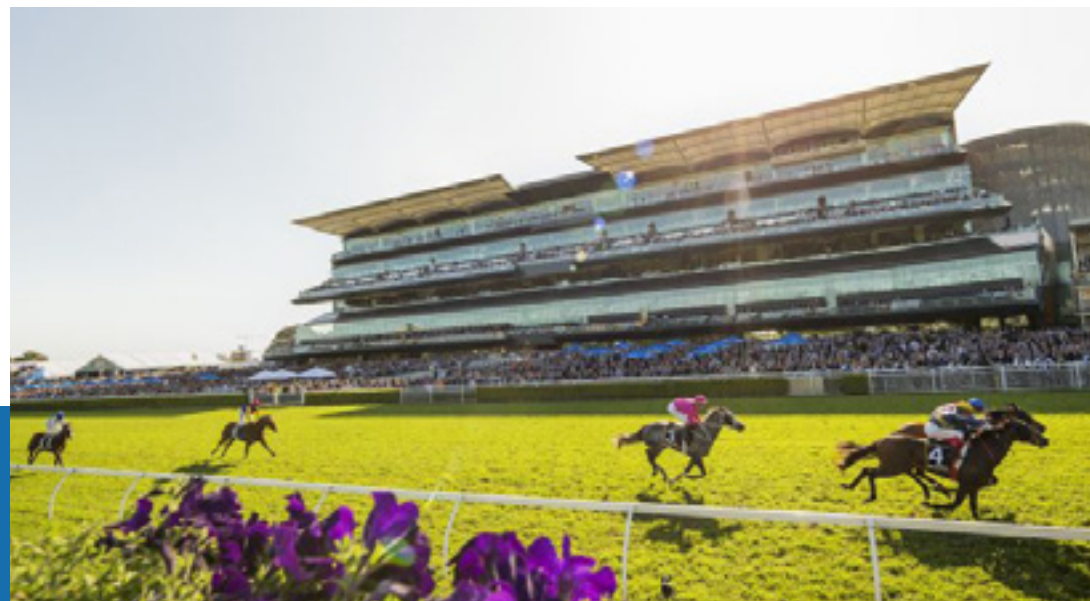




Conference Program Book



The BioProcessing Network is an association of scientists, engineers, students and others interested in fostering and advancing the knowledge and understanding of the technical aspects of the biotechnology industry.

2026 Conference Organising Committee



David
Bocanegra



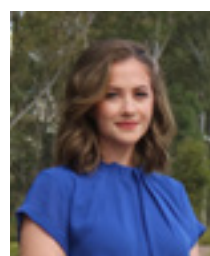
Ben
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Tizita
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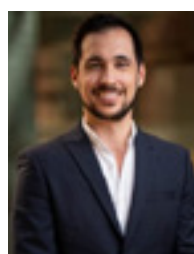
Annie Qu



Tara
Buse



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Maraldo



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Andreas
Kocourek



Sarah
Dower



Zlatibor
Velickovic



Jagan
Billakanti



Joshua
Stevens



Andy
Herbert



Hélène
Lebhar

Message from the President

Dear Esteemed Attendees,

It is with great pleasure and excitement that I welcome you to the Annual Bioprocessing Network Conference, hosted this year in the city of Sydney. As President, I am honoured to stand before this distinguished assembly of scientists, researchers, industry leaders, and innovators who play a pivotal role in advancing the field of bioprocessing.

Our topics this year, reflect the evolution of bioprocessing and our commitment to harnessing its power to address pressing global challenges. As we gather here, we are reminded of the immense potential this field holds in the realms of healthcare, environmental stewardship, commercialisation and more.

This conference serves as a platform for collaboration, knowledge exchange, and inspiration. Over the next few days, you will have the opportunity to engage in thought-provoking discussions, learn from experts, and forge valuable connections. Together, we will explore the latest breakthroughs, innovations, and best practices that will shape the future of bioprocessing.

I encourage you to take full advantage of this unique gathering, share your insights, and leave with a renewed sense of purpose and vision.

Once again, welcome to Sydney, we hope you enjoy the 19th Annual Bioprocessing Network Conference.

Sincerely,
Helene



Hélène
Lebhar
President

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Plenary Sessions

PLENARY 1

Upstream Processing

PLENARY 2

Upstream Processing

PLENARY 3

Upstream Processing

PLENARY 4

Upstream Processing

PLENARY 5

Upstream Processing

PLENARY 6

Upstream & Viral

PLENARY 7

Viral & Downstream

PLENARY 8

Downstream Processing

PLENARY 9

Downstream Processing

PLENARY 10

Downstream Processing

PLENARY 11

Downstream Processing

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Posters

ADELAIDE UNIVERSITY
Manuella Cazelato Pires
Sophie Oerlemans
Jessica Boutros

BASE FACILITY, UQ
Salina Tondwalkar
&
Abhishek Kulkarni

BIOCHROMATOGRAPHIX INTERNATIONAL
Sarah Dower

BIO-RAD LABORATORIES
Yuhua Ren

CARR BIOSYSTEMS
David Richardson

CELL BAUHAUS
Vishnu Mahamkali

CYTIVA
Christina Cahir

MERCK
Andrew Diamond
Janice Tan

SARTORIUS
Blaz Bakalar
Sherwin Ting

SOUTHERN RNA
Jonathan Peters

TOSOH BIOSCIENCE
Jukka Kervinen

UNIVERSITY OF MELBOURNE
Mohammed Golzarijalal
Navid Akhavan Attar
Pasindu Jayasooriya
Yuxiang Yang

UNIVERSITY OF QUEENSLAND
Neha Lal

UNIVERSITY OF SYDNEY
Mario Torrado del Rey

UNIVERSITY OF TECHNOLOGY SYDNEY
Dilshan Sonnadara

UNSW SYDNEY
Annika Johansson

Tuesday
September 15 | 2026

9:00AM – 9:15am Helene Lebhar BPN PRESIDENT
Conference Welcome

Plenary 1
9:15AM – 10:00AM Dr Michael Stumpf UNIVERSITY OF MELBOURNE
KEYNOTE From sequence to digital twin: closing the prediction gap in precision fermentation

10:00AM – 10:20AM Mr Yannis Karavias ADELAIDE UNIVERSITY
Fully Continuous manufacturing platform from feed to purified protein in *Komagataella phaffii*

Morning Tea – 10:20AM – 11:05AM

Plenary 2 – Upstream Processing
11:05AM – 11:35AM Dr Colin Scott ULUU PTY LTD
Harnessing Blue Carbon to Defossilise Materials Manufacture

11:35AM – 11:55PM Dr Mauro Torres THE UNIVERSITY OF QUEENSLAND
Engineering mammalian cell growth dynamics for biomanufacturing

11:55AM – 12:10PM Ms Janice Tan MERCK PTE LTD
Upstream intensification - Points to consider from cell line development to process development

Lunch – 12:10PM – 1:00PM

Plenary 3 – Upstream Processing
1:00PM – 1:30PM Christian Fercher, Franz Wagner Laurett Veras, Cinderella Nowak
Three 5-minute presentations from early-career researchers

1:30PM – 1:50PM Dr Alekhya Penumarthy CSL
Scale-Down Model Development: A Critical Enabler for Efficient Bioprocess Development and Manufacturing Success

1:50PM – 2:10PM Dr Ngoc-Phuong-Thao Nguyen SIFBI, A*STAR
A plasmid-free, antibiotic-free *Escherichia coli* chassis and two-stage continuous fermentation platform for stable and prolonged astaxanthin production

2:10PM – 2:30PM Mr Sebastian Schneider INFORS HT
Beyond the Setpoint: Control Transparency as a Foundation for Reproducible, QbD-Driven Bioprocess Development

Afternoon Tea – 2:30PM – 3:15PM

Plenary 4 – Upstream Processing
3:15PM – 3:45PM Dr Andrew Roberston BIOMEBANK PTY LTD
From Consortium Design to Manufacturing Scale: Development of a Co-Cultured Gut Bacteria Live Biotherapeutic Product

3:45PM – 4:05PM Mr Johnny Peng UTS
Predicting Lactate Runaway with Multi-path Latent ODE with Raman Data Fusion

4:05PM – 4:25PM Mr Hemasunder Reddy PFANSTIEHL, INC.
Addressing Aggregation and Viscosity Challenges in High-Concentration Monoclonal Antibody Formulations with Arginine.Glutamate

Mixer & Poster Review – 4:40PM

Plenary 5 – Upstream Processing

9:00AM – 9:10AM	Welcome	
9:10AM – 9:25AM	Ms Cher–Lynn Soh Integrated Bioprocess Development: From Cultivation to Product Characterisation	IN VITRO TECHNOLOGIES
9:25AM – 9:45AM	Dr Joseph Raphael Continuous cultivation and scale-up strategies for sustainable yeast biomanufacturing	LEVUR
9:45AM – 10:05AM	Dr Bhagya Yatipanthalawa Towards Predictive Optimisation and Control of Amino Acid Supply in CHO Cell Cultures	THE UNIVERSITY OF MELBOURNE

Morning Tea – 10:05AM – 10:50AM

Plenary 6 – Upstream & Viral

10:50AM – 11:05AM	Dr Sebastian Judd–Mole Bridging the Valley of Death: Approaching Therapeutic Nanoparticle discovery with a GMP Mindset	MILLENNIUM SCIENCE AND UNCHAINED LABS
11:05AM – 11:25AM	Dr Vasily Medvedev Establishment and Scale-Up of Australia’s First Recombinant Lentiviral Vector (rLV) Manufacturing Platform	VVMF
11:25AM – 11:45AM	Dr Sharon Cunningham Assessing Product Quality and Process Performance of an rLV Manufacturing Platform at 50 L Scale Using Orthogonal Analytical Testing Strategies	VVMF
11:45AM – 12:15PM KEYNOTE	Mr Chris Peck Pioneering Personalised Medicine in Australia	SOUTHERN RNA

Lunch – 12:15PM – 1:15PM

Plenary 7 – Upstream & Downstream

1:15PM – 1:35PM	Dr Henry de Malmanche Bioprocess Development of the ISVac™ Flavivirus Vaccine Platform Using Suspension Mosquito Cell Culture	THE UNIVERSITY OF QUEENSLAND
1:35PM – 1:55PM	Mr Dawson Goh UF/DF at the Extremes: Engineering Strategies for High Concentration, Low Mass and High Mass Processing	THERMO FISHER SCIENTIFIC
1:55PM – 2:40PM KEYNOTE	Mr Andrew Hodder Behind the scenes ISPE’s 2025 Facility of the Year.	CSL BEHRING BROADMEADOWS

Afternoon Tea – 2:40PM – 3:10PM

Plenary 8 – Downstream Processing

3:10PM – 3:30PM	Mr Noman Yousuf, Saumya Karunadhika, Eduardo Gorron Three 5-minute presentations from early-career researchers	
3:30PM – 3:50PM	Dr Bastian Oetomo Toward Model Predictive Control of Single-Pass Tangential Flow Filtration	THE UNIVERSITY OF MELBOURNE
3:50PM – 4:20PM	Dr Yvan Ruland Continuous Downstream Process Orchestration in Pionic® Platform	SARTORIUS

[See over](#)

4:20PM – 4:50PM	Dr Nick Boyd A new closed, single-use platform de-bottlenecking aseptic vial filling	CELLEO BIOTECH
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Poster Review – 4:50PM – 6:00PM

Buses Leave – 6:00PM

Conference Dinner – 6:30PM



Plenary 9 – Downstream Processing

9:00AM – 9:10AM	Welcome	
9:10AM – 9:30AM	Mr Shih-hsun Chen Application of Raman Spectroscopy for Real-Time Monitoring of Product Quality Attributes During Downstream Purification	CSL
9:30AM – 10:00AM	Dr Maciej Holówko Scaling up production of AI-designed enzymes for nylon recycling	SAMSARA ECO PTY LTD

Morning Tea – 10:00AM – 10:45AM

Plenary 10 – Downstream Processing

10:45AM – 11:30AM	Dr Sally Gras Optimising Biomanufacturing with AI: From Model Development to Industrial Adoption	UNIVERSITY OF MELBOURNE
11:30AM – 11:50AM	Dr Lukas Gerstweiler Influence of mRNA Length on Oligo-dT Affinity Chromatography Performance	ADELAIDE UNIVERSITY
11:50AM – 12:10PM	Dr Naish Millerick Process Intensification in Practice: Technologies That Accelerate Biomanufacturing	THERMO FISHER SCIENTIFIC

