AMERICAN BIO MANUFACTURING SUMMIT 2018

JUNE 14-15, 2018
HYATT REGENCY SAN FRANCISCO AIRPORT • SAN FRANCISCO, CA

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TOMORROW’S CONNECTION TODAY
Driving business performance through process and technological innovation

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PROGRAM
American Biomanufacturing Summit 2018 Program • Page 1

PROGRAM DAY ONE

* JOIN US FOR THE PRE-EVENT HAPPY HOUR ON JUNE 13, 2018 AT 6:00 PM - 7:00 PM

6:55 am – 7:55 am

DELEGATE REGISTRATION AND BREAKFAST

7:55 am – 8:00 am

CHAIR’S WELCOME AND OPENING REMARKS

8:00 am – 8:35 am

PLENARY

ADDRESSING THE CHALLENGES AND OPPORTUNITIES IN BRINGING ADVANCED THERAPEUTICS TO MARKET

- Exploring unique manufacturing, quality and supply chain issues in bringing novel treatments to patients
- What are the testing, capacity and financial considerations when planning for new product launches?
- Ensuring the control of supply chains for clinical trials and commercial launches
- Case study: Building a new facility to support the development of a hemophilia A gene therapy candidate

8:35 am – 9:10 am

PLENARY

INTEGRATED CAPACITY PLANNING AND OPTIMIZED PRODUCTION PROCESSES FOR SUCCESSFUL BIOMANUFACTURING OPERATIONS

- Examining Chugai’s biomanufacturing strategy based on existing products and development pipeline with Roche
- Exploring research, production and business sites in Japan and within the global network
- Discussing trends in bioreactor scale based on the progress technology
- Lowering costs while increasing speed and flexibility by utilizing enabling technologies:
  - Single-use
  - Continuous manufacturing
  - Automation
- Launch and post-launch strategies: Enhancing manufacturing facilities from early development to commercial launch

* PAUL DALY, PH.D.
  Corporate VP and Head, Global Quality
* RON BRANNING
  SVP, Quality
* JAYANT APHALE, PH.D.
  EVP, Technical Operations

* ROBERT A. BAFFI, PH.D.
  EVP, Technical Operations
* HITOSHI KUBONIWA, PH.D.
  SVP, Pharmaceutical Technology
PLENARY

NEXT STEPS IN CAR T-CELL IMMUNOTHERAPIES: PLANNING FOR SUCCESS IN WITH CONTINUOUS IMPROVEMENT

- What does operations launch and readiness look like for Kite Pharma in 2018-19?
- Examining enhanced, ongoing collaboration with the FDA to align expectations
- Working with partners to develop new automation and manufacturing capability
- Steps to fully automate the process: What is established and what is still needed?
- Market expansion: Exploring the progress and trajectory of partnerships in Japan and China
- Focusing on the future: What’s next?

TIM MOORE
EVP, Technical Operations

9:50 am – 11:10 am

PRE-ARRANGED 1-2:1 BUSINESS MEETINGS AND REFRESHMENTS (100 MIN.)

11:15 am – 11:50 am

MANUFACTURING AND TECHNOLOGY
RESTRUCTURING MANUFACTURING CAPABILITIES TO HANDLE MULTIPLE PRODUCT LAUNCHES AND NEW MODALITIES
- Exploring production considerations in bringing advanced therapeutics to market
- Improving operational agility and time to launch
- Examining challenges and opportunities for investing in facility design and technology
- Developing and executing an engineering and facilities infrastructure strategy
- Are companies designing facilities for multiple products up-front or retrofitting?
- Future-proofing facilities through design and continuous evaluation of operational performance
- Maximizing efficiency through new facilities concepts and challenges in renovating legacy plants

JOYDEEP GANGULY
VP, Corporate Engineering, Facilities and Operations Gilead

QUALITY AND COMPLIANCE
ESTABLISHING QUALITY AGREEMENTS AND INCREASING OVERSIGHT WITH CMOS IN EMERGING MARKETS
- What are the expectations of Quality Agreements in today’s industry?
- Working collaboratively to implement the right quality system and standards
- Best practices and lessons learned from managing 55 CMOs around the world
- Taking a proactive approach to improve quality operations:
  - Reviews
  - Training
  - Monitoring
- Assessing partner site performance to develop improvement programs where needed
- Troubleshooting data integrity issues
- Case study: Enhancing quality and manufacturing process with CMOs in India

