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 28 February 2019

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 *(Invitation Only)*

6:30 p.m. – 9:30 p.m.
PDA Awards Dinner *(Invitation Only)*

Monday, March 11

6:00 a.m. – 7:30 a.m.
5k Run/3k Walk: *A Walk/Run to support Global Genes, a non-profit organization advocating for the needs of the rare disease community*

8:00 a.m. – 12:00 p.m.
Regulatory Affairs/Quality Advisory Board (RAQAB) Meeting *(Invitation Only)*

9:00 a.m. – 11:00 a.m.
PDA Chapter Council Meeting *(Invitation Only)*

9:00 a.m. – 12:00 p.m.
Biopharmaceutical Advisory Board (BioAB) Meeting *(Invitation Only)*

9:00 a.m. – 12:00 p.m.
Manufacturing Intelligence Meeting *(Invitation Only)*

9:00 a.m. – 12:00 p.m.
Isolator Technology Team Meeting *(Invitation Only)*

9:00 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

11:30 a.m. – 12:30 p.m.
PDA Orientation Lunch *Sponsored in part by Amgen Inc. (Invitation Only)*

12:00 p.m. – 1:00 p.m.
Joint Advisory Board Mix & Mingle *(Invitation Only)*

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 LLC*

4:30 p.m. – 5:00 p.m.
Questions and Answers/Discussion

5:00 p.m. – 6:30 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. – 8:45 a.m.
Managing the Lifecycle of a Cell and Gene Therapy Product
Margit Jeschke, PhD, Global Head, Analytical Stewardship, *Novartis*

8:45 a.m. – 9:00 a.m.
Using Risk-Based Approaches to Reduce the PAC Regulatory Burden
Anders Vinther, PhD, Vice President, Quality & Engagement, *Intarcia Therapeutics, Inc.*

9:00 a.m. – 9:15 a.m.
Maximizing the Utility of Safety Surveillance for Post-Approval Manufacturing Changes
John D. Ayres, MD, Risk Assessment Clinician, *Pharma Safety Solutions, LLC*

9:15 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

POSTER PRESENTATIONS *(Listed alphabetically by presentation title)*
The following posters will be presented during refreshment breaks on Tuesday and Wednesday.
Please support the workforce of the future by visiting the posters by PDA Young Professionals, indicated by an asterisk!

Poster Presenter	Poster Number
***A Next-Generation Stability Budget for Refrigerated Biologics through Statistical Simulation and Visualizations** **Luke Settles,** Senior Statistician, *Eli Lilly and Company*	11
***A Regulatory Affairs Experience: The Drug Master File for Digital Medicine** **Lyanna Jauregui,** Master of Business and Science (MBS) Candidate '19, *Keck Graduate Institute*	3
Automated Media Fill Inspection of Sterile Products Using Laser-Based Gas Headspace Analysis **Tom W. Millner,** Senior Technical Sales Representative, *Lighthouse Instruments*	27
Characterization of a Potential Calibration Material for Assessing Bioburden by Bacterial Autofluorescence and a Comparison with Ralstonia Pickettii from a High-Purity Water Environment **Kurt Benkstein, PhD,** Research Chemist, *National Institute of Standards and Technology*	33
Comparability and Similarity Assessments: FDA's Totality of Evidence Concept for Biotechnology Products **Jose C. Menezes, PhD,** CEO, *4Tune Engineering*	28
Comparative Study of Preparation Time and Results Between a Quantitative Certified Reference Material and Traditional Culture Methods for Pharmacopoeia Grow Promotion Testing (GPT) **Lori Daane,** Director of Scientific Affairs, *bioMérieux*	13
Contamination Control: Bringing Materials into the Cleanroom	9

The Next Revolution in Compendial Bacterial Endotoxin Testing (BET) **Sydney Jannetta,** Product Application Specialist, *SUEZ Water Technologies and Solutions*	15
The Transition from Conventional Filling to a Flexible Fill-Finish Solution for Protein Therapeutics Using Gloveless Robotic Isolators and Nested Pre-Sterilized Containers and Closures **Kevin Gadient, Peng,** Senior Manager, Manufacturing & Filling, *Emergent Biosolutions*	4
Using Bioassays in Support of Carryover Calculations in Multi-Product Facilities **Adeyma Arroyo,** Principal Engineer/Network Technology Lead, *Genentech, Inc.*	5
Viscosity Consideration for Design and Development of Combination Products for Subcutaneous Administration **Swapnil K. Pansare, MS, PMP,** Scientist-I, *MedImmune*	16

