

2019 PDA Annual Meeting
Solving Manufacturing and Supply Challenges for Current and Future Medicinal Products
March 11-13, 2019 | Marriott Marquis San Diego | San Diego, CA
As of 27 November 2018

Sunday, March 10

1:00 p.m. – 7:00 p.m.

Exhibitor Set Up

4:00 p.m. – 7:00 p.m.

Registration Open

4:00 p.m. – 7:00 p.m.

Speaker Ready Room Open

5:00 p.m. – 6:00 p.m.

2019 PDA Annual Meeting Program Planning Committee Meeting

6:30 p.m. – 9:30 p.m.

PDA Awards Dinner (*Invitation Only*)

Monday, March 11

7:00 a.m. – 4:00 p.m.

Exhibitor Set Up

9:00 a.m. – 5:00 p.m.

Registration Open

9:00 a.m. – 5:00 p.m.

Speaker Ready Room Open

1:00 p.m. – 1:30 p.m.

Welcome and Opening Remarks from the Chair of the PDA Board of Directors, PDA's President and, the Meeting Program Planning Committee Co-Chairs

Rebecca Devine, Biopharmaceutical Consultant

Richard Johnson, President and CEO, *PDA*

Ghada Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, *Merck & Co., Inc.*

Melissa S. Seymour, MBA, Vice President, Global QC Operations, *Biogen, Inc.*

1:30 p.m. – 3:00 p.m.

P1: From Bench to Bedside

Moderator: Ghada Haddad, MBA, Executive Director, Global cGMP & Compliance Auditing Organization, *Merck & Co., Inc.*

Translational medicine is often described as the process of transferring a therapy “from bench to bedside” and the journey spans years to decades, even under the most expeditious conditions. Success depends not only on biological efficacy, but also on the collaboration of a diverse workforce crossing many disciplines to move the therapeutic through the “valley of death” between basic research and commercial production. Translational oncology has grown rapidly over the past 15 years, in part due to advances in both research and diagnostic tools. These advances have enhanced our understanding of human biology and improved countless human lives. In this session we explore the accelerated development and commercialization of a cancer immunotherapy and hear directly from a patient treated with that immunotherapy.

1:30 p.m. – 2:00 p.m.

Moving Heaven and Earth: The Manufacturing Commercialization of a Cancer Treatment...And What Came After

Michael P. Thien, Sc.D., Senior Vice President of Operations, Manufacturing Systems Design & Commercialization, *Merck & Co., Inc.*

2:00 p.m. – 2:30 p.m.

Recurrent Stage 4 Head and Neck Cancer, a Patient's Journey and Hope for the Future

Chester Kitchen, Director, Corporate Development, *Merck & Co., Inc.*

2:30 p.m. – 3:00 p.m.

Questions and Answers/Discussion

3:00 p.m. – 3:30 p.m.

Refreshment Break

3:30 p.m. – 5:00 p.m.

P2: Accelerating Pharmaceutical Innovation

Moderator: Michael R. De Felippis, PhD, Distinguished Research Fellow, Bioproduct Research and Development, *Eli Lilly and Company*

The arrival of personalized therapies, issues with product availability and affordability and evolving regulatory expectations are highlighting that conventional approaches to biopharmaceutical manufacturing are no longer adequate to meet current and future manufacturing demands. A reluctance to change further diminishes agility and impedes the ability to accelerate pharmaceutical innovation. Even though there are compelling reasons to move beyond business as usual, the pharmaceutical industry still lags other manufacturing sectors in adopting technologies such as robotics and automation, integrated process monitoring and control, and predictive modeling. This session explores needed transformation in sterile biopharmaceutical manufacturing. Case studies and specific examples will provide insights into the opportunities, challenges and potential solutions for facilitating necessary improvements now and into the future.

3:30 p.m. – 4:00 p.m.

Opportunities and Challenges in Implementing Next-Generation Technologies for Drug Product Manufacturing

Nitin Rathore, PhD, Director of Core Technologies, *Amgen Inc.*

4:00 p.m. – 4:30 p.m.

Sterile Biopharmaceutical Manufacturing Today and Tomorrow – A Call to Action

Hal Baseman, Chief Operating Officer, *ValSource*

4:30 p.m. – 5:00 p.m.