JASPREET GILL
EVP, Global Quality Compliance

SUPPLY CHAIN AND LOGISTICS
DEVELOPING JOINT AND SHARED AUDIT PROGRAMS TO ENSURE THE QUALITY OF RAW MATERIALS USED IN PRODUCTION
- 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
- Building a culture of quality across complex global supply chains
- Case study: Improving supply chain reliability through the standards and mechanisms of Rx-360 in conjunction with regulatory guidance

LUCY CABRAL
Head, Global Supplier Quality; Supply Chain Management Interest Group Leader, PDA

11:50 am – 12:00 pm

LUNCH
11:55 am – 12:30 pm

**ROOM 1**

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

- Does total cost of ownership of upstream equipment play hand-in-hand with the complexity of a system?
- Maintaining a high level of flexibility of equipment while dealing with many process unknowns
- Reviewing control systems and their implications on different scale equipment

**JEFF GUERTIN**
Technical Services Manager

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**ROOM 2**

**CAPACITY ANALYSIS AND PROCESS IMPROVEMENT USING A REAL-TIME MODELING SYSTEM**

- Identifying bottlenecks and improving processes
- Examining the decision to utilize Bio-G to build process models
- Advanced product features
- How a real-time scheduling system is being applied to analyze capacity
- What’s next in the program roll-out?

**RACHIT SHARMA**
Project Engineer, Operational Excellence and Logistics

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**JEFF GUERTIN**
Technical Services Manager

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**ROOM 3**

**HOW TO LEAD DURING CONSTANT CHANGE AND GET THE PERFORMANCE YOU NEED**

- Leading during times of continuous change is critical to:
  - Driving top-line growth
  - Launching new products
  - Improving productivity, reliability and safety
- Addressing the most often overlooked driver of change: Behavior
- Improving change results by leveraging 3 Core Elements
- Analyzing change to ensure better planning and execution

**KIM HUGGINS**
Partner

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12:35 pm – 1:35 pm

**LUNCH AND LEARN ROUNDTABLE DISCUSSIONS**

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

**APPLYING INNOVATIVE CHROMATOGRAPHY TOOLS FOR THE PURIFICATION AND RECOVERY OF BIOMOLECULES**

**MARK A. SNYDER, PH.D.**
R&D Manager, Process Chromatography Applications

**CONTINUOUS BIOPROCESSING: DISCUSSING THE ADVANTAGES AND PRACTICAL IMPLICATIONS OF TRANSITIONING FROM BATCH TO SEMI- OR FULLY-CONTINUOUS BIOPROCESS METHODS**

**PROF. IAN MARISON**
CEO

**COMPARATIVE ANALYSIS OF BOTTLES AND CARBOYS VS. BAGS IN SINGLE-USE MANUFACTURING**

**ALICE MOLTENI**
Director, BioProcess Sales

**QUALITY MANAGEMENT: CREATING SOLUTIONS TO TODAY'S CHALLENGES**

**LAUREL HACCHE**
Field Engineering Director

**TAKING GMP DOCUMENTATION OFF THE CRITICAL PATH: PLUG-AND-PLAY BATCH RECORDS FOR ANY PRODUCT, ANY TIME**

**ALICIA WOODFALL-JONES**
President

**STREAMLINING CUSTOM DEVICE ASSEMBLY FROM DEVELOPMENT TO COMMERCIALIZATION**

**DANIEL STEHN**
Director, Injectable Packaging

**BUYER AND SELLERS PERSPECTIVES: STREAMLINING TECHNICAL OPERATIONS AND QUALITY**

**RAMY KHALIL**
Senior Director

**IMPROVING COST SAVINGS IN YOUR COLD CHAIN OPERATIONS THROUGH THE REUSE OF TEMPERATURE ASSURANCE PACKAGING**

**ROB HAZELTON**
Regional Business Manager

**WHAT YOU NEED TO CONSIDER WHEN CHOOSING A CDMO: TIMELINES, TECHNOLOGY AND COMMUNICATION**

**SHELLY ADAMS**
Senior Director, Business Development

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

**MIKE MONTANA**
Senior Manager, Business Development

Seating is limited, so please sign up early. Sessions start at 12:35 PM and run for one hour. More seating will be provided if you would prefer to discuss other topics.
1:40 pm – 2:15 pm

ROOM 1
CASE STUDY: IMPROVING EFFICIENCY IN MEDIA AND BUFFER PRODUCTION TO ENABLE YOU TO GET TO MARKET RAPIDLY
- Ensuring single-use powder containment in today’s safety-focused manufacturing environment
- Preventing product from cross-contamination and reducing airborne particulates
- Understanding how modern bag designs can increase safety and speed
- Examining the ease of filling along with dispensing times and product loss

