BIOMANUFACTURING WORLD SUMMIT BMWS19

November 11-12, 2019 | Hilton La Jolla Torrey Pines | San Diego, CA | biomanworld.com

AGENDA

NOVEMBER 10, 2019

6:00 - 7:00 pm

Boehringer Ingelheim

Proud Sponsor of the

Drinks Reception

NOVEMBER 11, 2019

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

Sponsored By: emergent biosolutions®

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

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

Juno Therapeutics, A Member of the Roche Group — Genentech

Pat Yang
Former EVP
at Juno Therapeutics,
Roche and Genentech

8:00 - 8:35 am — **Keynote: The Successful History of Biologics Manufacturing Provides Foresights and Strategies for New Bio Modalities**

- Establishment of broad communities of practitioners in both manufacturing and process development accelerated maturation of both disciplines
- Convergence of these process and manufacturing technologies was driven by excellence and capacity in selected CMOs
- Manufacturing portability has provided remarkable stories of win-win capacity-exchange between proprietary companies
- Process convergence has resulted in remarkable progress in process yields and cost improvement
- Intro to Vir Bio: Capacity and cost improvements in bio-manufacturing facilitate global access to medicines for Infectious Disease

VIR

Michael Kamarck
Chief Technology Officer
Vir Biotechnology

8:35 - 9:10 am

New Modalities, New Players, New Technologies – How Can We Succeed in an Exponential Future?

- Economical and political power shift in an age of the Anthropocene, and biology and computing power converge. Population, volatility and ecosystem pressure grows, whole science and technology leaps
- What is changing for our industry, for technical development and operations?
- What are our challenges and how could we potentially master them?
- Examples of how Bayer Pharmaceuticals addresses challenges in Cell and Gene Therapy, Digital and Leadership

Wolfram Carius
EVP, Pharmaceuticals Product Supply
Bayer AG

ROOM 1 CHAIR

Pat Yang
Former EVP at Juno Therapeutics, Roche and Genentech

ROOM 2 CHAIR

Jack Garvey
CEO
Compliance Architects

ROOM 3 CHAIR

Rajesh Thangapazham
Cell & Gene Technologies Regulatory Affairs Expert
Lonza Pharma & Biotech

9:15 - 9:50 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

The Centenarian and the Start Up: How Merck is Realizing its Biomanufacturing Revolution

- Discuss how today's pipeline and technologies are reshaping our biomanufacturing
- Review case studies and strategies for rapid manufacturing scale up for leading products
- Focus on the criticality 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

Karin Shanahan
SVP, Global Biologics & Sterile Operations
Merck

1:35 - 2:10 pm

BREAKOUT ROOM 2
QUALITY

Leveraging Resilience and Reinvention to Advance Pharmaceutical Quality

- The future of pharmaceutical quality and how to get there
- Generating competitive advantage using the principles of resilience and learning agility
- Evolving current quality practices to be more efficient & agile without compromising product quality or supply continuity

Lisa Wyman
VP Quality
Acceleron Pharma

9:15 - 9:50 am

Change Leadership – Building and Driving a High Performing Organization

- Converting strategy into execution and results
- Creating an effective operating system
- Building a compelling case for change
- Achieving agility in times of uncertainty
- Leveraging OE to build, scale and improve the business
- Removing the roadblocks or overcoming the setbacks
- Leading the culture shift

BREAKOUT ROOM 3
CELL & GENE THERAPY

Stephen Hill
Chief Technical Officer
Lyell Immunopharma

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

Leveraging Predictive Technologies to Ensure Supply Chain Health – Case Study

- Deployed artificial and business intelligence to detect events that may create product availability issues, demand and supply related
- Implemented an automated management alarm and escalation system, emails and text messages, to accelerate response to supply-impacting events
- Implemented demand-driven scheduling system to connect production mix with actual demand
- Connected and integrated data across multiple platforms, e.g. PLCs, ERPs, QMS, LIMS, etc.

