BIOMANUFACTURING WORLD SUMMIT BMWS18

October 29-30, 2018 | Hilton La Jolla Torrey Pines | San Diego, CA | biomanworld.com

AGENDA

OCTOBER 28, 2018

6:00 - 7:00 pm

Boehringer Ingelheim

Proud Sponsor of the

Drinks Reception

OCTOBER 29, 2018

7:15 - 8:15 am — **Registration and Breakfast**

Sponsored By: emergent biosolutions®

8:15 - 8:30 am — **Chair's Welcome Address**

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

8:30 - 9:05 am — **Leadership: Guiding an Organization Through a Crisis**

- What should we, as leaders, be doing on a regular basis to prepare ourselves to deal with sudden unexpected incidents?
- Offering best practices to prepare and maintain a crisis management plan
- Reacting in the moment: Situational awareness, setting priorities, delegating responsibilities, and establishing clear lines of communication internally and externally
- Discussing the importance of workforce culture in weathering storms and overcoming new challenges
- Showcasing examples of effective emergency response and identifying commonalities between the case studies

MERCK

Sanat Chattopadhyay
EVP & President,
Merck Manufacturing Division
Merck

9:05 - 9:40 am

New Modalities, New Player, New Technology – How Can We Succeed in an Exponential Future?

- Dealing with accelerating disruption in economics, science, technology and business models
- Highlighting the importance of technology to succeed in a world of new biologic modalities and new players
- Digital transformation as key enabler for Bioprocess-, Analytical-,Robotics-, Nano-technology and competitiveness
- The combination of science and technology will make the quantum leap changing the business model
- Leadership including key performance indicators need to adapt for a digital world

Wolfram Carius
EVP, Pharmaceuticals Product Supply
Bayer

ROOM 1 CHAIR

Allogene THERAPEUTICS

Alison Moore
Chief Technology Officer
Allogene Therapeutics

ROOM 2 CHAIR

COMPLIANCE ARCHITECTS®
CONSULTING • TECHNOLOGY • OUTSOURCING

John Garvey
CEO
Compliance Architects

ROOM 3 CHAIR

Lonza
Pharma & Biotech

Thomas Fellner
Head of Cell & Gene Therapy
Lonza Pharma & Biotech

9:45 - 10:20 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Embracing Advanced Manufacturing Processes and Technologies to Build Capability and Competitive Advantage

- Discussing how the evolution of manufacturing processes and technologies have transformed the biopharmaceutical industry
- When does new manufacturing capabilities generating product innovations, and when does product development spur advances in manufacturing?
- Debating the role new tools, tactics, and technology will have in overcoming the ongoing challenges currently facing the sector
- How should the industry continue to grow and develop the next generation of advanced manufacturing technologies?

Bristol-Myers Squibb

Greg Guyer
Global Head of Operations
Bristol-Myers Squibb

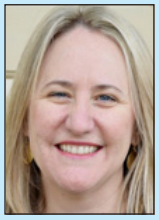
9:45 - 10:20 am

BREAKOUT ROOM 2
QUALITY

The Complexities of Managing Compliance Versus Cost

- What do we as an industry really need a QMS to do for us? Can we prune back what we have grown to return to a straightforward, efficient approach?
- Seeking input and ideas from all the relevant stakeholders to ensure everyone is part of the journey to bring about positive change
- Applying a logical, data-based decision-making process to identifying what can be simplified and improved without impacting existing quality and compliance performance
- How to identify the quick and easy wins and how to strategically implement these changes to drive cost savings
- Offering examples of successful reform: What do these instances have in common? What lessons can we learn to apply to further initiatives?

gsk GlaxoSmithKline



Jennifer McGee
Quality Head, Biopharmaceuticals External Supply and Central Testing Lab
GSK

9:45 - 10:20 am

Taking Our Industry to the Next Level

- Where are our organizations collectively heading together as a biopharmaceutical manufacturing community?
- Discussing practical leadership approaches that compel and empower participants to move their organization beyond the constraints of the past and set new, ambitious goals for the future
- Breaking down our current and future requirements and capabilities by geography, people, and technology
- Talking about next generation platforms and how they will change the way we succeed
- Illustrating these exciting next steps in action using case studies from Kite Pharma's experience