Questions and Answers/Discussion

6:00 p.m. – 7:30 p.m.

Grand Opening Celebration in Exhibit Hall

Tuesday, March 12

7:30 a.m. – 5:30 p.m.

Registration Open

7:30 a.m. – 5:30 p.m.

Speaker Ready Room Open

7:30 a.m. – 8:30 a.m.

Continental Breakfast

8:30 a.m. – 10:00 a.m.

P3: Overcoming Regulatory Hurdles to Manufacturing Innovation

Moderator: Ursula Busse, PhD, MBA, Head Quality Intelligence, External Relations, *Novartis*

Today's innovative therapies require a complete revision of the traditional manufacturing environment. Manufacturing of the future must become efficient, flexible and agile to adapt to rapidly changing demands and to meet evolving patient needs. Meanwhile, improvements need not compromise the quality and availability of therapies. This implies the use of innovative manufacturing and supply approaches and cutting-edge technologies. And it requires overcoming challenges and barriers to their implementation. This session will focus on challenges encountered when introducing improvements in the manufacturing space during a product's lifecycle. Participants will learn how companies manage to introduce continual improvements and manufacturing innovation despite the current global regulatory complexity for post-approval changes (PAC). Solutions using risk- and science-based approaches to PAC, leveraging effective quality systems, and using additional means such as safety surveillance to minimize residual risks will be presented. A panel discussion will explore how we can use current tools in addition to ICH Q12 to further reduce the regulatory reporting burden and encourage faster adoption of novel, state of the art technologies in manufacturing.

8:30 a.m. – 8:50 a.m.

**Managing Continual Improvement/Manufacturing Innovation during a Product's Lifecycle
Industry Presenter Invited**

8:50 a.m. – 9:10 a.m.

Using Risk-Based Approaches to Reduce the PAC Regulatory Burden

Emma Ramnarine, Senior Director, Global Head External Development Collaborations, *Genentech/Roche*

9:10 a.m. – 9:30 a.m.

Maximizing the Utility of Safety Surveillance for Post-Approval Manufacturing Changes

John D. Ayres, MD, Risk Assessment Clinician, *Pharma Safety Solutions, LLC*

9:30 a.m. – 10:00 a.m.

Questions and Answers/Discussion

9:45 a.m. – 4:00 p.m.

Exhibit Hall Open

10:00 a.m. – 10:45 a.m.

Refreshment Break and Poster Presentations in Exhibit Hall

10:45 a.m. – 12:15 p.m.

Concurrent Sessions

Track: Innovative Manufacturing Strategies

A1: Biomanufacturing of Tomorrow

Moderator: Aaron R. Goerke, PhD, Director, Head of MSAT, Singapore Technical Operations, *F. Hoffmann-La Roche*

New visions are on the horizon for the future of biologics manufacturing, and the field is on the cusp of great change. Shouldn't we therefore refer to these visions as Biomanufacturing of Tomorrow? The possibility of end-to-end continuous bioprocess facilities is coming to realization with recent advancements. Yet significant effort may be required to realise implementation for clinical and commercial manufacturing in terms of sophisticated analytics for monitoring and control, novel methodologies or technologies to bridge differences from traditional platform, change management mindset and establishing the business case. This session looks to discuss progress and strategies where technologies and continuous platforms will better serve our needs and in conjuncture with progress in data analytics with PAT enables predictive process control and ultimately attains real-time release.

10:45 a.m. – 11:15 a.m.

Stacey Ma, PhD, Global Head, Innovation, Technology & MSAT, *Genentech, Inc.*

11:15 a.m. – 11:45 a.m.

Large Scale Production of MABs and MAB-Like Products using Continuous and Integrated Processing

Jon Coffman, PhD, Global Head, Innovation and Technology, *Boehringer Ingelheim*

11:45 a.m. – 12:15 p.m.

Questions and Answers/Discussion

Track: Disruptive Technologies

B1: Connected Health and Drug Delivery

Moderator: Austin Caudle, Associate Director, Business Development, *IQVIA*

10:45 a.m. – 11:15 a.m.

Industry Presenter Invited

11:15 a.m. – 11:45 a.m.

Industry Presenter Invited

11:45 a.m. – 12:15 p.m.

