PHARMA MANUFACTURING
WORLD SUMMIT
PMWS22

March 29-30, 2022 | Boston Marriott Copley Place | Boston, MA | pharmamanworld.com

AGENDA

MARCH 28, 2022

6:00 - 7:00 pm

Welcome Drinks Reception

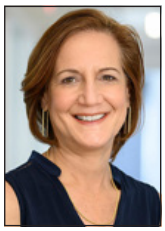
MARCH 29, 2022

7:00 - 7:45 am — **Registration and Breakfast**

7:45 - 7:50 am — **Opening Remarks and Important Announcements**

7:50 - 8:00 am — **Chair's Welcome Address**

BOSTON pharmaceuticals



Joanne T. Beck
Chief Operating Officer
Boston Pharmaceuticals

8:00 - 8:35 am — **What Lessons Should Pharmaceutical Manufacturers Take Away from Operation Warp Speed?**

- Offering an overview of the public-private partnership that facilitated and accelerated the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics
- During the pandemic our industry faced crisis and achieved the seemingly impossible. What drives an extraordinary performance?
- Building stronger bonds of communication, collaboration, and coordination between industry partners and regulators to serve patients better
- Discussing which parts of our experience with Operation Warp Speed can be built into our industry's long-term future

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

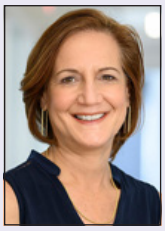
8:35 - 9:10 am

The Things We Can Achieve and Our Shared Journey Along the Way

- How the pandemic has impacted innovation, technology, people and our ways of working and thinking
- Understanding current capabilities and where we need to be collectively headed as a community of pharmaceutical manufacturers
- Strategies that compel and empower us to move beyond past constraints and set new, ambitious goals for the future
- Thinking beyond the data to find purpose and meaningful connections for people

Arleen Paulino
SVP Global Manufacturing
Amgen

ROOM 1 CHAIR



Joanne T. Beck
Chief Operating Officer
Boston Pharmaceuticals

ROOM 2 CHAIR

Jack Garvey
CEO
Compliance Architects LLC

ROOM 3 CHAIR

Michael Weisenbeck
VP
Körber Pharma Software

9:15 - 9:50 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Big Future for Small Molecules: How Merck is Reshaping the Manufacture of Small Molecules Within a Broader Manufacturing Transformation

- Outline how small molecule manufacturing is being reshaped within the broader transformation of a world-leading biopharmaceutical and vaccine manufacturer
- Discuss how today's pipeline and technologies are reshaping this future and how to remain agile for future changes
- Review case studies and strategies for rapid manufacturing commercialization
- Focus on the criticality of investing in people and how culture has to evolve as an enabler of transformation

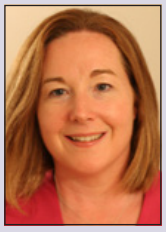
Ger Carmody
SVP, Global Pharmaceutical Operations
Merck

9:15 - 9:50 am

BREAKOUT ROOM 2
QUALITY

Global Quality in Takeda: Integration, Transformation, and Innovation

- Overview of Takeda
- Global Quality roadmap and transformation of Quality Management Systems
- Innovation through digitalization
- Quality Culture



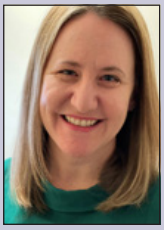
Elaine Shannon
Head of Oncology External Supply Small Molecule Global Quality
Takeda

9:15 - 9:50 am

Supply Chain Resilience: Navigating Uncertain Global Environment to Manage Successful Supply Chains

- Global supply chain disruptors: Is this the new normal?
- Building resilience in supply chain: Reactive, active or proactive approach
- Looking ahead: Don't lose hope!