BREAKOUT ROOM 3
LIVE MODALITIES

Kite, A GILEAD Company

Bradley Glover
VP, Strategy and Business Operations
Kite Pharma

10:20 - 11:35 am

Pre-Arranged One-to-One Meetings

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

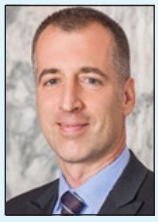
11:40 am - 12:15 pm

Ready or Not, Digitization Will Transform Biomanufacturing

- The Amazon-ization of Retail – How an industry-wide disruption unfolds
- The ongoing digitization of the Biopharma ecosystem – The transformation of drug delivery
- The Possible? Likely? Inevitable? Impacts on Tech Ops – Recent new roles analysis
- What it all means for Biomanufacturing leadership

WORKSHOP
BREAKOUT ROOM 1

Russell Reynolds Associates



Pascal Bécotte
Global Leader - Operations & Supply Chain Practice
Russell Reynolds

Jackie Ross
Executive Search Consultant, Life Sciences & Disruptive Healthcare
Russell Reynolds

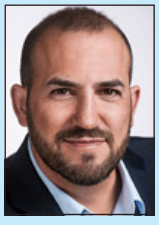
11:40 AM - 12:15 PM

Establishing a 'Culture of Data' in Biomanufacturing

- Biologics 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

WORKSHOP
BREAKOUT ROOM 2

BIOVIA



Christopher Andrews
BIOVIA Senior Solutions Consultant
Biovia – Dassault Systems

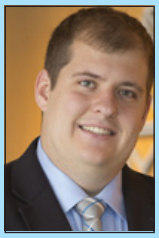
11:40 am - 12:15 pm

Obtaining Real-Time Shop-Floor Reconciliation and Operator Feedback with MES/Syncade Integration

- Operations and automation data – what's important, what's not
- Optimization of facility, maintenance and QC schedules
- Facility capacity analysis and delivering product "on time"
- Understanding schedule adherence and reconciliation

WORKSHOP
BREAKOUT ROOM 3

Bristol-Myers Squibb BIO-G Bioproduction Group



Ryan Burke
Senior Production Scheduler
Bristol-Myers Squibb

12:20 - 12:55 pm

Accelerating Delivery of New Medicines

- Examining technologies, tools, and platforms to accelerate the pace of biopharmaceutical development
- How development velocity can affect clinical development and what we learn in this process
- Examining how acceleration impacts our quality, regulatory, and supply chain functions. How do we all keep pace?
- Understanding how acceleration affects data monitoring and analytics throughout the product lifecycle
- Discussing what steps we as an industry will need to take together to make this the new normal

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Genentech
A Member of the Roche Group

Jerry Cacia
SVP, Head Global Technical Development
Genentech

12:20 - 12:55 pm

New Approaches to Quality that Streamline Operations and Simplify Regulatory Compliance

- Identifying where 'the way it has always been done' is holding your organization back
- Automating processes to track assets, inventory, throughput, and schedule preventative maintenance
- Customizing data collection and reporting to meet specific business and regulatory compliance requirements
- Upgrading systems for new functionality while minimizing downtime

BREAKOUT ROOM 2
QUALITY

AMGEN

Patrick Swann
VP, Quality Sciences and Technology
Amgen

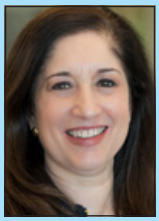
12:20 - 12:55 pm

Keeping CMC in Step with the Fast-Paced Product Development of Gene Therapy

- What are the challenges of taking a product from an academic institution late in clinical development to commercialization?
- Rethinking the traditional drug development paradigm that has become well established in the last several decades to ensure the rapid delivery of quality product to the patients
- Developing a robust CMC package that would meet the approval of Regulators when manufacturing for a rare disease and small patient population
- How we can level technology and insight from well-established biotech products?

