



# PHARMA MANUFACTURING WORLD SUMMIT **PMWS23**

May 15-16, 2023 | Boston Marriott Copley Place | Boston, MA | [pharmamanworld.com](https://pharmamanworld.com)

MAY 14, 2023

## AGENDA

6:00 - 7:00 pm

*Sponsored By:*



**Boehringer  
Ingelheim**

*Welcome Drinks Reception*



MAY 15, 2023

7:00 - 7:45 am

**Registration and Breakfast**

*Sponsored By:*



**vibraclean**<sup>TM</sup>  
Controlled Environment Services

7:45 - 7:50 am

**Opening Remarks and Important Announcements**

7:50 - 8:00 am

**Chair's Welcome Address**

 **Massachusetts  
Institute of  
Technology**



***Charles L. Cooney***

*Robert T. Haslam Professor of Chemical  
Engineering, Emeritus, and Faculty  
Director, Emeritus Deshpande Center for  
Technological Innovation*

**MIT**

8:00 - 8:35 am

## Operational Excellence, Innovation & Teamwork as Enablers for Reimagining Medicine

As Novartis begins its journey to become a focused innovative medicines company, the Operations organization is evolving to make this ambition into a reality. A few years ago, we undertook a systematic approach of improving and optimizing our manufacturing capabilities. We brought in best practices, methodologies and tools to streamline processes, eliminate waste, reduce costs, improve quality and efficiency. We recognize that we have embarked on a continuous journey and we are happy to share how far we have come on:

- **Operational Excellence:** Embedding operational excellence to improve productivity and deliver high-quality medicines
- **Innovation:** Expanding platform capabilities in RNA, Cell & Gene therapies, Radioligand therapies as well as in Large & Small Molecules
- **Teamwork:** Unleashing the power of our people to combine a wealth of experience and expertise, leveraging the diversity of our teams



**Steffen Lang**  
President of Operations  
Novartis

8:35 - 9:10 am

## Our Journey in Next Generation Manufacturing: What We Can Achieve Together

- Where our organizations are heading as a community of pharmaceutical manufacturers
- Our current and future capabilities by geography, people, and technology
- Practical leadership approaches that empower us to tackle challenges and set ambitious goals for the future
- Next generation platforms that will change how we work and succeed
- Examples from Pfizer that illustrate these pursuits in action



**Jim Cafone**  
SVP Global Supply Chain  
Pfizer

### ROOM 1 CHAIR



**Charles L. Cooney**  
Robert T. Haslam  
Professor of Chemical  
Engineering, Emeritus,  
and Faculty Director,  
Emeritus Deshpande  
Center for Technological  
Innovation  
MIT

### ROOM 2 CHAIR



**Teresa Gorecki**  
Practice Lead  
Compliance Architects  
LLC

### ROOM 3 CHAIR



**Tori Arens**  
VP GM & Site Head  
Resilience, Inc.

9:15 - 9:50 am

## Managing Innovation and Variability in a Growth Environment

- How the pandemic impacted the structure and responsiveness of our global networks
- Responding to new geographic fluctuation of demand by disease states and patient delivery
- The challenges and opportunities posed by new product innovation and managing lifecycles

**BREAKOUT  
ROOM 1**  
STRATEGIC  
MANUFACTURING



**Andy Wirths**  
SVP Supply Americas  
AstraZeneca

9:15 - 9:50 am

**BREAKOUT  
ROOM 2**  
QUALITY

**The Uncommon, Common Sense of Organizational Change Management**

- The unfortunate truth behind organizational change management failures.
- What every executive leader should know regarding organizational change management.
- The role of executive leaders in organizational change strategy and implementation.
- Practical examples of successful organizational change.



