



PHARMA MANUFACTURING WORLD SUMMIT **PMWS21**

May 17-18, 2021 | Virtually in CST | pharmamanworld.com

AGENDA

MAY 17, 2021

8:50 - 9:00 am

Chair's Welcome Address



Massachusetts Institute of Technology



Charles L. Cooney

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

9:00 - 9:30 am

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

- Highlighting what should the industry do differently to achieve an ambitious future where all patients can receive lifesaving medicines safely, swiftly, reliably and affordably
- Exploring how and where products will be made, and how those products will be delivered by adopting system-driven planning and automation capabilities, leveraging the power of data and advanced analytics
- Describing a patient-centric pipeline the industry needs in order to deliver transformative therapies for all humanity
- 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



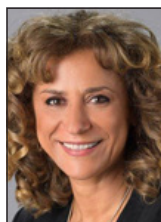
Sanat Chattopadhyay

*EVP & President,
Merck Manufacturing Division
Merck*

9:35 - 10:05 am

Keynote: Delivering Excellence While Navigating Transition

- Highlighting how operations and manufacturing can think differently to pivot for crises and global events
- Preparing for M&A opportunities and adapting for a changing business model
- Discussing the importance of equity, leadership and people as catalysts of culture and change within the industry as we work to serve patients better



Azita Saleki-Gerhardt

*EVP, Operations
Abbvie*

ROOM 1 CHAIR



Massachusetts Institute of Technology



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

ROOM 2 CHAIR



LOFTWARE™



Joe Ferreira
Life Science Executive
Loftware

ROOM 3 CHAIR



Ryan Hamilton
Business Development
Leader
Körber Pharma Software

10:10 - 10:40 am

BREAKOUT ROOM 1 STRATEGIC MANUFACTURING

Emerging Stronger Together – Toward a New Normal for a Post-COVID World

- Reflecting on how the covid-crisis enabled changes and drove unprecedented achievements in our industry
- Highlighting the challenges we will face in the future, in a World more uncertain than ever
- Reflecting on how Trust and Collaboration at all levels will be essential to strive and to continue serving patients and Public Health worldwide



Franck Chassant
Head of Rare Disease, Oncology
and Immunology Cluster (RDOI)
Sanofi

10:10 - 10:40 am

BREAKOUT ROOM 2 QUALITY

Reducing Drug Shortages...and High Prices

- How hospital systems and philanthropies came together to establish their own supply chain for essential quality generic medicines
- Living the mission to make quality generic medicines accessible and affordable to everyone
- Improving the resiliency of the supply of essential medicines used in hospitals, often for critical care, day-to-day and during a pandemic
- Ensuring a safe and stable supply of essential medicines for U.S. patients



Donna Gulbinski
Chief Quality
& Regulatory Affairs Officer
Civica Rx

10:10 - 10:40 am

BREAKOUT ROOM 3 SUPPLY CHAIN

Rethinking our Supply Chain to be Patient-Centric

- Challenges biotech companies are facing as patients expectations are increasing
- Ensuring the end-to-end supply chain can respond in the face of fierce competition for innovation
- Leveraging data and analytics to increase value and service to patients
- Keeping patients central as external factors accelerate need for resiliency

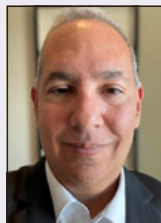


Kimberly Lounds Foster
SVP Global Supply Chain
Bristol-Myers Squibb

12:00 - 12:30 pm

**WORKSHOP
BREAKOUT
ROOM 1**
Leveraging Predictive and Behavioral Analytics to Ensure Supply Chain Health and Assess Compliance Risks – Case Study

- Deployed predictive and behavioral analytics to identify recently launched investigations that may create product availability issues
- Implemented an automated management alarm and escalation system, emails and text messages, to accelerate closure of those investigations
- Leveraged outcomes of reviews of quality system documents, e.g. batch records, CAPAs, Change Controls, etc. to assess multiple dimensions of compliance risk



