AGENDA

NOVEMBER 12, 2017

6:00 - 7:00 pm

Boehringer Ingelheim

Proud Sponsor of the

Drinks Reception

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
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

Wolfram Carius
Executive Vice President
Pharmaceuticals Product Supply
Bayer

9:45 - 10:20 am

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 = ... ?

Jacks Lee
SVP Manufacturing
Merck

9:45 - 10:20 am

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?

Andrew Jones
Head of Product Quality,
Biopharm and Steriles
GlaxoSmithKline

9:45 - 10:20 am

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

Maria Nieradka
SVP, Global Supply Chain
Biogen
11:40 am - 12:15 pm

**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.

**Shane Yount**
President
Competitive Solutions, Inc

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11:40 am - 12:15 pm

**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?

**Ryan Smith**
VP of Engineering and Product Development
Sight Machine

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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

**Ryan Burke**
Senior Production Scheduler
Bristol-Myers Squibb

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**Meeting Slot 1 / Networking**
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
<table>
<thead>
<tr>
<th>Time</th>
<th>Panel</th>
<th>Topic</th>
<th>Speakers</th>
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</thead>
<tbody>
<tr>
<td>12:20 - 12:55 pm</td>
<td><strong>BREAKOUT ROOM 1</strong></td>
<td><strong>STRATEGIC MANUFACTURING</strong></td>
<td><strong>Knowing and Protecting Your Assets</strong>&lt;br&gt;- Discussing options for biomanufacturing capacity management:&lt;br&gt;  - Effective strategies for capacity utilization&lt;br&gt;  - Spreading capacity among and across different business partners&lt;br&gt;  - When is the right time to hedge with CMOs?&lt;br&gt;- Understanding the attraction, retention, and development trends for talent assets&lt;br&gt;  - Illustrating these trends with metrics and examples from AstraZeneca’s own experience</td>
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<td>12:20 - 12:55 pm</td>
<td><strong>BREAKOUT ROOM 2</strong></td>
<td><strong>QUALITY</strong></td>
<td><strong>Simplicity as a Core Strength of Quality Management Systems</strong>&lt;br&gt;- Discussing how the regulatory world for the pharmaceutical industry continues to grow in complexity&lt;br&gt;- Embracing the philosophy that making a complex world simple to the end user will improve quality and safeguard compliance&lt;br&gt;- How has Novo Nordisk worked to generate and sustain simplicity as one of the more important features of its QMS?&lt;br&gt;- Demonstrating that reducing the average number of SOPs per employee has positive impacts on performance&lt;br&gt;- Addressing the robustness and agility of this approach to Quality Management Systems</td>
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<td>12:20 - 12:55 pm</td>
<td><strong>BREAKOUT ROOM 3</strong></td>
<td><strong>SUPPLY CHAIN MANAGEMENT</strong></td>
<td><strong>Sharing the Burden of Managing Supply Chain Costs, Risk and Volume Volatility</strong>&lt;br&gt;- How can manufacturing groups support other efforts to cultivate a partnership culture where that culture is desired?&lt;br&gt;- Can manufacturers and their customers truly align objectives for cost management, risk management and growth?&lt;br&gt;- Ensuring people and operational styles sustain a true partnership&lt;br&gt;- Structuring continuous improvement programs into supply chain operations to facilitate a win-win situation between clients and suppliers</td>
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<td>12:55 - 1:55 pm</td>
<td><strong>LUNCH-AND-LEARN ROUNDTABLE DISCUSSIONS</strong></td>
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<td>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:</td>
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<td></td>
<td><strong>ACHAOGEN</strong></td>
<td><strong>Fostering The New Generation of Women Leaders in Biotech</strong></td>
<td>Tina Larson&lt;br&gt;Vice President of Technical Operations&lt;br&gt;Achaogen</td>
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<td><strong>AMGEN</strong></td>
<td><strong>Building Flexibility into Manufacturing Processes</strong></td>
<td>Cathryn Shaw-Reid&lt;br&gt;Executive Director Process Development&lt;br&gt;Amgen</td>
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<td><strong>Bristol-Myers Squibb</strong></td>
<td><strong>Fostering a Positive Manufacturing Culture</strong></td>
<td>Lisa McClintock&lt;br&gt;Director Global Product Development &amp; Supply&lt;br&gt;Bristol-Myers Squibb</td>
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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

Jeff Carter
Strategic Projects Leader
GE Healthcare
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?
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.

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5:55 - 7:30 pm  
**Drinks Reception**

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8:00 - 8:40 am  
Registration and Breakfast

8:40 - 8:50 am  
Chair’s Welcome Address

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8:40 - 8:50 am  
Chair’s Welcome Address

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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

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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
Breakout Room 1: Strategic Manufacturing

10:05 - 10:40 am
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

Tina Larson
VP of Technical Operations
Achaogen

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

Ashraf Amanullah
VP of Biologics Development and Manufacturing
aTyr Pharma

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

Breakout Room 2: Quality

10:05 - 10:40 am
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

Jerry Murry
VP CMC Lifecycle Management
Amgen

Breakout Room 3: Supply Chain Management

10:05 - 10:40 am
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

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

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
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

Kimball Hall
SVP and Head of Drug Substance Biologics Manufacturing Genentech

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

Racho Jordanov
CEO & President JHL Biotech Inc.

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

Tony Parise
Product Strategist-Life Sciences EtQ LLC

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

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

Erin Zolna
Executive Search & Assessment Consultant Russell Reynolds
1:50 - 2:25 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**
  - **Kim Fellows-Peake**
    - Executive Director, Strategy Realization BioMarin Pharmaceuticals

- **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**

- **Weighing Genomic Strategies – Complexity, Cost, Benefit; Exploring the Evolving Landscape**
  - **Seattle Genetics**
  - **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 - 1:50 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

- **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

Lisa Wyman
Head of Quality Compliance & Risk Management
Shire

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