AMERICAN BIOMANUFACTURING SUMMIT 2020

JUNE 16-17, 2020
HYATT REGENCY SAN FRANCISCO AIRPORT • SAN FRANCISCO, CA

biomanamerica.com

TOMORROW’S CONNECTION TODAY
Exploring current trends, strategic insights and best practices in biomanufacturing

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PROGRAM
**PROGRAM**

**DAY ONE**

* JOIN US FOR THE PRE-EVENT HAPPY HOUR ON JUNE 15, 2020 FROM 6:00 PM - 7:00 PM

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7:00 am – 8:00 am

**DELEGATE REGISTRATION AND LIGHT BREAKFAST**

Exhibition Hall

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8:00 am – 8:10 am

**CHAIR’S WELCOME AND OPENING REMARKS**

Room 1

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8:10 am – 8:45 am

**KEYNOTE**

Room 1

**SUPPLY CHAIN 4.0: IMPLEMENTING SELF-DRIVING AND AUTOMATED TECHNOLOGIES TO SIMPLIFY AND IMPROVE COMPLEX GLOBAL SUPPLY CHAINS**

- Discussing the need for more intelligent end-to-end supply chains
- Achieving a connected supply chain from start to finish
- Variables to consider when designing an end-to-end supply chain
- Case studies on the implementation of best practices and lessons learned
- Examining how the project was conceptualized, pitched, implemented and managed
- Exploring the next frontier of Supply Chain 4.0 delivery at Baxter International

PHILIPPE REALE

SVP and Head, Global Supply Chain

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8:45 am – 9:20 am

**PLENARY**

Room 1

**EXPLORING THE FUTURE OF CELL, GENE AND CAR-T PRODUCTION**

- What activities in the past few year’s indicate about the future of CGT?
- Examining current operating models and new innovative models that work
- How to keep emerging companies productive and agile
- Care Delivery Approach: Considerations to make this a reality
- Examining hypothetical coordination between physicians and manufacturers
- Looking back to go forward: Taking inspiration from the past

ANDY RAMELMEIER, PH.D.

EVP, Technical Operations
PLENARY

Room 1

REGULATING INNOVATION IN CMC FOR CELL AND GENE THERAPY PRODUCTS: CHALLENGES AND OPPORTUNITIES

- Examining the landscape for innovative modalities and emerging technologies
- Future goals for efficiently regulating cell and gene therapy products
- What is the latest in harmonization and industry efforts?
- Regulatory CMC challenges associated with product development and approval

RAJ K. PURI, M.D., PH.D.
Director, Division of Cellular and Gene Therapies Office of Tissues and Advanced Therapies

10:00 am – 11:40 am

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND REFRESHMENTS

11:45 am – 12:20 pm

WORKSHOP

Room 1
CASE STUDY: ADDRESSING VIRAL VECTOR CAPACITY DILEMMA
- What are the unique challenges in the manufacturing of viral vectors?
- Reviewing promising results from clinical studies of the use of viral vectors to address important medical needs
- Developing scalable and cost-efficient manufacturing processes
- Ensuring products are well-characterized and manufactured to high purity, efficacy, and safety
- Examining GMP compliance and what requirements need to be met

SPEAKER TBA

WORKSHOP

Room 2
THE IMPACT OF INNOVATION ON BUILDING FACILITIES OF THE FUTURE
- How to maintain flexibility and adaptability during a facility build in the midst of constant changes
- Creating a modern facility using emerging technologies and cutting-edge equipment
- Adapting quickly and overcoming challenges while not losing sight of the envisioned goal
- Case study: Overcoming challenges and changes encountered during an innovative cell therapy facility build
- Discussing engineering and quality principles used to overcome obstacles

SPEAKER TBA

WORKSHOP

Room 3
ENSURING SAFE AND SECURE HANDLING OF BIOLOGICS IN YOUR SUPPLY CHAIN
- Why talent and innovation should be at the heart of a supply chain and logistics strategy
- Understanding the needs of specific, time-critical shipping requirements and the differences needed for clinical trials vs. commercialization
- Importance of inventory management and full integration with technology platforms
- Delivering on an unmatched level of customer service and superior handling
- Ensuring just-in-time delivery of products