BREAKOUT ROOM 3
LIVE MODALITIES

Spark™ THERAPEUTICS



Diane Blumenthal
Head Technical Operations
Spark Therapeutics

General Lunches Sponsored By: accenture

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:

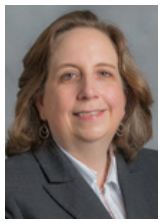
Emerging Challenges in Biotech Cyber Security

Pfizer

George Skillin
Sr. Director – Global Engineering
Pfizer

Continuous Manufacturing for Biologics: Lessons Learned from Small Molecules

MERCK



Christine Moore
Global Head and Executive Director, CMC Policy
Merck

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

Genentech
A Member of the Roche Group

Jeff Davis
Head of Operations and Engineering, US Biologics Process Development
Genentech

Challenges and Opportunities in Biosimilar Development

AMGEN

Aine Hanly
VP, Drug Substance Technologies
Amgen

Manufacturing, Quality and Innovation – Silos or Synergies?

BIOVIA

The Evolving Landscape of In Vivo/Ex Vivo Cell & Gene Therapy Manufacturing: Aligning the Market on How to Scale

Spark THERAPEUTICS

Christopher Stevens
Head of Manufacturing
Spark Therapeutics

Collaboration, Challenges, and Experiences in Cell and Gene Therapy Development

Biogen

Andrew Mica
Sr. Director, Gene Therapy Manufacturing Operations
Biogen

Experiences in Building Virtual Networks for Start Ups

VIR

Todd Renshaw
VP, Manufacturing
Vir Biotechnology

Modernizing Change Management – Opportunities for Better Intelligence to Improve Decision-Making and Enable Greater Agility

Veeva

Mike Jovanis
VP, Vault Quality
Veeva Systems

Digitization of the Supply Chain

WERUM
KÖRBER SOLUTIONS

1:55 - 2:30 pm

Building the Biomanufacturing Facility of the Future

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

- Discussing the challenge of supplying large patient populations: What makes sense now, and what does the future hold?
- How are cell-line improvements, fed-batch cell culture technology, and high-performance purification allowing our industry to increase output?
- Creating modular, scalable production facilities that will give our organizations the capacity to respond to changing global demand
- Illustrating the combination of process, plant, and operations using Biogen's NextGen facility in Luterbach, near Solothurn, Switzerland as an example

Biogen

Steve Doares
VP, Global Manufacturing Sciences
Biogen

1:55 - 2:30 pm

Staying Ahead of the Curve in an Increasingly Complex Regulatory World

BREAKOUT ROOM 2
QUALITY

- 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 you network of industry and trade organization connections
- Embracing the idea that keeping things simple even in a complex environment generates the best outcomes

novo nordisk

Henrik Friese
Corporate VP,
Novo Nordisk Quality
Novo Nordisk

Søren Thuesen Pedersen
Director, External Affairs
Novo Nordisk

1:55 - 2:30 pm

Collaborating to Build the Supply Chain of the Future

BREAKOUT ROOM 3
LIVE MODALITIES

- Discussing emerging technologies to Support innovative and individualized therapies' product supply
- What best practices can we borrow from current pharma supply chains?
- Understanding the unique challenges these new products and business models present
- Exploring challenges for managing raw material attributes and risks
- Ensuring chain of identity from collection to administration

gritstone ONCOLOGY

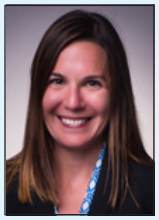
Jayant Aphale
EVP Technical Operations
Gritstone Oncology

2:35 pm - 3:10 pm

An Evolution into Biopharm 4.0

- Building a roadmap towards a digital vision starts with the destination in mind
- Developing a cohesive strategy based on a modular step-wise approach provides solid groundwork for future growth
- Gaining efficiencies in scale up and scale out capabilities with a standardized automation platform

WORKSHOP
BREAKOUT ROOM 1



Jennifer Staffin
Automation Solutions Director
GE Healthcare

2:35 pm - 3:10 pm

Digital Transformation of the Patient-Centric Value Chain

Driving down total cost of quality is a critical directive shared by all quality leaders regardless of their industry or company size. A strong foundation for a quality management system will uncover hidden cost-savings and value-add opportunities, and will help companies to thrive during this next stage of manufacturing. Highlights include:

