

# AGENDA



PHARMA MANUFACTURING  
WORLD SUMMIT

# PMWS24

May 13-15, 2024 | Boston, MA



## BOSTON MARRIOTT COPLEY PLACE

### MAY 13, 2024

5:00 pm - 6:00 pm

#### Welcome Day Panel: Planning for Pharmaceutical Manufacturing of the Future: What are the Five Big Things We Need to Talk About?

- Is talent and workforce development in our industry changing? If so how and why?
- What are the most important new technologies in manufacturing today?
- What current factors are affecting speed of development and efficient manufacturing?
- What Regulatory progress has been made and what future opportunities exist?
- How can we improve the access of innovative medicines?

**KYOWA KIRIN**



**Paul Testa**  
EVP Supply Chain  
and Operations  
Kyowa Kirin



**MERCK**



**Marian Gindy**  
Vice President, Small  
Molecule Science and  
Technology  
Merck

**MYTHIC  
THERAPEUTICS**



**Sandra Poole**  
Chief Operating Officer  
Mythic Therapeutics



**PHASE<sup>3</sup>**



**Alex Cooke**  
CEO  
Phase3



**Christine Sheaffer**  
Head of Manufacturing  
& Supply  
Spark Therapeutics

6:00 pm - 7:00 pm

WELCOME  
*Drinks*

## RECEPTION



# AGENDA

**MAY 14, 2024**

7:30 am - 8:15 am

**Registration and Breakfast**

**Sponsored By:**

**FLUOR®**

8:15 am - 8:20 am

**Opening Remarks and Important Announcements**

8:20 am - 8:30 am

**Chair's Welcome Address**



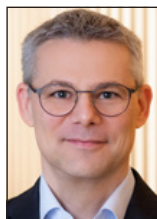
**Charles L. Cooney**

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

8:30 am - 9:05 am

**Manufacturing with An Agile and Flexible Mindset:**

- Building a strong manufacturing strategy that can cope with a constant changing environment
- Highlighting the importance of flexibility in asset design to better adapt to market fluctuation and reach desired time to market speed
- Becoming more agile and flexible in scaling-up new modalities (cell and gene therapies) to bring them at the required speed to patients
- Adapting to a new operating model to bring flexibility and agility in resource and capability planning unleashing the full potential of an organization



**Holger Weintritt**

*EVP, Head Pharmaceuticals  
Product Supply  
Bayer*

9:05 am - 9:40 am

**Strategic Expansion Roadmap: Fill & Finish Facilities for Global Growth**

- Exploring the strategies and considerations involved in building fill & finish facilities across a global manufacturing network.
- Discussing the importance of harmonization and global standards in pharmaceutical manufacturing and how we ensure consistency and quality across our facilities.
- Understanding the challenges and approaches in maintaining regulatory compliance when expanding fill & finish capabilities.
- Exploring the role of innovation and technology in enhancing efficiency and quality.



**Flemming Dahl**

*SVP; Head of Product Supply  
Fill & Finish Expansions  
Novo Nordisk*

# AGENDA

## 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

TBA

9:45 am - 10:20 am

### Panel: Optimizing Technical Operations: Best Practices for Manufacturing Next-Gen Medicines

**WORKSHOP  
BREAKOUT  
ROOM 1**

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

**PROJECT FARMA**  
A PRECISION FOR MEDICINE COMPANY



**Anshul Mangal**  
President  
Project Farma



**Flemming Dahl**  
Senior Vice President,  
Fill & Finish Expansions  
Management  
Novo Nordisk



**Ciaran Brady**  
Vice President MS&T  
Vertex Therapeutics



**Jason Politi**  
Chief Technology Officer  
Verve Therapeutics

9:45 am - 10:20 am

### Data Doesn't Lie - Digital Marketing ROI

**WORKSHOP  
BREAKOUT  
ROOM 2**

- Why digitizing production records and connecting to other systems is needed to remain competitive
- The areas where digital systems have significant impact and how that translates to the bottom line
- How digital systems can improve the work experience for operators
- How to clearly demonstrate the ROI of a digital system