Jaime Velez
Co-Founder and
Managing Director
OQSIE

12:00 - 12:30 pm

**WORKSHOP
BREAKOUT
ROOM 2**
Digital Transformation: Leverage Technology to Meet the New Quality Management Demands

- Overview – digital transformation and industry 4.0
- The opportunity for change – Intelligent and connected technologies such as cloud computing, artificial intelligence (AI), Internet of Things (IoT) and Augmented Reality
- What are the challenges faced by manufacturers in the changing healthcare environment to meet new quality management demands
- How intelligent and connected technology can help overcome challenges to meet quality demands –
 - Utilizing advance technologies to identify quality issues in early manufacturing process to minimize risk
 - Eliminating communication barriers between the shop floor and quality teams by using digital platform
 - Paperless documentation and workflow – Automated and digitally connected processes to align manufacturing process
 - Better tracking and visibility – proactive decisions using real-time data and analytics
 - Minimizing human errors to manufacture safe products
 - Equipping manufacturers to stay ahead of the competition and bring high-quality, safe products faster to the market
 - Allows continuous improvement during the manufacturing process
 - Managing quality requirements and high demand during global crisis such as COVID-19 and how to be prepared in the future
- Practical experience sharing and lessons learned



Steve McCarthy
VP, Digital Innovation
Sparta Systems

12:00 - 12:30 pm

**WORKSHOP
BREAKOUT
ROOM 3**
Striving to Achieve the Goals of the Digital Plant

- Know the current, actual shop-floor schedule and status in real-time
- Optimize production
- Arm your operators with the tools to respond to process challenges
- Enable changeovers and new product introductions faster



Michalle Adkins
Director, Life Sciences
Consulting
Emerson Automation Solutions

10:40 - 11:55 am

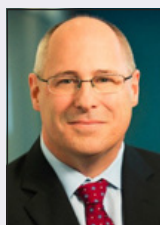
Lunch Break / Open Networking

1:30 - 2:00 pm

**BREAKOUT
ROOM 1**
STRATEGIC
MANUFACTURING

Science that Will Change the World: Lessons Learned from Bringing the First RNAi Therapeutics to Market

- What is RNA interference (RNAi)?
- A brief journey from Nobel Prize to ONPATTRO® (patisiran)
- Lessons from building commercial-scale manufacturing and supply chain operations
- What's next?



Al Boyle
*Chief Technical Operations
and Quality Officer
Alnylam Pharmaceuticals*

1:30 - 2:00 pm

**BREAKOUT
ROOM 2**
QUALITY

Lessons Learned From COVID-19 to Reduce Drug Shortages

- Health Authorities and Industry have found new ways to work together to reduce and avoid drug shortages as a result of the pandemic
- How have Post Approval changes (PAC) evolved from taking years to work through Regulatory approvals to now a matter of weeks and days?
- What can we learn from this new collaboration? How can we make this regulatory agility permanent?
- Chief Quality Officers (CQOs) from the top 25 pharmaceutical companies have developed a solution to reduce drug shortages and enhance innovation and continual improvement for marketed drug products and vaccines in the "1VQ on PAC" Initiative
- The solution is patient centric and science and risk-based built on the principles of ICH Q9 guidance, Quality Risk Management, and the regulatory flexibility described in ICH Q10 guidance, Pharmaceutical Quality System



Anders Vinther
*Site Head & VP Global Quality
Intarcia Therapeutics*

1:30 - 2:00 pm

**BREAKOUT
ROOM 3**
SUPPLY CHAIN

Future of Supply Chains: Enabling a Strategic and Competitive Advantage

- Understanding key forces/trends likely to disrupt the supply chain, implications and getting ahead of it.
- Identifying opportunities and areas to create a strategic/competitive advantage
- Digital, data and analytics as a key enabler in creating a strategic advantage
- Talent, culture, mindset needed to create and sustain a strategic and competitive advantage.