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. **Future of Sterile Drug Product Manufacturing: An Approach and Ideas to Increase Agility, Compliance, and Efficiency** **Sven Hauptmann, PhD,** Executive Vice President, Drug Product Manufacturing, *F. Hoffmann-La Roche* 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, *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*
Pharmaceutical companies are embracing connected drug delivery technologies to help differentiate their products and provide a balance between fostering innovation and cost containment. With drugs alone becoming less important, delivery technologies could be the key to market positioning and help propel companies to profitable growth and positive patient experiences. In the past, deployment of connected drug delivery devices has been hampered by high product cost, limited reimbursement, and lack of technology awareness with patients. This is changing however as manufacturers of connected drug delivery devices focus on collaboration with software companies and utilization of cloud-based data systems. This session focuses on how digital health and connected devices are pushing the healthcare industry in a fundamentally new direction.
10:45 a.m. – 11:15 a.m. **Digital Health Transformation and The Role of Drug Delivery** **Veena Rao-Mirmira,** Vice President, External Innovation, Digital Health, Delivery & Devices, *Eli Lilly and Company* 11:15 a.m. – 11:45 a.m. **Data, Analytics, Tech, and Knowledge and the Evolution of Emerging Technologies from "Idea to Industry"** **Malcolm Postings,** Vice President, Head of Innovation/Emerging Technologies & Chief Architect, *IQVIA* 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* and **Amanda Bishop McFarland,** Senior Consultant, *ValSource, LLC*

CGT Leaders: Michael Blackton, MBA, Vice President, Quality, *Adaptimmune LLC* and
Vijay Chiruvolu, PhD, Vice President, Process Development, *Kite Pharma, a Gilead Sciences company*

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:
Effective Application of Risk Management in the Cell and Gene Therapy Supply Chain
Polly M. Hanff, Global Regulatory Affairs & Quality Director, *Saint-Gobain Life Sciences*

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:

Tech Transfer Essentials: Benchmarking, Tools, Tips, and Supplemental TR Guidance
Beth J. Haas, Principal Consultant, *CAI*
John D. Wass, Global Business Lead, Process and Manufacturing Technology, *CAI*

12:15 p.m. – 1:45 p.m.
Portfolio Steering Committee *(Invitation Only)*

12:15 p.m. – 1:45 p.m.
Networking Luncheon and Tech Talks 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.
Industry 4.0: From Long Term Vision to Concrete Practical Steps
Arne Zilian, PhD, Manufacturing Science and Technology, Global Head Systems and Standards, *Novartis*

2:15 p.m. – 2:45 p.m.
Industry Representative Invited

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, Chief Technology Officer, *Pluristyx, Inc.*

2:45 p.m. – 3:15 p.m.
Questions and Answers/Discussion

IG3: Facilities and Engineering Interest Group
Leader: Shelley Preslar, General Manager, *Azzur Group South East*

In today's marketplace, we constantly deal with manufacturing and supply challenges. This becomes especially relevant when making renovations to an aging facility, while maintaining the supply chain. In this session, we will hear about an innovative approach to updating an aging facility, while maintaining minimal impact to the overall capabilities of the line. A case study will be shared, from a CMO facility that includes several key considerations:
- Planning for the project
- Aligning with customers / clients (internal and external)
- Documenting the project
- Executing the upgrade
- Reporting results
- Measuring success.

Following the presentation, there will be a panel approach to a detailed Q&A / Discussion session.

Speaker:
Renovating Aging Facilities
Susan Schniepp, Fellow, *Regulatory Compliance Associates Inc.*

Panelist:
Hal Baseman, Chief Operating Officer, *ValSource LLC*

IG4: Vaccines Interest Group
Leader: 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.

Speaker:
Responding to Challenges in the Development of a Strategy for Controlling Key Process Parameters for a New Vaccine
Philip R. Kuhl, PhD, Director, Engineering, Vaccine Process Development and Commercialization, *Merck & Co., Inc.*

2:00 p.m. – 3:00 p.m.
2020 Annual Meeting Exhibit Space Draw *(Invitation Only)*

3:15 p.m. – 4:00 p.m.
Refreshment Break, Passport Raffle and Poster Presentations in Exhibit Hall

4:00 p.m. – 5:00 p.m.
Exhibits Committee Meeting *(Invitation Only)*

4:00 p.m. – 5:30 p.m.
Concurrent Sessions

Track: Innovative Manufacturing Strategies

A3: Manufacturing Lessons Learned: Great Risks and Innovative Solutions
Moderator: Shelley Preslar, 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
Rob Schutte, Senior Director, Process Development, *Humacyte*

4:30 p.m. – 5:00 p.m.
A New Approach to Ensuring Uninterrupted Patient Supply
Greg Larsen, Business Partner, Business Services and Operations, *Civica Rx*

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.*

Novel drug products and treatments for severe conditions will have unique situations that may bring about rapid drug development. There are certain aspects of a typical drug development program that may not be practical for accelerating approval of medicines intended for serious or life-threatening conditions. Regulatory flexibility is an essential element for patient access to these life-saving medicines. In this session we will learn about the FDA programs for expedited approval pathways for unmet medical needs and challenges associated with accelerated development.

