

7:15-8:10

Registration and Breakfast

8:10-8:25

Chair's Welcome Address

Mark Paxton  
CEO  
Rx-360

8:25-9:00

Opening Keynote: State of the Industry Address – What Can We Look Forward To?

**Genentech**  
*A Member of the Roche Group*

- The big picture: the state of the biotech industry
- Challenges in capacity planning, make-buy decisions, and supply chain management
- Challenges and opportunities new markets and economies offer
- Keeping up with a complex and rapidly changing world
- The future: what can we expect? What can we look forward to?

Patrick Yang  
Former EVP, Technical Operations  
Genentech

9:00-9:35

Biologics Supply Chain: Modeling Point and Systemic Risks

**AstraZeneca**

- 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

Andrew Skibo  
Head of Global Biologics Operations & Global Engineering  
AstraZeneca Biologics

Lance Minor  
VP Global Biologics: Network Strategy & Performance  
AstraZeneca Biologics

9:40-10:15

CASE STUDY STREAM 1

STRATEGIC MANUFACTURING

Assessing the Climate of Single-Use Technologies

SANOFI PASTEUR

emergent  
biosolutions™

Shire  
AMGEN

- Real-world examples of single-use systems in industry and

9:40-10:15

CASE STUDY STREAM 2

SUPPLY CHAIN MANAGEMENT

Fill and Finish Supply Chain Management – Combining the Convenience of Local Manufacturing with the Security and Access of a Global Supply Chain

Actavis

- Why to plan your Fill & Finish supply chain strategy earlier than later
- How to balance the need for manufacturing resource efficiency

9:40-10:15

CASE STUDY STREAM 3

QUALITY

Creating a Clear Governance Model in your Organization to Successfully Implement New Processes and Quality Systems

Baxalta

- What can manufacturing teams do to enhance quality assurance and control?
- Which attributes can quality teams bring to process engineering and design?
- Managing manufacturing

comparability of product quality between single use and traditional processes

- Financial considerations in choosing between single use vs. traditional (stainless steel) equipment
- How do we manage the complexity without eliminating the flexibility and amenability for rapid response that are the benefits of single use systems?
- How does industry work with suppliers to improve reliability and ensure visibility while also allowing for constant improvement?

**Daniel Vellom**

Sr. Director, Global Technology Innovation  
**Sanofi Pasteur**

**Vijay Yabannavar**

Sr. VP, Manufacturing Ops. & Technical Development  
**Emergent Biosolutions**

**Alex Tschumakow**

Director Upstream Manufacturing  
**Shire**

**Jeff Ranney**

Director of Engineering  
**Amgen**

today with the need for an effective and secure global supply chain tomorrow

- Practical frameworks to evaluate prospective fill & finish manufacturing partners

**Carlos Villalobos**

VP Injectables and Biologics  
**Actavis**

complexity through:

- Opening communication lines in plant operations
- Aligning strategic decision making across the business
- Improving governance standards

**Allen Harmon**

Head of Quality  
**Baxalta**

10:15-11:30

**Pre-Arranged One-to-One Meetings**

- 10:20 am – 10:40 am: Meeting Slot 1/Networking
- 10:45 am – 11:05 am: Meeting Slot 2/Networking
- 11:10 am – 11:30 am: Meeting Slot 3/Networking

11:35-12:10

**WORKSHOP**

**STRATEGIC MANUFACTURING**

**Transformation Simplified: Creating a Sustainable Culture of Connectivity, Clarity and Consistency**

COMPETITIVE SOLUTIONS, INC.  
Process Based Leadership

- Identifying and revolutionizing your organization's benchmarking structure for enhanced performance, engagement, and response
- Optimizing scorecards to educate, facilitate, and motivate: passive reports or active positioning devices?
- Creating a communication cadence that drives focus, urgency, and accountability