WORKSHOP
BREAKOUT ROOM 1

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

11:40 AM - 12:15 PM

Stainless Steel to Single-Use: Transitioning Our Culture and Processes

- Utilizing a capital investment to spawn culture change at a mature manufacturing site
- Implementing equipment and automation platforms globally to boost speed to market
- Sharing past experiences with single-use bioprocessing technologies and our evolving strategy to support them

WORKSHOP
BREAKOUT ROOM 2

Jim Green
Single Use Technology (SUT) Platform Lead
Bayer Biotechnology Division

A Case Study Brought to you by

11:40 am - 12:15 pm

WORKSHOP

BREAKOUT ROOM 3

Are We There Yet? The Digital Transformation Journey

- The buzzwords abound: digital transformation.....Industry X.0....Industry 4.0.....but what are some practical approaches to achieving the promised benefits?
- What does digitalization actually mean in terms of transforming the biopharma product lifecycle?
- What are best practices to accurately assess and benchmark the capabilities of my organization and develop a transformation plan?
- Hear some recent experiences of successful digitalization initatives in biopharma R&D and manufacturing
- Learn from a variety of diverse perspectives for quantifying real benefits and what pitfalls to avoid (hint: don't focus just on technology)

EMERSON

Ron Rossbach
Sr. Life Sciences Industry Consultant
Emerson Automation Solutions

12:20 - 12:55 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Scaling Gene Therapy Manufacturing: What is Our Goal?

- Highlighting the scale-up opportunity for dramatic patient benefit through the lens of a patient
- Outlining the inextricable link between manufacturing and the patient experience for autologous cell therapies
- Considering the different scaling goals: commercial viability, reliability, patient access, etc.

bluebirdbio

Derek Adams
Chief Technology and Manufacturing Officer
bluebird bio

12:20 - 12:55 pm

BREAKOUT ROOM 2
QUALITY

The Evolution of a Quality Management System: Present and Future State

- How does the QMS evolve to enable flexibility and demonstrate value?
- What options are there to employ a continuous improvement thinking to the QMS?
- Can big data and risk management enable decision making?
- The importance to engage your organization for effective change management

BIOMARIN

Patricia Lufburrow
VP, Global Quality Operations
BioMarin Pharmaceuticals

12:20 - 12:55 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

Manufacturing a Cure: Advancing Cellular Therapies Towards Commercialization

- How should our industry build upon current cell therapy advances to create even more advanced and complex biopharmaceutical treatments
- Understanding how facility and process validation considerations change and become even more important when dealing with cell therapies
- Illustrating how investing in the relevant science directly informs product knowledge
- Demonstrating that this hard-won internal expertise can be harnessed into developing a successful new modality for cell therapies
- How to manage and maximize internal and external capacity to overcome product supply challenges

NOVARTIS

Therese Choquette
Analytical Project Leader
Novartis

12:55 - 1:55 pm **LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS**

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

On Time and Right First Time to Market: Early Engagement of Manufacturing with R&D to Speed Delivery of New Medicines to Patients

AstraZeneca

John Higgins
Director, Global Technical Operations
AstraZeneca

Implementing QbD in Cell & Gene Therapy

bluebirdbio®

Nick Keener
Sr. Director Vector Process Development
bluebird bio

The Evolving Landscape of Cell and Gene Therapy Manufacturing and Development

CRISPR THERAPEUTICS

Abhinav Shukla
VP and Head, Manufacturing
CRISPR Therapeutics

Leveraging Induced Pluripotent Stem Cell (iPSC) Technology to Create Allogeneic Cell Therapies

Fate THERAPEUTICS

Wen Bo Wang
SVP Technical Operations
Fate Therapeutics

Strategies to Address the Viral Vector Capacity Dilemma

GE

Olivier Loeillot
General Manager of Bioprocess
GE Healthcare Life Sciences Business

Optimizing Quality in Apheresis Starting Materials for Cellular Therapeutics

gsk GlaxoSmithKline

Rob Piperno
Director Cell & Gene Therapy QA
GSK

Acceleration and Innovation Enablers: Post-Approval Change Management

MERCK

Mihaela Simianu
Executive Director, Engineering, Head of Sterile Liquids Commercialization
Merck