SPEAKER TBA
**MANUFACTURING AND TECHNOLOGY**

Room 1

**FUTURE OPPORTUNITIES AND CHALLENGES IN VACCINE DEVELOPMENT: LEVERING BIG DATA, AI AND ML TO ENABLE VACCINE PROCESS DEVELOPMENT**

- Discussing the constraints and complexities of vaccine product development and manufacture
- Exploring potential technologies that could play a role in accelerating product development in the future:
  - Big data
  - Artificial Intelligence
  - Machine Learning, etc.
- Examining the evolution of bioprocess and analytics technologies to accelerate and overcome these challenges
- Leveraging innovation and technology for rapid product development to shorten time to clinical trials
- Case study: Accelerating process and analytical development

**WORKSHOP**

Room 1

**BEST PRACTICES AND IMPORTANT CONSIDERATIONS IN THE PROCUREMENT OF UPSTREAM BIOPROCESS EQUIPMENT**

- How does the total cost of ownership of upstream equipment tie into the complexity of a system?
- Maintaining a high level of flexibility of equipment while still dealing with many process unknowns
- Reviewing control systems and their implications on different scale equipment
- Looking forward: Increasing robustness and reliability of systems

**WORKSHOP**

Room 2

**MANAGING SUPPLY QUALITY FROM COMMERCIAL AND CLINICAL CONTRACT MANUFACTURERS AND MATERIAL SUPPLIERS IN A GLOBAL NETWORK**

- Examining threats to quality from suppliers of raw and manufactured materials to biotech and pharmaceutical companies
- Overcoming increasing complexity of the material supply chain
- Ensuring the quality supply of materials and components, excipients, and APIs
- Establishing strong business and process controls within your global network
- What are the materials and suppliers of the future?

**QUALITY AND COMPLIANCE**

Room 2

**DESIGNING INNOVATIVE QUALITY SYSTEMS FOR THE FUTURE MORE PERSONALIZED COMPLEX THERAPEUTICS**

- Creating quality systems that are positioned for a more regulated and complex future
- Bringing quality up-to-speed with next-generation innovative products
- Identifying and managing instances of noncompliance with GMPs
- Developing a new quality system infrastructure to ensure compliance
- Placing quality and compliance as the core strength of your organization and the industry
- Identifying, mitigating and preventing high-risk events through integration, automation and collaboration

**WORKSHOP**

Room 2

**SELECTING THE RIGHT THERMAL PACKAGING FOR YOUR END-TO-END SUPPLY CHAIN**

- Examining the latest designs and thermal solutions for temperature-controlled products:
  - Drop testing
  - Vibration sensitivity
  - Thermal chamber
- Reviewing ISTA and ASTM standards for biopharmaceuticals
- Ensuring quality and compliance in your global distribution system

**SUPPLY CHAIN AND LOGISTICS**

Room 3

**EMBRACING DIGITAL TRANSFORMATION AND PIONEERING HIGH-TECH NEW STRATEGIES ACROSS THE SUPPLY CHAIN**

- Optimizing the supply chain end-to-end to meet the needs of patients and anticipate how to meet their needs tomorrow in a transformational way
- Seeing digital and Industry 4.0 technologies as the next driver of innovation and patient-centricity
- Utilizing the convergence of technologies to deliver value to patients and the organization
- How to best onboard teams and executives to embrace digital transformation
- Examining the shift in corporate culture, investment and the skill set of the personnel required to deliver on transformation
- Ensuring innovations are permanently and intrinsically implemented into operations

**WORKSHOP**

Room 3

**SELECTING THE RIGHT THERMAL PACKAGING FOR YOUR END-TO-END SUPPLY CHAIN**

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**SPEAKER TBA**
1:45 pm – 2:45 pm

