BioProcess International Theater

Day One AM: Global Supply Chain and CDMO Capacity

Day One PM: Global Access & Affordability of Biologics

Day Two AM: Cells and Upstream Processing

Day Two PM: Recovery, Purification and Viral Safety

San Diego Convention Center, June 22-25, BC, San Diego, CA

https://convention.bio.org/

2026 Tracks:

- **Day One AM: Global Supply Chain and CDMO Capacity**
- **Day One PM: Global Access & Affordability of Biologics**
- **Day Two AM: Cells and Upstream Processing**
- **Day Two PM: Recovery, Purification and Viral Safety**

Day One

San Diego Convention Centre, San Diego, CA

Tuesday 23rd June, 2026 **Day 1**

Global Supply Chain and CDMO Capacity	
Theme: Building resilient biologic supply chains, global capacity constraints, expansion in Asia and Eastern Europe, long term partnerships versus transactional outsourcing, technology innovation among CDMOs, data integrity.	
10am-10.15am	*Welcome Session: BioProcess Insider, Hosted by BPI Magazine*
10.15am-10.45am	**Strategic Operations and Analysis: Realizing Integrated Planning and Gross-to-Net** Whether emerging or mature, branded, specialty or generic, Life Sciences manufacturers that have enabled Integrated Planning and Gross-to-Net analytical capabilities are more successful in meeting their market access objectives and optimizing their operations. Join Argano's Pharosity Consulting team as they discuss real-world examples, enablement approaches for manufacturers in different situations, and the light-bulb moments when the benefits are fully realized. The team will also discuss the tools available for manufacturers large and small, and how to begin or enhance your journey to implementation. *Speaker: Brian Barbash, Partner, Pharosity Consulting Inc, An Argano Company*
10.45am – 11.05am	**Engineering Commercial Readiness: Aligning Scale, Geography, and Launch Risk** As biologics programs approach Phase III and BLA submission, manufacturing decisions become strategic inflection points. Commercial geography, inspection exposure, and infrastructure resilience now directly influence launch timing and long-term supply continuity. This session explores how sponsors can structure scale-up, engineering batches, and tech transfer within commercial-intent systems to reduce switching risk and prevent late-stage disruption. Drawing on real-world expansion and operational design considerations, the discussion highlights how disciplined scale-up strategy and U.S.-anchored manufacturing can serve as controlled bridges from development through PPQ and commercial launch. *Speaker: Mike Alston Jr., Executive Director of Operations, Bora Biologics* Bora Biologics
11.05am-11.25am	**Case Study**
11.25am-11.45am	**Industry Case Study: Syngene International** Syngene Putting Science to Work
11.45am – 12pm	*NETWORKING BREAK*
12pm – 1pm	BioProcess Insider Focus – 3 x 10-minute presentations followed by a Panel Discussion with all presenters. *CDMO Capacity and Client Partnership Panel* • How do you ensure your capacity planning aligns with actual client requirements rather than assumptions? • How do you balance multiple clients competing for the same capacity windows? • How do you build flexibility into capacity planning when client needs can change rapidly? • How do you maintain quality standards while maximizing capacity utilization? • How do you communicate capacity constraints to clients while maintaining strong relationships? • What contingency plans do you have for equipment failures, product issues, or unexpected downtime? • What makes a CDMO-client relationship successful over the long term? *Speakers:* *Russell Miller, VP, Global Sales and Marketing, Enzene* *Dawn Ecker, Managing Director of bioTRAK Database Services, BDO*

	ENZENE
1pm – 2pm	*LUNCH BREAK*
2pm – 2.10pm	*Insider Interview: Enzene* *Himanshu Gadgil PhD, Chief Executive Officer, Enzene* ENZENE
2.10pm – 2.20pm	*Insider Interview: Rentschler Biopharma SE* *Speaker: Dr. Patrick Meyer, Global Head of Business Development, Rentschler Biopharma* Rentschler Biopharma
2.20pm – 2.30pm	*Insider Interview: Samsung Biologics* *Speaker: Jeff Mason, Vice President, New Jersey Sales Office, Samsung Biologics* SAMSUNG BIOLOGICS
2.30pm – 2.40pm	*Insider Interview: Catalent* *Speaker: John Tomtishen, Global Head of Cell Therapy Field Application Scientists and Strategic Alliances, Catalent* Catalent
Global Access and Affordability of Biologics	
Theme: Rising R & D and manufacturing costs, innovation versus affordability, Global biosimilar adoption, IP and patents, regional productoin hubs for access, tech transfer, cold-chain logistics, pricing models	
2.40pm – 3pm	**Enabling Affordable Biologics Through Advanced Process Optimization:** **A Manufacturing Case Study** Affordability remains a key challenge for biologic medicines, particularly for mature products under increasing cost and access pressure. Beyond innovation at the molecule level, manufacturing efficiency and robustness are critical enablers of sustainable patient access. This presentation demonstrates how systematic process optimization can significantly improve productivity, execution reliability, and cost-efficiency of biologic drug substance manufacturing. A real-life case study shows how an underperforming manufacturing process was transformed into a robust and scalable solution through structured postvalidation improvement. Targeted optimization and selective revalidation of critical process steps resulted in measurable gains in yield, consistency, and operational performance without major infrastructure changes. The case highlights the value of deep process understanding, data-driven decisions, and disciplined GMP execution. Ultimately, it illustrates how advanced manufacturing capabilities directly support cost reduction and supply sustainability, key drivers of biologics affordability, as well as showcases Rezon Bio's strength in continuously improving and future-proofing biologic manufacturing processes *Speaker: Anna Zamojska-Jaroszewicz, PhD, Director of Drug Substance Manufacturing, Rezon Bio* Rezonbio
3pm – 3.15pm	*NETWORKING BREAK*
3.15pm – 3.35pm	**Case Study From Enzene** *Shilpa Gadgil, VP, Head of Bioprocess Development, Head of CDMO Development, Enzene* ENZENE
3.35pm – 3.55pm	**Leveraging AI/ML for GMP processes** *Alexa Kopf, Manager, BDO USA*
3.55pm – 4.30pm	**PANEL DISCUSSION: Biologics Breakthrough: Cutting Costs While Expanding Global Reach**

