



KEY FACILITIES AND EQUIPMENT

- Fermentation at 5L, 30L and 500L scale
- Fed batch capabilities
- Cell recovery by continuous centrifugation or ultrafiltration
- Microfiltration
- High pressure homogeniser for cell rupture
- Chromatography
- AKTA 100 system
- AKTA Biopilot
- AKTA Bioprocess skid
- Chromatography columns to 200L
- Final product filtration
- Lyophilisation bulk



INOCULUM DEVELOPMENT

Area		28 m ²
Clean room class		Grade C (ISO 7)
Inoculum Preparation	Biohazard Cabinet	Class II
	Shaking incubator	Orbital



FERMENTATION

Area		60 m ²
Anaerobe Chamber		Coy
Clean room class	Grade D (ISO 8)	
Aseptic manipulation	Biohazard Cabinet	Class II
	30L	B.Braun
	500L	Custom
Harvest	Tubular Bowl Centrifuge	2x Alfa Laval AS26-SP
	Tangential flow filtration (Microfiltration)	Cytiva/Repligen/Sartorius
Cell Rupture	Sonication	Heat systems
	High Pressure Homogenisation	Microfluidics to 25K PSI
		GEA 300L/hr 15K PSI



PURIFICATION

Area		28 m ²
Anaerobe Chamber		coy
Clean room class	Grade C (ISO 7)	
Chromatography	AKTA Explorer	Up to 100mL/min
	GE Bioprocess Skid (6mm)	Up to 2000mL/min
	GE Bio pilot	Up to 800mL/min
	Columns	100mL – 200L
Filtration	Tangential Flow Filtration	Millipore / Pall / Sartorius
	Microfiltration	To 20 inch cartridge



PROCESS PREPARATION

Area		28 m ²
Clean room class		Grade D (ISO 8)
Autoclave		Getinge Clean Steam





DEVELOPMENT

Area		57 m ²
Fermentation		2x 4L Sartorius
4 x 1L Applikon		Biohazard Cabinet Shaking incubator
Chromatography		AKTA Explorer / FPLC
Spectrophotometry		UV / Fluorescence



STAGING

Area		28 m ²
Clean room class		Class D (ISO 8)
Pass through waste autoclave		Getinge
Equipment storage		various
Clean room class		Class C (ISO 7)
Reactors	150L Stainless Steel Agitated	Custom
Reactors	2x 20L glass	Custom
Reactors	50L glass	Chemglass
Fume Hoods		2x Hamilton



PACKAGING

Area		28 m ²
Clean room class		Class C (ISO 7)
Class II biohazard Cabinet		Class A
Freeze Dryer		Bulk



CONTAINED VACCINE PROCESSING

Area		14 m ²
Clean room class		Class C (ISO 7)
Work area	Type A2 biological safety cabinet	Gelaire
Incubators		20°C-50°C
Fume Hoods		2



COLD ROOM STORAGE

Area		2 x 8m ²
Classification		Hold / Passed



GOODS STORAGE

Area		Various
Temperature		-80°C to Room + Liquid N ₂
Areas		Hold
		Passed
		General
		Reject
		Finished Goods





UTILITIES

DI Water	Tribed System
Purified Water	USP grade
House Steam	100KW electric
Clean Steam	60KW electric
Clean dry compressed air	28 CFM FAD
Chilled Water	4°C Glycol
Vacuum	Reticulated
Medical Grade Gasses	N2 CO2 O2
Back Up Power	Diesel Generator



QUALITY CONTROL

Analytical capability and equipment includes:

HPLC (2 systems)
UV/Vis spectrophotometry
PAGE / Western Blot
Moisture Titration
TOC
ELISA
Fluorescence spectrophotometry



QUALITY ASSURANCE

Facility Licenses:

- TGA (Australian equivalent of the FDA) licence for the manufacture of human therapeutic API's from biological and synthetic sources
- APVMA (Veterinary equivalent of the TGA) licence for manufacture of immunobiological products
- OGTR license for the production of products from genetically modified organisms
- AQIS facility license for import and use of biologic materials
- Utilities, Equipment and Operations validated against GMP regulations
- Document System & Control
- Raw materials released according to EU/BP and US pharmacopoeia
- Batch Release
- Facility and Equipment monitored, logged and alarmed 24 hours per day



FACILITY DIAGRAM

