2017 PDA Annual Meeting

Manufacturing Innovation: The Next Wave of Sterile & Biopharmaceutical Science, Technologies & Processing

April 3-5, 2017 | Anaheim Marriott | Anaheim, CA

As of March 29, 2017

Sunday, April 2, 2017

6:30 a.m. - 9:00 a.m.
Registration Opens at 6:30 a.m.
Race starts at 7:15 a.m.
11th Annual Walk/Run Event: Benefiting *Global Genes* - Sponsored in part by the following PDA Chapters*: Capital Area, Delaware Valley, Metro, Midwest, Missouri Valley, New England and Southern California*

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

12:00 p.m. – 8:00 p.m.
Exhibitor Set Up

1:00 p.m. – 4:00 p.m.
Science Advisory Board (SAB) Meeting *(Invitation Only)*

1:00 p.m. – 4:00 p.m.
Biopharmaceutical Advisory Board (BioAB) Meeting *(Invitation Only)*

1:00 p.m. – 5:00 p.m.
Regulatory Affairs/Quality Advisory Board (RAQAB) Meeting *(Invitation Only)*

3:00 p.m. - 6:00 p.m.
Speaker Ready Room Open

4:00 p.m. - 5:00 p.m.
2017 Annual Meeting Program Planning Committee Meeting *(Invitation only)*

4:00 p.m. - 5:30 p.m.
Meet & Greet Reception

4:00 p.m. - 7:00 p.m.
Registration Open

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

Monday, April 3, 2017

7:00 a.m. - 8:00 a.m.
Continental Breakfast

7:00 a.m. - 8:00 a.m.
Orientation Breakfast - Sponsored by *Amgen, Inc.*

7:00 a.m. - 5:30 p.m.
Registration Open

7:00 a.m. - 5:30 p.m.
Speaker Ready Room Open

8:00 a.m. - 8:45 a.m.
Welcome & Opening Remarks
Hal Baseman, Chief Operations Officer, *ValSource, LLC*
Richard Johnson, President & CEO, *PDA*
Michael De Felippis, PhD, Senior Research Fellow, Bioproduct Research & Development, *Eli Lilly & Company* and
Morten Munk, Global Technology Partner, *NNE,* Co-Chairs, 2017 PDA Annual Meeting Program Planning Committee

8:45 am. - 10:15 a.m.
P1 - Opening Plenary Session: Focus on the Patient
Moderator: Michael De Felippis, PhD, Senior Research Fellow, Bioproduct Research & Development, *Eli Lilly & Company*

Session Description: The Opening Plenary session will provide an intriguing example of how scientific discovery in new frontiers of medicine is leading to novel, potentially life-saving treatment options. Emphasis will be placed on industry's role in helping to bring future pharmaceutical innovations to the patients we serve. As a reminder of the importance of our work, we will hear directly from a patient who has benefitted from advancements in medicine.

8:45 a.m. - 9:15 a.m.
Genome Engineering for Therapeutic Applications
Bruce Conklin, **MD,** Senior Investigator, Gladstone Institute of Cardiovascular Disease, Professor, Department of Medicine, *University of California, San Francisco*

9:15 a.m. - 9:45 a.m.
Making the Most of a Life, Interrupted
Suleika Jaouad, Well Columnist, *New York Times,* Health Advocate & Cancer Survivor

9:45 a.m. - 10:15 a.m.
Questions & Answers/Discussion

10:00 a.m. - 7:00 p.m.
Exhibit Hall Open

10:15 a.m. - 11:00 a.m.
Refreshment Break & Poster Presentations in Exhibit Hall

The following posters will be presented during refreshment breaks on Monday, April 3, 2017.