11:35-12:10

**WORKSHOP**

**SUPPLY CHAIN MANAGEMENT**

**Facility Scheduling and Data Integration**



Bioproduction Group

- 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

**Gary Wright**

Sr. Account Director  
**Bioproduction Group**

11:35-12:10

**WORKSHOP**

**QUALITY**

**Improving Biomanufacturing Operations and Plant Design through Single-Use Systems**



GE Healthcare

- What does the next generation manufacturing plant look like?
- Enabling speed to market through local manufacturing capacity
- Supporting manufacturing flexibility across single-use systems
- Considering technologies to go from campaign mode to parallel products in a ballroom concept

**Parrish M. Galliher**

- Building a sustainable operating system through non-negotiable business processes
- Leading your organization through a philosophy of accountability rather than dependency

**Shane Yount**  
Principal/Author  
Competitive Solutions, Inc

CTO Upstream and Founder  
**Xcellerex Inc.**  
GE Healthcare Life Sciences

12:15-12:50

**CASE STUDY STREAM 1**

**STRATEGIC MANUFACTURING**

**Strategies in Effective Tech Transfer**



- Establishing an error-proof system in internal and external tech transfer
- Right Actions at the Right Time operational excellence through documentation and business systems
- Tech transfer evolution to risk-based control strategy

**David Allen**  
Sr. Dir. Manufacturing, Science & Technology  
Eli Lilly & Company

12:15-12:50

**CASE STUDY STREAM 2**

**SUPPLY CHAIN MANAGEMENT**

**Managing Supply Chain in an Outsourcing Model**



- Establishing strong operational control and quality processes to drive supply chain transparency
- Mitigating supply chain risk through the application of regulatory guidance from the FDA, EU, and ICH
- Striking the balance between cost and security of materials manufacturing at suppliers and CMOs
- Assessing internal and external contractor's capabilities to build a culture of quality across complex global supply chains

**Stephen Liebowitz**  
Vice President, Technical Operations  
Shire

12:15-12:50

**CASE STUDY STREAM 3**

**QUALITY**

**Quality Value Index: Informed Risk-Based Decisions for Quality**



- Usefulness in determining effective utilization of resources
- Provides insights into whether we are becoming more effective as a result of the sum of the continuous improvement projects being implemented YOY.
- Ability to measure the aggregate impact of the Quality improvement efforts
- Enables focus on prevention rather than failure

**Janeen Skutnik-Wilkinson**  
PO&T Regulatory Intelligence Lead  
Biogen Idec

**12:50-1:50 THEMED LUNCHESES**

Themed lunches are roundtable discussions amongst industry leaders where you will have the opportunity to discuss the most pressing issues. Each roundtable will be lead by an expert in the field. Limited seating available. Select from:

<p><b>Ensuring Quality Within CMO's</b></p>  <p><b>Lucy Cabral</b> Sr. Director Global Supplier Quality Roche</p>	<p><b>Manufacturing Complexities of Animal Health</b></p>  <p><b>Bernd Eichenmueller</b> VP of US Operations-Vetmedica Boehringer Ingelheim Inc.</p>	<p><b>Engineering the Facility of the Future</b></p>  <p><b>Dave Steinberg</b> Director of Engineering &amp; Facilities Agensys</p>
<p><b>Human Error Reduction</b></p>  <p><b>Kathir Swamy</b> Head of Product Quality Management Sanofi Pasteur</p>	<p><b>The Value of Continuous Processing in Biopharmaceutical Manufacturing</b></p>  <p><b>Jon Coffman</b> Director of Bioprocess Engineering Boehringer Ingelheim Inc.</p>	<p><b>Tech Transfer - Quality, Cost &amp; Speed - Solving For All Three</b></p>  <p><b>Nick Keener</b> Director of Process Engineering and Process Validation Amgen</p>

1:50-2:25

**CASE STUDY STREAM 1**

1:50-2:25

**CASE STUDY STREAM 2**

1:50-2:25

**CASE STUDY STREAM 3**

**STRATEGIC MANUFACTURING****Single-Use Technologies for Rapid and Flexible Manufacturing**

- Versatility to handle products from microbial, mammalian, avian, and insect cell culture systems
- Products ranging from vaccines to bio therapeutics, and proteins to live viral vectors
- Standardization to allow rapid manufacturing to meet urgent demands
- Optimal scale to derive the benefits from reduced capital expenditure and increased flexibility
- Suitability for commercial and biodefense applications