Dennis Nsenkyire
*VP, Strategy & Deployment
Janssen Supply Chain
Johnson & Johnson*

2:05 - 2:35 pm

**WORKSHOP
BREAKOUT
ROOM 1**

How One Life Science Company Gained Control of 32 Million Labels

- Learn how this Life Science company streamlined label changes and quickly reacted to customer and regulatory labeling demands
- Understand the benefits of maintaining one source of truth for all label data and how it can trigger labeling from business transactions to drive labeling dynamically
- How one Life Science company standardizes on a single labeling solution to gain control of labeling across their organization
- Discover how this company ensures labeling consistency across the supply chain by minimizing label templates and using advanced business logic from the company's sources of truth



LOFTWARE™



Richard Burton
*Life Science
Account Executive
Loftware*

2:05 - 2:35 pm

**WORKSHOP
BREAKOUT
ROOM 2**

The Rapid Adoption of Intelligent Manufacturing & Pharma 4.0 During COVID

- Learn how Apprentice leverages AI, AR, intelligent technology and Pharma 4.0 to drive smart, data-driven manufacturing operations to increase an organization's speed to market
- Hear about common use cases and how some of the world's leading life science organizations applied this technology during COVID to steady supply chains, better manage operations and increase speed to market
- How to easily deploy intelligent manufacturing execution and collaboration platforms to scale faster, from COVID to cancer
- How to optimize productivity with global, remote collaboration systems that have changed the way manufacturing teams resolve issues and communicate across teams in or out of the lab and suite



APPRENTICE



Angelo Stracquatano
*CEO
Apprentice.io*

2:05 - 2:35 pm

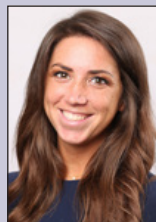
**WORKSHOP
BREAKOUT
ROOM 3**

Digital Supply Chain Management – Data Visualization, Optimization & Prediction

- Explore the importance of sponsor and supplier collaboration in fostering digital innovation
- Learn how to align customer services and digital experiences
- Unravel the benefits of real-time supply chain visibility from production to distribution
- Experience the power behind PCI's first-of-its-kind digital platform



YOUR BRIDGE BETWEEN LIFE-CHANGING THERAPIES AND PATIENTS



Morgan Brandt
*Global Director
of Digital Products
PCI Pharma Services*

2:35 - 3:50 pm

Networking Break

ROUNDTABLE DISCUSSION

**Building Resilient Supply Chains with
AI and Machine Learning**



Bill Green
VP Technology and
Solution Delivery
Adexa Inc.

ROUNDTABLE DISCUSSION

**Efficient Innovation – Application of
Lean Concepts to Drive Innovation
in Pharmaceutical Development and
Manufacturing**



Thomas Seewoester
VP External Supply
Operations
Amgen

ROUNDTABLE DISCUSSION

**Best Practices in Risk Management
for Combination Products**



Jon Cammack
Chief Quality and
Compliance Officer
Nevakar

ROUNDTABLE DISCUSSION

**Start-Up or Big Pharma: Challenges
in Development, Transfer and
Commercial Manufacturing
– A CDMO Perspective**



Timo Taghizadeh
Head of Business
Development
& Marketing
tesa Labtec GmbH

ROUNDTABLE DISCUSSION

**Managing the CMO Network:
Integrating New Technology with
Legacy Systems**



Jean Bender
VP Pharmaceutical
Sciences & Technology
Visterra Inc.

Developing Manufacturing Practices at A Rapid Pace for the Creation of Cell and Gene Therapies

- Exploring recent and significant milestones in the cell and gene therapy space
- Reviewing developments at bluebird bio to advance therapies through to commercialization
- Examining the technical, clinical, and manufacturing challenges involved in live modality therapies
- Exploring evolving health authority expectations for cell and gene therapies
- Finding ways to reduce costs and improve patient access



Derek Adams
Chief Technology and
Manufacturing Officer
bluebird bio

4:30 - 5:00 pm

Planning for Biomanufacturing of the Future: Setting the Course for Successful Industrialization of New Therapeutic Modalities

- How mRNA technology as well as cell and gene therapies promise to revolutionize medicine and may enable curative approaches for hard to treat diseases
- Why open innovation and external partnering in discovery and product innovation works – for both innovators and mature biopharma companies
- What are the biggest challenge of bringing these therapies to patients globally – stepping up the pace of adoption of new technologies, current industry limitations in CMC capabilities and capacity bottlenecks
- Delivering success in industrializing cell and gene therapies requires vision, leadership, diverse talent, the right organizational set-up and the right culture
- Case study: Discussing how Bayer is leveraging its core strengths in advanced manufacturing of difficult to make biologics in defining its technological approaches, including process integration, intensification, automation and digitalization which form the basis for creating our next generation cell and gene manufacturing platforms