Lunch – 12:10PM – 1:10PM

Plenary 11 – Downstream Processing

1:10PM – 1:25PM	Ms Christina Cahir Save More Doses to Treat More Patients: Improving Product Recovery During Sterilizing Filtration of High-Concentration Biotherapeutics	CYTIVA
1:25PM – 1:45PM	Mr Chandranil Gharekhan An Automated Chromatography Platform for Purification of In Vitro Transcription-Derived mRNA	ADELAIDE UNIVERSITY
1:45PM – 2:05PM	Ms Gianna Sim Downstream Processing of Small-molecule Drugs produced by Whole Cell Biotransformation	BIO21 INSTITUTE, THE UNIVERSITY OF MELBOURNE

Conference Awards – 2:05PM – 2:35PM

BioProcessing Network AGM – 2:35PM – 2:50PM

Event Close / Afternoon Tea– 2:50PM



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α,α-Trehalose Dihydrate, Low Glucose	6138-23-4	T-104-4-LG	NF, EP, JP, ChP
Sucrose (Beet Derived)	57-50-1	S-124-2-MC	NF, EP, BP, JP, ChP
Sucrose (Cane Derived)	57-50-1	S-124-1-MC	NF, EP, BP, JP, ChP
D-Mannitol	69-65-8	M-109-7	USP, EP, BP, JP, ChP

Product	CAS #	Product Code	Monograph Classification
L-Arginine	74-79-3	A-170	USP, EP, BP, JP, ChP
L-Arginine Hydrochloride	1119-34-2	A-171	USP, EP, BP, JP, ChP
L-Histidine	71-00-1	H-116	USP, EP, BP, JP, ChP
L-Histidine Hydrochloride Monohydrate	5934-29-2	H-117	EP, BP, JP, ChP
L-Methionine	63-68-3	M-168	USP, EP, BP, JP, ChP
L-Arginine L-Glutamate	4320-30-3	A-172	

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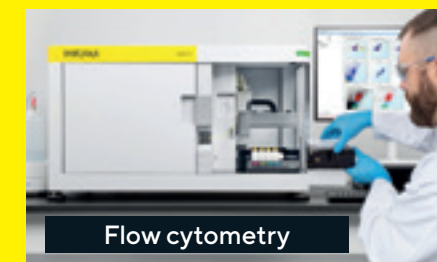
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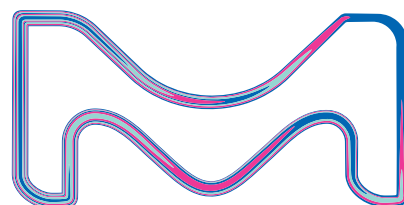
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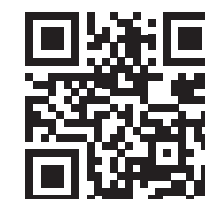


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Sucrose (Cane Derived)	57-50-1	S-124-1-MC	NF, EP, BP, JP, ChP
D-Mannitol	69-65-8	M-109-7	USP, EP, BP, JP, ChP
L-Arginine	74-79-3	A-170	USP, EP, BP, JP, ChP
L-Arginine Hydrochloride	1119-34-2	A-171	USP, EP, BP, JP, ChP
L-Histidine	71-00-1	H-116	USP, EP, BP, JP, ChP
L-Histidine Hydrochloride Monohydrate	5934-29-2	H-117	EP, BP, JP, ChP
L-Methionine	63-68-3	M-168	USP, EP, BP, JP, ChP
L-Arginine L-Glutamate	4320-30-3	A-172	
Glycine	56-40-6	G-140	USP, EP, BP, JP, ChP
Succinic Acid	110-15-6	S-142	NF, EP, BP, JP, ChP
Sodium Succinate Hexahydrate	6106-21-4	D-161	NF, JPE
TRIS base	77-86-1	T-153	USP, EP, BP, ChP
TRIS HCl	1185-53-1	T-154	Sponsoring USP Monograph
Ammonium Sulfate	7783-20-2	A-173	NF, ChP
Galactose (Plant Derived)	59-23-4	G-126-3	NF, EP, BP
D-Glucose	50-99-7	G-139	USP, EP, BP, JP, ChP
D-Mannose	3458-28-4	M-164-2	
Maltose (Monohydrate)	6363-53-7	M-167	NF, JP, ChP
L-Glutamine	56-85-9	G-137	USP, JP, ChP
Methotrexate (Powder)	59-05-2	M-166	USP, EP, BP, JP, ChP
Methotrexate (Sterile Solution)	59-05-2	M-166-S	

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01

Keynote

Upstream Processing



Dr Michael Stumpf

Professor Michael Stumpf, Chief Science Officer Cell Bauhaus; Professor of Theoretical Systems Biology, University of Melbourne

From sequence to digital twin: closing the prediction gap in precision fermentation

Dr Michael Stumpf

”

Precision fermentation is approaching an inflection point. Demand is growing, biofoundry infrastructure is reaching impressive scales, and strain engineering is taking centre stage across the sector. Nevertheless there is a persistent prediction gap: organisms optimised in shake flasks routinely underperform in production-scale fermenters, and the gap is discovered empirically rather than anticipated computationally. Bioengineering is arguably unique among the engineering disciplines in not having a robust set of in silico tools for the design and computational analysis prior to building.

I will argue that this (i) has been detrimental to parts of the industry, and (ii) is poised to change with the availability of digital twin technology for strain design and scale-up. I will illustrate this with examples where mechanistic and hybrid (mechanistic modelling + AI) approaches are speeding up strain design by orders of magnitude and I will map out where the current limitations are and how we will be able to overcome them.

02

Upstream Processing



Yannis Karavias
Adelaide University, PhD student

Fully Continuous manufacturing platform from feed to purified protein in *Komagataella phaffii*

Yannis Karavias; Robert John Falconer; Lukas Gerstweiler

” Switching from batch to continuous manufacturing provides the opportunity to reduce manufacturing costs, proven in many industries already. It offers several advantages, from lower equipment downtime, constant product quality to economical aspects like higher space-time yield, less investment costs and scaling by time not size.

Here we present a fully continuous and integrated biomanufacturing process based on *K. phaffii*, combining continuous chemostat culture upstream with continuous periodic counter current chromatography downstream processing. Instead of the widely used methanol, induction we investigated the use of constitutive promoters, coupled to the growth rate. This is the ideal promoter and process combination to use in a chemostat, as the promoter is coupled to the cell growth, which is directly controlled in the chemostat process and showed stable continuous culture for 10 days.

Additionally, the purification was embedded in the process to enable fully continuous recombinant protein production. Large Bead columns in radial flow were used and cell clarification could be skipped completely, enabling a simplified two-step platform process. Thereby media is fed continuously into the process and purified protein is harvested at the outlet.

The continuous chromatography approach leads to a simplified and integrated process, for easier scalability and process robustness. Furthermore, the developed platform process can be used as basis for future developments to establish autonomous biomanufacturing from media feed to purified protein as the modern production standard.

03

Upstream Processing



Dr Colin Scott
CSO, Uluu Pty Ltd
Adjunct Professor, The University of Western Australia

Harnessing Blue Carbon to Defossilise Materials Manufacture

Dr Colin Scott

” Uluu is an Australian biotechnology company replacing conventional fossil-fuel-derived plastics with biobased, biodegradable polymers (polyhydroxyalkanoates).

Using advances in synthetic biology, industrial fermentation, and marine biomass processing, Uluu converts renewable seaweed feedstocks into naturally derived polymers that are biodegradable, compostable, and suitable for a range of material applications. Uluu's integrated bioprocesses combine seaweed saccharification, microbial fermentation, and downstream materials processing to create scalable alternatives to petrochemical plastics.

Uluu's technology platform uses cultivated seaweed as a sustainable carbon source. Marine macroalgae are among the world's most productive biomass crops and can be cultivated without arable land, freshwater, or synthetic fertilisers. In addition to reducing pressure on terrestrial agriculture, seaweed farming can contribute to carbon sequestration and the development of carbon-negative manufacturing systems.

Beyond materials innovation, the company's activities will stimulate growth in the seaweed farming sector across Southeast Asia by creating long-term demand for sustainably cultivated biomass. This includes a strong emphasis on ethical sourcing, regional partnerships, and fair-trade principles that support coastal farming communities while enabling the transition toward circular and regenerative manufacturing systems.

Upstream Processing



Dr Mauro Torres

Lecturer/Research Group Leader, University of Queensland

Engineering mammalian cell growth dynamics for biomanufacturing

Dr Mauro Torres

” The biopharmaceutical industry often draws comparisons between the manufacturing of complex biological drugs and automobile production, particularly in terms of modular components and continuous production processes. By applying principles from automobile engineering to cell factories used in biotherapeutics production, it is possible to improve process control and efficiency. Just as cars have accelerators, brakes, and safety features like airbags, which make them predictable and controllable, cells also require careful regulation to avoid uncontrolled growth that can compromise the overall production process. For example, excessive cell proliferation without control can lead to crashes in cell processes, affecting product quality and yield. In this context, we propose the application of automobile-like engineering principles to Chinese hamster ovary (CHO) cell process engineering. By incorporating “safety” mechanisms such as modifications to apoptotic pathways, it is possible to create biological “airbags” that protect against process failures, especially in the late stages of cell culture.

To demonstrate this approach, we developed a proof-of-concept system using two orthogonal genetic circuits that regulate cell proliferation. System 1 acts as a “gas pedal” by accelerating cell growth, while System 2 functions as a “brake pedal” to stop growth and enhance productivity. This combination allows for precise control over both growth and productivity, improving the system’s overall performance. Specifically, we knocked out two pro-apoptotic proteins in a CHO-K1 host cell line to create a “cellular airbag” that reduces apoptosis during the later stages of cell culture, thereby improving cell viability and extending culture lifespan.

We designed and tested three cell lines: one with the “gas pedal” system, one with the “brake pedal” system, and one combining both systems. The results demonstrated that knocking out pro-apoptotic proteins significantly reduced cell death and extended the lifespan of the cultures. The “gas pedal” system increased cell proliferation in a dose-dependent manner, leading to a 52% increase in peak cell density. In contrast, the “brake pedal” system decreased cell growth but increased cell-specific productivity. The combined system allowed for dual control of proliferation, with rapid early growth followed by growth arrest and enhanced production in the later stages of the culture. This work highlights the potential of using synthetic biology and cell engineering to achieve high-level control in CHO cell factories, ultimately optimizing both cell growth and biotherapeutic production.

Upstream Processing



Janice Tan

Head of Upstream, Process Materials and Process Consultancy, Asia Pacific excluding China, Merck Pte Ltd

Upstream intensification – Points to consider from cell line development to process development

Janice Tan

” In this session, we will explore the strategic and technical imperatives behind intensifying upstream bioprocesses starting from cell line development to process development. We will dissect the primary drivers, ranging from accelerated timelines and higher titers to facility fit and sustainability goals, and align them with emerging technologies such as high-throughput screening, perfusion cultures, and advanced process analytics.

Case studies on optimizing cell line development of perfusion culture mode, optimizing media and feed strategies, and leveraged process analytical tools to enhance productivity will be shared along with best practices for designing and implementing robust, intensified upstream processes that improve yield, reduce cost of goods, and accelerate time-to-clinic while maintaining product quality and compliance.

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06

Upstream Processing



Christian **Fercher**, Franz Wagner Laurett **Veras**,
Cinderella **Nowak**

Three 5-minute presentations from early-career researchers



TM1 (Translational Manufacturing for Phase 1): Designing a National Manufacturing Accelerator for Translational Bioprocessing

Christian Fercher

The transition of innovative therapeutics from laboratory discovery to first-in-human clinical evaluation remains a major challenge in the bioprocessing ecosystem, with manufacturing capability often representing a critical bottleneck. TM1 (Translational Manufacturing for Phase 1) was designed to address this gap by providing a purpose-built national clinical manufacturing capability focused on enabling the translation of therapeutic candidates into early clinical development. Rather than functioning solely as a manufacturing facility, TM1 was conceived as a manufacturing accelerator that integrates production expertise, quality systems, and clinical-grade infrastructure to support the progression of promising therapies toward human studies. The design incorporates modern GMP principles, scalable infrastructure, quality systems, and adaptable manufacturing spaces capable of evolving alongside rapidly changing bioprocessing technologies.