BREAKOUT ROOM 3
SUPPLY CHAIN



Jennifer McGee
Supply Chain Strategy Director
GSK

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

Quality 4.0: Making the Shift to Continuously Monitor the Health of your Quality Management System

- Discuss the current Quality 4.0 environment and address common roadblocks and keys to success
- How we are applying what we've learned to help companies transition to continuously monitor the health of each component of the quality system with predictive and behavioral analytics
- Leveraging real-time actionable data to establish a collaborative, proactive and preventive culture
- Ensuring quick results and getting the most value of your investments in Quality 4.0 initiatives

WORKSHOP
BREAKOUT ROOM 1

Jaime Velez
Co-Founder
Operations & Quality Systems Improvement Experts (OQSIE)

11:40 am - 12:15 pm

Shaping the Future of Quality by Design by Integrating Digital QMS and Continuous Process Verification

Discover how AI-enabled continuous process verification and digital quality management are working together to:

- Significantly reduce manufacturing defects and the cost of poor quality
- Accelerate new product introductions and on-time delivery
- Enable continuous business process improvement and proactive quality management

Join us in this session when we'll discuss key capabilities including 'Review by Exception', which prevents costly product release delays; and 'Manufacturing Anomaly Capture', which optimizes CAPA effectiveness monitoring; and much more.

WORKSHOP
BREAKOUT ROOM 2

Steve McCarthy
VP of Digital Innovation
Sparta Systems, A Honeywell Company

11:40 am - 12:15 pm

Are We There Yet? Tackling Manufacturing Challenges with the Digital Plant

- Setting a destination that meets organizational and plant goals
- Mapping digital plant technologies that help me reach my destination
- Applications: speedy tech transfer, managing multiproduct facilities, and ensuring quality in continuous manufacturing

WORKSHOP
BREAKOUT ROOM 3

EMERSON

Michalle Adkins
Director, Life Sciences Consulting
Emerson Automation Solutions

12:20 - 12:55 pm

Moving at the Speed of Science

- Science Will Win: Pfizer's 5-point plan and industry pledge to finding solutions to the global health crisis
- Pushing the boundaries of what's possible: Moving at Lightspeed
- Hope Changes Lives: The development, manufacture, and distribution of the COVID-19 vaccine and oral treatment
- Key takeaway: Making the Impossible Possible

Pfizer

John Kelly
VP, Quality Operations and Environment, Health & Safety, Pfizer Global Supply
Pfizer Inc.

12:55 - 1:55 pm

LUNCH-AND-LEARN ROUNDTABLE 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:

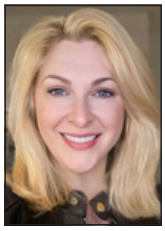
Tech Transfer: Quality, Cost, and Speed – Solving for All Three

ARCUTIS BIOTHERAPEUTICS

Greg Sukay
VP Manufacturing & Process Technologies
Arcutis Biotherapeutics

Scaling QMS for Small Biotech and Pharma

BOSTON pharmaceuticals



Kerry Hawitt
SVP Head of Quality & Compliance
Boston Pharmaceuticals

Speed, Scale, and Efficiency: How Can You Drive Additional Value from Manufacturing and R&D Facilities?

JLL®

Ernesto Gemoets
Executive Director, Life Sciences
JLL

Required Agility in Cell & Gene Operations

RubiusTherapeutics

Dannielle Appelhans
Chief Operating Officer
Rubius Therapeutics

Gene Therapy Manufacturing and Facility Design

Spark THERAPEUTICS

George Skillin
Head of Engineering, EHS & Facilities Management
Spark Therapeutics

Joseph O'Brien
Head of Engineering Operations – Scientific & Manufacturing Facilities
Spark Therapeutics

Competing for Resources and Materials for mRNA Therapeutics

Translate BIO

Greg Troiano
Chief Manufacturing Officer
Translate Bio, A Sanofi Company

1:55 - 2:30 pm

Network Strategy and Operations for an Innovative Pipeline

- Managing risk and unpredictability in a highly innovative environment
- Adapting to change
- Partnership skills as a differentiator
- Developing the culture to thrive
- Talent strategies in a competitive and changing marketplace

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Bristol Myers Squibb™

Manel Luis
Interim Pharma Operations Lead
Executive Director, Strategy and Business Operations | Global Manufacturing Operations
Global Product Development and Supply
Bristol-Myers Squibb

1:55 - 2:30 pm

Rethinking and Adapting Our Quality and Compliance Processes for the CGT Ride

- Discuss some of the challenges unique to cell and gene therapy given the nature of the products and hyper-accelerated development and regulatory timelines
- Accelerated timelines require agility. How do you apply 'phase-appropriate' standards when there is less distinction between phases?
- Process history may be limited and analytical complexity is high. How do we apply lessons learned from biologics and early approvals in CGT to improve CMC and operational success?
- Session will cover lessons learned and practical advice for navigating these and other aspects of Quality & Compliance for cell and gene therapy development and approval