Process Validation/Lifecycle Approach: Assessment Methodologies for Stage 2 & 3
Naheed Sayeed-Desta, Manager, Technical Operations Process Validation, *Apotex Inc.*

Gaining Value through External Collaborations towards Standardization of Single-Use Systems Aspects
Jeffrey Carter, PhD, Strategic Projects Leader, *GE Healthcare Pt Ltd.*

Automated Inspection of Parenteral Drug Products – Evaluation of Product Quality Impact of Small-Molecule Products and Biologics
Sean Tomlinson, PhD, Senior Process Engineer, *Pfizer Inc.*

Total Organic Carbon (TOC) Method Development for Low Solubility Compounds in Cleaning Validation
Jenny Watson, Global Pharmaceutical Applications Manager*, GE Analytical Instruments*

Container Closure Integrity Testing (CCIT): New USP for Pre-filled Syringes
Nicolas Thurin, PhD, Analytical R&D Manager, *Catalent Pharma Solutions*

Practical Applications and Benefits of Sterile Product Compliance Risk Assessments and case studies This poster is related to "Microbial Control Program/ Control Strategy Design"
Guenther Gapp, PhD, Microbiologist, *Gapp Quality GmbH*

Development of Predictive Risk Elements within an Internal Product Quality Risk Model for cGMP Manufacturing and Testing
Michael LaBruto, Director, Quality Process Improvement, *GSK*

Mixing/Blending Processes in Single Use Systems
Abhijit Banerjee, PhD, Director of Technical Services, *Advent*

Development and Validation of an Aerosol Method to Validate the Integrity of Single Use Systems
Kathleen Souza, R&D Manager, Microbiology**,** *EMD Millipore Corporation*

Product Commercialization is more than just Building a Facility; It's About Building Organizational Ability
Roger Filannino, Validation Engineer, Project Manager & Client Manager, *CAI*

Bioanalytical Assessment of Compatibility of Model Biologics with Commercial and Developmental Elastomeric Packaging Materials
Lloyd Waxman, PhD, Senior Chemist, *West Pharmaceutical Services*

Total Quality Allows for Continuous Production Process Improvement
Paul Bilotti, North America Sales Manager, *Wilco-USA*

Challenges of Implementing Sterile Single Use Systems for Non-Aqueous Parenteral Formulations
David Royle, Associate Principal Scientist, Pharmaceutics Project Expert, *AstraZeneca*

Case Study: Data on Liquid Shipping in Single-use Bags Supporting Biotech Process Qualification
Elisabeth Vachette, Senior Global Product Manager, *Sartorius Stedim FMT SAS*

Case Study: Reducing the Number of Validation Deviations during Project Implementation
Walid El Azab, Manager, Technical Services, *STERIS Corporation*

Process Analytical Technology (PAT) in Continuous Bioprocessing
Edita Botonjic-Sehic, PhD, Senior Principal R&D Scientist, *Pall Life Sciences*

Biofilm Remediation Strategies for the Pharmaceutical Industry
Paul Lopolito, Senior Manager, Technical Services, *STERIS Corporation*

The Effect of a Plunger Surface Roughening Treatment on CCI: Evaluation of Inherent Package Integrity by Helium Leak Detection in the Vacuum Mode
Brandon Zurawlow, Associate Director, CCIT, *Whitehouse Laboratories*

11:00 a.m. - 12:00 p.m.
Exhibits Committee Meeting *(Invitation Only)*

11:00 a.m. - 12:30 p.m.
P2 - Advanced Therapies /Cell and Gene Therapies: Quality Aspects
Moderator: Melissa Seymour, Vice President, Corporate Quality, *Biogen*

Session Description: Scientific progress over the last several years has led to novel methods for the transfer of genetic material into patients' cells for therapeutic purposes. Many quality challenges exist in this space including insertional mutagenesis, induced cellular changes and vector DNA mobilization. This session will address quality aspects in the production of gene transfer vectors and genetically modified somatic cells including appropriate characterization and validation requirements.