- The consequences of an inferior quality management system
- The GxP-regulated environment: challenges and benefits of cloud platforms and other digital innovations
- Cost saving and value add opportunities that help companies to thrive

WORKSHOP
BREAKOUT ROOM 2

Joe Goodman
VP, Global Sales Engineering
Sparta Systems

2:35 pm - 3:10 pm

Added Value for Biotech Companies Using CDMOs

- When is the right time to seek out a CDMO? Where does the cost-benefit ratio make the most sense?
- Showcasing laboratories equipped with the next generation of tools and technology to improve productivity, reduce costs, and make QA/QC and compliance the foundation of the working environment
- How does this new equipment contribute to improving visibility, traceability and compliance up and down the supply chain?
- Drawing the line that connects new capabilities to both the company's superior performance and improved patient outcome

WORKSHOP
BREAKOUT ROOM 3

Gregor J. Kawaletz
VP Global Sales and Marketing
IDT Biologika GmbH

3:15 - 4:25 pm

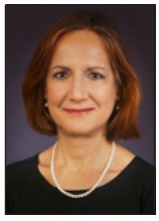
Pre-Arranged One-to-One Meetings

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

4:30 - 5:05 pm

Evolving External Collaboration Models

- Reviewing how our industry's business partnerships have changed over time. How will this trend continue into the future?
- Dividing the work and sharing the burden: How should biopharmaceutical companies align their objectives of cost management, risk management, productivity, and growth?
- Maturing business relationships over time through common culture through two-way communication, collaboration, and cooperation
- Walking through examples of external collaboration: What works, what does not, and why?



Joanne Beck
EVP, Global Pharmaceutical Development & Operations
Celgene Corporation

5:05 - 5:45 pm

Panel: Live Modalities and the Future of Biopharmaceutical Manufacturing

- 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?

Derek Adams
Chief Technology and Manufacturing Officer
bluebird bio

Andy Ramelmeier
SVP, Chief Manufacturing and Quality Officer
Sangamo Therapeutics

Bradley Glover
VP, Strategy and Business Operations
Kite Pharma

Loren Wagner
Head, CAR T Manufacturing Operations
Celgene

5:45 - 5:50 pm

Chair's Closing Address

Alison Moore
Chief Technology Officer
Allogene Therapeutics

5:50 - 7:00 pm

BIO-G Bioproduction Group
Proud Sponsor of the
Drinks Reception

OCTOBER 30, 2018

7:45 - 8:25 am

Registration and Breakfast

Sponsored By: emergent biosolutions®

8:25 - 8:35 am

Chair's Welcome Address

Alison Moore
Chief Technology Officer
Allogene Therapeutics

8:35 - 9:10 am

Panel: The Global Talent War in Biomanufacturing

- Learning about global talent trends influencing the job market for senior executives and those with critical, specialized skill sets
- Creating effective attraction, retention and development plans for top talent
- Navigating the generational talent gap in critical functions
- Understanding which leadership differentiators are needed to make it to Senior Executive and C-Level roles

Sanat Chattopadhyay
EVP & President, Merck Manufacturing Division
Merck

Joanne Beck
EVP, Global Pharmaceutical Development & Operations
Celgene Corporation

Alison Moore
Chief Technology Officer
Allogene Therapeutics

Pascal Bécotte
(Moderator) Global Leader - Operations & Supply Chain Practice
Russell Reynolds

9:10 - 9:45 am

Sustainable cGMP Compliance is Spelled with 4C's

- What do we mean when we talk about Quality Culture, and how has that changed over time?
- If we could start over from scratch, what would we want Quality Culture in our industry to look like?
- How do we move forward as leaders in our industry to harmonize the ideal with reality?
- Discussing the tools, tactics, techniques, and technologies we need to make part of this conversation
- Setting a challenging goal: What can we do next week to move forward with what we have discussed today?

Anders Vinther
Global Head of Quality and Engagement
Intarcia Therapeutics

9:50 - 10:25 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Looking at the Big Picture: Where is Our Industry Going, and How Should We Get There?