**Laquisha E. Crawford**  
*Executive Director, Development  
and Commercial Biologics Quality  
Gilead Sciences*

9:15 - 9:50 am

**BREAKOUT  
ROOM 3**  
CELL & GENE  
THERAPY

**Evolving Our Supply Chain: Enabling Competitive Advantage through Strategic E2E Integration**

- What is an Integrated Platform Supply Chain and how does it enhance Customer Centricity?
- What are the Core Foundational elements and business outcomes of a strategic integration?
- How is Talent development accelerated in an Integrated Supply Chain?
- How the creation of segmented partnerships and operational constructs have become an agility driver



**Luis Roman**  
*VP Global Platform Leader-  
Small Molecules  
Johnson & Johnson*

9:55 - 11:35 am

**Pre-Arranged One-to-One Meetings**

10:00 am – 10:20 am: Meeting Slot 1/Networking  
10:25 am – 10:45 am: Meeting Slot 2/Networking  
10:50 am – 11:10 am: Meeting Slot 3/Networking  
11:15 am – 11:35 am: Meeting Slot 4/Networking

11:40 am - 12:15 pm

**WORKSHOP  
BREAKOUT  
ROOM 1**

**Why Your Digital Strategy May Be Incomplete: How Legacy Models Prevent End-To-End Digital Manufacturing**

- Why pharma organizations must diversify their digitization strategy, looking beyond legacy models that prevent complete, end-to-end digital manufacturing
- How a light, configurable MES can remove paper from production entirely and enable any-sized pharma company to fully utilize their MES across all lines and sites
- How a modern MES can digitally connect different data sources to close offline data gaps, improve data integrity and visibility, and unlock critical business intelligence



**Marty Smyth**  
*SVP, Go-To-Market Strategy  
MasterControl*

11:40 am - 12:15 pm

**WORKSHOP**  
**BREAKOUT**  
**ROOM 2**

## AI in Action: Leveraging AI to Maximize Quality and Efficiency in Drug Manufacturing

- Advanced technologies like AI are the keys to making your manufacturing data more useful
- Leveraging AI in two different areas:
  - o From clinical supply to scale up to full production manufacturing: How can you use your historical data and AI to help you transform and improve your tech transfer and production processes?
  - o Yield optimization use case: How AI can help you reduce waste and optimize batch production

**aizon**



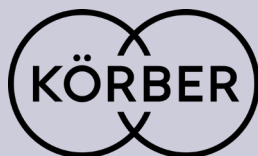
**Andy Alasso**  
Chief Product and  
Customer Success Officer  
Aizon

11:40 am - 12:15 pm

**WORKSHOP**  
**BREAKOUT**  
**ROOM 3**

## The Iterative Approach to a Digital Cell and Gene Therapy Process – an Overview & Best Practice

- Specific challenges in the digitization of CGT manufacturing
- Digital enablement of traceability in patient-specific processes
- A best practice approach to implementing electronic batch records for CGT
- An overview of digital data management for CGT processes



**Judith Koliwer, PhD**  
Principal Consultant, Cell & Gene Therapy  
Körber Pharma Software

12:20 - 12:55 am

**BREAKOUT**  
**ROOM 1**  
STRATEGIC  
MANUFACTURING

## Fireside Chat: The Emerging Role of the CDMO in Commercialization of Advanced Therapeutics

- With rapidly evolving science driving new therapeutic modalities, what is the role of a CDMO?
- The challenges of process development with accelerated approvals
- Building a manufacturing network to address tomorrow's needs
- What are the implications of the IRA legislation on the future of biotherapeutic manufacturing?

**[RESILIENCE**



**Spencer Fisk**  
Chief Technology Officer  
Resilience Inc.

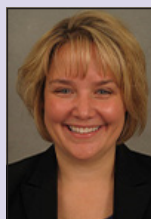
12:20 - 12:55 pm

**BREAKOUT**  
**ROOM 2**  
QUALITY

## Rethinking, Reinvesting, and Reinvigorating Our Quality and Compliance Processes

- Highlighting the Ultragenyx “Responsible Quality Mindset” culture
- Discuss the role of senior leadership commitment to implementing impactful change and creating a supportive, speak-up culture
- Driving ownership and employee engagement. Putting “Quality is everyone's responsibility” into practice.
- Establishing strong quality performance management. What are the KPIs and metrics that matter?
- Fostering a learning environment. How the focus on employee development drives quality performance.
- Encouraging continuous improvement
- Highlighting some of our success stories. What can other organizations on their own journeys learn from our experience?