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

5:00 - 5:05 pm

Chair's Closing Address



Massachusetts Institute of Technology



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

MAY 18, 2021

8:50 - 9:00 am

Chair's Welcome Address



Massachusetts Institute of Technology



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

9:00 - 9:30 am

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



E. Morrey Atkinson
*SVP and Head of Commercial
Manufacturing and Supply Chain
Vertex Pharmaceuticals*

9:35 - 10:05 am

Leading Global Supplies in Times of High Biologic Demands Now and After the Pandemic Crisis

- Strong wave of innovation and new Biologic therapies resulting in high demands
- Building flexible global capacities at various scales and multiple global locations to ensure reliable supplies and serve patients' needs worldwide
- Business continuity planning, crisis management, pandemic preparedness & implementation of additional specific protection measures
- Close collaboration, intensive and solution-oriented exchange with customers and partners to ensure global patient supplies
- Managing diverse and complex challenges through digital transformation
- Critical success factor: Operational excellence, capacity & capabilities expansion and our peoples dedication



Uwe Buecheler
Corporate SVP
Biopharmaceuticals
Boehringer Ingelheim

ROOM 1 CHAIR



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

ROOM 2 CHAIR



LOFTWARE™



Joe Ferreira
Life Science Executive
Loftware

ROOM 3 CHAIR



Ryan Hamilton
Business Development
Leader
Körber Pharma Software

10:10 - 10:40 am

BREAKOUT ROOM 1 STRATEGIC MANUFACTURING

A Scalable Manufacturing Platform for Global mRNA Vaccine Production

- 86% of the global population has yet to be vaccinated against Covid-19. It is likely that we will need to provide annual boosters to the majority of the world's population for the foreseeable future
- GreenLight has developed a unique mRNA manufacturing platform with the scalability to produce billions of doses a year in a cost-competitive manner, enough to catchup on vaccinating the world, and provide annual boosters, through Integrated, proprietary manufacturing platform less dependent on key raw materials supply
- GreenLight is developing its own COVID-19 vaccine candidate, currently finishing pre-IND studies, which has shown strong pre-clinical performance and is expected to enter the clinic later this year or early in 2022
- Our vaccine development and manufacturing platform is rapidly adaptable to address new variants of concern



GreenLight
BIOSCIENCES™



Andrey J. Zarur
Founder & CEO
GreenLight Biosciences, Inc.

10:10 - 10:40 am

**BREAKOUT
ROOM 2**
QUALITY

Integration and Transformation

- Overview of Takeda
- Learnings from Integration of two large pharma companies
- Global Quality roadmap and transformation of Quality Management Systems
- Ways of working during COVID-19
- Quality Culture



Traci Seaman
VP, Head of Global Quality
Strategy & Business Operations
Takeda

10:10 - 10:40 am

**BREAKOUT
ROOM 3**
SUPPLY CHAIN

Partnering with Contract Research and Manufacturing Organizations: Opportunities and Challenges

- Moving from pure “outsourcing” to “selective integration”
- Designing and implementing effective partnerships between client companies and CMOs/CDMOs
- Discussing strategies for building and maintaining trust and confidence with external partners
- Assuring that outsourcing work does not impact quality and compliance
- Presentation of several case studies discussing innovative strategic partnerships



Stephen Scypinski
VP Pharmaceutical
Technology
Daiichi Sankyo

10:40 - 11:55 am

Networking Break

10:40 - 11:15 am

Roundtable Discussions

ROUNDTABLE DISCUSSION
Avoiding Costly Shutdowns:
Hygienic Design with PVC Wall
Cladding and Adhesive-Free Flooring



Jared Clauberg
Regional Representative
Altro

ROUNDTABLE DISCUSSION
The Challenge to “Actually” Deliver
a Digital Strategy



Brendan Hughes
SVP Global
Manufacturing
Operations
Bristol-Myers Squibb

ROUNDTABLE DISCUSSION
Big Pharma Vs Start-Up:
Challenges and Opportunities
for CMC Development of Small
Molecules and Biologics



Saul Fink
VP Pharmaceutical
Development
Goldfinch Bio

12:00 - 12:30 pm

**WORKSHOP
BREAKOUT
ROOM 1**

Autonomous Planning of Production at Allergan — A Case Study

See how:

- S&OE is used to improve S&OP
- Demand prioritization to improve customer satisfaction
- Planners moved from weekly planning to daily execution



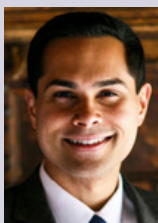
John Hosford
COO
Adexa Inc.