BREAKOUT ROOM 2
QUALITY

2seventybio

Kathleen Munster
SVP, Enabling Functions (Quality, Facilities, & IT)
2seventy bio

1:55 - 2:30 pm

Establishing and Managing Successful Partnerships with CMOs

- Why partnering with CMOs and when is the right time to seek out a CMO for commercial manufacturing?
- How to set up an external manufacturing organization? What are the ways of working with CMOs? How to measure performance?
- Can digital be leveraged while working with CMOs? To which benefits?

BREAKOUT ROOM 3
SUPPLY CHAIN

sanofi

Cedric Dubois
Head of Biologics External Manufacturing
Sanofi

2:35 - 3:10 pm

Is Your Electronic Batch Record Truly Complete?

- Explaining the difference between a partial and complete electronic batch record (EBR)
- Demonstrating that partially digital but disconnected batch record management is as inefficient as paper for managing production data
- Showcasing how fully digitized batch records enable smarter, faster manufacturing, so manufacturers can make immediate performance gains at every step
- Illustrating how today's technology is configurable to a variety of manufacturing scenarios to create a complete, beginning-to-end EBR that other solutions do not

WORKSHOP
BREAKOUT ROOM 1

MasterControl™

Brian Curran
SVP of Strategic Growth
MasterControl

2:35 - 3:10 pm

"Back to the Future": Weaving in a Virtual World into Our "Old Normal"

Since 2020, we have all heard the statement "a new normal" more times than we can count. So, how do we get back to "business as usual" and back to our old normal? The answer is, we don't. We need to adapt our way of doing business and weave our newly founded virtual world into our old way of doing business. Some helpful hints of how to do that, especially with Vendors, CMOs, and off-site audits:

- Introducing a hybrid system
- Planning and project management
- Outlining and managing risk

WORKSHOP
BREAKOUT ROOM 2

PROPHARMA GROUP®
Improving Patient Health and Safety

Simona Mills
Director of Product Lifecycle Management
ProPharma Group

2:35 - 3:10 pm

Value Creation Strategies for Early Phase Drug Products Using Prefilled Syringes

- The contract manufacturing industry has continually demonstrated its adaptability and ingenuity in better serving small to mid-size pharmaceutical and biotechnology companies
- To further grow capacity for sterile filling services, PCI is tackling the timeline challenges and cost of obtaining stability data by expanding the use of prefilled syringe availability in early phase development
- Learn about the benefits to using prefilled syringe filling to gather stability data for value to your early stage clinical programs

WORKSHOP
BREAKOUT ROOM 3

pci PHARMA SERVICES

Shawn Cain
SVP of Development and Manufacturing
PCI Pharma Services

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

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
- Our response to COVID: Operating with a global Supply Chain in a changing environment impacted by COVID and leveraging our assets to fight against the pandemic

sanofi

Brendan O'Callaghan
EVP, Global Industrial Affairs
Sanofi

5:05 - 5:40 pm

Idea to Performance: The Impossible Journey

- Moderna pre-pandemic times: Sciences, Platform, and Company History
- Moderna's preparation COVID-19. Operations insight for an unprecedented scale-up
- Execution against the plan. Overcoming challenges
- Moderna's future operations

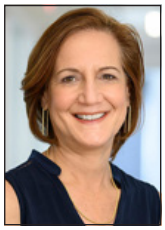
moderna

Juan Andres
Chief Technical and Quality Officer
Moderna

5:40 - 5:50 pm

Chair's Closing Address

BOSTON pharmaceuticals



Joanne T. Beck
Chief Operating Officer
Boston Pharmaceuticals

5:50 - 7:00 pm

Drinks Reception

MARCH 30, 2022

7:30 - 8:30 am

Registration and Breakfast

7:50 - 8:25 am

Establishing a 'Culture of Data' in Pharma Manufacturing

- Pharmaceutical manufacturers have worked diligently and successfully to foster a 'culture of quality' at their organizations. The result has been fewer overall regulatory citations year over year since 2010
- The evaluation of data, while helping improve the quality of products, has been a difficult transition for large and small manufacturers alike. Process improvement and potential efficiency gains are accomplished slowly and reactively
- Manufacturers must now establish a 'culture of data,' where decisions on the shop floor are made quickly and proactively based on evolving process information. This session will highlight the industry trends in these areas and provide examples of value that can be realized in making this new shift