**ultragenyx**  
pharmaceutical



**Kathy Azuara**  
SVP Global Quality  
Ultragenyx

12:20 - 12:55 pm

## Digitization and Visibility: The Future of Supply Chain Operations - a Small Parcel Distribution Case Study

TBA

**BREAKOUT  
ROOM 3**  
SUPPLY CHAIN



**Tim Elliott**  
Executive Director, North  
America Supply Chain Operations  
Merck



**Rich Kilmer**  
CEO  
CargoSense

12:55 - 1:55 pm

## EXECUTIVE LUNCH SEATING

Sponsored By:



12:55 - 1:55 pm

## THEMED LUNCH DISCUSSIONS

Themed lunches are roundtable discussions on specific industry issues and challenges during lunch hour. Each roundtable will be led by a sponsor or delegate who is an expert in the field. Limited seating is available, so please sign up for your preferred topic through the event app. Choose from:

### Using Effective Risk Communication to Facilitate Regulatory Approvals



**Sarah Miksinski**  
Executive Director  
AstraZeneca

### Last Mile to the Patient in Cell & Gene Therapy



**Christopher Temple**  
VP, Operations  
Athersys

### Building an Early Clinical-Stage Global Supply Chain to Support Autologous Cell-Based Product in Rare Indications



**José Manuel Otero**  
Chief Technical Officer  
Auregen

### Establishment of a Platform Technology: Process Characterization, Technology Transfer and Manufacturing Considerations for Success



**Aaron Allen**  
Director, Global Quality  
External Engagement  
Moderna

### Resource Forecasting and Agile Capacity Management Strategies



**Julie Go**  
Executive Director,  
Technical Operations -  
Strategy  
Seagen

### Lean/Six-Sigma Approaches in Biopharma Manufacturing



**Carl Finamore**  
Executive Director Gene  
Therapy Manufacturing  
Ultragenyx



Digitization in Clinical  
Manufacturing: Opportunities and  
Lessons Learned

**moderna™**



**Brendan Walker**  
Sr. Director, Digital  
Site Lead  
**Moderna**

Developing and Deploying a Quality  
Culture Excellence Program

**ultragenyx**  
pharmaceutical



**Ndidi Rickert**  
Associate Director, Quality  
Culture Excellence  
**Ultragenyx**

1:55 - 2:30 pm

**BREAKOUT  
ROOM 1**  
STRATEGIC  
MANUFACTURING

**The Vertex Story: Serial Innovation in Manufacturing**

- Sharing Vertex's track record for serial innovation in manufacturing to create transformative medicines for people with serious diseases and high unmet medical needs
- Highlighting Vertex's success with small molecule continuous manufacturing in Cystic Fibrosis
- Transforming manufacturing in cell and genetic therapies for Sickle Cell Disease, Beta Thalassemia, and Type 1 Diabetes



**Morrey Atkinson**  
SVP & Head, Commercial  
Manufacturing and Supply Chain  
**Vertex Pharmaceuticals**

1:55 - 2:30 pm

**BREAKOUT  
ROOM 2**  
QUALITY

**BEAST – Bioassay Standardization and Harmonization**

- Offering an overview of one of the more complex assays used to support therapeutic product development
- Discussing the practical and often complex elements of bioassays, ranging from critical reagents (e.g.-cell line, ligands, serum) to reference standard and plate control
- Demonstrating that the sustainability of these elements is vital to establishing and maintaining bioassays over the lifecycle of a therapeutic product
- Offering best practices to ensure testing is done at the right place and the right time
- Optimizing lab efficiency to provide timely accurate results
- Walking through our approach for standardization and harmonization of bioassays from initial commercialization through the end of the product lifecycle



**Babita Parekh**  
VP Analytical Sciences and Global  
Bioassay Steward  
**Eli Lilly**

1:55 - 2:30 pm

**Bespoke Dosing and Manufacturing for Pediatric Patients**



**Rick Panicucci**  
SVP CMC  
**BridgeBio**

**BREAKOUT  
ROOM 3**  
SUPPLY CHAIN

2:35 pm - 3:10 pm

**WORKSHOP  
BREAKOUT  
ROOM 1**



## Build vs Buy vs Blend: Comparing Challenges and Opportunities for Early-Phase Biopharmaceutical Manufacturing Options

- Exploring and comparing various options available to the biopharma industry for the manufacturing of clinical batches
- Looking at: Internal manufacturing, outsourced manufacturing, and hybrid models
- What are the current challenges and opportunities for these options? Discussing various considerations including economic and time



