BIOMANUFACTURING
WORLD SUMMIT
BMWS17

November 13-14, 2017 | Hyatt Regency La Jolla | San Diego, CA | biomanworld.com

AGENDA

NOVEMBER 12, 2017

6:00 - 7:00 pm

NOVEMBER 13, 2017

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

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

Alison Moore
SVP, Process Development
Amgen

8:30 - 9:05 am — **Leveraging Global Change to Create Strategic Opportunity —and Design a New Future— for Manufacturing and Supply Chain Leaders**

- Discussing the global forces shaping the healthcare environment. How is the industry's current business model being questioned and the definition of innovation shifting?
- Understanding how the evolution of patients, consolidation of customers, and pressures on cost will accelerate while new players continue to enter the industry and redefine our paradigms
- Shedding light on the impact of these changes on manufacturing, quality, and supply chain
- Making the case that the strategic opportunity for our leaders has never been greater
- Sharing examples of how Teva is taking a leading role in shaping our new future

R. Ananth
President and
Chief Executive Officer,
TAPI and Biologics Operations
Teva Pharmaceuticals

9:05 - 9:40 am

Future Challenges for Technical Operations in the Pharmaceutical Industry

- Discussing the uncertainties and new challenges facing our industry even as we enjoy strong pipelines, raising demands for better and more affordable treatments, and an attractive growth path
- Illustrating how the tech-ops organization should adapt to changing internal environment factors including new product classes, new technology, and new business models
- Highlighting ways to meeting changing external environmental pressures like accelerated approval paths, reimbursement for advanced therapeutics, customer demands, political barriers, and many others
- Where does scientific, technological, and manufacturing innovation fit into this evolving internal and external landscape?
- Focusing on creating sustainable value through innovation and managing productivity in times of change and high volatility
- Offering a long-term view on potential disruptive change as well as on proactive shorter term measures

Bayer HealthCare

Wolfram Carius
Executive Vice President
Pharmaceuticals Product Supply
Bayer

9:45 - 10:20 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Leading and Leadership in Lean Bio-Manufacturing Operations

- Lean applications in Bio-Manufacturing is both complex and simple
- Sustaining lean performances in Bio-Manufacturing is both science and art
- Good versus Great Lean leadership… It matters
- Successful OE polynomial equation for Lean Bio-Manufacturing = … ?

MERCK

Jacks Lee
SVP Manufacturing
Merck

9:45 - 10:20 am

BREAKOUT ROOM 2
QUALITY

Using Quality to Enable Performance Rather Than Measure Performance

- Laying out a roadmap to the future for Quality Leadership
- Establishing one objective across Quality, Commercial and Operations
- Discussing quality infrastructure
- Understanding you eat the elephant one bite at a time
- Taking a proactive Quality/Compliance approach
- Where will we be next?

gsk GlaxoSmithKline

Andrew Jones
Head of Product Quality,
Biopharm and Steriles
GlaxoSmithKline

9:45 - 10:20 am

BREAKOUT ROOM 3
SUPPLY CHAIN MANAGEMENT

Designing Supply Chains for Biologics

- Comparing and contrasting what Small Molecule and Large Molecule products require from their supply chains
- Discussing some of the key challenges supply chain executives face when supporting biopharmaceutical manufacturing operations
- Highlighting the opportunities for innovation when creating new infrastructure and processes
- Illustrating these points with examples from how Biogen's Supply Chain is working to build end-to-end capacity to support a new drug

Biogen

Maria Nieradka
SVP, Global Supply Chain
Biogen

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

WORKSHOP
BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Biotech Business Bootcamp – Treating Cultural Sclerosis…

- Repetitive engagement survey results with no sustainable action plan for improvement?
- Meeting mania dominating each and every day?
- Data, metrics, KPI's, and scorecards – Thermometers or Thermostats?
- OPEX tools and governance models that feel abstract and disconnected?

Struggling with any of these symptoms? If so, your organization is suffering from Cultural Sclerosis. While not fatal, it is debilitating. Fortunately, we have developed a 'Sustainable Treatment Plan' based upon 25 years of work with organizations including GSK, Pfizer, Genentech, Gilead, and Alcon that will drive Clarity, Connectivity and Consistency into both your team and leadership culture.

Competitive Solutions Inc.