**Vijay Yabannavar**  
SVP Manufacturing Operations & Technical Development  
**Emergent BioSolutions**

**SUPPLY CHAIN MANAGEMENT****Design to Value: Building a Patient-Driven Lifecycle Management Process and Robust Manufacturing Processes**

- Discussing Janssen Pharmaceutical's approach to "Design to Value"
- Building robust manufacturing processes to yield products that are more customer- or patient-centric over their lifecycle
- Describing each aspect of the implementation strategy with practical examples
- Offering lessons learned from Janssen's experience and talking about what comes next

**Remo Colarusso**  
VP, Manufacturing & Technical Operations  
**Johnson & Johnson**

**QUALITY****Technology Transfer to Fill/Finish CMO & Considerations for High-Value Biologic API**

- Designing and implementing a well-planned fill/finish program
- Performing Due Diligence and Process Risk Assessment to ensure your BDS/BDP design can be safely handled by a Fill/Finish CMO
- Do you have adequate budget for BDS/BDP to thoroughly analyze and characterize manufacturing sensitivities?
- Offering best practices to communicate and collaborate with CMOs to eliminate risk and improve performance

**Matt Dunlavy**  
Production Manager  
**One 2 One™**

2:30-3:05

**WORKSHOP****STRATEGIC MANUFACTURING****Increasing Single-Use Facility Intelligence: The Advent of SMART Technologies**

- How the biopharma market is changing and impact on facility planning
- A "Smart" automation approach to increase facility utilization
- How automation and integration with plan management will facilitate future processes

**Barbara Paldus**  
CEO/Co-Founder  
**Finesse Solutions**

2:30-3:05

**WORKSHOP****SUPPLY CHAIN MANAGEMENT****Ensuring the Security of the Materials Within the Supply Chain**

- Investigating what dangers are inherent in shipping between international markets
- Exploring what options are available for safe and secure international transport of clinical and commercial product
- Establishing how to ensure security in line with regulatory requirements as it relates to the GDP directive

**James Klingelhofer**  
Regional Director  
**World Courier**

2:30-3:05

**WORKSHOP****QUALITY****Developing Chromatography Technologies for Current and Future Bioprocessing**

- Innovation in resin design, membrane chromatography and novel chromatographic supports
- Accommodating future paths for disposable, continuous, single use or conventional batch bioprocessing
- Disposable membrane chromatography and its utility for Mab production
- Introducing Amspheretm A3, a best in class resin with capability for high productivity or high capacity driven processes
- A peek at a novel chromatographic supported bed that can change chromatography operations as we know it today

**Marty Siwak**  
Director Separations Sciences Group  
**JSR Life Sciences**

3:10-4:25

## 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

## Managing Manufacturing Complexity



- Ensuring business growth through smart planning, capital efficiency and talent development
- Case studies in managing trade offs and successful management execution
- Building quality into operations
- Using good science as a foundation
- Taking prudent risks and properly managing the product lifecycle

**Andy Ramelmeier**

SVP, Biologics Technical Operations  
**Portola Pharmaceuticals, Inc**

5:05-5:40

## Elevating the Healthcare Supply Chain to the Next Level of Performance



- Are you sure you really understand the performance level of your supply chain?
- How do you ensure you are meeting your customer expectations?
- Ensuring the upstream and downstream supply chains are aligned
- Ensuring optimized network structure and flow
- Defining what end to end really means