**Ravi Samavedam**  
Chief Innovation Officer  
Azzur Group



**Chris Mansur**  
EVP of Corporate  
Development  
Azzur Group

2:35 pm - 3:10 pm

**WORKSHOP  
BREAKOUT  
ROOM 2**

## Your “Future-Proofed” Platform Is Holding You Back: Look to the Future with Connected Life Sciences

- Is the platform approach the “be-all and end-all” of software solutions?
- Facing the challenge of no “one-size-fits-all” solution for every organization
- How certain approaches to quality can disrupt other parts of the business and upheave proven working systems in order to continue platform building
- Avoiding gaps in critical applications causing inefficiencies, as well as limiting the ability to make data-driven decisions
- Introducing you to a better way in which you don’t have to stop using the solutions and technology you’ve invested in
- Showing you how to enhance your infrastructure and pillar systems with minimal disruption
- Discussing why a connected life sciences approach is the future of quality



**Joe Goodman**  
VP Solutions Engineering & Customer  
Engagement  
Sparta Systems, A Honeywell Company

2:35 pm - 3:10 pm

**WORKSHOP  
BREAKOUT  
ROOM 3**

## Technical Operations Strategies for Transformative Medicines

- Current trends and manufacturing strategies for next-generation medicines
- Best in class practices for facility planning, build, operational readiness and startup
- New innovative technologies on the horizon

Panelists:



**Kara Price**  
VP, Site Lead  
Pfizer



**Charlie Harper**  
VP  
Project Farma



**David Ege**  
Chief Technology Officer, EVP Process  
Development, Quality & Supply  
Serres Therapeutic

Moderator:



**Adam Pfeiffer**  
VP  
Project Farma

3:15 - 4:25 pm

### Pre-Arranged One-to-One Meetings

3:15 pm – 3:35 pm: Meeting Slot 5 / Networking

3:40 pm – 4:00 pm: Meeting Slot 6 / Networking

4:05 pm – 4:25 pm: Meeting Slot 7 / Networking

4:30 - 5:05 pm

### Quality and Compliance from the Regulators' Perspective

- What are regulators looking for when they engage with QA/QC executives and other senior leaders? How can industry facilitate these interactions?
- Thinking about your processes and facilities from the point of view of the inspector: What are you taking for granted based on familiarity or habit or tradition that would not apply to a fresh pair of eyes?
- Highlighting best practices to make ongoing documentation a powerful quality and compliance tool for the future
- Using compliance as a starting point: What does exceeding expectations look like, and how should pharmaceutical manufacturers stay ahead of that moving target in perpetuity?



**Peter Marks**

Director – Center for Biologics  
Evaluation and Research (CBER)  
FDA

5:05 - 5:50 pm

### Panel: 'Next' Generation Manufacturing: What Did We Learn and Where Are We Going?

- Discuss how today's pipeline and technologies are reshaping biomanufacturing
- Looking at the technologies that enable next generation manufacturing processes
- Review case studies and strategies for rapid manufacturing scale up for leading products
- Focus on the necessity of investing in people and robust strategies to support the workforce and culture
- Show opportunities that allow for successful navigation in the future of manufacturing, including leveraging legacy and culture as drivers of change



**Chris Horan**  
Chief Technical  
Operations Officer  
Artiva Biotherapeutics



**Tim Moore**  
EVP, Chief  
Technical Officer  
Allogene



**Craig Kennedy**  
SVP Global  
Supply Chain  
Moderna



**Pat Yang**  
Vice Chairman &  
Co-Founder  
Resilience, Inc.

5:50 - 6:00 pm

### Chair's Closing Remarks



**Charles L. Cooney**

Robert T. Haslam Professor of Chemical  
Engineering, Emeritus, and Faculty  
Director, Emeritus Deshpande Center for  
Technological Innovation  
MIT



6:00 - 7:00 pm



6:30 pm

The Accenture logo, consisting of a purple chevron pointing right above the word "accenture" in a bold, black, sans-serif font.