Shane Yount
President
Competitive Solutions, Inc

11:40 AM - 12:15 PM

WORKSHOP
BREAKOUT ROOM 2
QUALITY

Operationalizing Digital Manufacturing in Life Sciences

By 2022, Smart factories will deliver an estimated $500B in value and a 7x increase in overall productivity. What can Life Sciences manufacturing leaders do today to ensure short-term investments support the capabilities required for near and long-term Digital Manufacturing success?

- How can companies identify their current level of Digital Readiness?
- What Life Science use-cases become feasible as a company increases their Digital Readiness?
- What pitfalls threaten successful Digital Manufacturing implementations within the Life Sciences field?
- What has Sight Machine learned from working with the world's most advanced Digital Manufacturers?

SIGHT MACHINE
Manufacturing Analytics

Ryan Smith
VP of Engineering and Product Development
Sight Machine

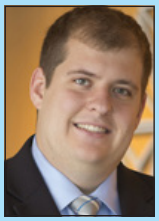
11:40 am - 12:15 pm

WORKSHOP
BREAKOUT ROOM 3
SUPPLY CHAIN MANAGEMENT

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

Bristol-Myers Squibb



Ryan Burke
Senior Production Scheduler
Bristol-Myers Squibb

BIO-G
Bioproduction Group

12:20 - 12:55 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Knowing and Protecting Your Assets

- Discussing options for biomanufacturing capacity management:
  - Effective strategies for capacity utilization
  - Spreading capacity among and across different business partners
  - When is the right time to hedge with CMOs?
- Understanding the attraction, retention, and development trends for talent assets
  - Illustrating these trends with metrics and examples from AstraZeneca's own experience

AstraZeneca

Darren Dasburg
VP and Head Learning and Development Global Operations
AstraZeneca

12:20 - 12:55 pm

BREAKOUT ROOM 2
QUALITY

Simplicity as a Core Strength of Quality Management Systems

- Discussing how the regulatory world for the pharmaceutical industry continues to grow in complexity
- Embracing the philosophy that making a complex world simple to the end user will improve quality and safeguard compliance
- How has Novo Nordisk worked to generate and sustain simplicity as one of the more important features of its QMS?
- Demonstrating that reducing the average number of SOPs per employee has positive impacts on performance
- Addressing the robustness and agility of this approach to Quality Management Systems

novo nordisk

Søren Thuesen Pedersen
Director, External Affairs
Novo Nordisk

12:20 - 12:55 pm

BREAKOUT ROOM 3
SUPPLY CHAIN MANAGEMENT

Sharing the Burden of Managing Supply Chain Costs, Risk and Volume Volatility

- How can manufacturing groups support other efforts to cultivate a partnership culture where that culture is desired?
- Can manufacturers and their customers truly align objectives for cost management, risk management and growth?
- Ensuring people and operational styles sustain a true partnership
- Structuring continuous improvement programs into supply chain operations to facilitate a win-win situation between clients and suppliers

SANOFI GENZYME

Laurent Boer
GM & VP Materials Management
Sanofi Genzyme

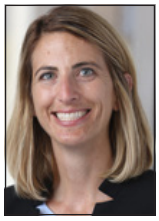
12:55 - 1:55 pm

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:

Fostering The New Generation of Women Leaders in Biotech

ACHAOGEN



Tina Larson
Vice President of Technical Operations
Achaogen

Building Flexibility into Manufacturing Processes

AMGEN

Cathryn Shaw-Reid
Executive Director Process Development
Amgen

Fostering a Positive Manufacturing Culture

Bristol-Myers Squibb

Lisa McClintock
Director Global Product Development & Supply
Bristol-Myers Squibb

Deploying Lean Concepts and Practices for the Execution of CAPEX Investments

Genentech
A Member of the Roche Group

Marc Lampron
Program Director
Genentech

Transforming Drug Product and Finished Goods Manufacturing into the Next Generation Finished Goods

Biogen

Marisa Bookman
Head of North America Commercial Supply Chain
Biogen

1:55 - 2:30 pm

Taking a Methodical, Documented, Risk-Based Approach to Establishing Quality and Compliance Programs

- Illustrating how highly procedural and well-documented commissioning and start up processes deliver successful new projects
- Eliminating the divide between Quality and Manufacturing functions and embracing a philosophy of manufacturing quality products
- Offering best practices for senior leaders as they create, update, and communicate the quality and compliance processes throughout the lifecycle of the project
- Talking about Risk Management and the importance of a well-understood and methodical sequence to scheduled tasks and bringing new operations online
- Highlighting best practices to make ongoing documentation a powerful quality and compliance tool for the future