The Role of Excipients in Stabilising Ready-to-Inject Lipid Nanoparticle Formulations

Franz Wagner Laurett Veras, Prof Dr Robert J Falconer

The use of excipients for RNA-lipid nanoparticles (LNPs) liquid formulations is very important to improve their stability during transportation and storage, where they can be exposed to vibration or high or low temperatures. This study evaluated the effect of common pharmaceutical excipients on the physical stability of RNA-LNPs exposed to freeze-thaw cycles, accelerated storage at 35 °C, and agitation.

Machine Learning-Guided Optimisation of In Vitro Transcription for mRNA Manufacturing: Surrogate Model Benchmarking and Process Parameter Sensitivity Analysis

Cinderella Nowak, Sha Liu, Lukas Gerstweiler

Bayesian optimization (BO) has emerged as a powerful framework for optimizing processes involving expensive-to-evaluate experiments. In vitro transcription (IVT) using T7 RNA polymerase represents an ideal application domain for BO, as each experiment is resource-intensive and the simultaneous optimization of mRNA yield and critical quality attributes — mRNA fragments and double-stranded RNA (dsRNA) — across multiple process parameters presents a complex multi-objective challenge. In this work, a multi-objective BO framework was applied to optimize the IVT reaction across an eight-dimensional design space to simultaneously increase mRNA yield while decreasing mRNA impurity formation.

Upstream Processing



Dr Alekhya Penumarthy

Tech Ops Scientist, CSL

Scale-Down Model Development: A Critical Enabler for Efficient Bioprocess Development and Manufacturing Success

Dr Alekhya Penumarthy

”

The development of robust scale-down model is a fundamental component of bioprocessing, enabling the study and prediction of large-scale manufacturing performance within a controlled laboratory environment. As bioprocesses are scaled from bench to commercial production, cells experience changing conditions, including gradients in dissolved oxygen, pH, nutrient availability, mixing, and shear stress.

Well-designed scale-down models recreate these manufacturing-relevant challenges, providing a powerful platform for process characterization, optimization, troubleshooting, and risk mitigation. This presentation will outline the systematic approach to scale-down model development, including defining critical process parameters, establishing engineering and biological comparability, and demonstrating model qualification and its challenges.

Case studies will highlight how scale-down models support process understanding, technology transfer, process validation, and continuous improvement initiatives. The talk will also discuss common challenges and best practices to ensure model relevance and predictive capability. Ultimately, effective scale-down models accelerate development timelines, reduce manufacturing risk, and strengthen process robustness throughout the product lifecycle.

Upstream Processing



Dr Ngoc-Phuong-Thao Nguyen

Senior Scientist, SIFBI, A*STAR

A plasmid-free, antibiotic-free Escherichia coli chassis and two-stage continuous fermentation platform for stable and prolonged astaxanthin production

Ngoc-Phuong-Thao Nguyen, Jasmin Jebarani Jebamony, Pachara Tangudomkan, Leonard Ong, Congqiang Zhang

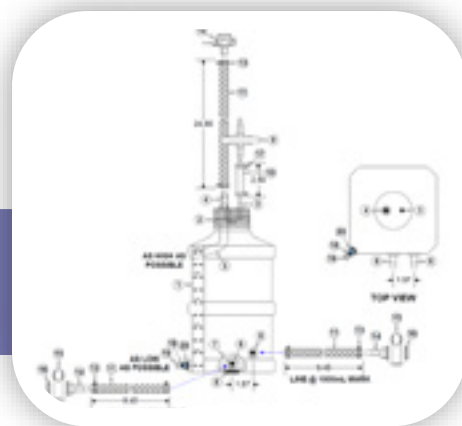
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Astaxanthin is a high-value ketocarotenoid with high antioxidant activity and broad applications in human nutrition, aquaculture, and animal feed. Microbial production in non-carotenogenic hosts such as *Escherichia coli*, *Saccharomyces cerevisiae*, and *Yarrowia lipolytica* has emerged as a sustainable alternative to chemical synthesis and natural extraction. We previously reconstructed the 14-gene astaxanthin biosynthetic pathway in *E. coli* across four plasmids, reaching a titer of 320 mg/L from glucose in a 5 L bioreactor scale. However, plasmid-based expression imposes a metabolic burden, suffers from segregational instability under the prolonged cultivation conditions of large-scale industrial bioreactors, and requires antibiotic selection, which increases process cost and complicates downstream purification. Here, we report on the construction of a fully plasmid-free and antibiotic-free *E. coli* chassis for astaxanthin production. Using an optimized CRISPR-Cas9 workflow, the complete pathway was integrated into the chromosome with high efficiency, and enzyme expression levels were rebalanced to maximize flux toward astaxanthin by multiple copies' integration. In fed-batch fermentation, the engineered strain reached an OD_{600} of 200 and a titer of 426 mg/L, a 1.3-fold improvement over our previous plasmid-based strain despite the reduction in gene copy number, demonstrating that systematic expression rebalancing can compensate for lower gene dosage while eliminating the instability and selection burden of plasmid systems.

Leveraging the genetic stability of the plasmid-free chassis, we developed a two-stage continuous fermentation process that decouples biomass formation from the astaxanthin production stage, prolonging astaxanthin synthesis at a productivity of X mg/L/h for 500 hours at a proof-of-concept scale of a 500 mL mini-bioreactor. Beyond astaxanthin, the integration of chromosomal pathway engineering with two-stage continuous bioprocessing constitutes a generalizable platform for stable production of inducible heterologous pathways in diverse microbial hosts.



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L-Glutamine	56-85-9	G-137	USP, JP, ChP
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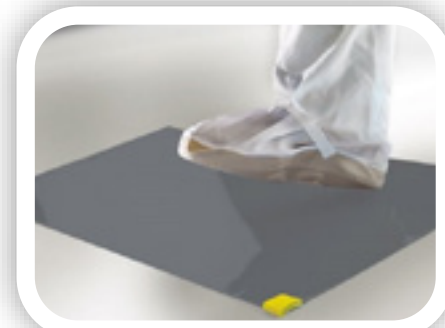
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Upstream Processing



Sebastian Schneider

Global Application Specialist, Infors HT

Beyond the Setpoint: Control Transparency as a Foundation for Reproducible, QbD-Driven Bioprocess Development

Sebastian Schneider

”

Identical setpoints do not guarantee identical bioprocess outcomes. Two bioreactors configured to the same dissolved oxygen, pH, and temperature targets can still produce divergent results, and the cause often lies not in the biology, but in the control system itself. Differences in controller tuning, configuration, and the underlying execution logic introduce variability that is rarely documented and frequently invisible to the user. This hidden layer undermines reproducibility, complicates root-cause analysis, and can delay technology transfer between development, pilot, and manufacturing scales.

As the industry moves toward Quality by Design (QbD), this lack of transparency becomes a critical bottleneck. QbD depends on a clear understanding of how process parameters relate to critical quality attributes. Yet if the control logic governing those parameters behaves as a black box, establishing a reliable design space and a defensible control strategy is far harder than it should be.

This presentation introduces an approach of a bioprocessing environment that addresses this gap by making control behaviour transparent and traceable. Control strategies become explicit and reproducible across systems, and the configuration that produced a given result can be captured and transferred alongside the data. Critically, this is achieved without adding operational complexity for the everyday user.

The talk will outline the rationale behind the design and its practical implications for reproducibility and tech transfer, giving attendees a clearer view of how hidden control variability can compromise bioprocess data, and how a more transparent approach strengthens QbD-driven process development.

Upstream Processing



Dr Andrew Robertson

Head of Research and Development, BiomeBank Pty Ltd

From Consortium Design to Manufacturing Scale: Development of a Co-Cultured Gut Bacteria Live Biotherapeutic Product

Dr Andrew Robertson

”

The gut microbiome is increasingly recognised as a critical regulator of human health, with reduced microbial diversity linked to diseases including ulcerative colitis (UC), irritable bowel syndrome, and other chronic inflammatory conditions. Live biotherapeutic products (LBPs) based on defined microbial consortia represent a promising approach to restoring microbiome function and addressing this growing global healthcare challenge.

This presentation describes BiomeBank's CONSORTIOME™ platform for the design, development, and scale-up of a co-cultured gut bacterial LBP, BB265. BB265 comprises 100 species of facultative and obligate anaerobic bacteria selected to restore key microbiome functions and increase microbial diversity for the treatment of UC. Early-stage development focused on understanding the growth dynamics of this complex co-culture and identifying process parameters required to control community structure, viability, and diversity. These strategies included optimisation of inoculation ratios, nutrient utilisation, pH control, anaerobic management through gas sparging, and fermentation duration.

A major challenge in the commercial manufacture of complex co-cultured LBPs is scaling oxygen-sensitive bacterial communities while maintaining critical quality attributes throughout upstream and downstream processing. We will discuss the application of seed train propagation to preserve community structure, diversity, and viability during upstream scale-up from 2 L to 200 L and beyond. The presentation will also cover development of downstream unit operations for biomass recovery, formulation, drying, and drug product manufacture, alongside analytical methods used to monitor critical product attributes.

BiomeBank will present practical strategies to overcome key barriers to scalable manufacture of co-cultured LBPs, helping pave the way for accessible microbiome-based therapies for chronic disease.

11

Upstream Processing



Johnny Peng
PhD Student, UTS

Predicting Lactate Runaway with Multi-path Latent ODE with Raman Data Fusion

Johnny Peng, Thanh Tung Khuat, Ellen Otte, Katarzyna Musial, Bogdan Gabrys

” Lactate runaway is a major risk in mammalian fed-batch cell culture because runs that appear similar during the first few days can later diverge into very different metabolic outcomes. By the time an off-trend lactate profile is confirmed through sparse offline sampling, the window for effective intervention may already be closing. This work presents a machine-learning framework for early, multi-day forecasting of cell-culture trajectories using sparse offline measurements, process data, and Raman-derived information.

We propose a multi-path latent ordinary differential equation approach that is designed for irregularly sampled bioprocess data and heterogeneous operating conditions. Instead of producing a single averaged forecast, the method retrieves historical runs with similar early behaviour, separates them into plausible future regimes, and fine-tunes a model for each regime. This generates multiple candidate forecast paths with confidence scores, helping operators recognise when a current run may follow a high-lactate trajectory even when early measurements remain ambiguous. To improve early observability, Raman spectroscopy is incorporated through soft-sensor predictions that act as dense pseudo-observations between offline assay measurements.

The framework was evaluated on 38 fed-batch 5 L bioreactor runs spanning 14 experimental conditions, including variation in cell line, feed, and media composition. Forecasts were generated from Day 3, before the major divergence in lactate behaviour typically becomes apparent. The proposed multi-path gated bottleneck latent ODE with Raman fusion achieved the best overall average rank across target variables and outperformed a global latent ODE baseline on 8 of 9 forecasted process variables. The results suggest that multi-path forecasting is especially useful when similar early profiles separate into distinct future outcomes, while Raman fusion provides the greatest benefit when early Raman-informed dynamics are representative of later behaviour. Overall, this approach supports earlier risk detection and more proactive decision-making in upstream bioprocess development and monitoring.

ACKNOWLEDGEMENTS

This research was supported under the Australian Research Council's Industrial Transformation Research Program (ITRP) funding scheme (project number IH210100051). The ARC Digital Bioprocess Development Hub is a collaboration between The University of Melbourne, University of Technology Sydney, RMIT University, CSL Innovation Pty Ltd, Cytiva (Global Life Science Solutions Australia Pty Ltd) and Patheon Biologics Australia Pty Ltd.

12

Upstream Processing



Hemasunder Reddy
Director-Asia Pacific, Pfanstiehl, Inc.

Addressing Aggregation and Viscosity Challenges in High-Concentration Monoclonal Antibody Formulations with Arginine.Glutamate

Hemasunder Reddy

” The growing adoption of high-concentration monoclonal antibody (mAb) formulations has enabled the development of more patient-friendly drug products, particularly for subcutaneous administration. However, increasing protein concentration often leads to significant formulation challenges, including enhanced protein-protein interactions, elevated viscosity, and an increased risk of aggregation, all of which can impact manufacturability, stability, and product performance.