DAVE HOWES
Regional Sales Manager

ROOM 2
USING SYSTEMATIC TOOLS TO EXPEDITE PROCESS CHARACTERIZATION AND MAXIMIZE RELIABILITY OF PROCESS VALIDATION CAMPAIGNS
- Using a suite of tools, standard practice and depth of experience in Process Performance Qualification protocol
- Effectively focusing attention on critical process understanding and control
- Scoping and completing the ideal scope and range of characterization studies to support reliable operations in manufacturing
- Maximizing reliability during PPQ and commercial manufacturing
- Enabling full preparedness for Pre-Approval Inspection (PAI) and regulatory review

ABEL HASTINGS
Director, Process Sciences

ROOM 3
LABORATORY EXCELLENCE: INTEGRATING AND LEVERAGING THE 4 DYNAMICS TO DRIVE SUSTAINABLE PROGRESSION IN LAB PERFORMANCE
- Human dynamics: Understanding, adoption, activation and anchoring; and building effective organization structures
- Asset Dynamics: Optimizing equipment and people productivity
- Value Dynamics: Eliminating or reducing non-value adding activities and losses
- Flow Dynamics: Making value flow; and resourcing and operation at leveled demand

GARY RYAN, PH.D.
Director, North American Operations

2:20 pm – 2:55 pm

MANUFACTURING AND TECHNOLOGY
CONTINUOUS PROCESS VERIFICATION OF NEXT GENERATION PROCESSES UTILIZING ADVANCED PROCESS CONTROL
- Minimizing process input variability through better raw material control
- Achieving greater process understanding and control through real-time analytics
- Reviewing examples of robust process design and advanced process control
- Applying tools to assure process and product quality consistency
- Discussing elements of a predictive model development strategy:
  - Data acquisition and population
  - Data pre-treatment and exploratory analysis
  - Model optimization and validation
- Seeing adaptive control as a critical element of process consistency

STEVEN DOARES, PH.D.
VP, Global Manufacturing Sciences

QUALITY AND COMPLIANCE
CASE STUDY: DISCUSSING THE ACHIEVEMENTS ON THE ONE-YEAR LAUNCH OF SECOND COMMERCIAL RUN OF A CONTINUOUS MANUFACTURING RIG
- Discussing the lessons learnt in the first launch of continuous manufacturing at Vertex
- Overcoming challenges in the second commercial rig
- Collaborating with suppliers and CMOs for improving the program build out
- Understanding regulatory inspection concentration areas
- Looking forward: What’s next to drive innovation and performance improvements in this space?

MICHELLE BAILEY
Head, GMP Validation

SUPPLY CHAIN AND LOGISTICS
DEVELOPING A MULTI-LAYERED APPROACH TO IMPROVE END-TO-END SUPPLY CHAIN SECURITY
- Improving security in your supply chain to reduce theft and possible threats
- Establishing key processes, tools and operational efficiencies to improve security
- Conducting thorough background checks, including:
  - Employees
  - Reputations of companies
  - Insurance
- Collaborating with suppliers, customs and law enforcement to enhance security
- Case study: What’s working and what are the next steps?

CHARLES FORSAITH
Senior Director, Healthcare Distribution Alliance

3:00 pm – 4:20 pm

PRE-ARRANGED 1:2:1 BUSINESS MEETINGS AND REFRESHMENTS (80 MIN.)
4:25 pm – 5:10 pm

PANEL DISCUSSION
CMO/CDMO SELECTION AND MANAGEMENT TECHNIQUES
- What are the greatest challenges for companies selecting CMO/CDMOs?
- Developing product manufacturing and joint quality strategies
- Important considerations: Relationships, cost and prioritization
- Best practices for contract negotiation with vendors for goal alignment and communication
- How to ensure a successful company-CMO relationship

5:10 pm – 5:45 pm

INNOVATION SPOTLIGHT
LOOKING TOWARD A FUTURE OF PERSONALIZED HEALTHCARE THROUGH 3D PRINTING
- Embracing 3D printing technology for the biomedical sphere:
  - Personalized implants and instrumentation
  - Surgical models
  - Bioprinting and printing APIs
- Exploring the impact this technology has in blazing new medical frontiers
- How does 3D printing help get much needed medicines and therapies to patients?
- Understanding the evolving regulatory landscape
- Discussing Johnson & Johnson’s role in shaping guidance with regulators