**Martin Smyth**  
SVP Go To Market Strategy  
MasterControl

# AGENDA

9:45 am - 10:20 am

## WORKSHOP BREAKOUT ROOM 3

### Improving Visibility and Collaboration with CMOs and Direct Suppliers

- What key challenges drive supplier management leaders to digital transformation in the pharmaceutical industry?
- Achieving more agility with CMOs and direct suppliers
- Linking systems, processes, people and enterprises into a collective information network to support intelligent business execution
- Improving visibility and collaboration in supplier management operations

10:25 am - 12:05 pm

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

10:30 am – 10:50 am: Meeting Slot 1/Networking  
10:55 am – 11:15 am: Meeting Slot 2/Networking  
11:20 am – 11:40 am: Meeting Slot 3/Networking  
11:45 am – 12:05 am: Meeting Slot 4/Networking

12:10 pm - 12:45 pm

## BREAKOUT ROOM 1 STRATEGIC MANUFACTURING

### Manufacturing as a Strategic Enabler for Serial Innovation

- 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
- Transforming manufacturing in cell and genetic therapies for Sickle Cell Disease, Beta Thalassemia, and Type 1 Diabetes
- Describing the specific technical innovations and breakthroughs that have been instrumental in Vertex's manufacturing success
- Emphasizing the importance of cross-functional collaboration to drive manufacturing innovations and deliver transformative medicines



**Ciaran Brady**  
*Vice President, Manufacturing Science  
and Technology, Cell and Gene Therapy  
Vertex Therapeutics*

12:10 pm - 12:45 pm

## BREAKOUT ROOM 2 QUALITY

### Proactivity - the Future of Quality

- Using Human and Organizational Performance (HOP) in designing quality into the end to end supply processes and how to implement effectively
- Adopting risk-based approaches to identify and mitigate potential issues, maintaining a focus on critical processes and regulatory compliance
- Fostering a culture of continuous improvement, leveraging digital tools to optimize processes and enhance overall quality management
- Establish a proactive approach to regulatory compliance and production effectiveness using appropriate problem solving and conducting regular self-assessments



**Anthony Mire-Sluis**  
*SVP, Head of Global Quality  
AstraZeneca*

# AGENDA

12:10 pm - 12:45 pm

## BREAKOUT ROOM 3 SUPPLY CHAIN

### Navigating the Complexities of Gene Therapy Commercialization and Manufacturing

- Scaling up gene therapy production, the challenges, solutions and real world examples exploring the next frontier of manufacturing and its significance
- The future of external gene therapy development, meeting growing demand for advanced therapies
- The impact and transformation of advanced technologies on improving efficiency and product quality
- Exploring strategies for collaboration and partnerships for large scale gene therapy production
- Regulatory challenges in gene therapy manufacturing
- Case studies of successful external gene therapy commercialization and manufacturing models and discussing the future outlook of meeting the growing demand



**Ryan Bartock**  
Head of Engineering,  
Technical & Digital  
Spark Therapeutics

12:45 pm - 1:45 pm

### Executive Lunch Seating

12:45 pm - 1:45 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:

#### Best Practices for Integrated Business Planning in Pharma: Leveraging Connected Planning to Drive Growth



**Robert Honer**  
PMP CPIM  
Anaplan

#### Industry Trends, Challenges, and Opportunities in Process and Technology Platforms for the Commercialization of Gene Therapy Products