This presentation will review the fundamental challenges associated with high-concentration mAb formulations and discuss current strategies for controlling aggregation and viscosity. Particular focus will be placed on A-172 Arginine.Glutamate (Arg.Glu), a multifunctional excipient that has demonstrated potential to improve protein stability while reducing solution viscosity.

A case study evaluating the performance of Arg.Glu as an anti-aggregation and viscosity-reducing agent will be presented, highlighting its effects on formulation stability and overall developability. The data will illustrate how Arg.Glu can help address key barriers encountered during the development of high-concentration biologics.

The presentation will conclude with a discussion of the potential role of Arg.Glu in enabling robust, stable, and patient-centric high-concentration mAb formulations and other next-generation biologic products.

Upstream Processing



Cher-Lyn Soh

Product Manager, In Vitro Technologies

Integrated Bioprocess Development: From Cultivation to Product Characterisation

Sara Sadeghipour, PhD, Product Manager – Bioprocess & Synthetic Biology; Cher-Lynn Soh, PhD Product Manager In Vitro Technologies Pty Ltd, Australia

”

Bioprocess development involves technical challenges across cultivation, process control, downstream processing and product characterisation. Optimising each stage requires an understanding of the biological system, critical process parameters and processing strategy to support robust and scalable biomanufacturing.

This work presents practical examples and case studies highlighting key considerations across different stages of bioprocess development.

Upstream examples include microbial and mammalian cell cultivation using incubator shakers and bioreactors, with applications including yeast, cyanobacteria, bacteriophages and Expi cells for protein expression. Bioreactor studies with *Escherichia coli* and *Yarrowia lipolytica* demonstrate the importance of controlled cultivation conditions and process strategy. *E. coli* achieved a specific growth rate of 0.63 h^{-1} and a final OD_{600} of approximately 6–7, while *Y. lipolytica* reached a peak OD_{600} of 131 and a final OD_{600} of 108. These studies highlight the importance of pH, dissolved oxygen, temperature, agitation and feeding strategy in achieving consistent cultivation performance.

Downstream processing considerations will focus on tangential flow filtration and ceramic crossflow filtration, including membrane selection, flux, concentration factor, clarification, concentration, diafiltration, fouling and scalability. These principles illustrate how filtration strategies can be selected according to process-stream characteristics, target product and processing objectives.

A separate analytical case study examines monoclonal antibody charge heterogeneity using capillary isoelectric focusing. Charge variants of the NIST monoclonal antibody reference material were separated and collected, followed by intact-mass analysis and peptide mapping, demonstrating how fractionation combined with orthogonal analytical techniques can support product characterisation.

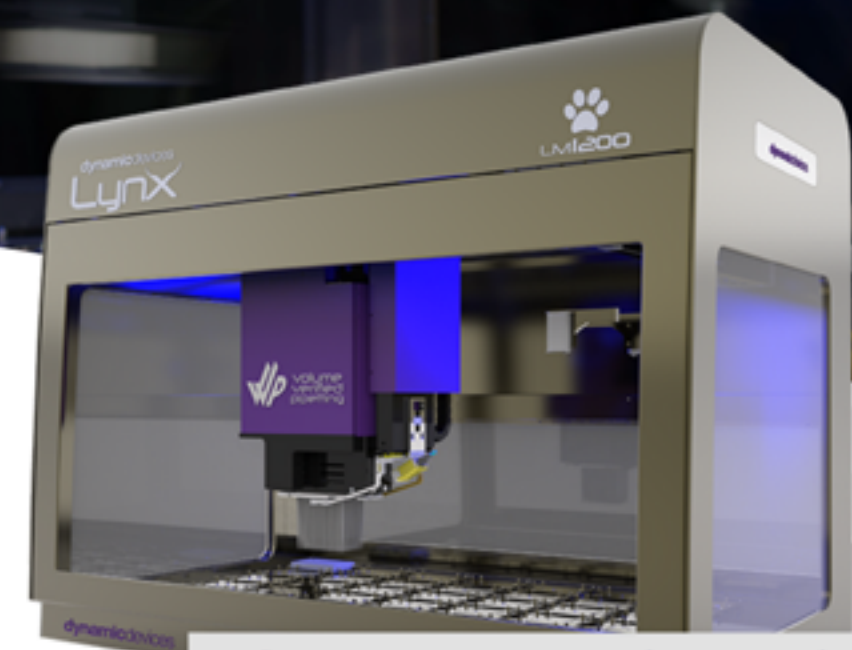
Technologies discussed include LabFlow™ bioprocessing platforms from In Vitro Technologies and the MauriceFlex™ platform from Bio-Techne. Collectively, the examples highlight practical and transferable principles across upstream processing, downstream processing and product characterisation.



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14

Upstream Processing



Dr Joseph Raphael

Bioprocess Engineer, Levur

Continuous cultivation and scale-up strategies for sustainable yeast biomanufacturing

Joseph Raphael, Tom Collier

” Levur is a biomanufacturing company utilising a microbial fermentation platform to produce sustainable oils as alternatives to conventional plant and animal derived oils, including palm oil. The company focuses on engineering yeast-based systems to enable scalable, commercially viable production of lipids and anti-inflammatory rich ingredients for applications across the food and personal care markets.

This presentation highlights two complementary bioprocess development processes that illustrate the translation of microbial fermentation from laboratory development towards commercial manufacturing. Together, these processes showcase how bioprocess engineering can enable robust, reliable and scalable fermentation platforms for sustainable ingredient production.

The first bioprocess explores the implementation of long-term continuous chemostat cultivation of recombinant yeast strains for the production of specific proprietary microbial lipids. Continuous operation offers the potential to improve productivity and manufacturing efficiency while providing valuable insights into long-term process stability, process control, and operational performance for non-traditional microbial lipid production.

The second bioprocess outlines the development of a scale-up strategy for fermentation of an antioxidant producing proprietary non-traditional yeast strain, progressing from 6 L laboratory bioreactors to pilot-scale production. The presentation will discuss key engineering considerations associated with scale-up, including process transfer, oxygen transfer, and mixing, with the goal of producing lipid and antioxidant rich biomass for downstream personal care applications. Of importance is how to adapt existing bioprocesses to non-traditional yeast strains in practice.

Together, these case studies highlight the role of bioprocess engineering in translating microbial fermentation from laboratory-scale development towards industrial implementation. By combining continuous processing with scalable fermentation strategies, this work demonstrates how robust process development can support the sustainable manufacture of high value bio-based ingredients.

15

Upstream Processing



Dr Bhagya Yatipanthalawa

Research Fellow, The University of Melbourne

Towards Predictive Optimisation and Control of Amino Acid Supply in CHO Cell Cultures

Bhagya S. Yatipanthalawa, Yih Yean Lee, Sally L. Gras, Gregory J.O. Martin

Chinese hamster ovary (CHO) cells remain the dominant platform to produce monoclonal antibodies. However, achieving high product yields and quality remains a significant challenge. Amino acids supplied through cell culture media are the building blocks of recombinant proteins, and play roles in energy metabolism, redox homeostasis, cellular signalling and the formation of key metabolic intermediates. Their availability directly influences cell growth, productivity and product quality, with both nutrient depletion and overfeeding negatively impacting culture performance. Despite their importance, amino acid feeding strategies in industrial fed-batch cultures remain largely empirical and often insufficiently account for culture dynamics.

Here, we present an overview of the current knowledge of amino acid metabolism in CHO cell cultures and discuss emerging opportunities for more rational nutrient management. We discuss how amino acid consumption patterns evolve throughout cultivation and highlight the implications for media design, feeding strategies and process optimisation. These include knowledge-driven media development informed by cellular metabolic requirements, improved feeding strategies that better balance the amino acid supply with cellular demand, and model-guided approaches for predictive nutrient management.

Building on this, we present two hybrid models developed to support predictive amino acid management. These models predict amino acid concentrations alongside other critical process parameters and key performance indicators. They combine data driven components that account for the biological complexity in CHO systems with mechanistic components that incorporate first-principle knowledge, improving interpretability and model robustness. The first model allows predictions over the full cultivation period, enabling in-silico evaluation of media composition and feeding strategies, reducing experimental burden during process development. The second model focuses on short-term culture dynamics, providing a foundation for future implementation of advanced amino acid monitoring and control systems. Together, these approaches demonstrate how metabolic knowledge can be integrated with predictive modelling to support the development of digital bioprocesses and next-generation biotherapeutic manufacturing.

16

Upstream & Viral



Dr Sebastian Judd-Mole

Product Manager, Millennium Science and Unchained Labs

Bridging the Valley of Death: Approaching Therapeutic Nanoparticle discovery with a GMP Mindset

Sebastian Judd-Mole and Ben Knappett

”

Therapeutic nanoparticles, including lipid nanoparticles (LNPs), have enabled major advances in nucleic-acid delivery. However, many promising formulations do not progress efficiently from discovery into clinical use. A key source of risk arises when instrumentation used for screening, scale-up and GMP manufacture each use different pumping methods, mixer sizes or operating conditions. Each transition creates a potential breaking point that can alter particle size, polydispersity, encapsulation efficiency or biological performance, and necessitates time-consuming re-optimisation and revalidation.

This presentation examines an alternative strategy that begins with the intended manufacturing pathway in mind. The workflow combines high-throughput, low-volume formulation screening with systematic optimisation of flow-rate ratio, total flow rate, mixer geometry and in-line dilution, followed by continuous production and GMP-ready manufacture using the same pumps and reusable glass microfluidic mixers. Sunscreen enables automated screening of up to 96 nanoparticle formulations at small volume. Sunshine then supports detailed optimisation and the transition from discrete experiments to continuous flow, while Sunbather carries the same underlying approach into a GMP-ready production environment.

Reliable scale-up also depends on rapid and informative analytical feedback. Stunner AF combines UV-Vis spectroscopy, fluorescence, rotating-angle dynamic light scattering (RADLS), and static light scattering to measure particle size, polydispersity, encapsulation efficiency, particle concentration and aggregation from microlitre-scale samples. Applying these measurements through screening and scale-up creates a continuous formulation-characterisation loop that supports candidate selection, process understanding and comparability.

Using the Sunny Suite and Stunner AF as an integrated case study, this talk will explore how maintaining continuity in both mixing and analytical strategy can reduce material use, limit translational uncertainty and help nanoparticle programs move from discovery towards clinical manufacture with greater confidence.

17

Upstream & Viral



Dr Vasily Medvedev

Chief Technology Officer, VVMF

Establishment and Scale-Up of Australia's First Recombinant Lentiviral Vector (rLV) Manufacturing Platform

Dr. Ken Hsu, Manuel DeValle Medina, Claire Pierret, Dr. Minh Phan, Dr. Kunal Kalra, Benjamin Kalma, Habib Rahaman, Dr. Teddy Chang, Vasily Medvedev

”

Lentiviral vectors (LVs) are a cornerstone clinical vector platform, enabling ex-vivo, genetically modified cell therapies and emerging in-vivo gene delivery applications. Despite rapidly growing clinical demand across the Asia-Pacific region, sovereign GMP-grade LV manufacturing capability in Australia has remained limited. Establishing a locally developed, scalable, and clinically relevant LV production process is therefore critical to accelerating patient access to advanced therapies and reducing reliance on overseas supply.

Here, we report — to our knowledge, the first novel process development in Australia for GMP-aligned recombinant lentiviral vector (rLV) production — the design and scale-up of a suspension HEK293-based upstream platform from small-scale development through 5 L rocking Wave bioreactors to a 50 L stirred-tank bioreactor. The process employed a third-generation, four-plasmid transient transfection system carrying a clinically relevant transgene, comprising seed-train expansion, N-1 Wave culture, pre-transfection growth, transient transfection, and vector production.

Across all scales evaluated, and across process runs conducted at both Cytiva (Boston, USA) and VVMF (Sydney, Australia), the platform demonstrated consistent cell growth, viability, metabolic performance, transfection efficiency, and overall process robustness. Downstream unit operations exhibited scalable performance with consistent product recovery, impurity clearance, filter capacity utilisation, and operational reproducibility. The integrated process enabled reliable scale-up while maintaining product quality attributes and manufacturing consistency.

A downstream purification process was implemented and translated to fully single-use process architecture. The purification strategy was designed to remove product- and process-related impurities while preserving lentiviral infectivity. Purification of lentiviral vector is a notable challenge faced in industry. Purification difficulties relating to clarification, tangential flow filtration, chromatography, and sterile filtration were overcome during development of the production platform allowing for demonstrated success of the process. Critical scale-up challenges, including consistency of vector quality attributes across scales (e.g. infectivity), and process troubleshooting were successfully addressed through process optimisation.