- Debating the merits of nimble and flexible facilities versus manufacturing battleships
- Preparing your pilot plants and manufacturing facilities to move forward with Phase II-III approvals
- Forecasting requirements for optimizing manufacturing equipment, facilities and partners to increase speed to market
- Achieving business goals to better manage times of product and economic uncertainty
- Putting theory into practice: Implementing key metrics to improve manufacturing flexibility

Uwe Buecheler
Corporate SVP, Biopharmaceuticals
Boehringer Ingelheim

9:50 - 10:25 am

Bringing Appropriate CXO Oversight to Continuously Monitor Ever-Changing Risk

- Identifying emerging risk and adjusting CXO oversight accordingly
- Using metrics to identify cross-functional enterprise risks
- Understanding the importance of accountability, communication, and collaboration between stakeholders when we talk about Risk
- What is the right way to apply risk assessment in CXO management
- Walking through real-world examples where implementing a risk-based strategy and making risk management part of the culture works

BREAKOUT ROOM 2
QUALITY

GILEAD

Bob Miller
SVP, Quality Assurance
Gilead Sciences

9:50 - 10:25 am

The Evolving Landscape of the Chinese Biopharma Industry

- Discussing the development of Biologics in China for global markets
- Understanding the unique business environment of the region. What do we need to do to succeed?
- Walking through recent changes in the regulatory and operating environment in China
- How will the evolution of biosimilars and bio-betters in China affect global markets and drug prices?

BREAKOUT ROOM 3
LIVE MODALITIES

Henlius

Scott Liu
CEO & Co-Founder
Henlius Biopharmaceuticals

10:25 - 11:15 am

Pre-Arranged One-to-One Meetings

10:30 am – 10:50 am: Meeting Slot 7 / Networking
10:05 am – 11:15 am: Meeting Slot 8 / Networking

10:25 - 11:00 am

Industry Focus Groups

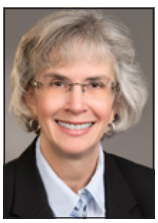
Industry focus groups are moderated conversations among executives who share a common interest and want to discuss a series of relevant issues that are too specific for a summit-wide town hall Q&A. Hosted by a thought leader with extensive experience and expertise on the topic at hand, these focus groups will ask the right questions and crowd-source innovative answers from an open forum attended by interested and engaged peers.

CELL & GENE THERAPY FOCUS GROUP

The Future of Emerging Technology in Cell and Gene Therapy: Where Are We Going?

- What should emerging companies pay most attention to when they consider "industrializing" a still-largely research process for cellular therapy and gene therapy?
- When considering a global launch for genetically modified cellular therapy, what efforts should a company take in an attempt to harmonize Global Regulatory Assessments?
- What are the hurdles for off-the-shelf CAR-T type therapies?
- What does the future of these therapies look like in 10 years? What are the biggest challenges still to overcome in realizing that future?

SeattleGenetics®



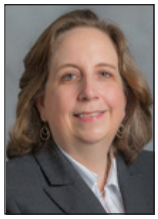
Karen Walker
VP Quality
Seattle Genetics

11:20 - 11:55 am

Panel: ICH Q12- Understanding from the Industry's Perspective

This panel is comprised of industry executives whose past work experience with the FDA, CDER, and CBER offer them unique insights into:

- Streamlining and Management of Post Approval Chemistry, Manufacturing & Control (CMC) changes
- How will these new guidelines affect how we manage operations across the product lifecycle going forward?
- What challenges and opportunities does the ICH Q12 present? How will this change the industry?
- How can these new guidelines facilitate innovation and reduce costs through the product lifecycle?
- Best practices for moving quality forward and coming into compliance with ICH Q12



Christine Moore
Global Head and Executive Director, CMC Policy
Merck

Andrew Chang
VP, Quality and Industry Compliance, CQ
Novo Nordisk

Patrick Swann
VP, Quality Sciences and Technology
Amgen

Sarah Kennett
Sr. Regulatory Program Director, Biologics
Genentech

12:00 - 12:35 pm

WORKSHOP
BREAKOUT ROOM 1

Leveraging Artificial and Business Intelligence to Drive Productivity Improvement and Compliance

