Microbial Process Development Solutions

Our team offers tremendous experience in microbial-based process development and clinical and commercial manufacturing, with most critical SME's having an average tenure of 15+ years at the Adelaide site.

Microbial Offerings

Our approach to process development emphasizes Quality by Design from the outset. We work closely with our clients to fully understand the concept product and establish a Quality Target Product Profile (QTPP). From the profile, we develop a process and a control strategy, to ensure our client's product and process can be relied upon to be robust, stable, and suitably designed for future scale-up. Our manufacturing processes utilize fully enclosed, single-use systems for both buffers and process intermediates, which helps ensure sanitary conditions throughout manufacturing.

Our state-of-the-art facility offers development and manufacturing equipment to seamlessly scale up from laboratory bench to commercial production scale.

BioCina's knowledge and experience of partnering with our clients from pre-clinical development to commercial production ensures we are capable of navigating your journey to approval.

Microbial Manufacturing Process

Fermentation → Cell Disruption / Lysis → Harvest / Extraction → Refold → Chromatographic Separation → Concentration / Formulation → Final Filtration

Microbial Development and Manufacturing Scales

Stage	Equipment	Working Volume	Yield
Process Development	2 L Fermenter x 8	400 mL — 1 L	.5 — 5 g per L
Scale-Up	30 L SS Fermenter	6 — 20 L	
cGMP Manufacturing	435 L SUB Fermenter 750 L SS Fermenter	65 — 300 L 200 — 500 L	
	2,000 L SS Fermenter	1,400 — 1,600 L	

Typical Microbial Development and Manufacturing Timelines

3 Months → | 6 Months → | 9 Months → | 12 Months → | 15 Months →

Cell Line Development, Cell Banking — 4.5 months to MCB release for use

Upstream, Downstream and Analytical Development, 20 L Pilot Batch — 8 months to Process Transfer / Scale-Up

14–15 months to cGMP Batch Release — Process Transfer / Scale-Up, ENG and cGMP Batch Manufacturing