Questions and Answers/Discussion

IG1: Quality Risk Management and Cell & Gene Therapy Interest Groups

QRM Leaders: Magaly Aham, Senior Director, Quality Compliance, *Takeda*, **Amanda Bishop McFarland, MS**, Consultant, *ValSource, LLC* and **Emma Ramnarine**, Senior Director, Global Biologics, *Genentech/Roche*

CGT Leaders: Michael N. Blackton, MBA, Vice President, Quality, *Adaptimmune LLC* and

Vijay Chiruvolu, PhD, Vice President of Process Development, *Kite Pharma*

The Quality Risk Management Interest Group and Cell and Gene Therapy Interest Group will join together in this session to explore the ways that QRM can help enable CTG firms to overcome regulatory and manufacturing challenges with strategic risk-based decision making. Cell and Gene Therapy products are experiencing a unique set of challenges with respect to navigating regulatory guidance and the personalized medicine supply chain. One of the ways to overcome these challenges is using strategic risk management practices and embedding a culture of risk-based decision making into the firm's culture.

Speaker:

Polly Hanff, Global Regulatory Affairs & Quality Director, *Saint-Gobain*

IG2: Technology Transfer Interest Group**Leader: Melissa S. Seymour, MBA**, Vice President, Global QC Operations, *Biogen, Inc.*

Technology transfer continues to be a major area of interest within the pharmaceutical industry. Recent advancements in knowledge and risk management play a significant role in how the industry is adapting technology transfer. The TT IG has submitted a proposal for a Technical Report focused on tools for technology transfer as well as an industry survey. This session will begin with a review of the tools and strategies being developed as part of the TR, followed by a summary of the survey results which will focus on the use and methodology for technology transfer including emerging technologies, knowledge and risk management, regulatory implications, documentation and business strategies. The session will end with an innovative manufacturing case study utilizing some of the tools discussed with a goal of making this interactive.

Speakers:**Beth J. Haas**, Senior Project Manager/Consultant, *Commissioning Agents International, Inc.***John D. Wass**, Business Area Lead, New Technologies and Technology Transfers, *Commissioning Agents International, Inc.*

12:15 p.m. – 1:45 p.m.

Networking Luncheon in Exhibit Hall

1:45 p.m. – 3:15 p.m.

Concurrent Sessions**Track: Innovative Manufacturing Strategies****A2: Turning Data into Operational Solutions****Moderator: Karen Walker**, Vice President, Global Quality, *Seattle Genetics*

In this era of Big Data, Data Lakes and the Internet of Things, this session will explore what is being done to capture knowledge and drive adaptability into the manufacturing, quality and supply chain processes.

1:45 p.m. – 2:15 p.m.

Arne Zilian, Manufacturing Science and Technology, Global Head Systems and Standards, *Novartis*

2:15 p.m. – 2:45 p.m.

Sadik Kassim, Chief Scientific Officer, *Mustang Bio*

2:45 p.m. – 3:15 p.m.

Questions and Answers/Discussion**Track: Disruptive Technologies****B2: Cell and Gene Therapy****Moderator: Kelly Waldron, PhD**, Senior Consultant, *ValSource LLC*

The advent of gene editing in the 1980s foretold next-generation lifesaving and life sustaining medicinal applications. As industry sought to develop and commercialize this technology into safe and effective treatments, challenges began to surface. PDA meetings and conferences have provided a forum for industry to discuss these issues and, more importantly, share potential solutions. This session is focused on solutions, rather than challenges, and will explore two potential approaches to common goals in the production of cell and gene therapies: non-target viral clearance, and best practices in biopreservation.

1:45 p.m. – 2:15 p.m.

A Stage Appropriate Viral Clearance Strategy for Sf9/Baculovirus Based Manufacturing of rAAV**Andrew M. Wood, MS**, Senior Engineer, *Voyager Therapeutics*

2:15 p.m. – 2:45 p.m.

Phase-Appropriate Application of Biopreservation: Best Practices to Support Regenerative Medicine Advanced Therapy Commercialization**Brian J. Hawkins, PhD**, Scientific Applications Director, *BioLife Solutions, Inc.*

2:45 p.m. – 3:15 p.m.

