA Explorer Systems (0.1 – 100mL/min)
			AKTA Avant Chromatography Systems (0.01 – 150mL/min)
			AKTA Pure Chromatography Systems (0.1 – 150mL/min)
			AKTA Pilot Chromatography Systems (4 – 400 mL/min)
			AKTA PCC (continuous chromatography) system
			High throughput resin screening
		TFF Filtration	SciLog PureTec System (0.2 m^2 – 2 m^2 membrane sizes)
		Micro-Filtration	SciLog FilterTec System
		Nano-Filtration	Single-Use
Operations	Upstream	Fed-Batch	50 L, 500L, 2000L Single-Use Bioreactors
		Perfusion	50L, 500L Single-Use Bioreactors and ATF
	Downstream	Column Chromatography	25cm – 1m diameter columns Both single use and acrylic / stainless steel construction Bioprocess Systems (gradient) max 2000L/h AKTA ready gradient max 510L/h
		Clarification	Single-Use, all sizes
			Millipore POD and Pall STAX
		TFF Filtration	Single-Use systems Automated single-use skids (up to 10 m^2) plus manual single-use skids (up to 15 m^2) Stainless steel automated TFF skids (up to 30 m^2)
		Nano-Filtration	Single use skids with multiple membrane holders
		Filling	Single use mixing/formulation and dispensing
		Mixing	50, 100, 200, 500, 1000, 2000 and 2500L single use mixers (jacketed and with load cells) from both Pall and GE Xcellerex
		In-process UV Concentration	Solo VPE and Shimadzu UV Spec

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