At the 50 L scale, the process achieved an infectious titre of 7.0×10^8 TU/mL with a quality attribute profile meeting the acceptance criteria for clinically applicable lentiviral vector production.

This work establishes Australia's first scalable, GMP-aligned lentiviral vector manufacturing platform and demonstrates successful integration of upstream production and downstream purification technologies from development scale through 50 L production. The platform provides a strong foundation for future clinical and commercial manufacturing and supports the growing Australian and Asia-Pacific cell and gene therapy sector through local production of clinically relevant lentiviral vectors.

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CHOvantage cells are cGMP-banked at a qualified facility. The manufacturing facility maintains ISO 14001 certification for its environmental management system and operates under 21 CFR Parts 210 and 211 (cGMP) for drug substance manufacturing and cGMP cell bank production supporting commercial biopharmaceutical products. The cGMP master cell bank (MCB) and the derived cGMP working cell bank (WCB) were manufactured in a qualified facility under controlled conditions in accordance with applicable cGMP requirements. Full traceability

is maintained through comprehensive chain-of-custody documentation. This includes cryopreservation in an animal origin-free (AOF), chemically defined medium.

Cell line lineage overview:

CHOvantage GS CHO-K1 cells are of United States origin. They are banked in an AOF, chemically defined medium. Documented lineage history is maintained within the cell line documentation package (CLDP).

Comprehensive cell line documentation package:

The CHOvantage cell line has a comprehensive CLDP that includes a full lineage history, cGMP-banking details, safety and adventitious agent testing, and characterization reports. The CLDP is available following execution of a commercial license agreement.

Support beyond the cells:

Thermo Fisher provides regulatory and technical support services to assist with IND filings. We want you to be confident that the CHOvantage platform is positioned for smooth regulatory review.

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18

Upstream & Viral



Dr Sharon Cunningham

Analytical Development Manager, VVMF

Assessing Product Quality and Process Performance of an rLV Manufacturing Platform at 50 L Scale Using Orthogonal Analytical Testing Strategies

Dr. Sharon Cunningham, Dr. Aduba Collins, Mikhail Tselebrovskiy

”

Recombinant lentiviral vector (rLV) manufacturing platforms require an appropriate analytical characterisation strategy to evaluate product quality and process performance at scale. Orthogonal methods enable assessment of multiple critical quality attributes (CQAs) and characterisation of vector recovery and impurity clearance across manufacturing operations. An integrated analytical characterisation was therefore performed for a 50 L confirmation batch produced using an established, partner-developed rLV platform. The product was a self-inactivating, VSV-G-pseudotyped rLV intended for ex vivo modification of human T cells. Selected process intermediates and final product samples were evaluated using orthogonal assays covering vector strength and process-related purity CQAs.

Assessment of strength-related CQAs using orthogonal titre assays demonstrated progressive vector enrichment through concentration stages and broadly comparable downstream recovery profiles. Physical titres based on particle (capsid) and genome measurements showed near-proportional behaviour across the process, while functional (infectious) titres based on expressed transgene and proviral measurement followed similar overall trends. Functional recovery was lower than particle- and genome-based recovery in later stages, highlighting the value of complementary information provided by infectivity-related and physical titre assays. Assessment of process-related purity CQAs showed substantial reductions in Host Cell DNA (HCD) and Host Cell Protein (HCP) through clarification and chromatography, while later increases in measured concentrations were consistent with final concentration steps rather than reduced clearance efficiency. Load- and vector-normalised analyses supported this interpretation. The proportion of residual HCD present as fragments below 200 bp increased approximately five-fold, residual plasmid DNA relative to vector genome content decreased by more than two orders of magnitude, and residual benzonase was below the assay lower limit of quantitation in the final product.

Together, these findings demonstrate the value of orthogonal analytical testing panels for integrated assessment of product quality and process performance. The results support confirmation of platform performance at 50 L scale and provide a basis for further characterisation and control strategy development.”

Upstream & Viral



Chris Peck

Managing Director & Co-Founder, Southern RNA Pty Ltd

Pioneering Personalised Medicine in Australia

Chris Peck

” The emergence of mRNA technology has transformed the possibilities for precision medicine, enabling therapies to be designed and manufactured for individual patients rather than broad populations. While the underlying science has advanced rapidly, the key challenge now is translation: converting scientific breakthroughs into clinically accessible treatments quickly, affordably, and at scale.

Using personalised cancer vaccines as a case study, including emerging initiatives such as paediatric brain cancer immunotherapy trials, the presentation highlights the end-to-end pathway from tumour sequencing and neoantigen design to mRNA manufacture and patient delivery. It examines why speed, sovereign capability, and integrated manufacturing ecosystems are essential to the future success of personalised therapies.

The discussion also considers Australia's unique opportunity to become a global leader in translational mRNA medicine by leveraging its strengths in research, clinical trials, advanced manufacturing, and biotechnology innovation. As healthcare moves from mass-produced treatments toward increasingly personalised interventions, small-scale GMP manufacturing will play a pivotal role in enabling the next generation of medicines.

Ultimately, the future of mRNA extends beyond vaccines. It represents a programmable platform for medicine itself, creating new possibilities in oncology, immunotherapy, regenerative medicine, and beyond. Building the systems, partnerships, and manufacturing capabilities required to realise this potential will determine Australia's place in the next era of healthcare innovation.

Viral & Downstream



Dr Henry de Malmanche

Postdoctoral Research Scientist, The University of Queensland

Bioprocess Development of the ISVac™ Flavivirus Vaccine Platform Using Suspension Mosquito Cell Culture

Henry de Malmanche, Jody Peters, Jessica Harrison

”

ISVac™ (Insect Specific Virus Vaccine) is a novel vaccine platform based on insect-specific flaviviruses that generates structurally authentic virus particles while remaining intrinsically incapable of replication in vertebrate hosts. While multiple ISVac vaccine candidates have demonstrated promising preclinical immunogenicity, scalable manufacturing remains a key translational challenge.

Here we describe the development of upstream and downstream bioprocesses for the ISVac™ platform for the manufacturing of a vaccine for Japanese Encephalitis Virus as the lead translational asset. A suspension-adapted *Aedes albopictus* C6/36 mosquito cell line was cultivated in benchtop Ambr®250 bioreactors to investigate process performance under controlled bioreactor conditions. Key upstream parameters, including cell growth, infection strategy and virus production, were evaluated to inform process optimisation and future scale-up.

Downstream process development focused on establishing a scalable purification workflow comprising tangential flow filtration and chromatographic polishing to concentrate virus particles while reducing process-related impurities. Preliminary studies assessed process recovery, concentration performance and compatibility with platform manufacturing requirements.

Collectively, these studies establish the foundations of an integrated manufacturing process suitable for further optimisation and technology transfer. The work demonstrates the feasibility of suspension mosquito cell bioprocessing for production of ISVac vaccine candidates and provides an important step towards regulator-informed manufacturing, analytical characterisation and clinical translation. Importantly, the manufacturing principles being developed are intended to be transferable across the broader ISVac™ flavivirus vaccine platform, supporting future development of vaccine candidates targeting Japanese encephalitis, dengue, West Nile, yellow fever and Zika viruses.

Viral & Downstream



Dawson Goh

Manager – Process Engineering (DSP), Thermo Fisher Scientific

UF/DF at the Extremes: Engineering Strategies for High Concentration, Low Mass and High Mass Processing

Dawson Goh, Weiwei Sun

”

Ultrafiltration/diafiltration (UF/DF) is often treated as a standard downstream unit operation, but the engineering problem changes significantly at the edges of the operating envelope. This presentation examines three distinct UF/DF extremes: extremely high concentration targets, extremely low product mass and extremely large protein mass. Although the same unit operation is used in each case, the dominant failure modes, process constraints and engineering responses are very different.

At very high concentration targets, the key challenges include rising viscosity, declining flux, increased transmembrane pressure, mixing limitations, shear sensitivity and greater exposure to hold-up effects. At very low product mass, the main risks shift to recovery loss, dead volume, adsorption, handling difficulty, poor analytical visibility and the challenge of maintaining control when operating below a system's preferred design range. At very large protein mass, the constraints are dominated by throughput, membrane loading, pump capacity, fouling, thermal management, process duration and the practical limits of large-scale concentration and diafiltration.

The presentation argues that these three cases should not be managed with one generic UF/DF strategy. Instead, each extreme requires a different engineering response. High-concentration operations benefit from staged concentration, viscosity-aware design and careful control of mixing and pressure. Low-mass operations require low-hold-up hardware, recovery-focused workflows and minimisation of transfer losses. High-mass operations require capacity planning, scalable membrane selection, robust pump and system design, and strategies to control fouling and cycle time.

Using anonymised examples, the talk will highlight the typical problems encountered at each extreme, the workarounds that are commonly attempted and the engineering decisions that make the difference between a robust UF/DF step and a process bottleneck. The central message is that UF/DF performance is not defined by membrane selection alone, but by how well the process is engineered for the specific extreme it is expected to handle.

Viral & Downstream



Andrew Hodder

VP Manufacturing and Site Head, CSL Behring Broadmeadows

Behind the scenes ISPE's 2025 Facility of the Year.

Andrew Hodder

”

Andrew Hodder, the Manufacturing and Site Head for CSL Behring Broadmeadows, located in Victoria, will take you behind the scenes of CSL's new \$800m Base Fractionation Facility, which incorporates cutting-edge technologies with a pioneering hybrid manufacturing platform. The facility subsequently went on to win the International Society of Pharmaceutical Engineering (ISPE) award for Facility of the Year for 2025.

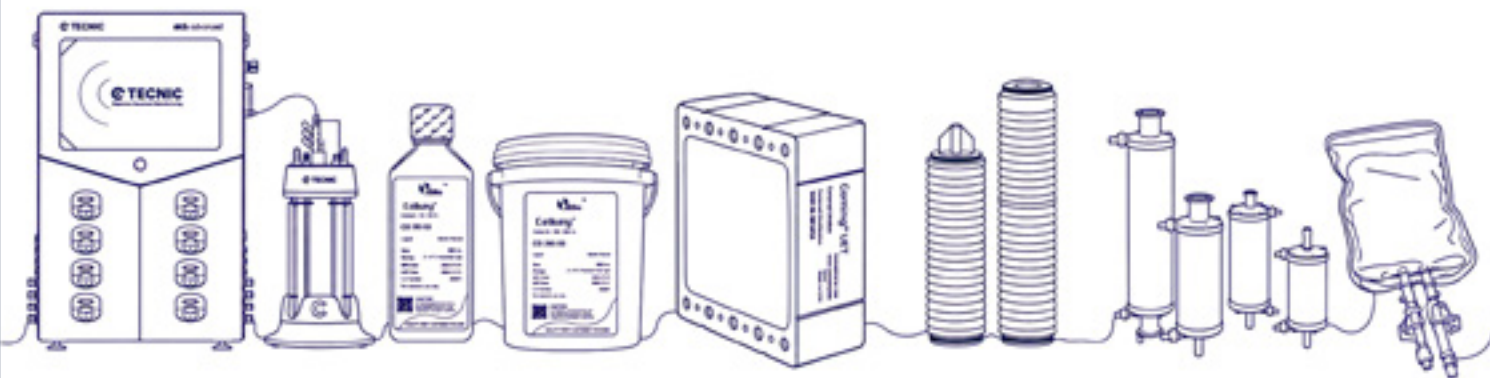
The Facility is purpose-built to optimise the production of plasma-derived therapies for conditions such as immunodeficiencies, neurological disorders, and burns, and is the biggest of its kind on the world, capable of processing over 10 million litres annually. The facility also won the ISPE Pharma 4.0 Award in 2025 for its advanced use of digital technologies and automation to transform pharmaceutical manufacturing.

In reflecting on the facility, Andrew will also reflect on CSL's continued investment in Australian Biotech Manufacturing, including the recent opening of a dedicated Influenza Manufacturing Facility alongside CSL's unique CBD-based R&D laboratories.

