



**BioProcess  
International**  
by informa...

## **Theater**

### **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  
–  
11.45am

This session will cover a series of 3 x 20-minute presentations involving current needs by the industry that need to be met are:

- Strategies for promoting competition and biosimilar uptake
- Innovative approaches to health technology assessment (HTA)
- Lean manufacturing and process optimization
- Technology transfer and local production in LMICs
- Strategies for managing supply chain risks and disruptions
- Leveraging digital technologies for cost reduction

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:*

*A Representative from Enzene,*

*Dawn Ecker, Managing Director of bioTRAK Database Services, BDO*








1pm  
–  
2pm

*LUNCH BREAK*

2pm  
–  
2.10pm

*Insider Interview: Enzene*



2.10pm – 2.20pm	<p><i>Insider Interview: Rentschler Biopharma SE</i>  <i>Speaker: Dr. Patrick Meyer, Global Head of Business Development, Rentschler Biopharma</i></p> 
2.20pm – 2.30pm	<p><i>Insider Interview: Samsung Biologics</i></p> 
2.30pm – 2.40pm	<p><i>Insider Interview: Catalent</i></p> 
<b>Global Access and Affordability of Biologics</b>	
<b>Theme: Rising R &amp; D and manufacturing costs, innovation versus affordability, Global biosimilar adoption, IP and patents, regional product hubs for access, tech transfer, cold-chain logistics, pricing models</b>	
2.40pm – 3pm	<p><b>Enabling Affordable Biologics Through Advanced Process Optimization: A Manufacturing Case Study</b></p> <p>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</p> <p><i>Speaker: Anna Zamojska-Jaroszewicz, PhD, Director of Drug Substance Manufacturing, Rezon Bio</i></p> 
3pm – 3.15pm	<p><i>NETWORKING BREAK</i></p>
3.15pm – 3.35pm	<p><b>Case Study From Enzene</b></p> 
3.35pm – 3.55pm	<p>This session will cover a series of 1 x 20-minute presentations involving steps to optimise and achieve global access and reduce costs. Current needs by the industry that need to be met are:</p> <ul style="list-style-type: none"> <li>• Strategies for promoting competition and biosimilar uptake</li> <li>• Innovative approaches to health technology assessment (HTA)</li> <li>• Lean manufacturing and process optimization</li> <li>• Technology transfer and local production in LMICs</li> <li>• Strategies for managing supply chain risks and disruptions</li> <li>• Leveraging digital technologies for cost reduction</li> </ul>
3.55pm – 4.30pm	<p><b>PANEL DISCUSSION: Biologics Breakthrough: Cutting Costs While Expanding Global Reach</b></p> <p>What manufacturing innovations have delivered the most significant cost reductions while maintaining product quality in your biologics operations?</p> <p>How are you balancing the capital investment required for continuous manufacturing against the long-term cost savings and efficiency gains?</p> <p>Which specific single-use technologies have provided the best combination of cost reduction and manufacturing flexibility in your experience?</p>

What strategies have most effectively reduced cold chain costs while ensuring product integrity during global distribution?

How are you leveraging data analytics to identify and eliminate hidden cost drivers in your biologics manufacturing and distribution networks?

What approaches have successfully reduced regulatory compliance costs without compromising quality or patient safety?

How do you optimize the trade-off between centralized manufacturing efficiency and the cost benefits of regional production closer to end markets?

Which emerging technologies show the most promise for dramatically reducing per-unit production costs of biologics in the next five years?

What innovative pricing or distribution models are you implementing to expand patient access in price-sensitive markets?

How are you measuring and balancing the sometimes competing priorities of cost reduction, manufacturing efficiency, and broader global distribution?

**End of Day 1**

## Day Two

Wednesday 24<sup>th</sup> 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**  
**ThermoFisher**  
S C I E N T I F I C

**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** **Presentation and Panel Session: Optimizing Upstream Bioprocessing and Cell Line Development: From Innovation to Implementation**  
**A Panel Discussion on Technologies, Strategies, and Services Driving Efficiency in Biomanufacturing**  
*A Representative from Abzena and Associates*



12pm – 1pm	LUNCH
1pm – 1.40pm	<p><i>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:</i></p> <ul style="list-style-type: none"> <li>• How do you see AI/ML changing upstream processing in the next 5 years?</li> <li>• What's your perspective on the sustainability challenges in biomanufacturing?</li> <li>• How would you approach implementing continuous manufacturing for a new product?</li> <li>• What are the key considerations for cell and gene therapy manufacturing scale-up?</li> <li>• How do you balance innovation with regulatory compliance?</li> <li>• What role should digital twins play in bioprocess development?</li> <li>• How do you evaluate the business case for new technologies?</li> <li>• What are the biggest supply chain risks in upstream processing today?</li> </ul>
<b>Recovery, Purification and Viral Safety</b>	
<p><i>Theme: Harvest and Clarification, Capture and Initial Purification, Polishing and Impurity Removal, Filtration, Viral Clearance, Formulation, PAT</i></p>	
1.40pm – 2.10pm	<p><b>Overview of the latest analytics innovations</b>  <i>Speaker: Kevin Zen, CMC Technical Operations, Opthea</i></p>
2.10pm – 2.40pm	<p><b>AI in Biopharma CMC: Practical Applications for Real GMP Environments</b>  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.</p> <p><i>Vadim Klyushnichenko, Ph.D., VP Bio/Pharmaceutical Development &amp; Quality, Calibr-Skaggs Institute for Innovative Medicines</i></p>
2.40pm – 3pm	<p><b>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</b>  <i>Dawn Ecker, Managing Director of bioTRAK Database Services, BDO</i></p>
<b>End of Theatre</b>	