How do You Scale Your Platform While You Continue Learning?

moderna™

messenger therapeutics

Kathrin Jinivizian
Head External Manufacturing & CMC Strategic Operations
Moderna Therapeutics

Translating Successful Research into Industrialized Medicine - Commercialization Challenges and Strategies for Cell and Gene Therapy

Orchard therapeutics

Ran Zheng
Chief Technical Officer
Orchard Therapeutics

Advancing Tomorrow's Medicines—Overcoming the Manufacturing Challenges of Today

patheon by Thermo Fisher Scientific

Paul Jorjorian
VP & General Manager, Biologics

Chris Murphy
VP & General Manager, VVS
Thermo Fisher Scientific

Machine Learning to Support Visual Inspection in Biopharmaceutical Manufacturing

the dev masters

Arshad Khan
Chief Data Scientist
theDevMasters

Live-Virus CMC and Manufacturing Strategies: From Vaccines to Viral Immunotherapy to Cell-Gene Therapy Applications for Emerging Organizations

TURNSTONE BIOLOGICS

Manny Otero
SVP, Technical Operations
Turnstone Biologics, Inc.

Transforming Quality Management with Cloud

Veeva

Paola DePaso
Director, Vault Quality
Veeva Systems

Best Practices for Overcoming Big Challenges in Your Manufacturing Digital Journey

WERUM KÖRBER SOLUTIONS

Samantha Zoleta
Manager Sales and Business Consulting
Werum IT Solutions

1:55 - 2:30 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Technology Roadmap for the Biopharmaceutical Industry

- Proving that the most valuable data in manufacturing is from production itself
- Choosing the right goals and outcomes to make a difference
- Connecting disparate IT systems together into a unified whole
- Building a scalable approach for the enterprise, step-by-step: Start small to go big
- Illustrating successful projects with concrete examples

Pfizer

Jun Huang
Director/Team Leader,
Process Monitoring, Automation & Control
Pfizer

1:55 - 2:30 pm

BREAKOUT ROOM 2
QUALITY

Innovative Quality Systems: Fit for the Future to Enable Personalized Medicine

- Demonstrating that Quality Systems as they exist today are not adequate for the next generation of innovative products
- Identifying and managing instances of noncompliance with GMPs
- Developing a quality system infrastructure to ensure compliance in a fast-growing company
- Placing quality and compliance as the core strength of your organization and the industry
- Identifying, mitigating and preventing high-risk events through integration, automation and collaboration
- Ensuring a strong quality and compliance focus with CMOs, partners and suppliers

Roche

Ronan Farrell
Head of Quality and Compliance
Roche

1:55 - 2:30 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

The Quest for Compliant, Reliable, Cost-Effective Viral Vector Supply to Meet the Rapidly Growing Demand

- Approaches to successfully transition viral vectors from small scale clinical trial use into cGMP approved commercial supply
- Next generation processing and analytics to enable increased vector supply capability
- Use of specialist viral vector CDMO's vs building in-house capability
- Oxford Biomedica's ongoing capacity and technology investments to meet our partners growing supply needs

Nick Page
Chief Operations Officer
Oxford BioMedica

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 1

Global Talent Trends in Biomanufacturing 2019

- An update on talent trends: what does it (seem to) take to make it to the top?
- Should I lead, over the next 10 years, the way I lead over the past 10 years?
- Culture: what is it (really) and how can we transform it as leaders?