5:45 pm – 6:30 pm

PANEL DISCUSSION
ADDRESSING CHALLENGES IN MEETING GLOBAL CAPACITY
- What are companies thinking about when building new capacities?
- How to best invest in capacity, emerging markets and technology
- Seeking partnerships and alliance models to help overcome production challenges
- How to best invest in capacity, contract manufacturers, emerging markets and technology
- Increasing the agility of your organization in global markets
6:30 pm – 6:35 pm

CHAIR’S SUMMARY AND CLOSING REMARKS

MANUFACTURING AND TECHNOLOGY CHAIR
PAUL DALY, PH.D.
Corporate VP and Head, Global Quality

QUALITY AND COMPLIANCE CHAIR
RON BRANNING
SVP, Quality

SUPPLY CHAIN AND LOGISTICS CHAIR
JAYANT APHALE, PH.D.
EVP, Technical Operations

6:35 pm – 7:35 pm

NETWORKING DRINKS RECEPTION

Sponsored By:

IDA Ireland
CHAIR’S OPENING REMARKS

MANUFACTURING AND TECHNOLOGY CHAIR
PAUL DALY, PH.D.
Corporate VP and Head, Global Quality

QUALITY AND COMPLIANCE CHAIR
RON BRANNING
SVP, Quality

SUPPLY CHAIN AND LOGISTICS CHAIR
JAYANT APHALE, PH.D.
EVP, Technical Operations

6:55 am – 7:55 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.

7:55 am – 8:00 am

KEYNOTE
LEVERAGING GLOBAL CHANGE TO CREATE STRATEGIC OPPORTUNITY AND DESIGN A NEW FUTURE FOR MANUFACTURING AND SUPPLY CHAIN LEADERS

- Examining global forces shaping the healthcare environment
- Discussing the new world of patients and players entering the industry and redefining our paradigms
- How is the current industry business model being questioned and the definition of innovation shifting?
- Assessing the impact of these changes on manufacturing, quality and supply chain
- Why the strategic opportunity for today’s leaders has never been greater
- How Teva is taking a leading role in shaping our new future

HERMANN ALLGAIER, PH.D.
Managing Director and Executive Board Member
8:40 am – 9:15 am

PLENARY
LEADERSHIP IN GLOBAL SUPPLIES OF BIOPHARMACEUTICALS: OPERATIONAL EXCELLENCE AND CONTINUOUS INVESTMENTS IN CAPACITIES AND NEW TECHNOLOGIES TO COVER EMERGING GLOBAL PRODUCT DEMANDS
- Improving flexibility and efficiency of large volume biopharmaceuticals and blockbuster product supplies
- Driving excellence in process transfer, scale up and PPQ
- What is needed to address the development of niche and novel products?
- Addressing planning for supply reliability and agility
- Expanding the scale and capacity of facilities: New advancements in bio-reactors, modular design, line expansion, single-use technologies, etc.
- Advancing global supply networks through leading expertise and technologies
- Automation and Digitization: Essential features to manage increasing complexity of a diverse product portfolio and thus drive customer satisfaction

UWE BUECHELER, PH.D.
SVP and Head, Biopharma Business Unit

9:15 am – 9:50 am

PLENARY
BUILDING A FLEXIBLE MANUFACTURING ENVIRONMENT
- Overcoming challenges of establishing multi-product operations
- Examining the benefits of flexible design for:
  - Smaller batch sizes
  - Personalized medicines
  - Efficiency, agility and profitability
- Identifying flexible equipment and robust manufacturing processes that work with frequent changeover and redeployment
- Discussing the effectiveness of restricted access barrier systems (RABS) and single-use systems
- Reducing human intervention and improving overall environmental control and project timing

JUDY CHOU, PH.D.
SVP and Global Head, Product Supply Biotech; Site Head, Bayer Berkeley

8:40 am – 9:15 am

ROOM 1
CASE STUDY: SIGNIFICANT TECHNOLOGY ADVANCES ENABLING INTEGRATED CONTINUOUS BIOPROCESSING
- Developing a strategy for continuous bioprocessing increasing the use of innovative single-use technologies
- Applying Lean thinking from batch to continuous bioprocessing
- Delivering better quality and productivity in a smaller footprint with shorter lead times
- Reviewing the journey to continuous bioprocessing
- Enabling unit operations platforms
- Delivering a robust platform process

