



# Brisbane, Australia

## Facility Facts:

Workforce:	160
Regulatory Approval:	Australian Government Dept of Health and Ageing Therapeutic Goods Administration (TGA)  PC2 Large Scale Facility – Australian Government Dept. of Health and Ageing Office of the Gene Technology Regulator (OGTR)
Contact Info:	37 Kent Street Wooloongabba Queensland 4102 Australia  Tel: +61-(0)7-3896-2800

## Unique Offering:

- Mammalian cell culture manufacturing. Scale up and cGMP manufacturing of recombinant protein and monoclonal antibodies.
- 2014 winner of the ISPE Facility of the Year Award for Process innovation
- 2015 winner of Frost and Sullivan APAC CMO of the year award.

## Specialized Capabilities:

- Optimized production from pre-clinical to commercial launch, including commercial supply
- Single use technology and flexible facility design
- Expertise in all process modes for all commercial cell lines
- Mobile equipment to match process needs
- Upstream and downstream technologies enabling lower investment costs and scale up risks, reduced labor costs and process time, resulting in shorter time to market
- Experience with all commercial cell lines (e.g. CHO's, myeloma, hybridoma, PER.C6® cell line)

## Analytical Offerings

### Analytical (Assays for in-process control and release)

CE-SDS	Bioburden	DNA by qPCR	TOC
icIEF	Endotoxin	HCP ELISA	Conductivity
Protein A UPLC	Gram Stain	Protein A ELISA	pH
SEC UPLC	Bioburden qualification	Activity ELISA	Osmolality
PMAP UPLC	Analytical transfers	Binding ELISA	Raman
SDS PAGE	Analytical qualification	A280	FTIR
Western Blotting	Analytical validation	Spectrophotometry	CEDEX HiRes Cell Counting
RP UPLC	Endotoxin qualification	Colour (EP, USP)	SoloVPE
CEX UPLC		Clarity (EP, USP)	NovaBioflex
Protein L UPLC		Opalescence (EP, USP)	

## Brisbane Key Equipment List

Process		Equipment
Upstream	Fed-Batch	50 L, 250L, 500L, 2000L Single-Use Bioreactors
	Perfusion	50L, 500L Single-Use Bioreactors
Downstream	Column Chromatography	7cm 10cm 14cm 20cm 25cm 35cm 44cm 45cm 63cm 80cm 2x Bioprocess Systems (gradient) max 2000L/h 2x AKTA ready gradient max 510L/h
	Dead-End Filtration / Micro-Filtration	Single-Use, all sizes
	TFF Filtration	Single-Use systems: 2x automated skids 2.5 – 10m <sup>2</sup> membrane area capacity. semi-automated small scale skid for 0.1 – 2m <sup>2</sup> membrane area capacity
	Nano-Filtration	Single-Use membranes
	Filling	Single use mixing/formulation and dispensing skid
	Harvest	Depth filtration (PALL, 3M, Millipore)
	Pool Tanks / Single Use Mixers	(SUM) 1000L & 2500L Jacketed SUM 50L, 100L, 500L, 1000L, 2000L Non-Jacketed SUM