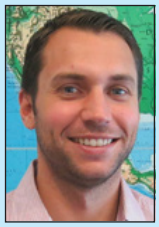
Pascal Bécotte
Co-Leader, Corporate Officers Sector (Global Functions) & Global Leader, Operations & Supply Chain Practice
Russell Reynolds Associates

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 2

SUT Facility Design Considerations

- History of Single-Use technology in BioPharm
- Why SUT versuss traditional SS? What are the pros and cons of each?
- SUT-specific design considerations:
  - Ergonomics/ Life Safety/ Code Compliance
  - Spatial Relationships/ Adjacencies
  - Regulatory Compliance
  - Mode of Operation
  - Modularity/ Repeatability
- Walking through an SUT facility case study



Jim Green
Single Use Technology (SUT) Platform Lead
Bayer Biotechnology Division

Bob Allen
Sr. Technical Director
Fluor

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 3

Cold Chain Validation Best Practices Including Immunotherapy

- Review recent FDA feedback on immunotherapy submissions
- Understanding damage boundaries for therapies
- Defining your operating space for transportation hazards
- Putting it all together: Cold chain validation strategies for monoclonal antibodies, antibody-drug conjugates, and cell therapies

Gary Hutchinson
President
Modality Solutions

Dan Littlefield
Principal
Modality Solutions

3:15 - 4:25 pm

Pre-Arranged One-to-One Meetings

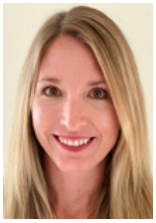
3:15 pm – 3:35 pm: Meeting Slot 5 / Networking
3:40 pm – 4:00 pm: Meeting Slot 6 / Networking
4:05 pm – 4:25 pm: Meeting Slot 7 / Networking

3:50 - 4:25 pm

Industry Focus Groups

These roundtable discussions will run during the morning of Day Two's pre-arranged one-to-one meetings. Each group will be hosted by a moderator who will guide the conversation through issues, challenges, and opportunities drawn from delegate profiles relevant to specific industry sectors.

CELL AND GENE THERAPY FOCUS GROUP
Better Cells for Better Therapies, The Promise and Practicalities of Synthetic Biology



Tanya Warnecke
Chief Technology Officer
ArtisanBio

Raja Srinivas
Co-Founder
Asimov

Nick Timmins
VP, Cell Technologies and Entrepreneur in Residence
ArtisanBio

Philip Lee
COO and Co-Founder
Senti Biosciences

4:30 - 5:05 pm

Cell and Gene Therapies and the Dawn of the Next Chapter of Biopharmaceutical Production

- What are some of the unique challenges and opportunities in commercializing live modalities like CAR-T?
- Weighing the pros and cons of centralized versus decentralized production models for these new treatments
- Discussing how our industry's quality culture informs these new products from R&D right through to the patient
- Offering lessons learned from the first generation of cell and gene therapies. How will their example inform what we are doing now?
- Setting timelines for the future: What are we going to be able to do next year, five years from now, and ten years from now? What are we doing to get there?
- Filling the innovation pipeline: What can we as an industry do to support the creation and discovery of new live modalities?

Tim Moore
President & Chief Technology Officer
PACT Pharma

5:05 - 6:00 pm

Panel: Setting Ambitious Goals to Improve the Biopharmaceutical Ecosystem

- Discussing how all the moving pieces of our industry fit together. Is the status quo really the best way to ineract with one another? What forces have driven us into our current relationships, and to what extent can we reshape our industry's landscape?
- Moving beyond just People, Processes, and Technologies when we talk about improvement. With Blue Sky Thinking, what would we change if we could?
- Seeking ways out of zero-sum thinking to create mutually advantageous business operations
- Bringing in additional perspectives from other industries and organizations to examine our businesses from the outside looking in
- Remembering that the patient always come first, even when discussing better ways of doing business. How will the new direction we forge together also redefine our ability to serve patients' needs?

Alison Moore
Chief Technology Officer
Allogene Therapeutics

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

Jerry Cacia
SVP, Head Global Technical Development
Genentech

Pascal Bécotte
Co-Leader, Corporate Officers Sector (Global Functions) & Global Leader, Operations & Supply Chain Practice
Russell Reynolds Associates

6:00 - 7:00 pm

6:00 - 7:00 pm

NEW TO BMWS19: HANGOUTS

From 6:00 pm onwards there will be three different 'Hangout' areas set up in the Exhibition Hall, each beside a bar. These are unmoderated opt-in networking opportunities for attendees to engage with their peers about the content and issues they enjoyed during the day's sessions. Choose the topic that interests you most and congregate at the appropriate Hangout.