**LUNCH AND LEARN ROUNDTABLE DISCUSSIONS**

Exhibition Hall

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Choose from:

- **ADDRESSING THE PHARMA AND BIOTECH COMMERCIALIZATION DILEMMA: SHOULD YOU GO IT ALONE, PARTNER, DIVEST OR ACQUIRE?**
  - Francis Dumont
  - Senior Director, External Drug Product Supply Strategy
  - Pfizer

- **IMPLEMENTING PAT AND ADVANCED PROCESS CONTROLS INTO CONTINUOUS BIOPROCESSING**

- **SUCCESSFUL TECH TRANSFER OF GENE AND CELL THERAPY PRODUCTS: EXPLORING THE DIFFERENCES/RISKS PARTICULAR TO THESE PRODUCTS**

Seating is limited, so please sign up early. Sessions start at 1:45 pm and run for one hour. More seating will be provided if you would prefer to discuss other topics.

2:50 pm – 3:25 pm

**MANUFACTURING AND TECHNOLOGY**

Room 1

**BIOPROCESS INNOVATIONS IN THE ERA OF ACCELERATION AND INTENSIFICATION**
- Examining current trends in clinical development acceleration and bioprocess intensification
- Discussing techniques to compress CMC development timelines
- Overcoming bioprocessing challenges downstream, such as in cell culture bioreactors
- Exploring a series of potentially disruptive innovations

**QUALITY AND COMPLIANCE**

Room 2

**REGULATORY AND QUALITY CONSIDERATIONS ASSOCIATED WITH THE DEVELOPMENT OF NOVEL MODALITIES**
- Understanding how novel modalities can challenge existing paradigms
- What science and risk-based thinking is required to develop new pathways?
- Examining quality attributes of a new molecular entity and its implications to analytical technology
- Creating robust manufacturing processes and control strategies for new modalities
- Thinking ‘outside of the box’ to help advance a product through to commercialization

**SUPPLY CHAIN AND LOGISTICS**

Room 3

**HOW TO ENSURE CUSTOMER-CENTRICITY LIES AT THE HEART OF YOUR GLOBAL SUPPLY CHAIN STRATEGY**
- What will future product portfolios demand and new technologies enable around the development of customer-centric operations?
- Why customer-centricity should be at the heart of every biopharma producer in the industry
- Examining key technological and regulatory shifts taking place in order to assure customer-centricity
- Ensuring significantly greater customer service through a process of segmentation
- Segmentation strategies for increasingly diversified product portfolios to ensure a more efficient global supply chain
- Creating additional benefits of quality, compliance, and customer service levels
- Improving the strength and performance of global operations and supply chain
### Workshops

**Workshop Room 1**

**Sustainability: Concerning Single-Use Systems Utilized in Biomanufacturing and the Environment**
- What are the wide-ranging differences of opinion in the utilization of SUS?
- Discussing the benefits and drawbacks of utilizing single-use systems
- Looking at the environmental advantage over traditional durable manufacturing facilities
- Looking at a holistic picture of “sustainability” to identify areas for improvement with SUS and single-use technologies
- What’s next for single-use technologies regulations, use and evolution?

**Workshop Room 2**

**Discussing Best Practices to Maintain a Quality and Compliance During Times of Change and Uncertainty**
- Examining potential product and supply chain risks that could affect quality and compliance
- Developing mechanisms to ensure management is engaged, accountable and able to react swiftly to unexpected events
- Tools and techniques to help monitor the impact on quality and compliance during times of change
- Clarifying responsibilities and opening up lines of communication, coordination and collaboration between teams in transition
- Using Quality Systems to proactively detect potential trends and actions to take before the trend becomes an issue
- Reviewing real-world case studies on positive outcomes and lessons learned

**Workshop Room 3**

**Global Supply Chain and Value-Add to Serialization Compliance**
- How to secure a global supply chain and add value beyond compliance
- Understanding the current status of Drug Supply Chain Security Act (DSCSA) and global serialization efforts
- Safely getting the product from the manufacturing facility to the patient
- Utilizing the latest tools for temperature management, info compliance and serialization
- Ensuring you’re making and distributing a good product