Lilly

Johna Norton
Senior Vice President, Global Quality
Eli Lilly and Company

2:35 pm - 3:10 pm

Establishment of Efficient Cell Culture Supply Chain through Partnerships

- Understanding GMP production of biologic therapies is a long-term commitment throughout the life-cycle of a product
- Discussing how for CDMOs this includes developing strong relationships with suppliers
- Demonstrating the importance of a solid supplier partnership, from early stages of technology implementation, is essential for long-term success
- Illustrating a successful Supplier-CDMO relationship in action using GE Healthcare and FUJIFILM Diosynth Biotechnologies as an example
- Showcasing how this partnership rapidly added cell culture manufacturing capacity through the implementation of single-use production systems

WORKSHOP
BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

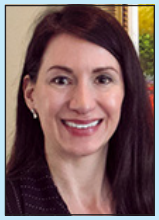
Jeff Carter
Strategic Projects Leader
GE Healthcare

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 2
QUALITY

Leveraging a Holistic Quality Approach to Improve Manufacturing Performance

- In today's complex environment of increasing regulations, global supply chains, local quality specifications and elevated patient expectations around drug availability and effectiveness, managing regulatory compliance and quality with a Quality Management System alone is not good enough
- Only organizations that implement and leverage quality in all stages of product development (upstream and downstream) by introducing a holistic Quality Culture can be successful and competitive
- This transformative Quality Culture requires data integration throughout the organization—horizontally (all manufacturing sites including CMOs) and vertically (from the shop floor to the board room)
- By leveraging end-to-end digitalization, managing data holistically and applying advanced analytics and deep learning, organizations can improve data quality and integrity while also enhancing manufacturing performance



Heather Valentine
Senior Vice President
Dassault Systèmes BIOVIA

2:35 pm - 3:10 pm

WORKSHOP
BREAKOUT ROOM 3
SUPPLY CHAIN MANAGEMENT

Advances in Real-Time Microbial Monitoring of Pharmaceutical Waters

- Discussion of the technology to monitor bioburden real-time in purified water and water for injection
- Adoption, implementation and evaluation of at-line microbial monitoring
- Benefits of real-time microbial monitoring versus traditional plate counts

James B. Cannon
Head of OEM and Markets
Mettler-Toledo Thornton

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

A New Way to Rapidly Develop Biomanufacturing Capacity and Add Greater Value to the Decision to Build

- Investing capital in capacity expansion when a drug is early in development is challenging. There are new manufacturing models that reduce risk and add value to your decisions through a concept called optionality
- Balancing options and critically evaluated risk against probability of success in to-build decisions
- Introducing a new biomanufacturing solution that leverages manufacturing ecosystems to reduce the need to build infrastructure
- Effectively transfer non-value added work from the manufacturing site to service providers with this new manufacturing model

Daniel Palmacci
VP of Drug Product Network and Site Head Schaftenau
Novartis

5:05 - 5:40 pm

The Past, Present, and Future of Quality Culture

- 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
Chief Quality Officer
Sanofi Pasteur

5:40 - 5:55 pm

Town Hall Q&A

This moderated Q&A session will answer questions that were gathered from the audience throughout the course of the summit and discussed in an open forum among speakers, delegates, and sponsors.

Alison Moore
SVP, Process Development
Amgen

5:55 - 7:30 pm

NOVEMBER 14, 2017

8:00 - 8:40 am

Registration and Breakfast

8:40 - 8:50 am

Chair's Welcome Address

Alison Moore
SVP, Process Development
Amgen

8:50 - 9:25 am

Evolving External Collaboration Models

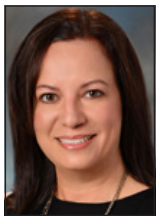
- Reviewing how our industry's business partnerships have changed over time. How will this trend continue into the future?
- Dividing the work and sharing the burden: How should biopharmaceutical companies align their objectives of cost management, risk management, productivity, and growth?
- Maturing 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?

Sid Advant
Executive Director,
Biologics Manufacturing
Celgene Corporation

9:25 - 10:00 am

Breakthrough Designations - How Can Quality Enable Speed to Innovation?

- Offering an overview of how breakthrough therapy designations have historically worked and how that process is changing
- Are we as an industry ready for major changes in how drug development is expedited?
- Discussing how our organizations' Quality Culture must be an integral part at all stages of this transition
- Working with all stakeholders to ensure we do not sacrifice safety and quality as we increase the pace of innovation
- What should we be doing right now to prepare for the future of these developments?