Questions and Answers/Discussion**IG3: Facilities and Engineering Interest Group****Leader: Shelley M. Preslar, MBA**, General Manager, *Azzur Group South East*

In today's marketplace, we are constantly running into manufacturing and supply challenges. In this session, we'd like to hear about some innovative solutions being put in place within the industry to address some of these issues. There are multiple opportunities to learn from – Focus will be on "hot topics" which may include:

1. Aseptic fill in a non-classified environment
2. Integrated manufacturing – real time data management
3. Facilities & Equipment risk management – so what?? Does it add value?
4. Manufacturing quality/supply chain issues

IG4: Vaccines Interest Group

Leaders: Jane Halpern, PhD, Regulatory Lead, *National Institutes of Health (NIH)* and Sabrina A. Restrepo, PhD, Director, Sterile & Validation Center of Excellence

The session will present to the participants the status of the ongoing activities within the Vaccines Interest Group which are mainly focused around the development of technical report(s) or key deliverables regarding vaccines lifecycle management, vaccines specifications and new technologies. Participants will have the opportunity to listen case study or studies that frame the relevance of these topics and share their perspective as well.

Update of the VIG opportunities in the PDA Biopharmaceuticals week will be presented.

3:15 p.m. – 4:00 p.m.

Refreshment Break and Poster Presentations in Exhibit Hall

4:00 p.m. – 5:30 p.m.

Concurrent Sessions

Track: Innovative Manufacturing Strategies

A3: Manufacturing Lesson's Learned: Great Risks and Innovative Solutions

Moderator: Shelley M. Preslar, MBA, General Manager, *Azzur Group South East*

Our industry continues to face increased challenges with solving unique patient needs and being able to deliver needed medicines to the patient population. With the growing complexity of human disease and manufacturing supply chains, there is a constant need to deliver innovative solutions. Success requires continually evolving thought processes to look at problems from a new perspective. In this session we explore how one company developed a truly unique approach to an existing patient issue by implementing groundbreaking technology with a unique process. Additionally, we will hear about a disruptive approach designed to eliminate drug shortages.

4:00 p.m. – 4:30 p.m.

The Power of Vascular Innovation

Heather L. Prichard, PhD, Senior Vice President, Process Development, *Humacyte*

4:30 p.m. – 5:00 p.m.

A New Approach to Ensuring Uninterrupted Patient Supply

Martin G. VanTrieste, President & CEO, *Civica*

5:00 p.m. -5:30 p.m.

Questions and Answers/Discussion

Track: Rapid Drug Development

B3: Accelerated Development for Unmet Medical Needs

Moderator: Diane M. Paskiet, Director of Scientific Affairs, *West Pharmaceutical Services, Inc.*

There are certain aspects of typical drug development programs which may not be practical for accelerating approval of medicines intended for serious or life-threatening conditions. Novel drug products and treatments for severe conditions will have unique considerations for enabling rapid drug development. Regulatory flexibility is essential for patient access to these life-saving medicines, while preserving appropriate standards for safety and effectiveness. There are four principle FDA programs to address expedited approval pathways for unmet medical needs. This session will provide a background from FDA on expedited programs for serious conditions. Since 2008 more than 320 drug products have been developed and approved based on breakthrough therapy designations and/or expedited pathways. In addition, a case study will be given based on pharma experience with expedited pathway designation and approval.

4:00 p.m. – 4:30 p.m.

Regulatory Presenter Invited

4:30 p.m. – 5:00 p.m.

Industry Presenter Invited

5:00 p.m. -5:30 p.m.

Questions and Answers/Discussion

IG5: Biopharmaceutical Manufacturing Interest Group

Leaders: Peter Makowenskyj, Sales Engineer, *G-Con Manufacturing, Inc.* and Arleen Paulino, Vice President, Singapore Site Operations, *Amgen, Inc.*

Major advancements in manufacturing continue to occur in the biopharmaceutical sector but our field also faces many challenges. We will look at two distinct areas where challenges and growth continue to exist, continuous manufacturing for Mabs and Cell and Gene Therapy. First, we plan to hear from a representative of the BPOG Continuous Manufacturing Road Map team and the work they have done over the past two years putting this together along with their findings. Next, we plan to have a panel discussion from industry experts in the field of cell and gene therapy reviewing the evolution in this space as well as how we plan to address challenges moving forward.