**Will Host an Executive Dinner**  
**Location: Eddie V's Restaurant**  
**(Huntington Room)**  
(Exclusive to Delegates and Speakers  
– By Invitation Only )

MAY 16, 2023

7:30 - 8:25 am

Registration and Breakfast

*Sponsored By:*



7:45 - 8:20 am

**SmartFactory Rx® 2.0: Lessons Learned to Digitize our Pharma Future**

- Optimizing productivity and quality for manufacturing resilience and sustainability
- The flavors of Pharma 4.0
- The journey of defining the high value problems and opportunities
- Initial gains and deployment of real-time technology for continuous improvement
- Practical use cases of SmartFactory Rx: End to ... well the journey never ends

**BREAKFAST  
WORKSHOP**  
**BREAKOUT  
ROOM 2**



**Amy Doucette**  
Head of Business Operations  
APG Pharma



**Rick Johnston PhD**  
Head of Manufacturing  
Data Science  
APG Pharma

8:25 - 8:35 am

## Chair's Welcome Remarks



**Charles L. Cooney**

*Robert T. Haslam Professor of Chemical Engineering, Emeritus, and Faculty Director, Emeritus Deshpande Center for Technological Innovation  
MIT*

8:35 - 9:10 am

## Leading Through Transformations and Integrations – The Evolution of Global Product Development and Supply

Karin Shanahan, EVP, Global Product Development and Supply at Bristol Myers Squibb joins us to discuss how she is leading one of the world's largest manufacturing operations through rapid transformation, while integrating cutting-edge technology into BMS.

Among the highlights, Karin will discuss:

- How GPS delivers value to the enterprise through the Product Development and R&D interface.
- The integration of Cell Therapy into GPS and how the company is working to improve predictability long-term.
- Establishing a competitive advantage for BMS from within GPS – an operational model built to last.

Karin will also include successful examples of GPS's evolution to support the New Product Pipeline, most notably the recently approved Opdualag.



**Karin Shanahan**

*EVP, Global Product Development and Supply  
Bristol-Myers Squibb*

9:10 - 9:45 am

## Fireside Chat: The New Normal and Beyond: How to Design the Fit for Purpose Technical Operations Organization of the Future

- The Pharma/BioPharma ecosystem is rapidly evolving with new technology and innovative business models
- People and how we organize and empower them is at the core of competitive advantage
- We must consider geography, education and culture in training and retaining our most important asset
- With an increase in new modalities such as cell therapy, there is a new generation of Tech Ops professionals to train and nurture
- We need to examine how automation and AI might change workforce activities, productivity and workflow
- The Message: The Tech Ops organization of the future is being built today, your success depends on how we train and organize our people



**Carlo de Notaristefani**

*Former Lead, Manufacturing & Supply Chain Advisor  
Operation Warp Speed*

### ROOM 1 CHAIR



**Charles L. Cooney**

*Robert T. Haslam Professor of Chemical Engineering, Emeritus, and Faculty Director, Emeritus Deshpande Center for Technological Innovation  
MIT*

### ROOM 2 CHAIR



**Teresa Gorecki**  
Practice Lead

**Compliance Architects LLC**

### ROOM 3 CHAIR



**Tori Arens**  
VP GM & Site Head  
**Resilience, Inc.**

9:50 - 10:25 am

**BREAKOUT  
ROOM 1**  
STRATEGIC  
MANUFACTURING

**A Look into the Future: How Pharmaceutical Manufacturing Is Transforming to Bring Hope to Patients**

- Highlighting what industry will need to do differently to achieve an ambitious future where all patients can receive lifesaving medicines safely, swiftly, reliably, and affordably
- Providing a glimpse of how the world will evolve as molecular complexity increases in the future for small molecules, blurring the boundaries between small and large molecules
- Exploring the role that new technologies will play in achieving that transformation



