

Advancing technical capability.

The Bioprocess Pathway Masterclass: From Early Design to Manufacturing Readiness

Upskilling Product and Process Development, Scale Up Principles, Manufacturing Readiness, GLP to GMP Compliance

Thursday 19th August 2026,

Australian Institute for Bioengineering and Nanotechnology, University of Queensland, St Lucia, QLD

Our Facilitators & invited Speakers

- **Steve Williams, CBE** an industry veteran with over 50 years experience, is a APVMA auditor and experienced in compliance audits, QMS design, development and operations. Steve consults to hundreds of organisations across the region, bringing a wealth knowledge of the industry, regulators, Quality and Compliance to his training.
- **Dr Owen Tatford, CBE** With 20+ years in bioprocessing, Owen has acquired in-depth technical expertise in a variety of roles, developing product manufacturing capabilities, making process and analytical improvements and scaling-up from R&D to commercial production. With experience from smaller companies to large global organisations, Owen consults across a broad range of R&D and process development projects, scaling operations to GMP manufacture and beyond.
- **Brian Gilmartin, Biointelect** with more than 20 years of international experience spanning pharmaceutical product development, clinical strategy, operations and commercialisation. Starting out in early-stage drug discovery within startup environments, into regulatory affairs and technical operations, supporting end-to-end product development across CMC, nonclinical, and clinical domains. Brian has worked across Europe, Asia-Pacific, Japan, US and Australia/New Zealand, providing him with a global perspective on regulatory frameworks and market access pathways.
- **Dr Wayne Adcock, Pure Solutions Australia** Wayne Adcock is a biologics biopharmaceutical leader with over 30 years of experience in Manufacturing, Quality, R&D, Continuous Improvement and Contract Management. Wayne has a reputation for having an energetic and pragmatic leadership style, with strong interpersonal relationship skills and a strategic approach to delivering outcomes.
- **Dr Angus Forster, Vaxxas** has worked in medical product development and commercialization for 20 years and has overall responsibility for the research, development and operations of Vaxxas. Since 2012, Angus has established the Vaxxas R&D team that includes more than 70 scientists, engineers, and professional staff, and led three phase I clinical studies. He brings considerable experience in pharmaceuticals, formulation development, analytical science, medical device design and development, risk management and quality systems.
- **Dr Kym Baker, Patheon Biologics, by Thermo Fisher Scientific** Kym is a UQ Honours graduate with a PhD from ANU with >30 years experience in the biomanufacturing field working with both academic and industry partners and for the last 25 years in contract manufacturing management positions in Lonza and Patheon, now part of Thermo Fisher Scientific. Kym now leads Thermo Fisher Scientific's advanced award winning and multi-regulatory body approved commercial biomanufacturing operations facility employing ~300 STEM professionals.
- **Andrew Diamond, Merck** Andrew Diamond has 30 years experience in the pharmaceutical industry and currently serves as Head of MSAT (Oceania) for Merck where he is responsible for assisting customers with process development, scale-up, troubleshooting and training. Prior to joining Merck, Andrew was employed at CSL where he was responsible for technology transfer of new processes from R&D to GMP manufacturing.

Timing	Topic	Presenter	Detail (team to review and revise)
From 8.30	Registrations		
8.45-9.00	WELCOME	Ben / David AIBN	UQ Welcome to the country, Housekeeping Why this is important to support and accelerate R&D/ new product development
9.00-9.45 45 mins	Developing with the end in mind	Brian Gilmartin, Biointellect	Considerations that R&D programs should keep in mind to prepare them for clinical trial and regulatory success
9.45-10.00	MORNING TEA		AIBN Courtyard
10.00-10.45 45 mins	Product & Process Development towards Scale-up and Commercial Manufacture	Owen Tatford, CBE	This session will focus on the principles of product and process development aimed at designing robust biological processes that can be scaled for commercial use. An overview of key considerations and general rules of thumb will be provided, supported by <i>practical examples and case studies</i> . The discussion will highlight appropriate analytical approaches to adopt prior to scale-up, best practices to implement, as well as common challenges and pitfalls to avoid.
10.45-11.15 30 mins	Scale-up of filtration operations in biologics processing	Andrew Diamond, Merck	
11.15-12.00 45 mins	PANEL	Chair: Helena Panel: Owen, Brian, Andrew	Interactive Q&A, Panel Discussion An interactive Q&A segment may include multiple-choice questions to encourage discussion and reinforce key concepts.
12.00-1.00	LUNCH		AIBN Courtyard
1.00-1.45 45 mins	Transitioning from GLP to GMP: Compliance & Technology Transfer	Steve Williams, CBE	The transition from pre-clinical GLP manufacture through to GMP clinical phase manufacture can be very challenging. It involves escalating rules and regulations, development of roadmaps to commercialisation and minimisation of risks along the journey. Technology transfer is a critical step in transitioning from R&D laboratory to clinical phase manufacturing. The presentation will discuss how to set up for successful technology transfer often to a 3 rd party CDMO
1.45-2.15 30 mins	Preparing for Clinical Trial Manufacture	Wayne Adcock (Project Development Manager) Pure Solutions Australia (Online)	Selecting a suitable C(D)MO partner is critical to development success. Pure Solutions, a critical micro laboratory and small-scale manufacturing organisation based in Melbourne, will present on their experiences and engagement with clients and what is needed to successfully prepare early phase clinical (bio)pharmaceuticals.
2.15- 2.45	AFTERNOON TEA		AIBN Courtyard
2.45-3.30 45 mins	Industry Case Studies	Angus, Vaxxas,	The session will include case studies that integrate the above topics, discussing challenges and pitfalls.

		Kym Baker, Thermo Fisher	
3.30-4.00 30 mins	PANEL	Chair: Ben Panel: Steve, Angus, Kym	Interactive Q&A, Panel Discussion An interactive Q&A segment may include multiple-choice questions to encourage discussion and reinforce key concepts.
4.00-6.00	NETWORKING		4-5 NBF (AIBN) Tours Light Refreshments / Networking