12:00 - 12:30 pm

**WORKSHOP
BREAKOUT
ROOM 2**

Enabling One-Click Tech Transfers

- Facilitate knowledge management & collaboration from development to manufacturing, across internal functions such as R&D, PD, CMC, MSAT, Regulatory, Quality, Manufacturing Automation & Engineering, and CDMOs
- Conduct 'facility-fit' scenarios for end-to-end processes in real-time during drug development
- Generate end-to-end tech transfer process documents with the click of a button



Suraj Pai
CEO
Fluxa Inc.

12:30 - 1:30 pm

Lunch Break / Open Networking

1:30 - 2:00 pm

**BREAKOUT
ROOM 1**
STRATEGIC
MANUFACTURING

Connecting Program Strategy with Operations Strategy: Creating Lifecycle Connections Between Development, Commercial, and Manufacturing & Supply

- Linking the manufacturing workforce and resources to the company leadership when planning for launch, expansion, plateau, technological shifts, and loss of exclusivity
- Going beyond near-term S&OP to guide manufacturing through lasting decisions
- How the right people, data, and long-range planning can lead to setting up right-sized manufacturing and supply chains



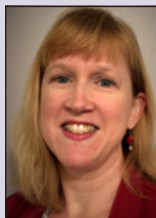
Michael Boyson
VP, Head of Product Operations,
Oncology & Small Molecule,
Strategy and Business Excellence
Takeda

1:30 - 2:00 pm

**BREAKOUT
ROOM 2**
QUALITY

Building Quality into Development

- Establish key values and cultural philosophies as the foundation for building Quality into development
 - Proactively collaborate with other functional lines to establish respect and transparency
 - Make risk-based decisions rooted in scientific merit
 - Change the perception: Quality and innovation are NOT mutually exclusive
 - Put patients first through integrity, trust, and accountability
- Create roles and tools which help perpetuate those values and philosophies
 - Quality Product Lead role
 - Efficient team structures and clear expectations
 - Knowledge management tools
 - Change management structure



Shannon Holmes
*Director, Product
Development Quality
Biogen*

2:05 - 2:35 pm

**BREAKOUT
ROOM 1**
STRATEGIC
MANUFACTURING

Challenges and Advancements in Microbiome Manufacturing: A Small Biotech's Perspective

- Overarching nuances to Microbiome Production
- Assessing CMO capabilities vs decision to build in house
- Exploring the considerations of Vedanta's choice to build internally
- Lessons learned through Vedanta's journey to commercialize microbiome therapeutics



Daniel Couto
*Chief Operating Officer
Vedanta Biosciences*

2:05 - 2:35 pm

**BREAKOUT
ROOM 2**
PHARMA 4.0

Digitization for Pharmaceutical Manufacturing

- Aligning tech and business strategy
- Opportunities and lessons learned from the front line



Michele D'Alessandro
*VP and CIO,
Manufacturing IT
Merck*

2:40 - 3:25 pm

Panel: The Past, Present and Future of the Global Pharmaceutical Industry

- How our “new normal” is affecting our critical materials procurement and how do we adapt for the future?
- Examining changes, risks, opportunities within changing supply chains and manufacturing networks
- What does short term post-COVID19 Pharma Industry look like?
- Outlining the struggles and opportunities in executing a Digital Strategy and Transformation
- How do novel modalities with existing challenges cope with these new global constraints?
- Seismic shifts and emerging fault lines create lasting affects, what are they and how do they shape our industry in the years to come?



Andrey J. Zarur
Founder & CEO
GreenLight Biosciences, Inc.



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



Pascal Bécotte
*Global Executive Committee,
Global Sector Leader –
Functional Practices,
Country Manager – Canada
& Managing Director*
Russell Reynolds Associates

RESILIENCE

3:25 - 3:35 pm

Chair's Closing Address



Massachusetts Institute of Technology



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