IG6: Filtration Interest Group**Leader: Russell Madsen**, President, *The Williamsburg Group, LLC*

The main topic of discussion will be PDA's PUPSIT initiative, including the status of blocking studies and the ability of the post-filtration integrity test to detect a flawed or non-integral filter. Attendees will be updated on the current status of the PUPSIT initiative and its potential impact on regulators' requirements for performing PUPSIT.

6:30 p.m. – 9:30 p.m.

Reception**Wednesday, March 13**

7:30 a.m. – 3:15 p.m.

Registration Open

7:30 a.m. – 8:30 a.m.

Continental Breakfast

7:30 a.m. – 1:45 p.m.

Speaker Ready Room Open

8:30 a.m. – 10:00 a.m.

P4: Bridging Current Technology with the Future of Medicine**Moderator: Morten Munk**, Global Technology Partner, *NNE*

The pharma industry is moving beyond the traditional "one drug, one protein, one disease" paradigm to pipelines with multiple sophisticated new drug modalities, covering a wide array pharmaceutical product ranging from simple proteins to cell-based therapy. This transition will require deployment of a range of new technologies, but the future manufacturing challenges can also benefit from an increased use of tools, that are currently established or in the process of being developed. To a large extent those tools are based on a better utilization of available data to develop an increased amount of product and process knowledge, as both data and established knowledge often are not explored sufficiently, as it is not structured and accessible enough. The two presentations in this session, will discuss how an improved Control Strategy can be deployed by using tools from the Pharma 4.0 world, which include increased use of statistical methods, data analysis, real time monitoring and not at least Artificial Intelligence to help exploring, interpreting and presenting all the obtainable data.

8:30 a.m. – 9:00 a.m.

Artificial Intelligence use in the Pharmaceutical Industry - Quality performance in a Pharma 4.0 world**Gilad Langer, PhD**, Vice President of Business Development, *Bigfinite***Chris Watts, PhD**, Principal, *VolPal*

9:00 a.m. – 9:30 a.m.

Databased Road Map to Continuous Control Strategy and Real-Time Release**Per Vase, PhD**, Managing Partner, Applied Manufacturing Science, *NNE*

9:30 p.m. – 10:00 a.m.

Questions & Answers/Discussion

9:45 a.m. – 1:45 p.m.

Exhibit Hall Open

10:00 a.m. – 10:45 a.m.

Refreshment Break and Poster Presentations in Exhibit Hall

10:45 a.m. – 12:15 p.m.

Concurrent Sessions**Track: Rapid Drug Development****A4: Novel Modalities Driving Changes in Traditional Manufacturing Approaches****Moderator: Tia L. Bush**, Vice President, Rhode Island Site Operations, *Amgen Inc.*

Increasingly diverse product pipelines and technological advances are driving innovation in the biomanufacturing space. Historically, marketed biologics were comprised primarily of recombinant proteins and monoclonal antibodies. Today, human biology is driving multiple modalities including Car T cells, RNAi, and bi-specific T-cell engagers in drug discovery and development. This session will focus on how companies are designing their manufacturing footprint to accommodate these novel modalities by building new manufacturing capabilities while increasing speed and flexibility in their supply chain.

10:45 a.m. – 11:15 a.m.

Industry Presenter Invited

11:15 a.m. – 11:45 a.m.