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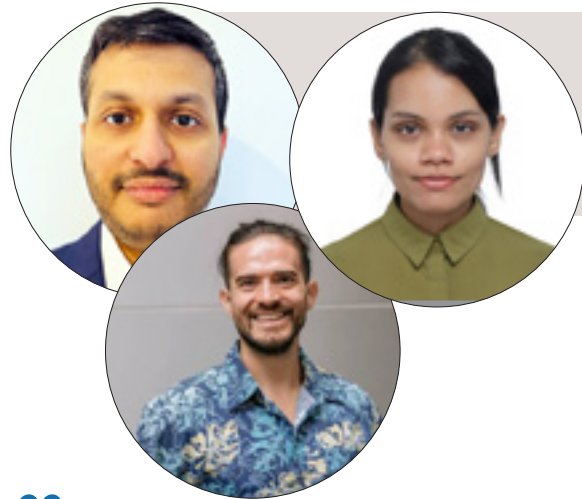
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Quantification & Sizing

- Size, PDI, aggregation
- Particle concentration
- Dye-free total RNA quant

Downstream Processing



Norman **Yousuf**, Saumya **Karunadhika**,
Eduardo **Gorron**

Three 5-minute presentations from early-career researchers

”

CFD-Informed Zonal Rate Model Development for Membrane Chromatography

Noman Yousuf, Yuxiang Yang, Ben Hunt, Innocent Bekard, Sandra Kentish

Membrane chromatography has emerged as a preferred alternative to packed-bed resin chromatography for high-throughput downstream processing of monoclonal antibodies due to its rapid convective transport and shorter processing times. However, device performance is governed not only by intrinsic adsorption kinetics, but also by hydrodynamic non-idealities arising from device geometry. In axial-flow capsule geometries, large aspect ratios induce significant radial velocity heterogeneity across the membrane cross-section, producing broadened residence time distributions (RTDs), early solute breakthrough, and asymmetric tailing even under non-binding conditions. Likewise, in radial pleated membrane configurations, non-uniform streamline contraction and expansion within pleat channels generate substantial axial and radial dispersion, strongly influencing breakthrough sharpness and binding performance. These effects become more pronounced at a large scale, where increased flow maldistribution and hold-up volumes reduce membrane utilisation and compromise scale-up predictability. Failure to decouple these geometry-dependent hydrodynamic effects from intrinsic adsorption kinetics during calibration can result in inaccurate mechanistic models that break down during model-based scale-up.

Real-Time Adaptive System Modelling for Downstream Purification Processes

Saumya Karunadhika, Ling Luo, Bastian Oetomo, Sandra Kentish, Sally Gras, and Uwe Aickelin

Bioprocessing is shifting towards continuous manufacturing, increasing the need for adaptive and robust process modelling for real-time monitoring and control. In this context, Machine Learning (ML) offers significant potential for system modelling. However, bioprocesses rarely remain static over extended operation. Changes in process and equipment conditions, as well as machine degradation, can cause the relationship between process inputs and outputs to evolve over time, a phenomenon known as “concept drift”. This challenge is particularly important in Single-Pass Tangential Flow Filtration (SPTFF), an emerging method for continuous purification of biomolecules that eliminates recirculation to improve process efficiency. Consequently, reliable models are required for application under changing operating conditions for effective use of SPTFF.

A model of a two-stage tangential flow filtration system optimised for purification of recombinant proteins

Eduardo Gorron, Kira Schipper, John Roles, Ian Ross, Ella Shan, Ben Hankamer

Downstream processing remains a critical bottleneck in microalgae- and plant-based recombinant protein production, where low expression yields and complex host cell protein (HCP) backgrounds result in high purification costs compared to conventional production host-systems. Nonetheless, microalgae- and plant-based production systems offer advantages such as lower upstream costs, scalability, and reduced risk of contamination with human pathogens, making them attractive alternatives for recombinant protein manufacturing. This study presents the development and optimisation of a two-stage Multistep Single-Pass Tangential Flow Filtration (MSPTFF) system model as an intermediate clarification strategy for microalgae expression platforms.

Downstream Processing



Dr Bastian **Oetomo**

Postdoctoral Research Fellow, The University of Melbourne

Toward Model Predictive Control of Single-Pass Tangential Flow Filtration

Bastian Oetomo, Ling Luo, Saumya Karunadhika, Michele Discepolo, Sahebagoada Alagur, Buddy Heydon, James Atherton, Sandra E. Kentish and Sally L. Gras

”

Single-pass tangential flow filtration (SPTFF) offers a possible route to continuous bioprocessing within the ultrafiltration/diafiltration unit operation by eliminating the recirculation loop used in conventional batch tangential flow filtration. However, its successful integration into continuous biomanufacturing requires a consistent retentate concentration despite nonlinear, delayed and history-dependent dynamics, in addition to progressive membrane fouling and strict pressure limitations. This study develops and experimentally demonstrates a data-driven model predictive control (MPC) strategy that regulates retentate protein concentration by manipulating permeate pump speed while maintaining a feasible operating pressure range.

Initial experiments were performed using whey protein isolate as a model protein solution, a 10 kDa, 0.1 m² cassette with Omega polyethersulfone membrane and a constant feed flow rate of 46 mL/min. Inline index-of-refraction sensors on the feed, retentate and permeate lines provided continuous background-corrected estimates of protein concentration. Retentate and permeate pressures were measured simultaneously using pressure transducers. Dynamic identification data were collected at 5-second intervals using varying permeate pump inputs. A 10-step process delay was incorporated into a Gaussian Process Nonlinear Autoregressive model with exogenous inputs (GP-NARX). Direct future output prediction was used to avoid recursive error accumulation, while the Gaussian Process formulation provided both predicted concentration and uncertainty. Alternative ARX, neural-network NARX, and ARIMAX structures were also evaluated. The GP-NARX model was selected for control because it represented nonlinear dynamics while allowing prediction uncertainty to be included directly in the MPC objective.

The controller was designed to concentrate a 3 mg/mL feed to a retentate setpoint of 30 mg/mL. At each control update, the MPC balanced predicted setpoint tracking error, prediction uncertainty and changes in pump speed. The permeate pump was restricted to 40 to 80 RPM to limit aggressive actuation and maintain acceptable retentate and permeate pressures. Following an initial period at 60 RPM, the controller reduced the pump speed in response to a rapid increase in the output concentration and subsequently increased it to compensate for the gradual decline in permeate flux associated with membrane fouling. After the retentate concentration first reached the lower boundary of the 5% target band, it remained within that band for 97.9% of the remainder of the experiment, while maintaining the absolute permeate pressure above the minimum allowable value of 0.6 bar. Post-experiment evaluation of the deployed predictor produced a root mean squared error of 0.953 mg/mL and a mean absolute error of 0.609 mg/mL over the complete run.

These initial results indicate that data-driven MPC can maintain stable SPTFF outlet concentration under realistic nonlinear behaviour, fouling and operating restrictions. The approach provides a promising pathway for automated integration of SPTFF into continuous downstream processing.

Downstream Processing



Dr Yvan Ruland

Technology Consultant - Chromatography, Sartorius

Continuous Downstream Process Orchestration in Pionic® Platform

Alexandre Espachs, Jérôme Chevalier, Niclas Storck, Cyril Mak, Yvan Ruland

”

In the biomanufacturing space, flexibility is paramount to adapting to diverse production needs and optimizing processes. Our modular platform for downstream processing (DSP) exemplifies this flexibility by allowing the rearrangement of unit operations to suit specific production requirements. This adaptability is ensured by the design of the system hardware, flow kits, control and orchestration software. Furthermore, the principle of continuous operation enables the platform to maintain an extensive operating range, accommodating different scales and types of biomanufacturing tasks. This flexibility not only enhances efficiency but also supports rapid responses to changes in demand, making it an invaluable asset in modern biomanufacturing environments.

In this presentation, we will embark on a journey through the downstream process to demonstrate how Pionic® orchestration adjusts product flow changes between each module. We will start with continuous capture, proceed to inflow low pH virus inactivation, bridge to polishing steps, and continue onto nano and normal flow filtrations. The process concludes with a single pass through the concentration, diafiltration, formulation, and filtration steps to the drug substance. We will also share preliminary data generated from running these modules as orchestrated units, including results from ongoing work with our collaboration partner Sanofi, to illustrate system performance under real process conditions. Throughout this connected, data-driven, and continuous journey, we will discuss options for managing different flow rates, surge tank fill levels, ramp-up/steady state/ramp-down phases as well as deviation handling.

Downstream Processing



Dr Nick Boyd

Head of Biology, Celleo Biotech

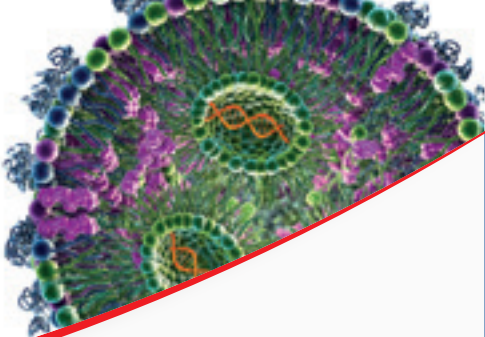
A new closed, single-use platform de-bottlenecking aseptic vial filling

Dr Nick Boyd

”

Aseptic vial filling at scales of 10–1,000 vials is a routine requirement across cell therapy, viral vector, lipid nanoparticle, and critical reagent workflows - spanning QC, drug product, and banking applications. Yet fill-finish remains a persistent industry bottleneck with reliance on open processing. This introduces sterility risk, slow fill speeds amplify DMSO exposure in cryopreserved biologics, and high vial-to-vial and run-to-run variability undermines product consistency. This presentation features a case study evaluating a new technology platform for cell bank manufacture. Benchmarked against industry-standard pipetting controls, fill-finish consistency and production speeds were improved through a simplified, closed-system automated fill, whilst maintaining cell viability, concentration, and functionality. Beyond banking, the same fill platform is showing meaningful gains in production capacity and consistency across a broader cohort of bioprocessing applications, whilst avoiding demand on high-grade cleanrooms.

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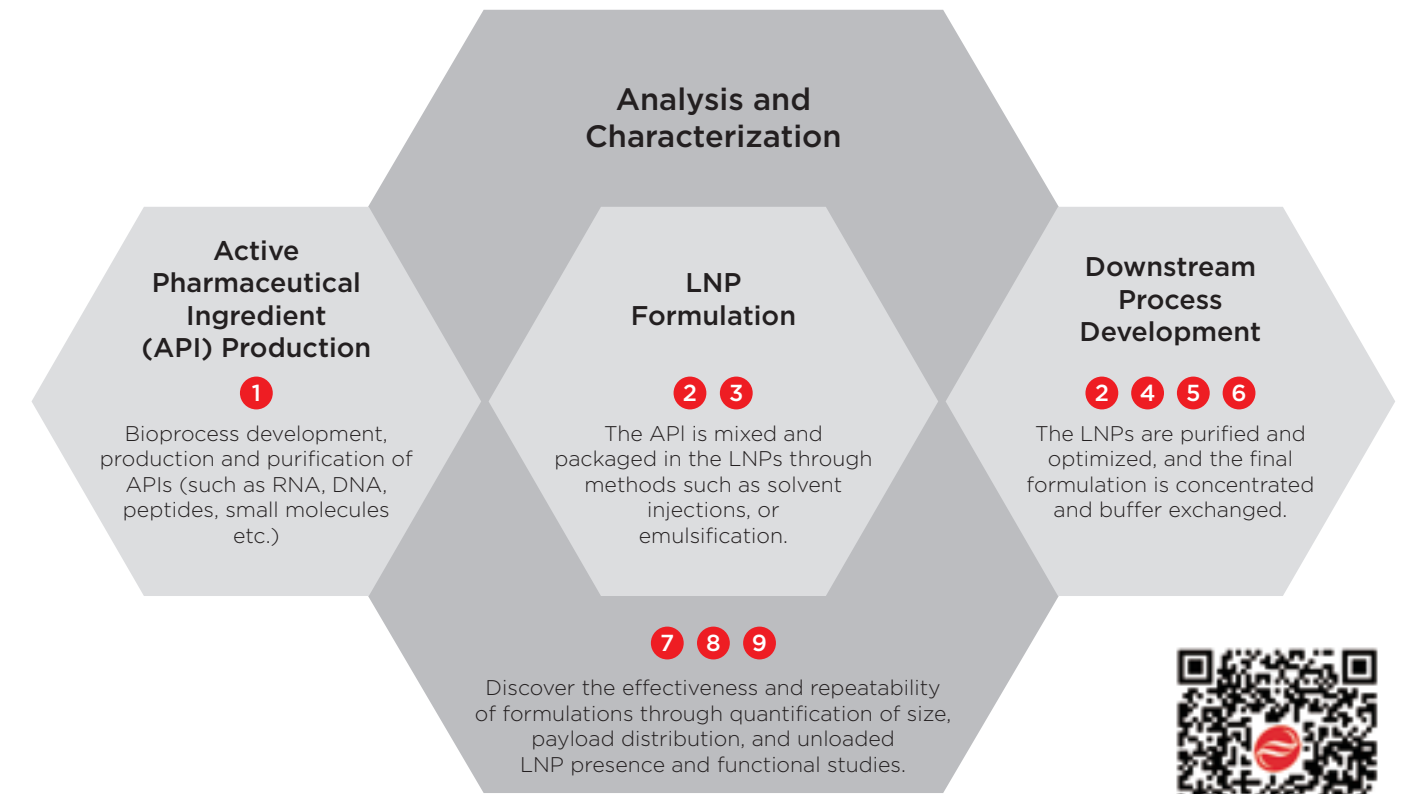
Echo 650 Series Acoustic Liquid Handler