11:00 a.m. - 11:30 a.m.
CTL019: Journey to Industrialization
Karen Walker, Global Head of Technical Development & Manufacturing, Cell & Gene Therapies Unit, *Novartis Pharma Corp.*

11:30 a.m. - 12:00 p.m.
Overcoming Quality Challenges in Cell Therapy
Bethany Dudek, Senior Director, Site Head Quality, *Kite Pharma*

12:00 p.m. - 12:30 p.m.
Questions & Answers/Discussion

12:30 p.m. - 1:45 p.m.
Publishing Meeting *(Invitation Only)*

12:30 p.m. - 2:00 p.m.
Networking Luncheon in Exhibit Hall

12:30 p.m. - 2:00 p.m.
Chapter Council Meeting *(Invitation Only)*

12:30 p.m. - 2:00 p.m.
Education Advisory Board *(Invitation Only)*

12:30 p.m. - 2:00 p.m.
Networking Luncheon in Exhibit Hall

2:00 p.m. - 3:30 p.m.
Concurrent Sessions

Technology Track: Advances in Analytical Sciences & Quality Control Strategies	Science Track: Developments in Patient-Centered Precision Medicine	Processing Track: Next Generation Manufacturing
A1 - Analytical Sciences & Process Monitoring *(Include LER in discussions)* **Moderator: Aaron Goerke, PhD,** Associate Director/Head of Downstream Global Manufacturing Science & Technology, *Genentech, A Member of the Roche Group*	**B1 - Delivery System Design** **Moderator: Ghada Haddad,** Director, Global Quality Risk Management Center of Excellence*, Merck & Company /Merck, Sharp & Dohme*	**C1 - Future Facility Design** **Moderator: Morten Munk,** Global Technology Partner, *NNE*
Session Description: The manufacture of pharmaceutical products is a complex process. These processes and products are susceptible to contamination by adventitious agents such as bacteria, fungi and viruses. Adventitious agent contaminations can have a significant impact on manufacturing operations, product quality and patient safety. This qualifies the increased attention by both Industry and Health Authorities. Perspectives, forward looking practice and new technologies surrounding adventitious agent control and detection will emerge from this session.	**Session Description:** Delivery Systems for Pharmaceuticals/Biopharmaceuticals, which includes combination products, has expanded when measured by many parameters, the number of drugs involved, the therapeutic areas treated, and the size of the patient population targeted. But the goal remains the same, ensuring that the patient gets the right drug at the right dose at the right time. No longer restricted to administration by healthcare professionals, delivery systems need to be robust to accommodate patient's lifestyles, and be as user friendly as a smartphone. Do we understand how the patient is using the delivery system, are they intimidated or empowered? How can we make sure that the drug, when in the patient's control, is protected from light or stored at the appropriate temperature? The presentations will discuss some of the challenges of designing drug delivery systems in this rapidly changing environment.	**Session Description:** There is a growing trend in the pharma industry towards 'personalisation' of healthcare. More and more specialised products used by a small group of patients are being developed and the regulatory authorities support this trend by offering accelerated approval processes for this type of products. Additionally, with an increased focus on reducing manufacturing costs and with less predictability of the future demands for different products, there is a need for more flexible and agile facilities. This session highlights some of the tools, which need to be activated to accommodate this trend for a new type of facilities and manufacturing strategies. The focus of the second presentation is to address the concern from the industry regarding how the authorities view introductions of new technologies in general plus a specific focus on continuous manufacturing.
2:00 p.m. - 2:30 p.m. **Microbiological Control and Adventitious Agents** **Patricia Hughes, PhD,** Team Leader, Biotech Manufacturing, *FDA*	2:00 p.m. - 2:30 p.m. **Navigating Risk Management and Design Control Challenges for Combination Products: A Deeper-Dive Look into Complex Drug/Device Combination Products and Co-Packaged Kits** **Tracy TreDenick,** Head of Regulatory & Quality Assurance, Founding Partner, *BioTechLogic*	2:00 p.m. - 2:30 p.m. **Flexible Manufacturing Strategies: Applying QRM to Implement Straight Thru Processing** **Lisa Sykes,** Director, Vaccine Operations, *Merck & Company /Merck, Sharp & Dohme*
2:30 p.m. - 3:00 p.m. **Virus Control, Safety, and New Technologies for Virus Detection** **Arifa Khan, PhD,** Senior Investigator, CBER, *FDA*	2:30 p.m. - 3:00 p.m. **System Integration of Drugs, Pre-filled Syringes and Delivery Devices** **Galen Shi, PhD,** Engineering Advisor, *Eli Lilly & Company*	2:30 p.m. - 3:00 p.m. **Small Molecule/Continuous Biomanufacturing** **Rapti Madurawe, PhD,** Division Director (Acting), Process Assessment I, CDER, *FDA*
3:00 p.m. - 3:30 p.m. **Questions & Answers/Discussion**	3:00 p.m. - 3:30 p.m. **Questions & Answers/Discussion**	3:00 p.m. - 3:30 p.m. **Questions & Answers/Discussion**