- Common drivers for success:
  - Leveraging Artificial and Business Intelligence to deploy automated systems to detect abnormal performance
  - Deploying an automated management alarm and escalation system; used emails and text messages to accelerate response to performance-impacting events
  - Creating real-time management dashboards and alerts, tailored for each role
  - Connecting and integrating data across multiple platforms, e.g. PLCs, ERPs, QMS, LIMS, etc.
- Manufacturing Case Study: 300% productivity improvement in a capacity-constrained environment

Jaime Velez
Partner
OQSIE

12:00 - 12:35 pm

WORKSHOP
BREAKOUT ROOM 2

Scaling Out Using a Digitized Supply Chain for Autologous and Allogenic Cell Therapies

- Discussing the supply chain and operational challenges involved in autologous therapies
- Comparing and contrasting these issues to allogeneic therapies
- How can manufacturers leverage Industry 4.0 solutions to improve performance and increase productivity?
- Offering real-world working examples of a rollout of these tools in both new and existing organizations

Benjamin Pieritz
EVP & GM
Werum IT Solutions – America

General Lunches Sponsored By: accenture

12:35 - 1:35 pm **LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS**

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What Should We Do Today to Prepare for the Supply Chain of the Future?

Spark Therapeutics

Ryan Bartock
Head of Supply Chain and Network Strategy
Spark Therapeutics

Process Intensification: Process and Technology Strategies to Maximize Productivity in New and Existing Facilities

Boehringer Ingelheim

Nuno Fontes
Executive Director, Process Science
Boehringer Ingelheim

Tech Transfer: Quality, Cost and Speed— Solving For All Three

Aptevo Therapeutics

Randy J. Maddux
SVP and Chief Manufacturing Officer
Aptevo Therapeutics

Retaining Talent and Keeping Them Engaged in Uncertain Times

MOMENTA

Elsie DiBella
VP, Bioprocess & CMC Development
Momenta Pharmaceutical

Using Digital Innovations to Address Biomanufacturing and Supply Challenges

Takeda

Piper Trelstad
Sr. Director, Strategy and Project Management
Takeda Pharmaceuticals

High Quality Plasmid Use in the Lifecycle of Gene Therapies

gsk GlaxoSmithKline

Rob Piperno
Director Cell & Gene Therapy Quality Assurance
GSK

Implementation of QbD to Commercial Programs

Shire

Diana Hoganson
Director CMC Lead
Shire

1:35 - 2:10 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Digital Transformation with Business Impact for Biopharmaceutical Manufacturers

- 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
- Understanding why data lakes and bespoke projects do not scale
- Illustrating successful projects with concrete examples

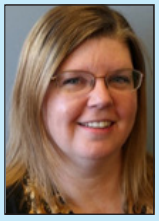
Matthew Shields
VP & Global Head Specialty Care Manufacturing Operations
Sanofi

1:35 - 2:10 pm

BREAKOUT ROOM 2
QUALITY

Promoting Professional Growth to Inspire Your QA/QC Team

- Evaluating and aligning your leadership style with the shifting needs of up-and-coming demographics within your QA/QC organization
- Establishing group- and function-specific development resources to promote professional growth and maintain employee engagement even during times of business transformation
- Identifying and accommodating your personnel's changing aspirations for their careers
- Best strategies for feeling fulfilled in your profession and getting the most out of your team by helping them to do the same



Paulien Groll
Head of Regulatory Compliance, Technical Operations
Shire US

2:15 - 2:50 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Boosting Traceability and Security in the Supply Chain with Serialization

- What is serialization?
- Global serialization mandates
- Impact on manufacturing and the pharma supply chain
- Implementation challenges
- Technologies – Now and into the future

George Skillin
Sr. Director – Global Engineering
Pfizer

2:15 - 2:50 pm

BREAKOUT ROOM 2
QUALITY

Inspiring a Quality Culture: Why Culture is the Key To Competitive Advantage

- Culture is the driving force of quality. Explore ways that quality culture contributes to organizational performance
- How do you transform culture in an industry that is moving and shifting fast?
- What actions are needed to help an organization shift from a rules-based quality environment to a true culture of quality?

Lisa Wyman
Executive Director, Head of Quality
Mersana Therapeutics

2:50 - 3:00 pm

Chair's Closing Address

Alison Moore
Chief Technology Officer
Allogene Therapeutics