**Christopher Klem**  
Sr. Director Global  
Manufacturing  
AskBio

#### Knowledge Retention in a Time of High Turnover



**Kari Borroel**  
Head of Operations  
Quality Learning &  
Development  
AstraZeneca

#### Automation Technology to Unlock the Future of Cell Therapy Manufacturing



**Paul Kopesky**  
VP Cell Process  
Development  
Beam Therapeutics

# AGENDA

## Lessons and Opportunities in Value Stream Mapping



**Alok Bhatt**  
Senior Director, Biologics  
Value Chain, Global  
Manufacturing & Supply  
BMS

## Supply Chain Revolution: Prioritizing Patients in Pharmaceutical Logistics



**John Glavas**  
AVP External  
Manufacturing  
Merck

## Creating the Multi-Launch CTOs of the future: Who, How, & When?



**Alex Cooke**  
CEO  
Phase3

## Modernizing the Pharma Quality System. What is it and does it drive results?



**Lisa Winstead**  
Sr. Director – Site  
Quality Head  
Resilience

## Culture Transformation: from Compliance to Performance



**Yana Collins**  
Head of Quality Culture  
and Transformation  
Sanofi

## Leveraging Platform Processes for Efficient and Effective Gene Therapy Manufacturing



**Christine Sheaffer**  
Vice President of  
Manufacturing & Supply  
Spark Therapeutics

**Rusty Shreve**  
Director, Manufacturing Operations  
Spark Therapeutics

## Changing the Compliance Paradigm in Large, Global Companies



**Peter Shearstone**  
VP, Global Quality &  
Regulatory Affairs  
Thermo Fisher Scientific

# AGENDA

1:45 pm - 2:20 pm

## Driving Transformation in Quality to Meet the Needs of Our Customers

- Quality as a business driver by “Flipping the Ratio”
- Transforming business growth through Proactive Quality
- Preparing our organization for the future of Quality Assurance

**Johnson&Johnson**



**Robin Kumoluyi**  
*VP & Chief Quality Officer,  
J&J Innovative Medicine  
Johnson & Johnson*

2:25 pm - 3:00 pm

**WORKSHOP  
BREAKOUT  
ROOM 1**

## Accelerate Your Bench to Production Timeline by Collocating Research with Process Development and Pilot Scale Production

- Facilitate tech transfers between teams
- Transition from a PD lab to Pilot lab as business needs change
- Ensure quality of pharmaceutical products
- Improve your process as it evolves during optimization

**SmartLabs**



**Peter Genest**  
*Head of Client Solutions  
SmartLabs*

2:25 pm - 3:00 pm

**WORKSHOP  
BREAKOUT  
ROOM 2**

## The Value of a Unified Life Sciences Solution in Pharma 4.0

- Manage the production process and quality in real time from order to batch release in one browser-based user interface visualizing real-time and historical data
- Streamline collaboration between manufacturing and quality people and processes to maximize throughput and accelerate batch release
- Digitize all direct batch execution (EBR) and execution related activities (Logbooks and Digital Procedures) to eliminate paper or unstructured electronic records where data is trapped
- Take advantage of configurable functionality
- Analyze and report on operational data in one place for a single source of the truth
- Achieve measurable results in cost reduction, risk mitigation, and revenue opportunities

**Honeywell**



**Zillery Fortner**  
*Industry & Business  
Development Director  
Honeywell*



**April VanDenDriessche**  
*MES Technical  
Solutions Consultant  
Honeywell*

# AGENDA

2:25 pm - 3:00 pm

**WORKSHOP  
BREAKOUT  
ROOM 3**

## From “Impossible” to Commercialization

- Boehringer Ingelheim BioXcellence™ demonstrates how effective collaboration in contract manufacturing can expedite the delivery of innovative medicines
- Leveraging expertise in microbial development and manufacturing
- Toolbox approach for a groundbreaking cancer vaccine platform, that was honored with European Inventor Award in 2022
- Showcasing two perspectives from CMO and partner
- The session will highlight the power of collaboration and innovation in the pharmaceutical industry



**Boehringer  
Ingelheim**



**Scott DeWire PhD**  
*US Head, Business  
Development & Licensing  
Boehringer Ingelheim*



**Michael Kraich PhD**  
*Vice President of Global  
Project & Product  
Management BioXcellence  
Boehringer Ingelheim*

3:05 pm - 4:15 pm

## Pre-Arranged One-to-One Meetings

- 3:05 pm – 3:25 pm: Meeting Slot 5/Networking
- 3:30 pm – 3:50 pm: Meeting Slot 6/Networking
- 3:55 pm – 4:15 pm: Meeting Slot 7/Networking

4:20 pm - 4:55 pm

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

- 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
- Examples of GPS's evolution to support the New Product Pipeline