	What manufacturing innovations have delivered the most significant cost reductions while maintaining product quality in your biologics operations? How are you balancing the capital investment required for continuous manufacturing against the long-term cost savings and efficiency gains? Which specific single-use technologies have provided the best combination of cost reduction and manufacturing flexibility in your experience?
End of Day 1	

Day Two

Wednesday 24th June, 2026 **Day 2**

	Cell & Gene Therapies
Theme: Innovations in bioprocessing technologies for cell and gene therapies, overcoming scalability challenges in manufacturing, ensuring product consistency and quality in cell and gene therapies.	
9.30am-10am	**Industry Keynote: Case Study – How a QbD Approach Assisted with the Commercialisation of a Stem Cell Therapeutic Drug, Accelerating the Product to Market** This presentation describes the progress of a stem-cell therapeutic & commercial development from phase 3 and lessons learned. Specific challenges existing within the stem cell therapeutics and regenerative medicine arena will be discussed. The application of QbD & DoE to the process and the assays used to address CPPs and CQAs aspects of the product will be discussed as well as how these approaches aided successful PAI and BLA approval. *Speaker: Lee Smith, Principal Consultant, Director, Greyrigge*
10am – 10.20am	**Industry Case Study by Thermo Fisher Scientific** *Speaker: Adam Goldstein, Sr. Director, R&D Collaborations, BioProduction Group* ThermoFisher SCIENTIFIC
10.20am – 10.40am	This session will cover a series of 1 x 20-minute presentations involving bioprocessing of the future. The aims of these….. • Single-use vs. stainless steel considerations • Perfusion and fed-batch optimization • Scale-down models and predictive capabilities • Real-time monitoring and control systems • High-producing cell line generation • Genetic stability and characterization • Media optimization and chemically defined formulations • Clone selection and banking strategies
10.40am – 11am	**Challenges and Innovations for cell and gene therapy – focusing on drug product formulation, fill-finish processes, and packaging for these advanced therapies** *Stephen Orosz, PhD, Managing Director, BDO*
	Cells and Upstream Processing
Theme: Clone selection and screening, stable cell line generation, transfection technologies, custom media development,Bioreactors, Upstream automation and PAT	
11am – 12pm	BioProcess Insider Focus – 10-minute presentation followed by a Panel Discussion with all presenters. Suggested Topic: Optimizing Upstream Bioprocessing and Cell Line Development: From Innovation to Implementation A Panel Discussion on Technologies, Strategies, and Services Driving Efficiency in Biomanufacturing
12pm – 1pm	*LUNCH*
1pm – 1.40pm	*BioProcess Insider Interviews: 4 x 10-minute interviews. Key Opinion Leaders will give their take on hot topics facing the industry at this time. This could include:*

	• How do you see AI/ML changing upstream processing in the next 5 years? • What's your perspective on the sustainability challenges in biomanufacturing? • How would you approach implementing continuous manufacturing for a new product? • What are the key considerations for cell and gene therapy manufacturing scale-up? • How do you balance innovation with regulatory compliance? • What role should digital twins play in bioprocess development? • How do you evaluate the business case for new technologies? • What are the biggest supply chain risks in upstream processing today?
Recovery, Purification and Viral Safety	
Theme: Harvest and Clarification, Capture and Initial Purification, Polishing and Impurity Removal, Filtration, Viral Clearance, Formulation, PAT	
1.40pm – 2.10pm	**Analytical Technologies: Innovations and Trends in Biologics Development** Analytical technologies and methods play a pivotal role in quality attribute understanding and control which are essential to the rapidly evolving filed of biologics development and manufacturing. This presentation explores some emerging technology trends and applications. Key innovations include multi-attribute method (MAM) via mass spectrometry, rapid microbial testing, AI-driven high-throughput screening (HTS), and Raman spectroscopy. These advancements facilitate Quality by Design (QbD), Process Analytical Technology (PAT), and digital twins, which accelerate drug development and enhance product quality and safety. *Speaker: Kevin Zen, Senior Director, CMC Technical Operations, Opthea*
2.10pm – 2.40pm	**AI in Biopharma CMC: Practical Applications for Real GMP Environments** This presentation explores practical applications of artificial intelligence across biopharmaceutical CMC, focusing on real-world use in GMP environments. It highlights AI-driven approaches to QMS, deviation and CAPA management, CDMO oversight, and Module 3 preparation. Emphasis is placed on implementation strategies that enhance efficiency while maintaining compliance, data integrity, and regulatory expectations. *Vadim Klyushnichenko, Ph.D., VP Bio/Pharmaceutical Development & Quality, Calibr-Skaggs Institute for Innovative Medicines*
2.40pm – 3pm	**A summary of how to manufacture a recombinant Capsid-based product (vaccine or vector) and how to apply Solvent/Detergent treatment for its viral safety validation** *Dawn Ecker, Managing Director of bioTRAK Database Services, BDO*
End of Theatre	