BREAKFAST WORKSHOP
BREAKOUT ROOM 2

aizon

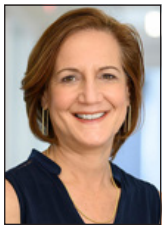
Andy Alasso
SVP, Product Management
Aizon

MERCK

Michele C. D'Alessandro
Retired CIO of Manufacturing IT
Merck

8:30 - 8:35 am

Chair's Welcome Remarks



Joanne T. Beck
Chief Operating Officer
Boston Pharmaceuticals

8:35 - 9:10 am

Pharmaceutical Development and Manufacturing — The New Post-Pandemic Realities

- Discussing how the business model change accelerates
- Highlighting transformation needs in business setup, technology and ways of working
- Impact on Development and Manufacturing of different modalities
- How does Bayer gets prepared for such opportunities and challenges?

Wolfram Carius
EVP Pharmaceuticals
Bayer AG

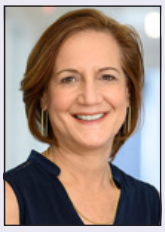
9:10 - 9:45 am

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

Linzell Harris
SVP Global Supply Chain and Strategy
AstraZeneca

ROOM 1 CHAIR



Joanne T. Beck
Chief Operating Officer
Boston Pharmaceuticals

ROOM 2 CHAIR

Jack Garvey
CEO
Compliance Architects LLC

ROOM 3 CHAIR

Michael Weisenbeck
VP
Körber Pharma Software

9:50 - 10:25 am

Creating and Maintaining a Resilient Supply Chain: Lessons Learned from a Pandemic

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

- How do you define a supply chain?
  - The what, the who, the where and the how
- Risk categorization
  - Impact, probability and detectability
- Risk approach
  - Detection, prevention/mitigation and response
- Near-miss lessons learned

Ken Kent
SVP, Chemical Development and Manufacturing Operations
Gilead

9:50 - 10:25 am

Panel: Contemporary Pharmaceutical Quality Topics

BREAKOUT ROOM 2
QUALITY

Jack Garvey
CEO
Compliance Architects LLC

Kathy Azuara
SVP Quality Assurance
Ultragenyx

Kathleen Munster
SVP, Enabling Functions (Quality, Facilities, & IT)
2seventy bio

Christy Tobias
Executive Director, Global Quality
CoreRx

9:50 - 10:25 am

Maximizing Cell Therapy Supply Chain

BREAKOUT ROOM 3
SUPPLY CHAIN

- Overview of BMS Cell Therapy successes and footprint
- Showcasing supply chain complexities and strategic learnings in launching and expanding Cell Therapy modality
- Discuss the role of digital evolution and transformation in enabling Cell Therapy supply chain successes

Celia Xue
Executive Director Integrated Product Strategy-Cell Therapy Supply Chain
Bristol-Myers Squibb

10:25 - 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

10:40 - 11:15 am

Industry Focus Group

INDUSTRY FOCUS GROUP — TALENT

Pipelines for Talent Development: How to Hire, Retain, and Grow Talent

Laurent Boer
VP & General Manager, Allston Site
Resilience

11:20 - 11:55 am

Advancing Pharmaceutical Manufacturing Quality

- Using innovative thinking to realize a future more "immune" to supply chain disruptions
- Incentivizing improvements to the pharmaceutical manufacturing infrastructure that enhance the reliability of manufacturing and supply
- Delivering on the promise of advanced manufacturing to provide reliable, available, high-quality drugs for patients

Michael Kopcha
Director, Office of Pharmaceutical Quality, CDER
FDA

12:00 - 12:35 pm

WORKSHOP
BREAKOUT ROOM 1

Avoiding the Pitfalls of Initial GMP Programming and Clinical Production Space Planning