**Catalina Vargas**  
*SVP Global Supply Chain  
Bristol Myers Squibb*

4:55 pm - 5:30 pm

## Sanofi Manufacturing Transformation: Turning Science into Reality for Patients

- Our new purpose: we chase the miracles of science to improve people's lives
- Our race to make available breakthrough treatments & vaccines for patients supported by diverse modalities: accelerate product launches and optimize our asset performance
- Our ambition to develop a network of Factories of the Future



**Daniela Ottini**  
*SVP, Manufacturing and Supply  
Head of Specialty Care  
Sanofi*



# AGENDA

5:30 pm - 5:35 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*

5:35 pm - 6:35 pm

## Drinks RECEPTION



6:30 pm

**THE Executive DINNER SERIES**

**accenture**

**WILL HOST AN EXECUTIVE DINNER AT DEL FRISCO'S DOUBLE EAGLE STEAKHOUSE – BOLYSTON ROOM**  
(EXCLUSIVE TO DELEGATES AND SPEAKERS – BY INVITE ONLY)

**MAY 15, 2024**

7:30 am - 8:20 am

## Registration and Breakfast

**Sponsored By:**

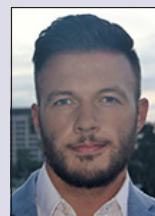
**FLUOR®**

7:45 am - 8:20 am

## BREAKFAST WORKSHOP BREAKOUT ROOM 2



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



**Jordan Croteau**  
*Sr. Director, Manufacturing Operational and Engineering Technology  
Moderna*

## Pioneering Manufacturing Automation Innovation with AI

- Leveraging lessons learned from the semiconductor industry for tech-first companies
- The journey of defining the high value problems and opportunities for personalized medicine
- Optimizing productivity and quality for manufacturing resilience and sustainability
- Speed to insights for "Right First Time"
- Innovation enabling improvements in key achievement drivers

# AGENDA

8:25 am - 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 am - 9:10 am

## A Vision for the Future: Moderna's Plans for mRNA Technology, Manufacturing and Scale

- Pivoting fearlessly: How Moderna transitioned from a pandemic to an endemic market
- Building for scale: Where the company is investing and partnering as it plans to launch up to 15 products in 5 years
- Prioritizing culture: What it took to encode the company's mindsets and unique culture



**Jerh Collins**

*Chief Technical Operations and Quality Officer*

**Moderna**

9:10 am - 9:45 am

## Integrating Customer Centricity and Innovative Technology into a Forward-Looking Manufacturing & Compliance Strategy

- How are biology and patient needs influencing risk-based investment and networking structure in the manufacturing space?
- Discussing route and location of administration, including MDCP considerations, components and suppliers, design standards
- Exploring flexible facilities, integrated clinical launches, and capital risk avoidance in the quest to get fast to clinical and fast to respond
- Understanding the need for early investment in platform changes. How is the emergence of ADCs, modality blurring, and market
- How do we ensure quality, risk management and compliance processes are in lock step as our technology and platforms evolve



**Anil Sawant**

*SVP Global Quality Compliance*  
**Merck**

# AGENDA

## 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



**TBA**

9:50 am - 10:25 am

### BREAKOUT ROOM 1 STRATEGIC MANUFACTURING

#### **Innovations in Personalized Medicine Manufacturing: A Glimpse into the Future**

- The growth of biologics and precision and personalized medicine is driving the need for new types of solutions across automation, manufacturing, and quality and compliance
- Learn how to modernize your operations and achieve manufacturing excellence using a future forward, agile, integrated, manufacturing solution that supports compliance and real-time quality management
- Take an industry standard approach to reach new levels of maturity in your digital transformation journey
- A look ahead at the expanding role of personalized medicine in pharma and overcoming hurdles in personalized medicine production and scalability



**Patrick Gammell**  
VP, Global Manufacturing Sciences  
**Biogen**

9:50 am - 10:25 am

### BREAKOUT ROOM 2 QUALITY

#### **Regulatory Update**

- Grasping the significance of FDA-CBER's oversight in pharma manufacturing, ensuring adherence to strict quality standards, safety measures, and ethical guidelines for global health and patient well-being
- Discuss efforts to expedite development of products for small populations through increased use of accelerated approval
- Review efforts toward global regulatory convergence
- Summarize internal changes and external initiatives at FDA in support of expeditious product development



