AMERICAN BIOMANUFACTURING SUMMIT

MAY 13-14, 2015

Hyatt Regency La Jolla in San Diego
www.bio-summit.com

Tomorrow’s Connection Today
Driving business Performance through process and technological innovation

PROGRAM
PROGRAM
DAY ONE: MAY 13

07:00-08:00
DELEGATE REGISTRATION & LIGHT BREAKFAST

08:00-08:10
MANUFACTURING CHAIR’S WELCOME
Ron Branning
Former VP, Quality
GILEAD

QUALITY & COMPLIANCE CHAIR
Robert Sparadoski
AVP, Quality Assurance
FERRING PHARMACEUTICALS

08:10-08:45
KEYNOTE
TRANSFORMING A MANUFACTURING SITE FROM CONSENT DECREE REMEDIATION TO OPERATIONAL EXCELLENCE & SUSTAINED CONTINUOUS IMPROVEMENT
- Examining Continuous Improvement methods and OpEx tools to improve business processes and technology
- Discussing key elements of a transformative plan:
  - Improvements to the operational and performance culture
  - Systems and procedures implementation
  - Physical remediation and facility upgrades
- Turning 30+ year old manufacturing sites into future-proof facilities
- Reviewing lessons learned in turning a major challenge into an operational opportunity

Christopher Murphy
VP, Operations
GENZYME
A SANOFI COMPANY

08:45-09:20
PLENARY
MANAGING PRODUCT QUALITY ACROSS AN INCREASINGLY GLOBAL MANUFACTURING NETWORK
- Examining challenges in establishing a successful Quality Management System
- Discussing preventative strategies and corrective solutions
- How can the industry come together to ensure quality?

Anthony Mire-Sluis Ph.D.
VP, North America, Singapore, Contract & Product Quality
AMGEN

09:20-09:55
PLENARY
UNDERSTANDING COMPLEXITY IN BIOLOGICAL SYSTEMS THROUGH BIG DATA ANALYTICS
- Improving understanding the relationship between protein production, data and process optimization
- How IT and big data approaches can help navigate complex of biological systems
- Creating algorithms to monitor normal and abnormal trends
- Discussing applications to biosimilars and novel biologics

Ganesh V. Kaundinya, Ph.D.
Co-Founder, Chief Scientific Officer & SVP, Research
MOMENTA
MANUFACTURING EXCELLENCE
RESPONDING TO CHANGING PRIORITIES & VOLATILVE BIOLOGICS MARKETS BY IMPLEMENTING SINGLE-USE & DISPOSABLE SYSTEMS
- Increasing flexibility in your facilities and manufacturing networks
- Ensuring disposable systems will deliver quality and improved costs
- Reviewing the latest advances in disposable systems:
  - Technology advancement
  - Process implementation
  - Bioreactors and sensors
- Reviewing the potential of extractables and leachables
- Warranting due-diligence from a quality and supply perspective before moving forward with single-use and disposable systems

QUALITY & COMPLIANCE
QUALITY RISK MANAGEMENT: ESTABLISHING QUALITY AND COMPLIANCE PRACTICES ACROSS MULTIPLE MANUFACTURING SITES
- Developing a standardized, system-based framework for local and global implementation—the “how” of maintaining product quality.
- Creating allowances for variability within local practices and procedures.
- Achieving product quality attribute understanding and a Quality System that demonstrates process control.
- Ensuring local SOPs adhere regulations set forth by ICH Q10.

Ron Branning
Former VP, Quality
GILEAD

MANUFACTURING EXCELLENCE
RESPONDING TO CHANGING PRIORITIES & VOLATILVE BIOLOGICS MARKETS BY IMPLEMENTING SINGLE-USE & DISPOSABLE SYSTEMS

Yan-Ping Yang, Ph.D.
Head, Bioprocess R&D, NA
SANOFI PASTEUR

11:50-12:25
PLENARY
IOT AND ITS IMPACT ON LIFE SCIENCES: USE CASES ACROSS THE VALUE CHAIN FROM R&D TO CONNECTED CARE
- Accelerating lean manufacturing initiatives through flexible, connected platform
- Accelerating research, lowering risks and improving health outcomes through precision medicine
- Leveraging information from new connected data sources
- Creating Smart Factories by enabling manufacturers to increase compliance, reduce cost and increase OEE with IoT
- Connecting the supply chain to increase visibility, traceability and compliance
- Discussing case studies on improving patient health through connected care

Randal Kenworthy
Managing Director, Manufacturing & Energy, Cisco Business Transformation
CISCO

12:25-01:25
LUNCH AND LEARN ROUNDTABLE DISCUSSIONS
Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Seating is limited, so please sign up early. Sessions will start at 12:50pm and run for one hour. Additional seating will be provided if you would prefer to discuss other topics. Choose from:

CMOs / Technology Transfer / Manufacturing Oversight / Quality Monitoring
LUNCH & LEARN SESSIONS
CMO Management Via the Establishment of Meaningful Metrics: A Longer Range Vision to Outsourced Management
Mark Fromhold
Director, Biologics Outsourcing
GILEAD