- Discussing the common pitfalls observed during establishment of initial GMP programs in the areas of quality systems, materials management, supplier qualification, etc.
- How are companies adopting organizational changes and leveraging digital systems to avoid these pitfalls?
- Important factors to consider when assessing build vs. buy for early-phase clinical production, and considerations for scaling a GMP program up and/or out
- Illustrating the importance of establishing clear process requirements and conducting informal and formal facility fit assessments using real-world examples

Chris Mansur
President, Azzur Consulting
Azzur Group

12:00 - 12:35 pm

WORKSHOP
BREAKOUT ROOM 2

Enabling a Digital Culture Through Integrated Business Processes

- From zero to minimal viable product: Adoption of Pharma 4.0 through factory automation
- Leveraging the digital culture to accelerate value through integrated supply chain
- Ensuring future readiness in dynamic market

Sara Sheriff
VP of Integration/Engineering Operations Services Optimization Leader
Thermo Fisher Scientific

12:35 - 1:35 pm

LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS

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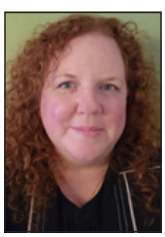
Enabling Volume-Driven Growth and Staying Efficient Through Continuous Improvement and Technology Advancement



Heather Nunn
Process Development Principal Scientist
Amgen

CMC Strategies to Re-Purpose a Clinical Candidate

Rajiv Panwar
Sr. Director, CMC, Tech Ops and Supply Chain
Disc Medicine

Shifting Regulatory Standards in Cell and Gene Therapy

David Bottari
QA Contract Manufacturing Lead
Spark Therapeutics

Operating a Biotech Business in the Wake of a Pandemic: People, Supply Chain, Virtual Communications, and Capital Markets

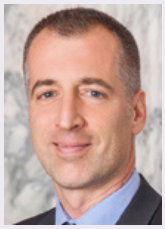
Daniel Couto
Chief Operating Officer
Vedanta Biosciences

1:35 - 2:10 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Global Talent Trends in Pharma Manufacturing

- Our knee-jerk leadership reaction to the pandemic: from managing change to managing burn-outs!
- Recovery: how to reboot culture, leading with purpose and agility
- Defining and adopting next-gen performance and talent management



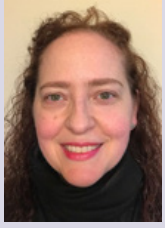
Pascal Bécotte
Managing Director
Russell Reynolds Associates

1:35 - 2:10 pm

BREAKOUT ROOM 2
QUALITY

Bringing a Global, Holistic Approach to Quality Selection and Qualification of Contract Manufacturing Organizations and Suppliers

- Supplier Selection Process
  - Defining quality deliverables to include into an RFP (Request for Proposal)
  - Considerations to outsourcing analytics and Quality Control
  - Rating suppliers and final selection criteria
- Quality Agreements – establishing and negotiating with partners
- Auditing – navigating virtual audits and qualifying of CMOs and Suppliers



Kim Burson
Head of Quality Assurance and Quality Control
Denali Therapeutics

2:15 - 3:00 pm

Panel: Leadership Strategies to Survive and Excel in a Post-COVID World

- What are some of the unexpected lessons —good and bad— we have taken away from 2020 and 2021?
- Discussing examples of innovations created by necessity during the global pandemic that will continue on long into the future
- Taking this chapter in our working lives as an opportunity to re-evaluate, reconsider, and rethink some of the processes and strategies we had in place before COVID-19
- How should we adjust our approach to communication, coordination, mentoring, and management in the emerging 'new normal' of work?
- Has the global pandemic changed the way people think about their personal and professional development? What should we as leaders be doing to better understand and support how our people want to grow?

Bristol Myers Squibb™

Brendan Hughes
SVP Global Manufacturing Operations
Bristol-Myers Squibb

Massachusetts Institute of Technology

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

PlateletBio®

Derek Adams
Chief Operating Officer
PlateletBio

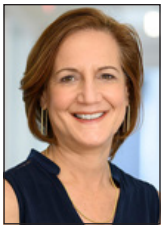
VIR

Aine Hanly
Chief Technology Officer
Vir Biotechnology

3:00 - 3:05 pm

Chair's Closing Remarks

BOSTON pharmaceuticals



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