# AGENDA

9:50 am - 10:25 am

## BREAKOUT ROOM 3 SUPPLY CHAIN

### Fireside Chat: Supply Chain Excellence: Balancing Resiliency and Efficiency to Enable Growth

- Exploring the complexity of the biopharma industry and using R&D to market authorization and global challenges
- Highlighting Amgen's supply chain optimization and discussing strategies for efficiency and network enhancement
- Showcasing Amgen's commitment to industry excellence while diving into it's leading manufacturing capabilities
- Ensuring reliable access to medicines with a patient focused supply assurance



**Nkem Ogbechie**  
*Head of Operations Strategic Planning, Risk and Analytics  
Amgen*

10:25 am - 11:15 am

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

10:30 am – 10:50 am: Meeting Slot 8/Networking

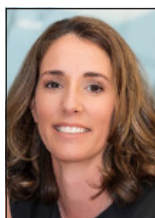
10:55 am – 11:15 am: Meeting Slot 9/Networking

10:30 am - 11:15 am

### Focus Group

Focus group is 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 into any focus group that interests them. The focus group will take place in the corners of the Exhibition Hall in well-marked areas that include a sound barrier. All participants will be provided with wireless headphones to ensure everything said can be heard over the background noise of the Exhibition Hall.

## Focus Group Panel: The Evolving Future of Quality – Signals, Trends and Lessons

 Bristol Myers Squibb®

**Karin Ann Payne**  
*Vice President Corporate Quality  
Bristol Myers Squibb*

 **Kite**  
A GILEAD Company

**Vaishali Shukla**  
*VP Quality  
Kite Pharma*



**Lisa Winstead**  
*Sr. Director – Site  
Quality Head  
Resilience*

# AGENDA

11:20 am - 11:55 am

**WORKSHOP  
BREAKOUT  
ROOM 1**

## Three Essential Steps to Competitive Advantage

- Developing a step-by-step modular content production workflow suited to your organization, from inception to implementation
- Mapping key functions and resources for each stage of workflow including external partners
- Identifying critical enablers and challenges you may encounter at each stage and how to address them



11:20 am - 11:55 am

**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



11:20 am - 11:55 am

**WORKSHOP  
BREAKOUT  
ROOM 3**

## Beyond Capabilities and Capacity: What Traits Should Biopharma Companies Look for When Partnering with CDMOs

- Best traits to look for when partnering with a CDMO, besides just capabilities and capacity
- Best practices for discerning which CDMO's are best for biopharma companies to partner with
- Key steps for helping biopharma companies navigate complex sales processes with CDMOs



12:00 pm - 12:35 pm

**BREAKOUT  
ROOM 1  
STRATEGIC  
MANUFACTURING**

## Real Time Release: A Distant Dream or Reality?

- Insight into J&J's journey to implement real time multivariate analytics, PAT, modeling and feedback control
- Achieving integrated quality objectives, reducing non-conformance, enhancing quality control, and enabling real time release
- Integration of digitalization, data, and Quality By Design to intensify processes for flexible and modular manufacturing tailored to customer requirements in quality, price, quantity, and delivery
- Exploring the lessons learnt from the real-time release journey and their alignment with J&J's long-term vision of quality-driven progress

**Johnson&Johnson**



**Olav Lyngberg**  
*VP Innovation and Technology  
Deployment, Janssen Supply Chain  
The Janssen Pharmaceutical  
Companies of Johnson & Johnson*

# AGENDA

12:00 pm - 12:35 pm

## BREAKOUT ROOM 2 QUALITY

### Enhancing Quality Agility: Leveraging Insights from Cell and Gene Therapy for a Swift Clinical to Commercial Transition