Christie Bielinski
Vice President of
Product Quality
Management
Janssen
Pharmaceuticals

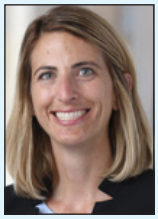
10:05 - 10:40 am

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Panel: Disrupting the Biotech Industry- How Small & Mid-Sized Innovators Create a Competitive Advantage

- Advantages of smaller more agile organizations' ability to react to patient, regulatory & market pressures
- Discussing internal innovations in production technologies and working with external partners to do the same
- How do we adapt our leadership, organizational structure and people management strategies?
- Lean implementations as a Smart Risk management tool
- Leveraging collaborations with big pharma to foster innovation and increase speed to market

ACHAOGEN



Tina Larson
Vice President of Technical Operations
Achaogen

Celgene

Mayo Pujols
VP Global Head Car-T Operations and Technology
Celgene Corporation

aTyr Pharma

Ashraf Amanullah
VP of Biologics Development and Manufacturing
aTyr Pharma

SUTRO BIOPHARMA

Heidi Hoffmann
Senior Director, Supply Chain and CMC Team Lead
Sutro Biopharma

10:05 - 10:40 am

BREAKOUT ROOM 2
QUALITY

The Power of Digitizing Life Cycle Management

- Focusing on the key pain points that can alleviate pressure and establish proficiency within the development cycle
- Collaborating with technology providers to customize solutions in alignment with product development needs
- Tracking the progression of critical teams in achieving specific strategic goals

AMGEN

Jerry Murry
VP CMC Lifecycle Management
Amgen

10:05 - 10:40 am

BREAKOUT ROOM 3
SUPPLY CHAIN MANAGEMENT

Developing Gene Therapy Capability for the Treatment of Hemophilia A

- The next generation of biopharmaceuticals are increasingly complex and can present distinct facility and process validation considerations
- Successfully developing a new modality requires building internal expertise and effectively leveraging existing capabilities
- Recent gene therapy clinical trials have shown remarkable therapeutic benefits and an excellent safety record
- The foundation of development is investing in relevant science leading to product knowledge
- There may be fewer options for new modalities when considering buying versus building capacity

BIOMARIN

Erik Fouts
VP, Novato Manufacturing and Facilities/Engineering
BioMarin Pharmaceuticals

10:40 - 11:30 am

Pre-Arranged One-to-One Meetings

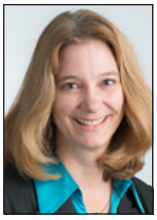
10:40 am – 11:00 am: Meeting Slot 7 / Networking
11:05 am – 11:25 pm: Meeting Slot 8 / Networking

11:35 - 12:10 pm

Redefining Competition: Thinking About Our Industry in a Revolutionary Way

- What are we doing today to get ready for the realities of our industry a decade from now?
- Debating what we will need in terms of leadership, people, technology, territory, and resources to grow into new markets with new products in an ever-changing regulatory landscape
- Is the answer steady growth, or improving agility and versatility, or some third option?
- Making the case that our industry needs to work together better as individual actors on a shared stage

Genentech
A Member of the Roche Group



Kimball Hall
SVP and Head of Drug Substance Biologics Manufacturing
Genentech

12:15 - 12:50 pm

WORKSHOP
BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Development of Biologics in China for Global Markets: Lessons From Wuhan, China

- Discussing the approach required to success in the unique business environment of the region
- Walking through recent changes in the regulatory and operating environment in China
- Offering lessons learned by JHL Biotech, a biologics development and manufacturing firm with headquarters in Taiwan and a commercial-scale production site in Wuhan, China
- Highlighting JHL Biotech's path to rapidly building and operating two production facilities in Asia, with an emphasis on JHL's use of modular and single-use technologies to accelerate facility construction and accelerate product timelines

喜康
JHL BIOTECH

Racho Jordanov
CEO & President
JHL Biotech Inc.