**Jennifer Baxter**  
*VP, Small Molecule Science and  
Technology*  
**Merck**

9:50 - 10:25 am

**BREAKOUT  
ROOM 2**  
QUALITY

**Integrating OE and QMS- An (In Process) Journey to Quality as a Competitive Advantage**

- How setting up formal structures and investing in key people capabilities engages all levels of employees and allows a Quality Management System to push beyond a sole focus on processes and procedures



**Kaoru Nishino**  
*Executive Director, Global  
Quality Management Systems*  
**Bristol-Myers Squibb**

9:50 - 10:25 am

**BREAKOUT  
ROOM 3**  
SUPPLY CHAIN

**Supply Chain Constraints of High Value Raw Materials in mRNA Product Manufacturing**

- Discussing the challenge of supplying small, medium and large patient populations: What makes sense now, and what does the future hold?
- Implementing emerging technologies to facilitate modern demand driven supply chain processes
- Leveraging Data and Analytics to build a smarter supply chain to better serve patients
- Improving communication and visibility across the supply chain to drive efficient outcomes
- Assessing the potential of Machine Learning, IoT, Blockchain & Artificial Intelligence to drive our supply chain goals



**Murali Muralidhara**  
*Chief Technical & Manufacturing Officer*  
**RVAC Medicines, Boston, US**

10:25 - 11:15 am

**Pre-Arranged One-to-One Meetings**

10:30 am – 10:50 am: Meeting Slot 8 / Networking  
10:05 am – 11:15 am: Meeting Slot 9 / Networking

10:40 - 11:15 am

**Industry Focus Group**

An industry focus group is an informal moderated conversations among peers that occur during networking time outside the regularly scheduled conference agenda. There is no sign up. Delegates and speakers are welcome to opt in. The focus group will take place in the Exhibition Hall in a well-marked area. All participants will be provided with wireless headphones to ensure everything said can be heard over the background noise of the Exhibition Hall.

## INDUSTRY FOCUS GROUP — TALENT

### The Evolution of Manufacturing: Exploring the Digital Vision for the Future of our Industry



**Richard D. Braatz**  
*Edwin R. Gilliland Professor  
of Chemical Engineering  
MIT*

11:20 - 11:55 pm

#### Transforming a Global Development & Product Supply Network for Delivering a Multi-Modal Portfolio – It's More than Flexible Facilities

- Re-designing your organization to leverage capabilities across modalities in agile ways
- Designing technology platforms as you design products
- Laying the foundation for change during a pandemic builds flexibility and resilience in employees, setting the course for new ways of working and breaking down silos
- Strengthening a culture of inclusion and driving diversity in leadership ranks



**Jens Vogel**  
*SVP & Global Head of Biotech  
Bayer Pharmaceuticals*

12:00 - 12:35 pm

#### WORKSHOP BREAKOUT ROOM 1

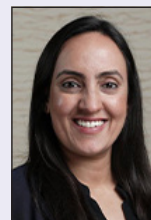
#### Can AI Deliver a 'Real' Advantage for Life Sciences Manufacturing?

- Exceed customer expectations, earn stakeholder trust, and positively impact the future of health
- How an increasing focus on digital transformation is creating opportunities for manufacturers to meet the challenges of disruption and a competitive marketplace
- Are you making the most of the tremendous volume of data being collected?
- Leveraging your organization's data foundation to provide actionable insights that enable improved decision-making and lead to positive outcomes across the manufacturing process
- Learn how data analytics and AI can help deliver insights that:
  - o Improve product yield
  - o Increase manufacturing efficiencies
  - o Streamline quality control
  - o Reduce maintenance and equipment costs
  - o Improve sustainability
  - o Plug into existing platforms.

Through consistent results, fuel your company's growth strategy and build a competitive advantage in delivering essential drugs and health care supplies to patients and their care givers when and where they are needed.