IAN SELLICK
Director, Marketing

ROOM 2
STRATEGIC QUALITY PLANNING: A RISK-BASED APPROACH CONTRIBUTING TO BIOTECH MANUFACTURING EXCELLENCE
- Discussing elements of a risk-based approach and why focus matters in biotech manufacturing quality
- Examining methodology and toolsets to drive strategic quality planning
- Case study: How Bayer U.S. LLC is embedding strategic quality planning into its existing quality management systems
- Creating cross-organizational alignment and improving stakeholder engagement, focus and participation via strategic quality planning

JACK GARVEY
Founder and CEO

ROOM 3
IMPROVING THE EFFICIENCY AND ECONOMICS OF YOUR UPSTREAM AND DOWNSTREAM FILTRATION OPERATIONS THROUGH SINGLE-USE SYSTEMS
- How to improve the economics of your cross-flow filtration processes utilizing membrane separation technologies
- Eliminating the costs of validation and risks associated with cleaning and reuse
- Examining proprietary antifouling, low binding technologies with consistent high process flux and product yields
- Retiring your reuse crossflow system to create more flexible and efficient operations
- Case studies: Decreasing filtration costs from 4-6 times at pilot and small production scales and even more at larger scales

TINA SELF
VP, Quality, Supply Center
Berkeley

BENGT PERSSON
VP, Marketing and Business Development
10:35 am – 11:35 am

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

11:40 am – 12:15 pm

FIRESIDE CHAT
DISCUSSING GLOBAL FORCES SHAPING THE BIOMANUFACTURING INDUSTRY
• What does the next 5 years look like and what’s needed to be successful?
• Discussing an industry in transition and what’s on the horizon
• Examining industry drivers and trends, and their impact on operations:
  • Evolution of medicines
  • Industry consolidation
  • Capacity and complexity
  • Cost pressures
• Examining the tools and capabilities needed to drive business performance
• Exploring new regulations and industry’s ability to meet them

PAT YANG, PH.D.
Special Advisor, Global Cell Therapy Technical Operations

KELVIN H. LEE
Director

12:20 am – 12:55 am

PLENARY
PREPARING YOUR OPERATIONS AND WORKFORCE FOR THE DIGITAL ERA
• What are the trends and drivers for fully digitizing the value chain?
• Discussing approaches and initiatives to meet Industry 4.0 requirement standards:
  • Big Data and the Industrial Internet of Things
  • Network transparency
  • Self-driving operations
• Examining pilot launch experiences with R&D, quality and manufacturing groups
• Helping teams adapt to new processes and procedures during roll-out
• Leveraging current innovations, such as augmented reality in facilities
• Understanding what’s still needed and where we need to go

MARIA TERESA RODO CIMA
SVP and Head, Global Pharma Operations
1:00 pm – 1:35 pm

**MANUFACTURING AND TECHNOLOGY**

**INDUSTRY 4.0: DIGITIZATION IN PHARMA**
- Examining trends in pharmaceutical and vaccine production in the digital age
- Embracing modular automation, PAT and the Internet of Things to increase agility and flexibility
- People and technology: How are these forces working together to grow and mature our industry?
- Discussing the improvements cloud-based data, data analytics and data integrity have towards continuous improvement

**QUALITY AND COMPLIANCE**

**BUSINESS CHALLENGES AND THE QUALITY IMPERATIVE**
- Examining unique quality challenges and opportunities in the development of novel products for rare and ultra-rare diseases
- Creating a culture of quality for global clinical and commercial quality operations
- Leading and achieving transformational change in your organization

**SUPPLY CHAIN AND LOGISTICS**

**THE 6 KEY WAYS TO CREATE WIN-WIN PARTNERSHIPS WITH CDMOS**
- Ensuring the same high quality from external partners that is established internally
- Harmonizing internal procedures with CDMOs/CMOs
- Understanding your contractor's flexibility to adapt to new processes
- Conducting gap analysis to enhance regulatory compliance at your contractor's site