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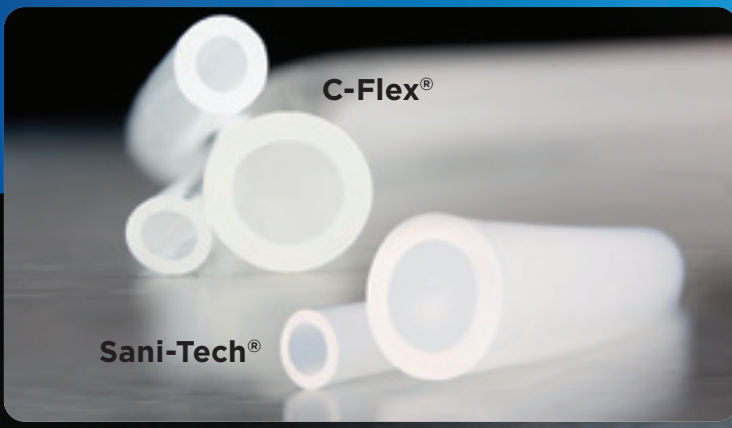
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Downstream Processing



Shih-hsun Chen
Senior Scientist, CSL

Application of Raman Spectroscopy for Real-Time Monitoring of Product Quality Attributes During Downstream Purification

Krishni Sayanthan, Sabrina Yang, Aytac Unal, Shih-hsun Chen, Kevin Grollier, Hadi EL Radi and Johan Cailletaud

”

Raman spectroscopy was evaluated as a Process Analytical Technology (PAT) tool for real-time monitoring of critical quality attributes during monoclonal antibody downstream purification. In-line and at-line Raman measurements were integrated with Protein A chromatography and tangential flow filtration (TFF) operations and correlated with conventional analytical methods. Predictive models were developed to quantify product concentration, monomer content, high and low molecular weight species, host cell proteins, and formulation excipients.

The Raman-based models demonstrated strong predictive performance, enabling real-time monitoring of product quality and impurity partitioning throughout purification processes. In TFF applications, Raman spectroscopy accurately tracked excipient exchange behaviour and provided rapid insight into diafiltration performance. The technology delivered fast, non-destructive measurements with high accuracy, supporting improved process understanding and accelerated decision-making.

These results demonstrate the potential of Raman spectroscopy as a versatile downstream PAT platform, reducing reliance on offline testing while supporting advanced process control and future real-time release strategies for biopharmaceutical manufacturing.

Downstream Processing



Dr Maciej Holówko
Director of Bioproduction, Samsara Eco Pty Ltd

Scaling up production of AI-designed enzymes for nylon recycling

Dr Maciej Holówko

”

Samsara Eco is pioneering enzymatic recycling technologies to enable a fully circular economy for plastics and synthetic fibres. Central to this approach is the use of AI designed enzymes capable of breaking down polymers such as nylon into their original monomers. While advances in machine learning-based enzyme design has rapidly expanded what is possible at the discovery stage, scaling production of these novel enzymes to industrial volumes remains a major technical and operational challenge, especially in the Australian context.

This talk focuses on how Samsara Eco approaches the scale up of AI designed nylon degrading enzymes, from computationally generated sequences to commercial bioproduction. It explores how enzyme performance, manufacturability, and process economics are co optimised to ensure that recycling technologies can be deployed at the scale required to make meaningful environmental impact.

Key topics include translating AI generated enzyme designs into high producing microbial strains, selecting and engineering suitable production hosts, and developing scalable fermentation and downstream processing strategies.

The talk will conclude by sharing lessons learned from building industrial enzyme production pipelines for nylon recycling, and by outlining the capabilities required to manufacture enzymes reliably at global scale. These insights illustrate how AI, synthetic biology, and bioprocess engineering can be combined to turn plastic eating enzymes into practical, circular recycling solutions for hard to recycle polymers.

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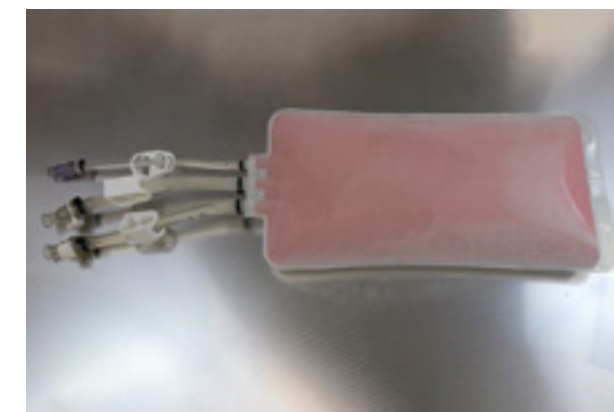
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Keynote

Downstream Processing



Dr Sally Gras

Redmond Barry Distinguished Professor, Digital Bioprocess Development Hub, University of Melbourne

Optimising Biomanufacturing with AI: From Model Development to Industrial Adoption

Dr Sally Gras

”

Advances in machine learning and its application to bioprocessing, together with strengthened industry-research partnerships, have transitioned AI from a prospective concept to tools and implementations within process-development pipelines.

In this talk I present three years of progress from the ARC Digital Bioprocess Development Hub and describe AI-driven tools being developed across the Australian bioprocessing sector to accelerate scale-up, enhance product quality, optimise yield, reduce wet-lab experiments, de-risk and streamline processes and build workforce capability. International advances and industrial deployments will be presented as benchmarks and collaborative opportunities for broader adoption across the Australian bioprocessing sector discussed.

30

Downstream Processing



Dr Lukas Gerstweiler

Senior Lecturer, Adelaide University

Influence of mRNA Length on Oligo-dT Affinity Chromatography Performance

Lukas Gerstweiler, Federico Moreno Sibaja

”

Oligo-dT affinity chromatography is widely used to selectively capture polyadenylated messenger RNA, yet limited understanding of its binding mechanisms complicates process development and scale-up. This study investigated how mRNA length influences equilibrium binding capacity, adsorption kinetics, dynamic binding capacity and elution performance using POROS™ Oligo (dT)25 affinity resin.

Four mRNA constructs ranging from 831 to 4,227 nucleotides were evaluated using a high-throughput static binding methodology and laboratory-scale column experiments. Binding increased with NaCl concentration and reached a plateau at approximately 0.8 M NaCl. Langmuir isotherms described the adsorption data well and revealed a strong inverse relationship between mRNA length and maximum binding capacity. Constructs of approximately 1,000 nucleotides achieved static capacities of approximately 8.6–8.8 mg/mL resin, compared with 5.1 mg/mL for a 1,773-nucleotide construct and 3.3 mg/mL for a 4,227-nucleotide construct.

Binding kinetics also became slower with increasing mRNA length. Fitted mass-transfer coefficients decreased from approximately 0.022 min⁻¹ for the shorter constructs to 0.0088 min⁻¹ for Cas9 mRNA. Under dynamic conditions, increasing residence time from 60 to 240 seconds improved the 10% dynamic binding capacity of Cas9 mRNA by approximately 61%, compared with approximately 31% for mCherry mRNA. Water provided the highest elution recovery, reaching 80.3%, compared with 69.6% using Tris buffer and 59.6% using citrate buffer.

These findings demonstrate that mRNA length strongly affects resin accessibility and mass transfer during oligo-dT chromatography. Incorporating mRNA size, structure and steric exclusion into mechanistic models could improve process prediction, resin utilisation and scale-up of mRNA purification processes.

Downstream Processing



Dr Naish Millerick

Business Development Manager and Lead, Bioproduction Group, Thermo Fisher Scientific, Australia and New Zealand

Process Intensification in Practice: Technologies That Accelerate Biomanufacturing

Dr Naish Millerick

”

Process intensification has become a strategic priority for biomanufacturers seeking to improve productivity, strengthen process robustness, and reduce the risks associated with scaling from development to commercial manufacturing. Achieving these outcomes, however, requires more than adopting individual technologies—it demands an integrated approach across the entire bioprocess workflow.

This presentation will explore how connected upstream, downstream, analytical, and digital technologies can be combined to create efficient, scalable manufacturing platforms. Drawing on practical experience supporting biopharmaceutical manufacturers, we will discuss key considerations for reducing development risk, improving process performance, and enabling more effective technology transfer.

Rather than focusing on individual products, this session will demonstrate how integrated workflows help manufacturers make better process decisions, simplify implementation, and build scalable manufacturing strategies with greater confidence. Attendees will gain practical insights into technologies and approaches that can support process intensification from early development through commercial manufacturing.

Downstream Processing



Christina Cahir

Senior Sales Specialist – Bioprocess Filtration & Hardware – Cytiva

Save More Doses to Treat More Patients: Improving Product Recovery During Sterilizing Filtration of High-Concentration Biotherapeutics

Christina Cahir

”

As biopharmaceutical processes continue to trend toward highly concentrated monoclonal antibodies, vaccines, and other advanced therapeutics, sterile filtration has become an increasingly critical determinant of overall product yield. High viscosity, elevated particulate burden following UF/DF, and fouling-prone process fluids can reduce filtration capacity, increase hold-up losses, and ultimately impact the number of patient doses recovered from each batch.

This presentation examines recent advances in sterilizing-grade membrane filtration designed for challenging downstream bioprocess applications. Performance data generated across 17 high-fouling protein feeds, including concentrations ranging from 70 to 220 g/L, demonstrated significantly higher throughput capacity compared with alternative sterilizing-grade membrane technologies ($p < 0.01$). In addition, studies evaluating polysorbate transmission showed rapid attainment of excipient recovery, helping minimize losses associated with filter conditioning and flushing.

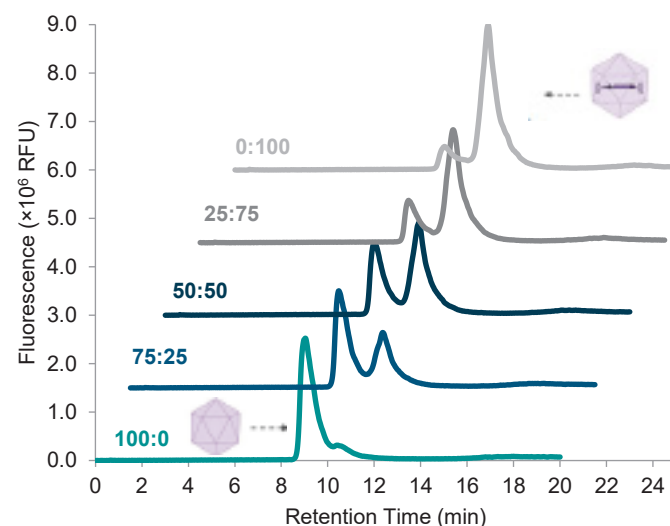
By combining high throughput performance, high flow rates, scalable single-use formats, and comprehensive validation data, optimized filtration strategies can reduce required filtration area, lower hold-up volumes, and improve product recovery while maintaining sterility assurance. Case studies from commercial bioprocessing applications, including monoclonal antibodies, vaccines, and complex formulations, illustrate how filtration optimization can increase manufacturing efficiency, support process robustness, and ultimately maximize the number of therapeutic doses available for patients.

This work highlights the growing importance of filtration performance as a contributor to yield, sustainability, and patient access in modern biopharmaceutical manufacturing.



