The BIOPROCESSING SUMMIT

Bioprocessing Summit 2025

Conference Track Summary – Intensified & Continuous Bioprocessing

Bioprocessing Summit, a Cambridge Healthtech Institute Event

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Executive Overview

The 2025 Bioprocessing Summit highlighted how biopharmaceutical manufacturers and technology developers are advancing toward more efficient, scalable, and cost-effective production models. Across sessions, speakers focused on process intensification, continuous manufacturing, and automation as key enablers of next-generation biologics production. Rather than incremental optimization, the emphasis was on rethinking traditional workflows, integrating unit operations, and addressing fundamental cost drivers such as media consumption, downstream complexity, and process variability.

Most Frequently Covered Issues

1. **Cost of goods and resource intensity**
   Media, consumables, and downstream processing remain major contributors to manufacturing cost, driving interest in strategies that reduce material usage, increase yield, and improve overall process efficiency.
2. **Transition from batch to continuous processing**
   While continuous manufacturing offers potential benefits in productivity and footprint, adoption is constrained by complexity, cost, and uncertainty around scale, demand, and development timelines.
3. **Process integration and system complexity**
   Combining multiple unit operations into integrated systems introduces challenges in scheduling, control, and risk management, requiring new approaches to automation and process design.
4. **Maintaining product quality and consistency**
   Ensuring stability, purity, and reproducibility across intensified or continuous processes remains a critical concern, particularly over longer run durations and across multiple processing steps.
5. **Scalability of advanced therapies and novel modalities**
   Emerging modalities such as iPSC-based therapies introduce additional complexity in cell processing, requiring scalable, automated solutions that preserve cell quality and enable consistent manufacturing.

Recurring Takeaways

- Automation and real-time control are essential to managing variability and enabling continuous operations at scale.
- Early process and platform decisions have long-term implications for scalability, cost, and flexibility.
- Reducing bottlenecks, whether in upstream, downstream, or system capacity, is critical to achieving true efficiency gains.
- Collaboration across technology providers and manufacturers is accelerating innovation and enabling more robust, end-to-end solutions.

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Downstream Process Intensification: Reducing Complexity and Cost in Bioprocessing

Full Video Here

Jennifer Knister, Tosoh Bioscience

The presentation examined how process intensification strategies are reshaping downstream bioprocessing, with a focus on reducing complexity, improving throughput, and lowering cost of goods. Intensification was defined as achieving more output with fewer resources, including shorter runtimes, reduced material usage, and higher productivity per run. These improvements are increasingly aligned with both economic and sustainability goals across biomanufacturing. (00:00:35–00:01:21)

One key approach discussed was reducing the number of chromatography steps in a traditional downstream workflow. By leveraging improvements in upstream product quality and advanced resin capabilities, it is now feasible in some cases to eliminate a polishing step while maintaining high purity and yield. Modeling data demonstrated that simplifying from three chromatography steps to two can significantly reduce material use, labor, and facility costs, with meaningful impact on overall process efficiency. (00:02:33–00:05:40)

The presentation also highlighted multi-column chromatography (MCC) as a complementary strategy for intensification. By operating columns in parallel and enabling higher load levels and flow rates, MCC can significantly increase productivity while maintaining comparable recovery and product quality. In addition to improving throughput, MCC reduces resin and buffer consumption, with modeling showing substantial cost reductions, particularly in clinical manufacturing scenarios. (00:07:13–00:12:00)

Finally, the role of modern resin design was emphasized as an enabler of intensification. Advances in resin materials allow for higher binding capacity and faster flow rates without compromising performance, offering incremental gains even within existing process frameworks. Combining these approaches, including integrated multi-step systems, represents a path toward more streamlined and scalable downstream operations. (00:13:25–00:16:07)

Key Takeaways

- Process intensification focuses on increasing output while reducing time, materials, and cost.
- Reducing chromatography steps can significantly improve efficiency without sacrificing quality.
- Multi-column chromatography enhances productivity through parallel processing and higher utilization.
- Advances in resin technology enable faster, more efficient downstream operations.

Media Recycling in Bioprocessing: Reducing Costs Without Compromising Productivity

Full Video Here

Jongyoon Han, PhD, Massachusetts Institute of Technology

The presentation explored a novel approach to reducing biomanufacturing costs by addressing one of the most significant contributors to cost of goods: cell culture media. While advances in upstream processing have improved productivity, gains have often been offset by increased media consumption, particularly in perfusion systems. Traditional attempts to recycle spent media have typically resulted in reduced productivity due to the accumulation of inhibitory byproducts such as ammonium and lactate. (00:00:00–00:03:02)

The speaker introduced a regeneration strategy designed to enable media reuse without compromising cell performance. By selectively removing charged waste products using an ion-based separation process, the system preserves key nutrients such as glucose while reducing toxic metabolites. Experimental results demonstrated that this approach can significantly reduce ammonium levels while maintaining nutrient balance, supporting continued cell growth and productivity. (00:04:30–00:07:24)

When applied within a perfusion system, the approach enabled up to 75% media recycling without meaningful impact on titer or productivity. Key performance indicators, including metabolite levels and product quality, remained stable over the course of the experiment, suggesting that controlled recycling can be integrated into existing workflows without disrupting downstream processes. (00:10:33–00:12:19)

Techno-economic modeling indicated that media regeneration has the potential to meaningfully reduce cost of goods and environmental impact, with further gains possible through higher recycling rates and extended run durations. While additional validation is required at scale, the approach represents a promising pathway toward more sustainable and cost-efficient biomanufacturing. (00:13:56–00:15:29)

Key Takeaways

- Media cost remains a major driver of bioprocessing economics, especially in perfusion systems.
- Selective removal of inhibitory byproducts enables effective media recycling.
- High levels of media reuse can be achieved without sacrificing productivity or quality.
- Media regeneration offers a path to lower costs and improved sustainability.