STRATEGIC MANUFACTURING HANGOUT

QUALITY HANGOUT

CELL & GENE THERAPY HANGOUT

NOVEMBER 12, 2019

7:30 - 8:25 am — **Registration and Breakfast**

Sponsored By: emergent biosolutions®

7:45 - 8:20 am

SESSION
BREAKOUT ROOM 2
STRATEGIC MANUFACTURING

Smart Operations, Smart Business: Achieving End-to-End Performance with Smart Factory and Digital Transformation

- Define "Smart Factory" and the dimensions of performance
- Explore why companies may not reap value from Smart Factory initiatives and how to overcome barriers
- Understand how to balance the need for digital capabilities against the objective to be lean and nimble
- Identify opportunities to turn real-time data and insights into profitable business decisions that could effectively meet demand reducing inventory levels and costs
- Understand what talent strategies smart factories need and future of work implications
- Get to the bottom line: How is Smart Factory changing the way work is done on the shop floor and what this could mean in terms of dollars and cents?

Kite, A GILEAD Company

Jian Irish
SVP, Global Head of Manufacturing
Kite, A Gilead Company

Spark THERAPEUTICS

Chris Stevens
Head of Manufacturing
Spark Therapeutics

Deloitte.

Matt Humphreys
Principal, Life Sciences Supply Chain and Network Operations Leader
Deloitte Consulting LLP

8:25 - 8:35 am — **Chair's Welcome Address**

JUNO THERAPEUTICS — Genentech, A Member of the Roche Group

Pat Yang
Former EVP at Juno Therapeutics, Roche and Genentech

8:35 - 9:10 am

Manufacturing Autologus Ex Vivo Genetically Modified Cell Therapies have Challenges, but the Future is Bright

- Review the supply chain
- Examine the contributors of costs
- Solution for industrial scale viral vector manufacturing
- Cell processing and viral transduction hubs
- Rapid analytics for product testing
- Brighter future for patients with fitter cell therapies

gsk GlaxoSmithKline

Joseph Tarnowski
SVP, Cell & Gene Therapy, R&D Medicinal Science and Technology
GSK

9:10 - 9:45 am

Keynote: When Your Process Equipment is a Raw Material and Your Raw Material is a Human: The Adaptation of Biotechnology CMC Skills to Cell Therapy

- CMC/Operations disciplines have an important role in the commercialization of powerful new cell therapies
- Well understood development principles can be applied, though there are challenges
- It is important to identify when to draw on experience and when to adapt/grow to address gaps
- Comparability is key in an emergent technology space, but may be limited by product understanding
- Growing development skills to advance important new medicines

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

9:50 - 10:25 am

The Future of Biomanufacturing: Leveraging Flexible Networks, Quality Culture and Cutting Edge Innovation

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

- How biomanufacturing can address the dichotomy of small volume precision medicines and high volume blockbuster drugs
- Building flexible global manufacturing networks to meet our industry's evolving needs
- Leveraging cutting edge innovation to maximize process intensification and augment flexibility
- Creating high performance teams and building and maintaining a culture of quality, reliability and innovation as key differentiator and foundation for continued success

Boehringer Ingelheim

Jens Vogel
President & CEO, BI Fremont Inc.
Boehringer Ingelheim Biopharmaceuticals GmbH

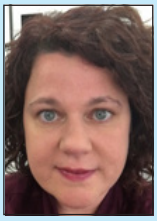
9:50 - 10:25 am

How to Ensure Quality and Compliance in Turbulent Times

BREAKOUT ROOM 2
QUALITY

- Discussing best practices to maintain a quality and compliance focus during times of change and uncertainty
- Providing a mechanism to ensure management is engaged, accountable and able to react quickly to unexpected events
- Clarifying responsibilities and opening up lines of communication, coordination, and collaboration between teams in transition
- Using Quality Systems to proactively detect potential trends and actions to take before the trend becomes an issue
- Offering examples of positive outcomes and lesson's learned to provide the audience with tools to help monitor impact to quality and compliance during times of change