Industry Presenter Invited

<p>11:45 a.m. – 12:15 p.m.</p> <p>Questions and Answers/Discussion</p> <p>Track: Handling Complexity in the Product Value Chain</p> <p>B4: Supply Chain Complexity Moderator: Magaly Aham, Senior Director, Quality Compliance, <i>Takeda</i></p> <p>Supply chain complexity is a system with a broad range of variations. A typical example would be a globally operating corporation with multiple production sites, all of which are in contact with numerous distribution centers worldwide, supplying thousands of end points. But there are other issues that pose further threat to the supply chain and consequently patients such as counterfeiting, natural disasters, cargo theft and diversion among others. Health Authorities and Companies need to be prepared to rapidly respond to potential health crisis in order to minimize risks to patients. Planning ahead is key to enabling a continuous and secure supply chain that adapts to changes in environment and market demand. This session will discuss some of these challenges and available routes and suggestions to deal with these worst-case scenarios.</p>
<p>10:45 a.m. – 11:15 a.m.</p> <p>Living in Uncertain Times: Challenges with Accelerated Development and Deployment of Pharmaceutical Countermeasures for Unanticipated and Unmet Medical Needs Douglas Kiehl, Research Advisor, <i>Eli Lilly and Company</i></p> <p>IG7: Environmental Monitoring/Microbiology Interest Group Leaders: Julie Barlasov-Brown, Associate Director, Sterile and Microbiology Quality Assurance, <i>Merck & Co. Inc.</i> and Marc Glogovsky, Senior Consultant, Microbiology, <i>ValSource, LLC</i></p> <p>Majority of testing in the microbiology laboratory are being performed manually and many companies still use paper-based systems to collect the data. Some use a combination of paper and digital records. Having well validated and properly functioning electronic systems will create strong data integrity and less regulatory issues. This session will touch base on regulatory expectations, industry direction and will provide a case study on going paperless in microbiology laboratory testing (from EM to sterility). After the presentation there will be extensive Q&A and round table discussion on the subject.</p>
<p>Young Professionals/Workforce of the Future Moderators: Jason Kerr, Quality Assurance Specialist, <i>Amgen Inc.</i> and Kristin Valente, Director, Vaccine Process Development & Commercialization, Downstream, <i>Merck & Co. Inc.</i></p> <p>Every day, approximately 10,000 baby boomers (individuals born between 1946 and 1964) reach retirement age. As these critical scientists and leaders exit the workforce, training the workforce of the future represents a significant challenge that is crucial to the success of pharmaceutical organizations. This session begins with knowledge transfer tools and capabilities for a products entire life cycle and highlights its importance. Additionally, this session highlights case studies from two young professionals: The first example explores potential career options facing young professionals early in their careers and the second presents a case study in the development of innovative antisense oligonucleotide therapies by a scientist early in her career. The collection of knowledge management, career development and scientific achievement, presented here, will explore the factors necessary for young professional development and workforce evolution.</p>
<p>10:45 a.m. – 11:15 a.m.</p> <p>Capture and Reuse of Critical Knowledge during Technology Transfer Paige E. Kane, PhD, Director, Knowledge Management, <i>Merck & Co., Inc.</i> Martin J. Lipa, Executive Director, Knowledge Management, <i>Merck & Co., Inc.</i></p> <p>11:15 a.m. – 11:30 a.m.</p> <p>Where Do You See Yourself in Five Years? And Why I Was Wrong Five Years Ago Garnet Kim, MBS, Manager, Risk Management Scientist, Pharmacovigilance & Epidemiology, <i>Gilead Sciences, Inc.</i></p> <p>11:30 a.m. – 11:45 a.m.</p> <p>Antisense Oligonucleotide Therapies: Molecule Requirements from a Packaging Perspective Amy A. Kim, Analyst-Specialist, <i>West Pharmaceutical Services, Inc.</i></p> <p>11:45 a.m. – 12:15 p.m.</p> <p>Questions and Answers/Discussion</p>

12:15 p.m. – 1:45 p.m.
Networking Luncheon and Passport Raffle in Exhibit Hall

1:45 p.m. – 3:15 p.m.

P5: When Disaster Strikes: Business Continuity for Continuous Supply

Moderator: Melissa S. Seymour, MBA, Vice President, Global QC Operations, *Biogen, Inc.*

1:45 p.m. – 2:05 p.m.

How Crisis Management & Business Continuity Plans Sustained Product Supply to Patients during Hurricane María

Yaritza Rodriguez Falero, Risk Management Manger, *Amgen Manufacturing Limited*

2:05 p.m. – 2:25 p.m.

Innovative Vaccine Delivery Methods

Linda Pulli, Chief of Staff, Global Supply Chain, *Merck & Co. Inc.*

2:25 p.m. – 2:45 p.m.

Cyber Threats and Readiness Activities

Steve Thompson, Sr. Manager Professional Services, *ValGenesis*

2:45 p.m. – 3:15 p.m.

Questions and Answers/Discussion

3:15 p.m.

Closing Remarks & Adjournment from Co-Chairs of the 2020 PDA Annual Meeting Program Planning Committee