12:15 - 12:50 pm

WORKSHOP
BREAKOUT ROOM 2
QUALITY

Current Data Integrity Initiatives and How eQMS Supports Compliance with Regulatory Guidelines

In this session we will review:

- Current state of DI guidelines from key global authorities
- Review some current DI audit trends, DI risks migrating from paper to eQMS
- Explore need to conduct an internal DI Assessment
- Review eQMS DI features and solutions to support DI Compliance

EtQ

Tony Parise
Product Strategist-Life Sciences
EtQ LLC

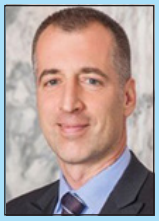
12:15 - 12:50 pm

WORKSHOP
BREAKOUT ROOM 3
SUPPLY CHAIN MANAGEMENT

How to Win the Global Talent War in Biomanufacturing

- Learn about global talent trends in end-to-end Technical Operations
- Create effective attraction, retention and development plans for top talent
- Navigate the generational talent gap in critical functions
- Find out what leadership differentiators are needed to make it to C-Level roles

Russell Reynolds ASSOCIATES



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

Russell Reynolds ASSOCIATES

Erin Zolna
Executive Search & Assessment Consultant
Russell Reynolds

12:50 - 1:50 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:

Using Quality Metrics to Transform the Quality Culture

BIOVIA

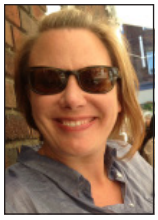
Personalized Therapeutics for Biotech Startups: Re-thinking the classical CMC Strategy

TURNSTONE BIOLOGICS

Manny Otero
VP Manufacturing & CMC
Turnstone Biologics

Strategy Development in a Changing Landscape

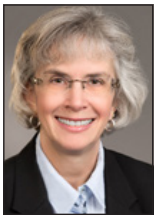
BIOMARIN



Kim Fellows-Peake
Executive Director, Strategy Realization
BioMarin Pharmaceuticals

Weighing Genomic Strategies – Complexity, Cost, Benefit; Exploring the Evolving Landscape

SeattleGenetics®



Karen Walker
VP Quality
Seattle Genetics

Added Value for Biotech Companies Using CDMOs

IDT

Beyond the Molecule Innovation for Biopharmaceutical Products

AMGEN

Arun Tholudur
Executive Director, Process Development
Amgen

1:50 - 2:25 pm

BREAKOUT ROOM 1
STRATEGIC MANUFACTURING

Integrated Supply Planning: A Critical Capability for BioPharma Innovator Companies

- Competition and strong market forces are creating unprecedented volatility in the all the traditional lifecycle phases for innovative biopharmaceuticals
- Speed and agility are now, more than ever, critical business imperatives for supply chain management to enable to maximize global patient supply and business results
- Within BMS Global Supply Chain we are implementing an Integrated Supply Planning model, leveraging a planning team concept to integrate network, product, and site planning perspectives
- Key learnings from major brand launch and growth over the last 5 years will be discussed, as well as how elements of people, process, and technology contribute to establishing a transformative new supply chain planning capability

Bristol-Myers Squibb

Paul J. Staid
Head, Global Supply Planning
Bristol-Myers Squibb

1:50 - 2:25 pm

Harnessing Collective Ambition: The Competitive Advantage to Quality

- Change in our industry is constant. How does an organization pro-actively shape, influence and adapt rather than react?
- Disciplined execution and quality excellence are critical to achieving business goals. How to build a quality management system and an insightful culture that can endure mergers & acquisitions, rapid growth and disruptive technology?
- How can we be more effective in shaping an organization's talent strategy to drive innovation, diversity and market growth?

BREAKOUT ROOM 2
QUALITY

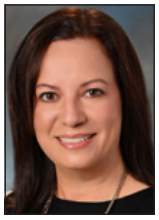
Lisa Wyman
Head of Quality Compliance & Risk Management
Shire

2:30 - 3:05 pm

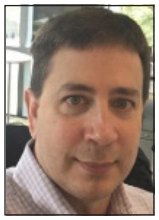
Panel Discussion: Pharma 4.0 – Biopharmaceutical Production in the Digital Age

- Addressing the state of the biopharmaceutical industry today: Which emerging trend will see the most growth?
- Embracing modular automation, PAT and continuous processing to increase agility, flexibility and improve efficiencies
- People and technology: How are these forces working together to grow and mature our industry?
- IoT- how will cloud based data, data analytics and data integrity evolve compliance and quality towards continuous improvement
- How will these technologies affect patient and product needs towards more individualized therapies?

Rohini Deshpande
VP Process Development
Amgen



Christie Bielinski
Vice President of Product Quality Management
Janssen Pharmaceuticals



Craig Beasley
VP Manufacturing Operations
Juno Therapeutics

3:05 - 3:15 pm

Chair's Closing Address

Alison Moore
SVP, Process Development
Amgen