BAYER



Tina Self
VP Quality
Bayer AG

9:50 - 10:25 am

Learnings from Launching LUXTURNA™ and Considerations for Building Gene Therapy Supply Chains of the Future

BREAKOUT ROOM 3
CELL & GENE THERAPY

- Understanding the unique challenges in launching the first ever FDA approved Gene Therapy
- Discussing emerging technologies to support innovative and individualized product supply strategies
- What best practices can we borrow from current pharma supply chains?
- Exploring challenges for managing gene therapy supply chain risk

Spark THERAPEUTICS

Ryan Bartock
Head of Supply Chain and Network Strategy
Spark Therapeutics

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

10:25 - 11:15 am

NEW TO BMWS19: INTERACTIVE THINK TANKS

During the Day Two Morning Networking Break there will be three different 'Interactive Think Tank' areas set up in the Exhibition Hall. These are pre-scheduled networking opportunities for attendees to get together in small groups to brainstorm and discuss issues of common interest. Delegates will find their assigned topic on their colored schedule in their delegates kits. Signage will direct you to the table for the appropriate Think Tank.

INTERACTIVE THINK TANK
DIGITAL TRANSFORMATION TACTICS & STRATEGIES

INTERACTIVE THINK TANK
TALENT ATTRACTION, TRAINING, & RETENTION

INTERACTIVE THINK TANK
CMO/CDMO CHALLENGES

10:40 - 11:15 am

Industry Focus Groups

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BIOPROCESSING FOCUS GROUP

Intensification, Integration and Interrogation - The Future for Biomanufacturing

- Addressing patients needs
- Fulfilling the business case
- Managing quality, speed, cost and flexibility

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

11:20 - 11:55 am

Case Study: Challenges and Opportunities in Analytical Development for Cell and Gene Therapies

- With no standardized methods in analytical development of cell and gene therapies, we must define our own best practices
- Looking at the evolution and industrialization of analytical development in biologics over the past 20 years: what did we learn and how can we leverage it now?
- With the current speed of evolution, what new tools will emerge to help us solve these complex challenges
- The high cost of analytical development and need for greater efficiency begs the question how do we get to where we need to be… And where do we need to be?

Sana Biotechnology

Stacey Ma
EVP Technical Operations
Sana Biotechnology

12:00 - 12:35 pm

Improving Product Quality During Technical Transfers

- The definition of Technology Transfer and its many applications
- Planning for tech transfer the "right way," using "Calculated Risk Reduction" and other tools to ensure all bases are covered
- Common pitfalls and best practices – what to do, and what not to do
- Ways to ensure optimal planning and execution using actionable tools

WORKSHOP
BREAKOUT ROOM 1

PROPHARMA GROUP®

Eric Good
Director, Compliance
ProPharma Group

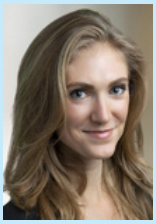
12:00 - 12:35 pm

Digital Transformation in Pharma Manufacturing for Quality and Productivity

- How pharma can learn state-of-the-art manufacturing from a more digitally advanced industry
- Connecting the plant: Turning data into knowledge and end-to-end business orchestration
- Successful industry 4.0 pharma use cases
- Integrating systems to create transparency and effective and timely decision-making
- Examining how improved quality also creates efficiencies and measurable cost savings

WORKSHOP
BREAKOUT ROOM 2

APPLIED MATERIALS® make possible



Amy Doucette
Americas Manager and Global Strategic Accounts
Applied Materials

12:00 - 12:35 pm

Top Lessons Learned When Choosing a Digital Manufacturing Strategy

- A case study from Atara Bio's experience on how when and why to digitize
- Taking the first step: how building digital capabilities can streamline production for scaling up success
- Obstacles faced and overcome

