

Groningen, Netherlands

Facility Facts:

Workforce: 200

Regulatory Approval: EMA & FDA

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Unique Offering:

Mammalian cell culture manufacturing. Scale up and cGMP manufacturing of recombinant proteins and monoclonal antibodies.

Specialized Capabilities:

- cGMP manufacturing for early and late clinical and commercial supply, including process validation and PPQ
- Over 6 years (>70 batches produced) commercial manufacturing experience
- Wide range of Single-Use technologies
- Modular set-up to match process needs
- Experience in Fed Batch, Perfusion, n-1 Perfusion, and XD® processes
- Experience with all commercial cell lines

Development Offerings:

Analytical Development Equipment	Assay Examples
HPLC/UPLC based assay using both UV and fluorescent detectors	Size exclusion chromatography Analytical proteinA chromatography Ion exchange chromatography (CEX, AEX) Glycan analysis Peptide-mapping (UV)
96-384 well ELISA plate reader with UV/Vis and fluorescent detection.	Product specific binding activity Product Identity Impurities: HCP, ProteinA, Long IGF, total protein
Spectrophotometer (UV/Vis) Solo VPE (UV/Vis)	Protein concentration
Capillary electrophoresis Capillary isoelectric focusing (Ice3)	R/NR CE-SDS cIEF for Identity and Purity
LAL reader (96 well)	Endotoxins
TOC reader	Total organic carbon
Bioburden filtration setup	Bioburden
FTIR	Raw material ID testing

Groningen Key Equipment List:

		Process	Equipment
cGMP Manufacturing	Upstream	Seed train	Shake flask Rocker-mixed bioreactor and up to 250 L Single-Use stirred tank bioreactors
		Fed-Batch	50 L, 1000 L and 2000 L Single-Use Stirred tank Bioreactors
		Perfusion	250L or 500L Single-Use Bioreactors (ATF and TFF-technology)
		Clarification	Pall Stax & Merck Millistak+ POD 3M Zeta Plus Encapsulated System
	Downstream	Column Chromatography	Prepacked columns Single-Use Bioprocess systems (3 L/h -510 L/h) Single-Use Bioprocess systems (45 L/h - 3500 L/h)
		TFF Filtration	Single-Use automatic TFF systems with 1.14 – 20 m ² membrane area capacity Single-Use TangenXTM SIUSTM holder for 0.5 m ² – 5 m ² membrane area capacity
		Bulk drug substance final filtration & filling	Disposable sterilizing grade filtration and filling assemblies
		Virus-Filtration (Nano-Filtration)	Planova Filtration from 1 – 4 m ² Filters Virus Solve filtration Single-Use membranes up to 12.5m ² Virosart filtration BioEx filtration

For detailed capabilities and capacity information please contact your Thermo Fisher Scientific representative.

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