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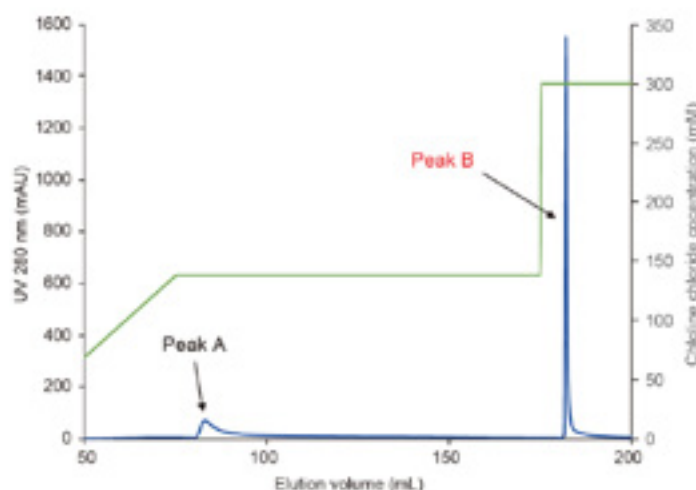
Full/Empty Capsid Analysis Using TSKgel Q-STAT



Conditions	
Column	TSKgel Q-STAT, 7 µm, 4.6 mm I.D. × 10 cm
Buffer A	20 mmol/L Tris-HCl, pH 9.0
Buffer B	1.0 mol/L choline chloride, 20 mmol/L Tris-HCl, pH 9.0
Gradient	10 – 35 % B, 20 min
Flow rate	1.0 mL/min
Detection	Fluorescence, excitation at 280 nm, emission at 350 nm
Temperature	30°C
Sample	AAV5

TSKgel Q-STAT enables effective separation of full and empty AAV capsids.

Full/Empty Capsid Purification Using TOYOPEARL GigaCap Q-650S



Conditions	
Resin	TOYOPEARL GigaCap Q-650S
Column	SkillPak 5 mL, 8 mm × 100 mm
Buffer A	20 mmol/L Tris-HCl, pH 9.0
Buffer B	0.3 mol/L choline chloride, 20 mmol/L Tris-HCl, pH 9.0
Gradient	0 % B → 46 % B → 100 % B
Sample	AAV8, 15 mL, 7.4 × 10 ¹⁴ capsid particles (cp)

HPLC and AUC Analysis Results of Each Fraction

Sample	Full Capsid Ratio (Q-STAT)	Full Capsid Ratio (AUC)
Load	35 %	35 %
Peak A	0 %	0 %
Peak B	94 %	88 %

Step-gradient purification using TOYOPEARL GigaCap Q-650S enables fractionation of full and empty AAV capsids.

33

Downstream Processing



Chandranil Gharekhan

Postdoctoral Researcher, Adelaide University

An Automated Chromatography Platform for Purification of In Vitro Transcription-Derived mRNA

Hamza Baali, Chandranil Hridaynath Gharekhan, Lukas Gerstweiler, Tien-Fu Lu, Robert John Falconer

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The purification of messenger RNA (mRNA) produced by in vitro transcription (IVT) remains a critical quality bottleneck in RNA therapeutic manufacturing. Residual DNA templates, abortive transcripts, and double-stranded RNA (dsRNA) byproducts must be efficiently removed to meet product quality requirements. Here we describe the design and implementation of a custom-built, fully automated chromatography platform developed in-house for the purification of IVT-derived mRNA.

The platform employs a pressure-based fluidic architecture operating within validated limits of 5 bar and 1.67 mL/min. Precise flow control is achieved through a Bronkhorst mini CORI-FLOW module, which integrates a Coriolis sensor with a piezoelectric valve under PID-based feedback, simultaneously providing inline measurements of mass flow rate, buffer temperature, and fluid density — offering an order of magnitude greater accuracy than conventional thermal methods. Three 3-way valves, actuated by an embedded processor board, manage buffer reservoir switching and mRNA sample injection. Passive check valves throughout the flow path prevent backflow, protecting column and sample integrity. All wetted tubing is 0.8 mm ID PTFE, selected for chemical inertness and RNA compatibility. Differential pressure across the chromatography column is continuously monitored for real-time detection of column fouling or blockage. UV absorbance is acquired directly by the control PC and integrated within a unified graphical user interface (GUI) alongside all process data.

System automation is managed through the GUI, from which the operator loads batch recipes defining flow setpoints, UV thresholds, pressure limits, and valve transition criteria. Once initiated, execution proceeds autonomously via the embedded processor board. A centralized data historian timestamps all process data, providing a complete auditable record. Automated safety interlocks operate independently of recipe logic, triggering an immediate flow-freeze upon any out-of-limit event. A dedicated software module estimates mRNA quantity from UV peak area integration, currently being benchmarked against commercial quantification systems alongside HPLC-based purity analytics.

This work demonstrates that a high-precision, fully instrumented purification platform can be built in-house, offering a flexible and cost-effective alternative for mRNA manufacturing workflows.

Downstream Processing



Gianna Sim

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Downstream Processing of Small-molecule Drugs produced by Whole Cell Biotransformation

Gianna S.S. Sim, Sally L. Gras, Enrico Mancini, Tim Bowser, Sandra E. Kentish, George Q. Chen

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Microbial cell factories are increasingly used as chassis for the biosynthesis and biotransformation of high-value pharmaceutical compounds. One important example is the biotransformation of oripavine to nororipavine by engineered *Saccharomyces cerevisiae*, where nororipavine serves as a key precursor in the manufacture of opioid antagonist drugs. As synthetic biology research in upstream processing continues to drive higher titres, downstream processing has become the primary bottleneck and cost-driver [1], shifting the focus of recent research. This challenge is compounded by the increasingly complex impurity profiles that accompany high-titre upstream processes [2], creating an urgent need for intensified, alternative purification technologies.

Cell clarification by membrane filtration often forms the first step following fermentation to separate the product from the cells. Tangential flow ultrafiltration (UF) can serve as a single unit operation to remove cells and host cell proteins while recovering the target extracellular, small molecule drugs in the permeate. Pretreating cells prior to membrane filtration may increase the efficiency of this clarification and product recovery step. Cell viability is not critical during downstream processing and in some cases cell death can be beneficial, as it halts residual enzymatic activity that would otherwise degrade the product or release additional contaminants into the process stream. Preservation of yeast cell structural integrity is desirable for extracellular products, however, in order to achieve efficient solid-liquid separation and to avoid product losses that can occur following cell permeabilisation. pH and temperature can therefore be applied to impose controlled stress on yeast cells, modifying their physical characteristics without rupture to aid filtration without compromising product quality.

Microscopy and flow cytometry show that both pH and thermal pretreatments (80°C) can reduce cell rupture during filtration. This improves permeate flux by approximately three-fold relative to untreated microbial fermentation broth, while maintaining high protein rejection (98% and 87% for alkaline and thermal treatments, respectively). Small molecule transmission is also significantly improved ($106 \pm 5\%$ and $97 \pm 3\%$ for alkaline and thermal treatments, respectively, versus $94 \pm 3\%$ for untreated), which is of direct economic significance given the high value of these pharmaceutical compounds. However, both pretreatments increase yeast cell permeability, leading to intracellular accumulation of product. This suggests that an additional diafiltration step would be required to maximise overall yield. Such a step is commonly incorporated in industrial UF processing to manage viscosity constraints during concentration and would simultaneously serve to wash retained product from within the cells. These findings offer practical insights for optimising membrane-based downstream processing in yeast-based biomanufacturing and synthetic biology workflows.



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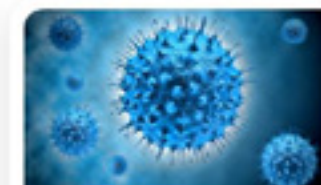
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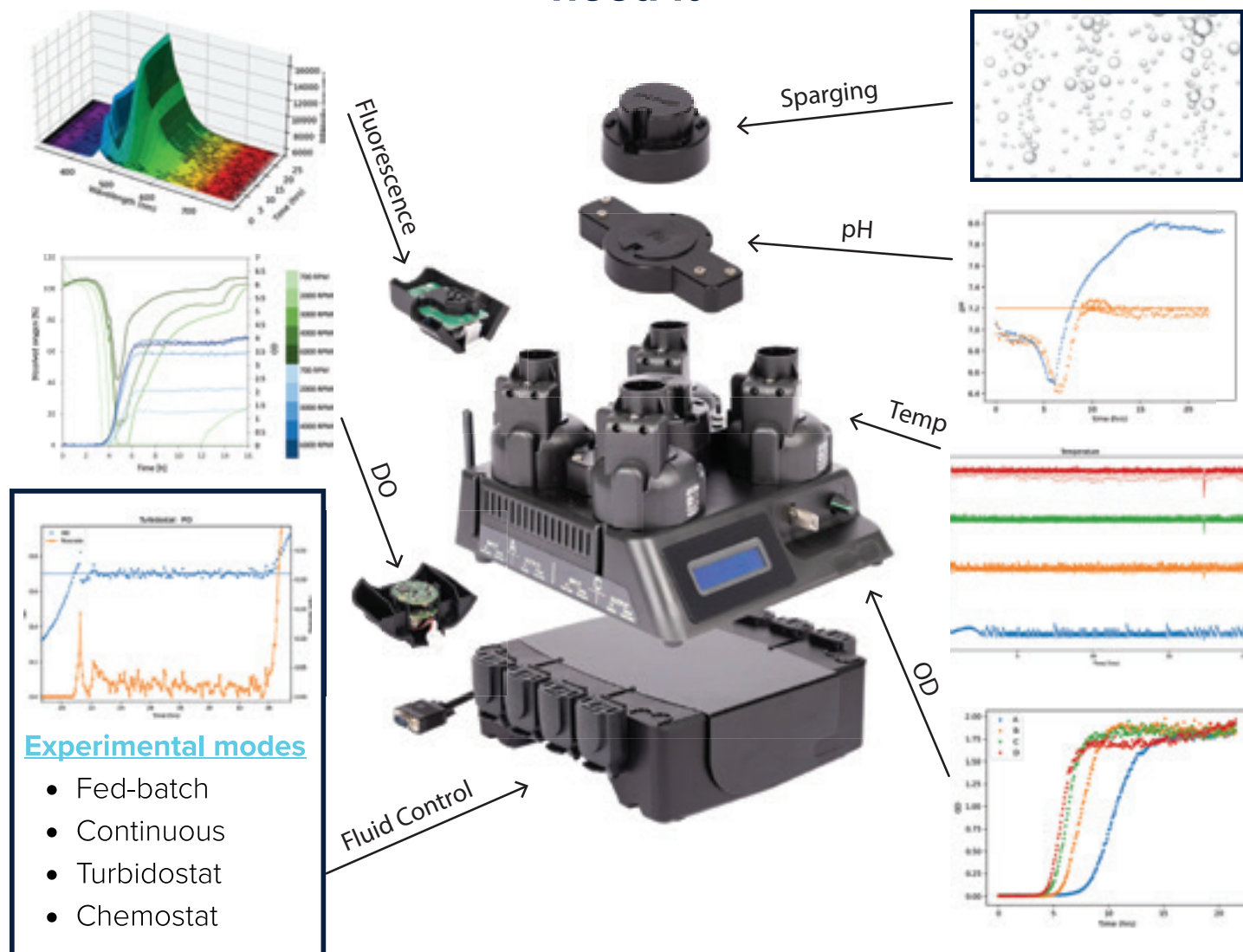
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The BioProcessing Network committee sincerely hopes you found this conference enjoyable and enriching.

Our central mission revolves around fostering collaborations through the exchange of technical knowledge, placing a deliberate emphasis on technical aspects rather than a purely business-oriented approach.

As we witness the emergence of new fields, we strongly believe that the accrued knowledge from one domain can prove invaluable when applied to the next, even as the challenges may differ. The presence of a network to facilitate connections across these diverse fields is more crucial than ever. Such a network not only accelerates progress but also provides a collaborative platform for addressing the multifaceted challenges we encounter today

Our aspiration is for you to depart with a strong sense of belonging to a community where your active contributions are highly valued. We strongly encourage your participation in shaping the 2027 BPN conference program and eagerly anticipate your presence next year!

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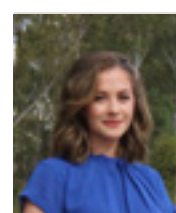
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