WORKSHOP
BREAKOUT ROOM 3

ATARA BIO

Joe Maguire
Sr. Director, IT
Atara Biotherapeutics

A case study brought by:

WERUM
KÖRBER SOLUTIONS

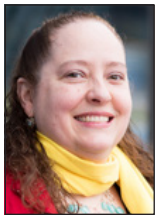
12:35 - 1:35 pm

LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS

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

Quality (QA/QC) Challenges of Managing External Contract Manufacturing Organizations (CMOs)

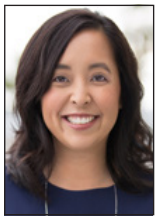
DENALI™ THERAPEUTICS



Kim K. Burson, PhD
Head of Quality Assurance & Quality Control
Denali Therapeutics

Attracting, Developing, and Retaining Women in Biopharmaceutical Manufacturing

Dendreon®



Christina Yi
Chief Operations Officer
Dendreon

Collaboration Studies: Cultivating Successful Relationships

Genentech
A Member of the Roche Group

Denise Steckel
Head, Clinical Collaborations Management
Genentech

Semi-Continuous Downstream Processing Strategies and Enabling Technologies for Supply Chain Flexibility

Antonio Ubiera
Sr. Director, Downstream Process Development, BioPharm Product Development and Supply
GSK

Real-Time Release for Biologics—Using Innovative Technologies

Carin Huibers
Global Platform Leader, Large Molecules
Janssen

Supply Chain Management for Complex Cell Therapy Products

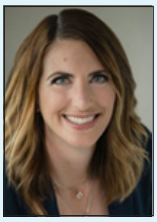
Dave DiGiusto
Chief Technical Officer
Semma Therapeutics

1:35 - 2:10 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Industrialization of Drug Discovery: Manufacturing and Discovery Reimagined Through Artificial Intelligence

- Illustrating how AI is already changing the small molecule side of the pharmaceutical industry in both drug discovery and R&D
- Extrapolating from these examples to suggest biopharmaceutical manufacturing applications
- Drawing parallels from the industrialization of biologics manufacturing. How far away are we, and what should we as an industry be doing now to get ready?
- Discussing what small pilot programs and early test cases might look like, and the timelines involved in moving from proof of concept to industry-wide applications



Tina Larson
Chief Operating Officer
Recursion Pharmaceuticals

1:35 - 2:10 pm

BREAKOUT ROOM 3
CELL & GENE THERAPY

Compliant, Creative, and Efficient C&Q Strategies to Bring up New Manufacturing Facilities of Cutting Edge Off-the-Shelf Allogenic CAR-T Immunotherapies

- Strategies to minimize impact caused by long-lead time items when bringing up a facility
- Building relationships between commissioning, qualification, and systems to improve staging
- Establishing creative system boundaries which focus on patient and product risks increases efficiencies without compromising compliance

Merrick Endejann
Sr. Validation Manager
Cellectis

2:15 - 2:50 pm

Panel: Staying Ahead of the Curve in the Increasingly Complex Regulatory World of Cell and Gene Therapy

- Discussing the growing regulatory complexity in the world of pharmaceutical manufacturing. How are new guidelines and regulators' expectations during inspections changing?
- Taking a process-based approach to impact assessment, and customizing a setup that identifies and acts on signals proactively
- Bringing a structured approach to your advocacy within your network of industry and trade organization connections
- Embracing the idea that keeping things simple even in a complex environment generates the best outcomes

Murali Bilikallahalli
VP & Head Technical Operations
Acceleron Pharma

José Eduardo Vidal
SVP, Quality Assurance and Process Sciences
Atara Biotherapeutics

Snehal Patel
VP and JuMP Site Head
Juno Therapeutics

Prentice Curry
SVP, Quality and Compliance
Kite, A Gilead Company

2:50 - 3:00 pm

Chair's Closing Address

Pat Yang
Former EVP at Juno Therapeutics, Roche and Genentech