- Exploring how the cell and gene therapy revolution is transforming the landscape of modern medicine
- The critical role of quality assurance and navigating unique quality and compliance challenges in advanced therapies
- Strategies for efficient scaling and market entry for the clinical to commercial transition and ensuring uninterrupted access to advanced therapies examining supply chain resilience
- Ensuring safety and efficacy as therapies reach wider populations utilizing real time monitoring and agile adjustments
- Showcasing real world case studies and demonstrating successful clinical to commercial transitions and their impact

B:OMARIN®



**Evelyn Marchany-Garcia**  
SVP, Chief Quality Officer,  
Technical Operations  
BioMarin

12:00 pm - 12:35 pm

## BREAKOUT ROOM 3 SUPPLY CHAIN

### Creating Resilient Supply Chains and Robust Manufacturing Platforms: Expediting the Commercialization of Cell and Gene Therapies

- Exploring the need for global collaboration among various stakeholders to expedite the delivery of cell and gene therapies worldwide, ultimately improving healthcare outcomes
- The complexities of cell and gene therapy supply chains and the importance of building resilience to ensure consistent access for patients
- The revolutionary potential of cell and gene therapies in healthcare and the unique manufacturing challenges they present
- Leveraging advanced technologies for automation resulting in driving efficiency and consistency adhering to regulatory compliance in the commercialization of these therapies, ensuring patient safety and satisfaction

12:35 pm - 1:35 pm

## Executive Lunch Seating

12:35 pm - 1:35 pm

## Themed lunch Discussions

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### CMC Considerations as We Revolutionize Cell Therapy Manufacturing



**Matthew Conover**  
Sr. Director Cell  
Therapy CMC  
BMS

### Integrating Green Chemistry Principles into Manufacturing Supply Chains



**Jonathan Tripp**  
Principal Scientist  
Gilead Sciences

**Michael O'Keefe**  
Senior Research Scientist  
II/Associate Director  
Gilead

# AGENDA

## Navigating Quality 4.0: Initiating Your Path in Pharmaceutical Manufacturing



**JR Humbert**  
VP Quality  
INCOG BioPharma Services

## Keeping Pace with the Evolving Quality and Regulatory Trends in Cell Therapy



**Scott Nichols**  
Director Quality  
Kite Pharma

## Realtime Manufacturing While Stabilizing The Workforce



**Dottie Barr**  
SVP Manufacturing &  
Technical Operations  
Lantheus

## Achieving Speed to Market in an Evolving CGT landscape Via Laser Focus on Compliance, Systems and People



**Elena Kichula**  
Sr. Director – Manufacturing,  
Science, and Technology and  
Process Engineering  
Spark Therapeutics

**Vaishal Patel**  
QA Site Lead  
Spark Therapeutics

1:35 pm - 2:10 pm

## Maximizing Quality and Compliance: A Strategic Approach for Pharmaceutical Manufacturing

- Introduction to the need for quality and compliance transformation and the impact of shifting regulatory landscapes on quality assurance and compliance
- The role of advanced technologies in enhancing quality practices, ensuring data integrity and improved product safety and efficacy
- Strategies for supplier quality management for maintaining consistency and building a culture of quality and compliance
- Case studies highlighting quality driven practices that have led to improved transformation in enhancing quality practices
- Real world success stories in transforming quality practices for the modern pharmaceutical landscape



**Valerie Brown**  
SVP, Global Quality Assurance  
Gilead Sciences Inc.

# AGENDA

2:10 pm - 2:45 pm

## Panel: Looking Backwards, Looking Forwards: Maximizing Our Impact on the Future of Medicine

- How has this changed the CMC ecosystem, and are we overbuilding capacity again?
- Avoiding the dangers of fragmentation. How should we better communicate, collaborate, and consolidate our best ideas so we all succeed?
- Discussing the reasons to set up a new company today, and imagining how our business ecosystem will continue to grow and evolve
- Debating which production platforms will best suit the newer modalities
- Exploring the next steps for existing platforms like mAbs, ADC's, mRNA: How do we efficiently serve giant markets such as Alzheimer's indications, for example?



**Joanne Beck**  
Chief Technology Officer  
Aerium Therapeutics



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



**Alex Cooke**  
CEO  
Phase3



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

2:45 pm - 2:50 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