**Joerg Heidrich**

Bayer HealthCare

**SVP Global Product Supply**

5:40-5:45

## Chair's Closing Remarks

**Mark Paxton**

CEO

**Rx-360**

5:45

## Drinks Reception

8:00-8:35

**Registration and Breakfast**

8:35-8:40

**Chair's Welcome Address**

**Mark Paxton**  
CEO  
Rx-360

8:40-9:15

**Leadership and Lean: Let's Talk About You For a Minute**



A Member of the Roche Group

- Understanding how your leadership impacts the day-to-day operations in your facilities:
  - What are your true objectives?
  - Are you planning and communicating those goals to your team effectively?
- Setting performance targets and timelines for the creation and sustainment of a continuous improvement culture
- Identifying what you need in terms of tools and culture change to achieve your objectives
- Using the soft skills of 'people power' to win hearts and minds
- Seeking out new ways to motivate and empower your team
- How does your role evolve as lean programming moves into a CI culture?

**Tim Moore**  
SVP, Global Head, Pharmaceutical Technical Operations Biologics  
Genentech

9:15-9:50

**Can We Advance Technology in the Current Regulatory Environment? Operating in the Post-Approval Change Jungle**



- While the pharmaceutical industry is globalizing their business it looks like health authorities are nationalizing their processes more. What can we do together to advance new technologies in our industry?
- Where did Process Analytical Technology (PAT) go? Has the innovation train lost steam due to too many hurdles?
- How can the Pharmaceutical Quality System be used effectively to reduce regulatory burden and enhance innovation?

**Anders Vinther**  
Chief Quality Officer  
Sanofi Pasteur

9:55-10:30

**CASE STUDY STREAM 1**

**STRATEGIC MANUFACTURING**

**Economics of Biosimilars – Challenges in Bringing the Next Generation of Biosimilars to Market**



- Balance between innovation and competition
- The potential entry into the US market and the barriers to entry that exist
- The European experience of biosimilars
- Market opportunities and

9:55-10:30

**CASE STUDY STREAM 2**

**SINGLE USE TECHNOLOGIES**

**Assessing the Latest Advances in Single-Use Bioreactor Control Strategies for Process Optimization**



- Overcoming challenges to scale-up, process development and technical transfer from single-use or traditional bioreactors
- Demonstrating dual sparger designs for more predictable process development and scale-up
- Achieving a well-characterized

9:55-10:30

**CASE STUDY STREAM 3**

**QUALITY**

**Harmonizing the Scientific and Technical Principles of ICH Q11**



- Moving from a traditional approach to an enhanced approach for process development
- How this progression aids in product lifecycle management and the development of a robust control strategy
- Applying the concept of design space to your operations and its



- competitive response
- Examining the future of the Biologics Market

**Dr. Joseph Fuhr**  
Professor of Economics  
**Widener University**

- hydrodynamic environment
- Employing key scale-up parameters:
  - Power input per unit volume
  - Mixer tip speed
  - Oxygen transfer coefficient
- Enhancing cell growth and productivity by balancing the need for CO2 stripping and O2 delivery

**Christopher Stevens**  
Director, Manufacturing Operations  
**GSK**

- relationship to change management
- Successfully submitting information from manufacturing process development in the CTD format

**Peter Carbone**  
VP, Global Head External Relations, Group Quality  
**Novartis**

10:30-11:10

**Pre-Arranged One-to-One Meetings**

- 10:35 am – 10:55 am: Meeting Slot 7/Networking
- 11:00 am – 11:20 am: Meeting Slot 8/Networking

11:25-12:00

**CASE STUDY STREAM 1**

**STRATEGIC MANUFACTURING**

**Generating Competitive Advantage and Improving Performance through Lean Biomanufacturing**



- Securing buy-in and input from both management and the workforce
- Developing and applying lean principles to your biomanufacturing operations
- Using OpEx programming to drive quality and compliance performance
- Correcting inefficiencies through coordinating internal and external manufacturing efforts
- Taking the next step – evolving current standard operating procedures for continuous improvement

