

# Summary of capabilities

## Groningen, Netherlands

### Facility facts:

Workforce: 200  
 Regulatory approval: EMA&FDA  
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 The Netherlands  
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### 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 XO® processes
- Experience with all commercial cell lines

### Unique offering:

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

### 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)	Protein concentration
Solo VPE (UV/Vis)	
Capillary electrophoresis	R/NR CE-SOS
Capillary isoelectric focusing (Ic3)	cIEF for identity and purity
LAL reader (96 well)	Endotoxins
TOG reader	Total organic carbon
Bioburden filtration setup	Bioburden
FTIR	Raw material ID testing

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

## 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 U <sub>h</sub> -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 <sup>2</sup> membrane area capacity Single-Use TangenXTM SIUSTM holder for 0.5 m <sup>2</sup> - 5 m <sup>2</sup> 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 <sup>2</sup> Filters Virus solve filtration Single-Use membranes up to 12.5m <sup>2</sup> Virosart filtration BioEx filtration

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