Key Lessons Learned During Technology Transfer Across the Product Lifecycle
Jayant Aphale, Ph.D.
SVP, Technical Operations
SAREPTA THERAPEUTICS

Pilot Plants: Discussing Operational Challenges, Flexibility & Scheduling from Tech Transfer to End of Campaign
Silas Nwagwu
Associate Director, BioProcess Engineering
MedImmune

WORKSHOP
BUILDING GLOBAL BIOLOGICS CAPACITY
• Discussing capacity constraints globally and considerations for expanding:
  • Infrastructure
  • Technology
  • Talent development
• Determining the rate of eternal expansion and strategies for risk management
• New risk-sharing models for building capacity: External vs. in-house capacity

Robert Sparadoski
AVP, Quality Assurance
FERRING PHARMACEUTICALS
Enda Moran, Ph.D.
Senior Director, BioManufacturing Sciences Group
Pfizer
Chin Tah Ang
Regional Director, Eastern & South America
EDB Singapore

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND REFRESHMENTS (60 MIN)
04:45-05:20 INNOVATION SPOTLIGHT
BIOLOGICALLY-DERIVED MEDICINES ON DEMAND FOR THE BATTLEFIELD
• Investigating cutting-edge technologies to manufacture pharmaceuticals on-demand so that more medicines are near the region of fighting
• Reviewing DARPA’s innovative Battlefield Medicine program
• Developing flexible, miniaturized synthesis and manufacturing platforms for producing multiple protein-based therapeutics on-demand
• Leveraging continuous flow approaches to develop new on-demand manufacturing techniques
• Shortening timelines between manufacture and delivery of protein therapeutics to battlefield front line
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<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<th>Sponsored By</th>
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| 05:20-05:30 | MANUFACTURING CHAIR’S CLOSE              | Ron Branning  
Former VP, Quality                                           | GILEAD       |
| 05:30-06:30 | QUALITY & COMPLIANCE CHAIR               | Robert Sparadoski  
AVP, Quality Assurance                                      | FERRING      |
| 05:30-06:30 | NETWORKING DRINKS RECEPTION              |                                                                         | IDA Ireland  |
08:00-08:30
DELEGATE REGISTRATION & BREAKFAST REFRESHMENTS

08:30-08:40
MANUFACTURING CHAIR’S REMARKS
Ron Branning
Former VP, Quality

QUALITY & COMPLIANCE CHAIR
Robert Sparadoski
AVP, Quality Assurance

08:40-09:15
PLENARY
EXPLORING REVOLUTIONARY APPROACHES FOR CHANGING PATIENT HABITS WITH DIGITAL FEEDBACK SYSTEMS
• Linking patients, doctors and companies through smart pill devices
• Demonstrating real-time data aggregation using proprietary digital health technology
• Assessing applications for dispersal monitoring in clinical trails: What are the benefits?
• Examining data to support safety and efficacy
• Looking forward: What is the scalability of the technology for biologics

Jeremy Frank, Ph.D.
VP, Product Platform

09:15-09:50
PLENARY
DISCUSSING CMO SELECTION AND TECHNOLOGY TRANSFER TECHNIQUES: HOW DO YOU BALANCE BETWEEN TIME, COST AND QUALITY
• Examining tech transfer aspects for external manufacturing
• Conducting tech transfer from a holistic standpoint
• Overcoming cultural challenges with CMOs in Asia
• Ensuring proper cultural alignment and the culture aspects

Suketu Desai Ph.D.
VP, Biologics Development Drug Substance & Drug Product

09:50-10:25
PLENARY
MAXIMIZING THE VALUE OF VACCINES: WHAT’S WORKING, WHAT’S NOT AND WHERE WE NEED TO GO
• Are vaccines still blockbuster products?
• Examining growth opportunities in the global vaccines market:
  • Paediatric medicines
  • Geriatric medicines
• Discussing product innovations over the past 10 years
• Exploring projected growth of the vaccine markets
• Meeting evolving compliance standards of regulators

Rahul Singhvi
Chief Operating Officer, Takeda Vaccines

09:15-10:25
KEYNOTE
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Rahul Singhvi
Chief Operating Officer, Takeda Vaccines
10:25-11:25

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND REFRESHMENTS (60 MIN)

11:25-12:00

MANUFACTURING EXCELLENCE
TECHNOLOGY TRANSFER TO EMERGING MARKETS: STREAMLINING OUTSOURCING ACTIVITIES AND SCALE-UP
- Balancing time pressures with CMOs by ensuring robust processes
- Providing leadership to validations, regulatory and quality operations
- Using a risk-based approach for complex technology transfer
- Communicating process challenges openly with partners to ensure quality alignment
- Adhering to local regulatory requirements

Rakesh Kakkar Ph.D.  
Director, Technical Operations  
Emerging Markets

QUALITY AND COMPLIANCE
OUTSOURCING COMPLEX NANOPARTICLE FORMULATIONS
- Evaluating CMOs for their capabilities to compound Accurin nanoparticles that delivery cytotoxic APIs.
- Building and maintaining good relationships with CMOs.
- Scale- and phase-appropriate approaches to creating a robust clinical supply chain.
- Ensuring quality systems work in-line with your expectations for:
  - Utilities and facilities
  - Environmental monitoring (EM)
  - Out of Specification (OOS) results
  - Investigation handling
  - Producing high quality materials with non-conventional processes.