### Happy Hour and Pre-Arranged 1:2:1 Business Meetings

Exhibition Hall

### Innovation Spotlight

**Room 1**

**Process and Analytical Development for Complex Cell and Gene Therapy Products**
- Best techniques in managing the development and production of very complex products
- Developing innovative approaches to meet safety requirements, clinical, market demands and cost of goods targets
- Utilizing a combination of traditional downstream approaches and new novel technologies
- Establishing scalable and robust purification processes for cell and gene therapy products

**Sarah Yuan, Ph.D.**

VP, Process and Analytical Development
6:10 pm – 6:55 pm

**PANEL DISCUSSION**

Room 1

**Evolving Quality Thinking and Operational Approaches for the Next Wave of Therapeutics**

- Exploring the historical role of quality and what’s needed to be successful in the future
- How can the quality and operations team collaborate more, and be of greater benefit to an organization beyond compliance?
- What motivations do both quality and operations teams need have to modernize?
- How to recruit and inculcate your workforce with quality thinking?
- Discussing examples of how quality and operations are working in tandem to help take organizations to a new modern state
- Learning from the successful quality and operations improvements that propel change

6:55 pm – 7:00 pm

**Chair’s Summary and Closing Remarks**

7:00 pm – 8:00 pm

**Networking Drinks Reception**

Exhibition Hall
PROGRAM  DAY TWO

7:00 am – 8:00 am

NETWORKING BREAKFAST

WOMEN IN LEADERSHIP ROUNDTABLE
Enjoy breakfast refreshments and informal networking in the Exhibition Hall. We also invite our attendees to network at a Women in Leadership Roundtable with discussion from inspirational leaders in manufacturing, quality and supply chain. Seating is limited, so please sign up early.

8:00 am – 8:10 am

CHAIR’S OPENING REMARKS
Room 1

8:10 am – 8:45 am

KEYNOTE
Room 1
DESIGNING A FLEXIBLE AND AGILE GLOBAL MANUFACTURING NETWORK TO PLAN FOR PRODUCT AND ECONOMIC UNCERTAINTY
• What are some of the trends and drivers that impact capacity needs for biomanufacturers?
• Forecasting requirements for optimizing manufacturing equipment, facilities and partners to increase speed to market
• Maximizing plant flexibility in multi-product settings
• Achieving potential future capacities, such as 2000 liter scale for new therapies
• Optimizing media utilization to dramatically reduce media consumption
• Utilizing next-generation platforms to achieve 10x productivity compared to traditional fed-batch systems

8:45 am – 9:20 am

PLENARY
Room 1
ACCELERATING GLOBAL PERFORMANCE IN THE CELL AND GENE THERAPY SPACE
• What is the next chapter in the commercialization of cell and gene therapy products?
• Understanding needs to improve a company’s performance and perseverance
• Building on existing capabilities to deliver innovative cell therapies
• Making continued investments in achieving technical advances
• Establishing a new viral vector facility: Factors in the make or buy decision
• Aligning priorities, clear escalation paths, performance and metrics
• Creating strategic partnerships with external suppliers where capabilities are required
10:00 am – 11:20 am

PRE-ARRANGED 1:2:1 BUSINESS MEETINGS AND REFRESHMENTS

11:25 am – 12:00 pm

MANUFACTURING AND TECHNOLOGY
Room 1
BIOPROCESSING 4.0: DIGITAL TECHNOLOGIES ARE TRANSFORMING BIOMANUFACTURING
- Examining the evolution of biomanufacturing over the years to where we are today
- How digital technologies are a large part of the next step forward
- Discussing how other industries are incorporating digital technologies
- Applications of digital technologies in biomanufacturing
- Achieving reliable, efficient and agile multi-product and multi-process manufacturing operations
- Striving toward providing uninterrupted global supply