Continuous Bioprocessing Adoption: Balancing Flexibility, Risk, and Scale

Full Video Here

Panelists: Jeffrey Odum (Moderator), **Andrew Sinclair**, BioPharm Services, **Kenneth Hamilton,** Genentech

The panel explored the factors influencing the transition from traditional fed-batch processing to continuous biomanufacturing, emphasizing that the decision is highly context-dependent. Organizations must evaluate multiple variables, including product demand, process productivity, and development timelines, recognizing that shifting to continuous operations can solve certain constraints while introducing new complexities. (00:00:00–00:02:56)

A central theme was the importance of aligning production scale with demand and process capability. Continuous systems may offer advantages for specific production volumes, but they require careful consideration of scale-out versus scale-up strategies, as well as the uncertainty of future demand. Early platform decisions are critical, as switching between processing modes later in development can introduce significant challenges. (00:06:01–00:08:28)

Panelists also highlighted cost and infrastructure considerations, noting that continuous processing can involve higher fixed costs due to control systems and integration requirements. As a result, smaller-scale operations may struggle to justify the transition without sufficient efficiency gains. Ongoing innovation in integrating unit operations and reducing system complexity is expected to improve the economic case over time. (00:09:12–00:11:24)

Operational risks, including cell line stability, process consistency, and extended run durations, remain key considerations. While continuous processes can offer improved efficiency and reduced downtime, they also require robust platform strategies to manage variability and ensure consistent product quality over longer production cycles. (00:17:36–00:20:07)

Key Takeaways

- The shift to continuous processing depends on demand, productivity, and development strategy.
- Early platform decisions are critical due to limited flexibility later in development.
- Cost and system complexity remain barriers, particularly at smaller scales.
- Continuous processes require strong control of stability and consistency over extended runs.

Automating Cell Processing: Enabling Scalable iPSC Expansion and Differentiation

Full Video Here

Jacob Andrews, CARR Biosystems

The presentation examined how automated cell processing technologies can improve the scalability and consistency of induced pluripotent stem cell (iPSC) workflows. As iPSC-based therapies require multiple media exchanges, passages, and handling steps, maintaining cell health and consistency during expansion and differentiation is a critical challenge. Traditional methods such as gravity settling and manual centrifugation can introduce limitations in scalability, processing time, and reproducibility. (00:01:54–00:03:29)

The speaker introduced an automated centrifugation-based platform designed to streamline media exchange and cell handling within a closed system. By continuously separating cells from media and reintroducing fresh media within the same system, the approach reduces manual intervention while maintaining process control. Comparative studies demonstrated that cell expansion rates and aggregate morphology remained consistent with traditional methods, indicating that automation did not negatively impact cell quality. (00:03:29–00:05:04)

Further evaluation across multiple passages showed that the automated process preserved key quality attributes, including cell proliferation and pluripotency markers. In downstream differentiation studies, the system achieved comparable or improved performance relative to conventional approaches, supporting its applicability across different stages of the iPSC workflow. (00:05:04–00:06:50)

Scalability was highlighted as a key advantage, with the platform supporting both scale-up and scale-out strategies across a range of bioreactor volumes. Modeling and early implementation suggest that automated cell processing can reduce processing time while maintaining high recovery rates and consistent performance, positioning it as a viable solution for clinical and commercial manufacturing of advanced therapies. (00:06:50–00:08:26)

Key Takeaways

- iPSC workflows require consistent, scalable cell processing across multiple steps.
- Automation can reduce variability and improve process efficiency.
- Cell quality, proliferation, and differentiation can be maintained with automated systems.
- Scalable platforms support transition from development to clinical and commercial production.

Integrated Continuous Manufacturing: Operational Learnings from GMP Implementation

Full Video Here

Jill Paddock, Pfizer

The presentation examined the implementation of an integrated continuous manufacturing system for biologics, highlighting both technical and operational learnings from GMP campaigns. The system combines continuous, periodic, and batch unit operations into a single platform, enabling streamlined processing from upstream perfusion through downstream purification. This hybrid approach allows flexibility while maintaining the benefits of continuous processing, including improved resin utilization and reduced in-process holds. (00:01:49–00:04:11)

A key focus was the complexity introduced by integrating multiple unit operations, particularly in scheduling and process coordination. Decoupling steps, such as separating Protein A elution from downstream processing, was critical to preventing cascading disruptions across the system. Automation played a central role, with real-time monitoring and control strategies enabling dynamic adjustments to flow rates, loading times, and diversion decisions without operator intervention. (00:04:11–00:06:03)

Operational data revealed important insights into system capacity and efficiency. Variability in upstream titer and high-productivity molecules exposed bottlenecks in chromatography cycling, leading to product loss when the system could not process material quickly enough. Addressing these constraints required adjustments to alarm thresholds, sequencing of events, and prioritization of critical steps to improve throughput and reduce downtime. (00:11:04–00:14:48)

Process-specific learnings also highlighted the impact of operating conditions on product quality. Factors such as temperature during Protein A loading influenced impurity profiles, while optimization of downstream parameters improved impurity clearance and filtration performance. These findings underscore the importance of aligning process control strategies with both system dynamics and molecule-specific characteristics. (00:18:11–00:21:45)

Key Takeaways

- Integrated continuous systems require careful coordination across unit operations.
- Automation and real-time control are essential to managing process variability.
- System capacity constraints can lead to product loss if not properly addressed.
- Process conditions and control strategies directly impact product quality and efficiency.