Thomas Page, Ph.D.  
AVP, Engineering

11:25-12:00

QUALITY AND COMPLIANCE
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Thomas Page, Ph.D.  
AVP, Engineering

12:00-12:35

WORKSHOP
IMPROVING SUPPLY CHAIN EFFECTIVENESS THROUGH DIGITAL PRINT PRODUCTION AND SUPPLY CHAIN SERVICES
- Examining industry trends and challenges driving the need for technology change
- Introducing digital printing as a proven production process
- Discussing benefits and reviewing case studies on how drug makers reduced total cost while meeting changing customer demand
- Reviewing the benefits of offset printing in today’s competitive marketplace

Joe Tenhagen  
Marketing Director, Healthcare NA

WORKSHOP
IMPLEMENTING A CONTINUOUS PROCESS VERIFICATION PROGRAM TO IMPROVE PROCESS MANAGEMENT & COMPLIANCE
- Examining recent updates to the FDA and ICH guidance on process validation and quality agreements
- Satisfying FDA validation guidelines with a process intelligence system
- Managing process data management and visibility across departments and geographies
- Harnessing the power of process and quality data in electronic and paper records
- Effective habits, software and technologies for sustaining process monitoring plans

Greg Troiano  
Senior Director, Particle Engineering & Manufacturing

12:35-01:10

PLENARY
DISCUSSING BIOGEN IDEC’S STRATEGY FOR PROCESS CONTROL AND PARAMETRIC RELEASE
- Reviewing the current state of biological process platforms and process understanding
- Enabling teams to develop robust processes that yield consistent product quality
- Making smart investments in process technology for high output processes and product quality control

Patrick Swann, Ph.D.  
Senior Director, Technical Development, Analytical Group

01:10-02:10

NETWORKING LUNCH
THOUGHT LEADERSHIP
DEVELOPING PROCESS EXCELLENCE CULTURE TO ENABLE ORGANIZATIONAL RESILIENCY AND COMPETITIVE ADVANTAGE

- What is process excellence and why is developing a PE culture important?
- Engaging your workforce in the pursuit and elimination of process variation and its source
- Establishing a PE culture on several key factors:
  - Leadership
  - Improvement Methodologies
  - Culture
  - Performance Measures
- Improving current business performance through process excellence
- Case studies: PE deployments and improvements at sites in the Americas and Europe

Marilyn Jacobs
Director, Global Business Excellence

MANUFACTURING EXCELLENCE
EXPLORING INDUSTRY STEPS TOWARDS THE STANDARDIZATION OF SINGLE-USE SYSTEMS

- Harmonizing best practices by improving communications across your sites
- Comparing competing products and provide guidance on preferred suppliers
- Standardizing approach to extractables and leachables
- Working towards internal standardization of single-use components
- Addressing the progress of organizations to standardize single use technologies

Mark Petrich
Director, Component Engineering

PANEL DISCUSSION
DEVELOPING NEXT GENERATION BIOMANUFACTURING FACILITIES

- Seeing the forest from the trees – determining which technologies to include during new facilities planning and plant upgrades
- Matching your facilities with the need for more manufacturing capacity flexibility
- Exploring cutting-edge manufacturing technologies and trends in:
  - Equipment
  - Facility integration
  - Operational Excellence
  - Process innovation
- Discussing the latest facility management tools, such as cloud-based systems and automated production, to improve operational efficiency

Ron Branning
Former VP, Quality
Moderator

Richard W. Welch, Ph.D.
VP, Process & Analytical Development

Ran Zheng
Executive Director, Plant Manager

Matt Gray
Director, QA Systems

Sarah Yuan, Ph.D.
Director, Manufacturing Sciences

Faraz Siddiqui
Head, Biologics Drug Product Tech Transfers

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CLOSING KEYNOTE

DISCUSSING THE NEXT FRONTIER FOR THE VACCINES INDUSTRY—WHAT WILL THE FUTURE HOLD?

• Maintaining and optimizing existing production processes that work
• Examining complex process architecture for areas of improvement
• Seeking new areas of growth and innovation: Which technologies to invest in?
• Examining the impact of standardization on other industries and what can the bio industry learn
• Decreasing costs and time while increasing productivity and profitability

Alain Pralong Ph.D.
VP, New Product Introduction & Technical Life Cycle Management

04:40-04:50

MANUFACTURING CHAIR’S CLOSE

Ron Branning
Former VP, Quality

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QUALITY & COMPLIANCE CHAIR

Robert Sparadoski
AVP, Quality Assurance

FERRING PHARMACEUTICALS