QUALITY AND COMPLIANCE
Room 2
DATA MONITORING AND ANALYTICS: ACCELERATING DELIVERY OF NEW MEDICINES
- What tools, technologies, and processes will help propel biomanufacturing?
- Discussing how acceleration impacts quality, regulatory, and supply chain functions
- Making uncompromising decisions to deliver consistent, high-quality product
- Data monitoring and analytics: How these can help improve supplier management and quality
- What’s next: Where are we headed and what will be the next generation of biomanufacturing

SUPPLY CHAIN AND LOGISTICS
Room 3
HOW TO STRATEGIZE FOR AND IMPLEMENT DATA-DRIVEN END-TO-END SUPPLY CHAIN OPERATIONS ON GLOBAL SCALE
- What is meant by ‘data-driven operations’ and what are the most significant benefits to the organization?
- Examining tools and technologies required to achieve better end-to-end supply chain operations
- Gaining buy-in from top-level management to embrace and implement data-driven operations
- Lessons learned and best practices derived from at-scale implementation

12:05 pm – 12:40 pm

WORKSHOP
Room 1
CONNECTED PACKAGING, LABELS AND THE INTERNET OF THINGS
- What does connected packaging look like today and where is it headed?
- Creating immersive brand stories at the point of consumption and point of use
- Utilizing VR and AR to deliver real-time engagement while gathering data
- Applying this data to transform how brands are understood and managed

WORKSHOP
Room 2
EXPLORING SPECIALIZED EQUIPMENT AND FILMS FOR PROPPELLING PACKAGING INNOVATION
- Creating product differentiation and increased visual impact on-the-shelf and online
- Examining applications of ultra high gloss, matte and holographic finishes
- What does the cast and cure decorative coating process look like?
- Utilizing cost-effective and environmentally-friendly decorative printing processes

WORKSHOP
Room 3
REVOLUTIONIZING SUSTAINABILITY THROUGH NEW PRODUCTS AND INNOVATION
- How packaging innovation and sustainability help drive growth
- Understanding the needs and habits of today’s consumers
- Meeting the demands of circular packaging
MANUFACTURING AND TECHNOLOGY
Room 1
SINGLE-USE BIOMANUFACTURING: WHERE WE CAME FROM AND WHERE WE'RE HEADED OVER THE NEXT 5 YEARS
- Discussing the maturity curve of single-use systems and where we are today
- Building on standards and best practices for SUS/SUT for the industry
- SUStainability: Examining the plastics concerning single-use systems utilized in biomanufacturing and the environment
- Modular, moveable and ballroom facility design: What is the best choice?
- Utilizing 3D printing to create on-demand components for SUS/SUT applications
- Increasing the number of sensors, barcoding and Industry 4.0 technology to fully realize the potential of single-use manufacturing

QUALITY AND COMPLIANCE
Room 2
BEST TECHNIQUES FOR SCALE-UP AND PRODUCT COMPARABILITY FOR LEGACY PRODUCTS
- Examining the current production process and desired future states of operating
- What is needed to take manufacturing, quality and analytical to the next level?
- Increasing process control and improving product quality
- Building modern facilities for production and employing new technology for continuous monitoring of product quality

SUPPLY CHAIN AND LOGISTICS
Room 3
HOW TO LEVERAGE PROCESS MINING FOR REALISTIC SUPPLY CHAIN MATURITY ASSESSMENTS
- Creating a supply chain efficiency program to achieve higher customer service, reduced inventory and better data
- Leveraging technology to cut excess inventory and improve customer service
- Implementing demand sensing and enterprise inventory optimization
- Improving techniques predicting demand at more granular levels

MARK PETRICH, PH.D.
Director, Single-Use Engineering, Global Sterile and Validation Center of Excellence
1:25 pm – 2:25 pm

LUNCH AND LEARN ROUNDTABLE DISCUSSIONS
Exhibition Hall

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Choose from:

**BRINGING PRECISION MEDICINE TO MARKET:**
DIVERSE THERAPIES CREATING COMPLEXITY AND
DIGITAL INNOVATIONS DRIVING MODERNIZATION