**Kim Forte**  
*Principal, SCNO  
Deloitte Consulting LLP*



**Iknam Gill**  
*Sr. Manager, SCNO  
Deloitte Consulting LLP*

**Deloitte.**



**Aishwarya Mantha**  
*Product Management Lead  
Deloitte Consulting LLP*

12:00 - 12:35 pm

**WORKSHOP  
BREAKOUT  
ROOM 2**



**Global Talent Trends in Pharma and Biotech Technical Operations: A Perfect Storm**

- The great reckoning – single-asset company valuation recalibrations reverse top talent trend and lead to unprecedented layoffs in the industry
- The generational gap continues to progress – leading only becomes more challenging
- Leaders in the healthcare industry indicate the greatest drop in leadership confidence across industries



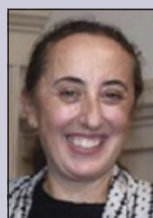
**Michael Kamarck**  
*Board of Directors  
Passage Bio*



**Pascal Bécotte**  
*Managing Director  
Russell Reynolds Associates*

12:00 - 12:35 pm

**WORKSHOP  
BREAKOUT  
ROOM 3**



**Amy Lovasco**  
*New Products Integration  
Lead, External Supply  
Pfizer*



**Omar Kassim**  
*Director of CDMO  
Relationship Management,  
PharmSci R&D  
Takeda Pharmaceuticals*

**Moderator:**



**Brad Wynja**  
*VP of Business Development  
INCOG BioPharma Services*

12:35 - 1:35 pm

**EXECUTIVE LUNCH SEATING**

*Sponsored By:*



12:35 - 1:35 pm



**INTERACTIVE THINK TANK LUNCHES**

During the Day Two Executive Lunch there will be three different 'Interactive Think Tank' topics set up in the Exhibition Hall.

These are informal and unmoderated networking opportunities for like-minded attendees to get together in small groups to brainstorm and discuss issues of common interest. Icebreaking questions and topics of possible conversation will be provided but are by no means mandatory.

**TOPIC 1**

Digital Transformation  
Tactics & Strategies

**TOPIC 2**

Talent Attraction, Training,  
& Retention

**TOPIC 3**

CMO/CDMO Challenges



1:35 - 2:10 pm

## Designing the Next-Generation Advanced Therapeutics Manufacturing Process

**BREAKOUT  
ROOM 1**  
STRATEGIC  
MANUFACTURING



**Richard D. Braatz**  
*Edwin R. Gilliland Professor  
of Chemical Engineering  
MIT*

1:35 - 2:10 pm

**BREAKOUT  
ROOM 2**  
QUALITY

## Quality Leadership before Quality Metrics and Quality Management Maturity

- CDER, FDA, has low confidence in quality management of the pharmaceutical industry due to drug shortages, which they state has manufacturing quality issues as the main cause.
- Industry is accountable for ensuring cGMP compliance and quality of products. However, companies can't continually improve their manufacturing processes to prevent drug shortages in a matter of weeks or months as changes require national health authorities approval prior to implementation. This usually takes years for full global approval of each change. So how do we solve this paradox of need for change, yet change takes years? By working together in new ways.
- From industry side it takes quality leadership, which is being discussed in this presentation. You'll hear about engaging the C-Suite and employees at all levels, what an effective quality system looks like, effective communication, how to apply Deming and Juran's teaching and more.

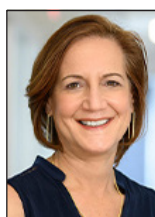


**Anders Vinther**  
*SVP Pharmaceutical  
Development & Manufacturing  
Kronos Bio*

2:15 - 3:00 pm

## Panel: How will the Way People, Processes, and Technologies Interact Change in the Next Ten Years?

- Discussing some of the forces and factors that are changing the way we operate
- Debating how these influences will continue to evolve, and how they will shape our organizations
- Technological progress is a given, but will there also be fundamental changes to our people and our processes in the next decade, or should we expect incremental modifications rather than a sea change?
- Thinking about Risk Management: How should we brace ourselves for the unexpected in a global business environment whose only constant factor is change?



**Joanne Beck**  
*Chief Technology  
Officer  
Aerium Therapeutics*



**Tim Moore**  
*EVP, Chief Technical Officer  
Allogene*



**Craig Beasley**  
*Chief Technology Officer  
BlueRock Therapeutics*

3:00 - 3:05 pm

## Chair's Closing Remarks



**Charles L. Cooney**  
*Robert T. Haslam Professor of Chemical  
Engineering, Emeritus, and Faculty  
Director, Emeritus Deshpande Center for  
Technological Innovation  
MIT*