**JOHN PINION II**
EVP, Translational Sciences and Chief Quality Operations Officer

**1:40 pm – 2:40 pm**

**LUNCH AND LEARN ROUNDTABLE DISCUSSIONS**

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

**TAKING A RISK-BASED APPROACH TO SUPPLIER AND RAW MATERIALS MANAGEMENT**

**VENKATESH SRINIVASAN, PH.D.**
Director, Manufacturing Sciences

**MEASURING THE EFFECTIVENESS AND MATURITY OF YOUR QUALITY SYSTEMS AT MANUFACTURING LOCATIONS AND CORPORATE FUNCTIONS**

**JENNIFER MAGNANI**
Quality Systems Interest Group Leader, PDA; Head, Quality Academy

**ENSURING QUALITY SUPPLY OF MATERIALS AND COMPONENTS IN YOUR OPERATIONS**

**LUCY CABRAL**
Supply Chain Management Interest Group Leader, PDA; Head, Global Supplier Quality

**DEVELOPING EFFECTIVE BIOMANUFACTURING OPERATIONS FROM THE GROUND UP**

**CHRIS MCDONALD**
VP, Operations and General Manager, Colorado Operations

**FDA METRICS AND ESTABLISHING A QUALITY CULTURE**

**RON BRANNING**
SVP, Quality

**RISK-BENEFIT CONSIDERATIONS IN ACCELERATED PRODUCT QUALITY DEVELOPMENT**

**EARL DYE**
Director, CMC Regulatory Policy

Seating is limited, so please sign up early. Sessions start at 1:40 PM and run for one hour. More seating will be provided if you would prefer to discuss other topics.
2:45 pm – 4:00 pm

MANUFACTURING AND TECHNOLOGY
EXAMINING ADVANCES AND CHALLENGES IN VACCINE DEVELOPMENT AND MANUFACTURE
• Reviewing of the constraints and complexity of vaccine product development and manufacture
• Discussing the evolution of bioprocess and analytics innovation
• Examining technologies to accelerate timelines and get products to clinical studies and market faster
• Utilizing advanced analytic technologies
• What does a futuristic vaccine manufacturing facility look like?

QUALITY AND COMPLIANCE
APPLYING DESIGN PRINCIPLES TO YOUR QUALITY MANAGEMENT SYSTEM
• What is good design and what does it have to do with quality management?
• How do good design principles enable both compliance and business performance?
• Proposing ten design principles for the Pharmaceutical Quality System
• Sharing practical tips for applying these principles in new and existing systems

SUPPLY CHAIN AND LOGISTICS
CASE STUDY: SUPPLY CHAIN MANAGEMENT CHANGES DURING AND POST M&A
• Identifying elements of change and analyze impacts of changes
• Planning for success and changes across various functions
• Defining budgets, timelines, roles and responsibilities
• Assessing change readiness and risks across supply chain
• Executing a change plan and mitigating risks

KIM H. WONG, PH.D.
Director, Operations and Support, BioProcess R&D

CHRISTOPHER BELL
VP, Quality Systems and Compliance

PRASHANT KULKARNI
Director, Supply Chain Applications

3:25 pm – 4:00 pm

INNOVATION SPOTLIGHT
TRANSFORMING THE APPROACH TO VACCINES AND PROTEIN-BASED THERAPEUTICS
• What are the unique manufacturing processes developing plant-based flu vaccines?
• Discussing Medicago’s propriety manufacturing platform that saves time and provides cost savings
• Breaking outside of fertilized chicken eggs to incubate vaccines for new advantages
• Overcoming regulatory difficulties posed by the seasonal influenza vaccine approval
• Case study: Examining the pilot and launch facility in North Carolina

INNOVATION SPOTLIGHT
DEVELOPMENT, MANUFACTURING AND REGULATORY CONSIDERATIONS FOR DRUG DEVICE COMBINATION PRODUCTS
• Discussing trials and tribulations of getting complex combination products to market
• Assessing the unique challenges of dry powder manufacturing for respiratory delivery:
  • Materials handling
  • Moisture protection and confinement
  • Manufacturing procedures
  • Accurate dosing
• The second component: Blow-molding and filling the device
• Weighing the decision for manufacturing internally or externally
• Exploring the regulatory landscape and path to approval

MICHAEL SCHUNK, D.V.M., D.V.SC.
EVP, Operations

BILL DOLLARD, PH.D.
VP, Technical Operations
PANEL DISCUSSION
DEVELOPING NEXT GENERATION BIOMANUFACTURING FACILITIES

- What are the best ways to prepare your operations for the future?
- Matching your operations with the need for:
  - Quality Systems
  - Process innovation
  - Increased flexibility
  - New technologies
- Assessing decisions to build manufacturing capabilities domestically and/or internationally
- Discussing the importance of technology partners, government incentives, training solutions, etc. in developing next generation facilities
- Navigating the barriers to adoption of the latest technology and solutions to improve operational efficiency

4:05 pm – 4:50 pm

CHAIR’S REMARKS AND DELEGATE SURVEY PRIZE DRAW