



## KEY FACILITIES AND EQUIPMENT

- Fermentation at 5L, 30L and 500L scale
- Fed batch capabilities
- Cell recovery by discrete or continuous centrifugation or ultrafiltration
- Ultrafiltration
- High pressure homogeniser for cell rupture
- Chromatography
- AKTA 100 system
- AKTA Biopilot
- AKTA Bioprocess skid
- Chromatography columns to 200L
- Final product filtration
- Lyophilisation bulk and stoppering up to 40L



### INOCULUM DEVELOPMENT

Area		28 m2
Clean room class		Grade C (ISO 7)
Inoculum Preparation	Biohazard Cabinet	Class II
	Shaking incubator	Orbital



### FERMENTATION

Area		60 m2
Clean room class	Grade D (ISO 8)	
Aseptic manipulation	Biohazard Cabinet	Class II
Fermenters	20L	Applikon
	30L	B.Braun
	70L	Applikon
	500L	Custom
Harvest	Tubular Bowl Centrifuge	2x Alfa Laval AS26-SP
	Tangential Flow Filtration	Millipore/Pall/Sartorius
Cell Rupture	Sonication	Heat systems
	High Pressure Homogenisation	Microfluidics to 25K PSI GEA 300L/hr 15K PSI



### PURIFICATION

Area		28 m2
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 m2
Clean room class		Grade D (ISO 8)
Autoclave		Getinge Clean Steam





## DEVELOPMENT

Area		57 m2
Fermentation		2x 4L Sartorius
4x 3L Applikon		Biohazard Cabinet
1x 20L Applikon		Shaking incubator
Chromatography		AKTA Explorer / FPLC
Spectrophotometry		UV / Fluorescence



## STAGING

Area		28 m2
Clean room class		Class D (ISO 8)
Pass through waste autoclave		Getinge
Equipment storage		various



## CHEMICAL SYNTHESIS

Area		28 m2
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



## FORMULATION & PACKAGING

Area		28 m2
Clean room class		Class C (ISO 7)
Class II biohazard Cabinet		Class A
HEPA soft cell processing unit		Class A
Freeze Dryer		Bulk



## CONTAINED VACCINE PROCESSING

Area		14 m2
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		2x 8m2
Classification		Hold / Passed



## GOODS STORAGE

Area		Various
Temperature		-80°C to Room + Liquid N2
Areas		Hold
		Passed
		General
		Reject
		Finished Goods



## UTILITIES

DI Water	Tribed System
Purified Water	USP grade
House Steam	100KWelectric
Clean Steam	60KWelectric
Clean dry compressed air	28 CFM FAD
Chilled Water	4°C Glycol
Vacuum	Reticulated
Medical Grade Gases	N <sub>2</sub> CO <sub>2</sub> O <sub>2</sub>
Back Up Power	Diesel Generator

## QUALITY CONTROL

Analytical capability and equipment includes:

HPLC (3 systems)
Capillary electrophoresis (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 licence for the production of products from genetically modified organisms
- AQIS facility licence for import and use of biological 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