4:00 p.m. – 4:20 p.m.
US Approval Pathways for Drugs and Biologics: Traditional Approval or Use of an Expedited Program?
Candis Morrison, PhD, Senior Clinical Analyst, CDER, *FDA*

4:20 p.m. – 4:35 p.m.
Nusinersen: A Case Study on Acceleration
Mayra Reyes-Armour, PhD, Senior Director, ADPM Operations & Program Management, *Biogen*

4:35 p.m. – 5:05 p.m.
Living in Uncertain Times: Challenges with Accelerated Development and Deployment of Pharmaceutical Countermeasures for Unanticipated and Unmet Medical Needs
Douglas Kiehl, Research Advisor, *Eli Lilly and Company*

5:05 p.m. -5:30 p.m.
Questions and Answers/Discussion

IG5: Biopharmaceutical Manufacturing Interest Group
Leader: Peter Makowenskyj, Director of Sales Engineering, *G-CON Manufacturing*

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.

Speaker:

Biomanufacturing Evolution and a Glimpse into the Future in the Context of Broader Technological Transformations
Chetan Goudar, Executive Director, Process Development, *Amgen Inc.*

Panelists:
Shannon S. Eaker, PhD, Cell Therapy Enterprise Technical Leader, *GE Healthcare*
Heather Francis, Senior Director, Global Quality Manufacturing, *Kite Pharma, a Gilead Sciences Company*
Chetan Goudar, Executive Director, Process Development, *Amgen Inc.*
Sterling Wall, Scientist, Vector Process Development, *bluebird bio*

IG6: Filtration Interest Group
Leader: Maik W. Jornitz, CEO, *G-CON Manufacturing*

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 preforming PUPSIT.

Speakers:

Update on PUPSIT
Maik W. Jornitz, CEO, *G-CON Manufacturing*

Update on the Prefilter Task Force
Kelly Waldron, PhD, Senior Consultant, *ValSource LLC*

6:30 p.m. – 9:30 p.m.
Nautical Nights Celebration: *Admission is included with a Full Conference registration. Guests are welcome to attend at $70 per person!*

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

9:00 a.m. – 9:30 a.m.
Artificial Intelligence use in the Pharmaceutical Industry - Quality Performance in a Pharma 4.0 World
Claus Abildgren, Director of Sales, North America, *Bigfinite Inc.*

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, Passport Raffle 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.
The Rise of Polymodal Therapeutics is Driving the Evolution of Biomanufacturing
Arthur Hewig, Executive Director Process Development, *Amgen Inc.*

11:15 a.m. – 11:45 a.m.
Concepts, Challenges and a New Landscape from POC to Commercial Scale Manufacturing in Allogeneic Cell Therapy
Jose Vidal, PhD, Senior Vice President, Quality Assurance and Process Sciences, *Atara*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

Track: Handling Complexity in the Product Value Chain

B4: Supply Chain Complexity
Moderator: Magaly Aham, Senior Director, Quality Compliance, *Takeda*

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.

10:45 a.m. – 11:15 a.m.
Managing Risks to your Supply Chain and Increasing Patient Safety
Leo Vaytsman, Regional Manager, Global Product Protection, *Takeda*

11:15 a.m. – 11:45 a.m.
Product and Process Authentication
John P. Jasper, PhD, Chief Scientific Officer, *Molecular Isotope Technologies LLC/Nature's Fingerprint Authentication*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

IG7: Environmental Monitoring/Microbiology Interest Group
Leaders: Julie Barlasov-Brown, Associate Director, Sterile and Microbiology QA, *Merck & Co., Inc.* and
Marc Glogovsky, MS, S.M., Senior Consultant, Microbiology, *ValSource, LLC*

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.

Speaker:
Implementing a Paperless Lab
Staci Williams, Microbiologist, *Adaptimmune LLC*

Young Professionals/Workforce of the Future
Moderators: Jason Kerr, Quality Assurance Specialist, *Amgen Inc.* and
Kristin Valente, Director, Vaccine Process Development & Commercialization, Downstream, *Merck & Co., Inc.*

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.

10:45 a.m. – 11:15 a.m.
Capture and Reuse of Critical Knowledge in an Evolving Workforce: A Model for Technology Transfer
Martin J. Lipa, Executive Director, Knowledge Management, *Merck & Co., Inc.*

11:15 a.m. – 11:30 a.m.
Considerations and Proof of Concept Data for the Development of a Next-Generation Sequencing Method for Adventitious Virus Detection
Maria M. Bednar, PhD, Scientist I, *Biogen, Inc.*

11:30 a.m. – 11:45 a.m.
Antisense Oligonucleotide Therapies: Molecule Requirements from a Packaging Perspective
Amy A. Kim, Analyst-Specialist, *West Pharmaceutical Services, Inc.*

11:30 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m.
Education Advisory Board *(Invitation Only)*

12:15 p.m. – 1:45 p.m.
Networking Luncheon and Tech Talks 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 M. Rodriguez, Risk Management Manger, *Amgen Manufacturing Limited*

2:05 p.m. – 2:25 p.m.
Innovative Vaccine Delivery Methods
Garrett Smith, Head of Sales and Marketing, *Volans-i*

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