**Maureen Skowronek**  
VP Operations Biologics  
**Merck & Co.**

11:25-12:00

**CASE STUDY STREAM 3**

**QUALITY**

**Implementing an Automated Environmental Monitoring Technology on the Manufacturing Floor**



- Streamlining the environmental monitoring operation
- Reducing the transfer of materials and equipment between the microbiology laboratory and the manufacturing facility
- Improving environmental control with collaboration between manufacturing technicians and QC microbiology scientists
- Reducing human error in environmental sampling and data collection
- Business value proposition of technology implementation

**Amy McDaniel**  
Technical Operations Director  
**Pfizer, Inc.**

12:05-12:40

**WORKSHOP**

**STRATEGIC MANUFACTURING**

**Establishing an Effective Quality Focus to Improve Bioprocessing Operations**



12:05-12:40

**WORKSHOP**

**SUPPLY CHAIN MANAGEMENT**

**Bringing the Internet of Things to Life Sciences: Improving Visibility, Communication, and Collaboration Both Internally and Externally**

- Creating a quality focus early in the product lifecycle to ease the path to product realization and a state of control
- Balancing phase appropriate applications of:
  - Quality systems
  - Knowledge and risk management
  - Product control
- Practically embedding a quality focus into the product lifecycle

**Abel Hastings**

Director of Process Sciences  
**FUJIFILM Diosynth**  
**Biotechnologies**



- How is the IoT movement changing the way biopharmaceutical manufacturers do business?
- Showcasing Smart Factories that increase compliance, reduce cost and increase OEE through M2M communication
- Improving visibility, traceability and compliance up and down the supply chain through new technologies
- Avoiding the crush of Big Data through clear goals and an understanding of the real KPIs
- Drawing the line that connects new capabilities to both the company's superior performance and improved patient outcome



**Ibrahim Khalid**

Practice Advisor, Business Transformation – Life Sciences  
**Cisco Systems**

12:40-1:40

**Lunch and Learn Roundtables**

Themed lunches are roundtable discussions amongst industry leaders where you will have the opportunity to discuss the most pressing issues. Each roundtable will be lead by an expert in the field. Limited seating available. Select from:

<p><b>Rapid Microbiology Detection through On-Line Bioburden Analyzers</b></p> 	<p><b>Leveraging the Power of Connected Intelligence</b></p> 
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1:40-2:15

**The War Against Fake Medicines – What You Need To Know**



- What are today's current threats to our industry and our patients?



- How is industry mobilizing around these threats to tighten our supply chains?
- What are regulators doing and how will this impact industry?
- What should you consider for your companies supply chain security program?

**Mark Paxton**  
CEO  
Rx-360

2:15-2:50

### Strategies for Disruptive Process Development and Future Biologics Manufacturing



- Trend of the biopharmaceutical industry and needs for affordable biologics worldwide
- Challenges and opportunities in current process development and biomanufacturing practices
- Disruptive biomanufacturing processes and systems enabling global supply of cost-effective and high quality biologics
- Strategic integration of relevant technologies from biotech and other industries
- Future manufacturing plant employing continuous bioprocesses for various biologics including biosimilars and cell therapies

**Steven Lee**  
Head, Biologics Technical Operations & CEO Singapore Operations  
Dr Reddys Laboratories

2:50-3:35

### Panel Discussion: Improving Quality and Communication Up and Down the Supply Chain



- How can the commercial organization engage with manufacturing teams to better manage supply?
- Anticipating and mitigating variations in product quality and delivery times
- Building a robust two-way flow of information into multi-region transportation collaborations
- Ensuring supply and demand is balanced – key supply chain metrics

**Edward Bjurstrom**  
Vice President Operations  
Gilead Sciences

**Diane Petitti**  
VP, Head of Global Biologics Quality  
Bristol-Myers Squibb

**Anthony Hurley**  
VP, Head External Manufacturing  
Genentech

**Matt Gray**  
Director QA Systems  
Biomarin

**James Klingelhofer**  
Regional Director  
World Courier

**Gary Barrera**  
Head of Quality  
Theravance Biopharma

3:35-3:40

### Chair's closing address

**Mark Paxton**  
CEO  
Rx-360