**CREATING ECTD-COMPLIANT QUALITY MODULES**
AND RELATED SUBMISSION COMPONENTS

**STORAGE AND DISTRIBUTION OF TEMPERATURE SENSITIVE BIOLOGICS: HOW DO YOU KNOW WHAT’S HAPPENING TO YOUR PRODUCT AFTER IT’S LEFT YOUR FACILITY?**

**SPEAKER TBA**
SCIMITAR INC.

**SELECTING THE RIGHT CDMO COMMERCIALIZATION PARTNER FOR CELL AND CELL-MEDIATED GENE THERAPY PRODUCTS**

**USING RISK-BASED TOOLS FOR A SEAMLESS AND EXPEDITED TRANSITION FROM CLINICAL MANUFACTURING TO PROCESS PERFORMANCE QUALIFICATION (PPQ) READINESS**

**TRANSFORMING THE BIOMANUFACTURING INDUSTRY THROUGH THE ASSISTANCE OF 3D PRINTER TECHNOLOGY**

**SPEAKER TBA**
Cognate
FUJIFILM Di-epithelio lithoSciences

**HELPFUL STRATEGIES FOR A SUCCESSFUL PHASE I-II RELATIONSHIP WITH YOUR CDMO**

**DISCUSSION AND INTERACTION BETWEEN END-USERS, INTEGRATORS AND DISTRIBUTORS DURING THE PROCESS OF QUOTING SINGLE-USE PROJECTS**

**UTILIZING DIAGNOSTIC TOOLS THAT ACCELERATES MEDICAL DISCOVERIES THROUGH A NOVEL APPROACH TO CELL ANALYSIS AND SORTING**

**SPEAKER TBA**
Nitto
Foxx Life Sciences
LumaCyte

**EXAMINING CLOUD-BASED SYSTEMS IMPLEMENTATION IN YOUR PRODUCT SUPPLY NETWORK**

**OPTIMIZING YOUR CONTRACT SUPPLY CHAIN PARTNERSHIPS: A CPO PERSPECTIVE**

**ACHIEVING GLOBAL CONTRACT MANUFACTURING EXCELLENCE**

**SPEAKER TBA**
Skyland Analytics
Sharp
Boehringer Ingelheim

2:30 pm – 3:15 pm

PANEL DISCUSSION
Room 1

**ADDRESSING CHALLENGES IN MEETING GLOBAL CAPACITY**

- What are companies thinking about when building new capacities?
- How to best invest in capacity, contract manufacturers, emerging markets and technology
- Seeking partnerships and alliance models to help overcome production challenges
- Increasing the agility of your organization in global markets

**SPEAKER TBA**
IDA Ireland
3:15 pm – 3:50 pm

PLENARY
Room 1
THE FUTURE OF BIOMANUFACTURING: LEVERAGING FLEXIBLE NETWORKS, QUALITY CULTURE AND CUTTING EDGE INNOVATION
- How biomanufacturing can address the dichotomy of small volume precision medicines and high volume blockbuster drugs
- Building flexible global manufacturing networks to meet our industry's evolving needs
- Leveraging cutting-edge innovation to maximize process intensification and augment flexibility
- Creating high-performance teams and building and maintaining a culture of quality, reliability and innovation as key differentiator and foundation for continued success

3:50 pm – 4:35 pm

PANEL DISCUSSION
Room 1
ADDRESSING SUPPLY CHAIN STRENGTHS AND WEAKNESSES TO CREATE BETTER PRODUCTION PLANNING FOR LIFECYCLE MANAGEMENT
- How ready is the industry for the tidal wave of biopharma demand?
- Examining specific product categories and their associated supply risks
- From clinical to launch: Best techniques for demand and uncertainty planning
- Recognizing the importance of risk assessment in your operations
- Managing risks: How and when to allow risk during capacity planning
- Risk maturity: What has worked and what hasn't?

4:35 pm – 4:45 pm

CHAIR’S REMARKS AND ATTENDEE SURVEY PRIZE DRAW