3:30 p.m. - 4:15 p.m.
Refreshment Break and Poster Presentations in Exhibit Hall

4:15 p.m. - 5:30 p.m.

Concurrent Interest Group Sessions

IG1 - Advanced Virus Detection	**Leader: Dominick Vacante, PhD,** Scientific Director, *Janssen Pharmaceutical R&D*	**Interest Group Description:** Advanced nucleic acid based technologies are emerging, cutting-edge techniques with various potential applications for biologicals, such as detection of unknown adventitious viruses in novel cell substrates as well as product and raw material characterization. Additionally these new methods have the potential to complement some current assays. This interest group (IG) is comprised of experts representing industry, academia, government agencies, and regulators that discuss the current thinking and planned efforts regarding application of new technologies for virus detection in biologicals.
IG2 - Facilities & Engineering	**Leader: Shelley Preslar,** General Manager, *Azzur Group*	**Interest Group Description:** The Facilities and Engineering Interest Group provides a forum for the discussion of topics and interests related to the design, construction, operation and maintenance of the production and research facilities used for GMP and GLP purposes. Discussions are held in conjunction with two of the PDA meetings: the Annual Meeting and the PDA/FDA Joint Conference, as well as a discussion forum on the PDA website. The format of the Facilities and Engineering Interest Group meetings are an open forum for discussion, where attendees select the topic for discussion and the leader moderates the discussion of peers seeking to reach a better understanding of regulatory expectations and opportunities to share and learn best practices. Where appropriate, the Facilities and Engineering Interest Group will compile these understandings and best practices into technical reports with the contributions and review of interested members.
IG3 - Filtration	**Leader: Maik Jornitz,** CEO, *G-Con Manufacturing, Inc.*	**Interest Group Description:** On April 11, 2016, EMA issued the document "Guideline on the sterilization of the medicinal product, active substance, excipient and primary container" for comment. The document contains a section on sterilizing filtration requirements that is of interest to the members of the Filtration IG. Under "Sterile filtration" the document states, "The integrity of the sterilised filter should be verified before use but after its sterilization unless specifically justified and validated, and should be confirmed immediately after use. Nominal pore sizes of 0.22 µm or less are acceptable without further justification, in accordance with Ph. Eur." Note that the document suggests that mandatory post-sterilization integrity testing of the filter is not necessary if validated and justified. Interesting and not entirely clear is the statement about the acceptability without justification of filters having nominal pore sizes of 0.22 µm or less. Also, the previously stated pre-filtration bioburden limit of NMT 10 CFU per100 mL has been softened. The comment period on the document closed October 13, 2016.
IG4 - Management of Outsourced Operations	**Leader: Sharon Ayd, PhD,** Chief Scientific Officer & Senior Vice President, Pharmaceuticals, *Regulatory Compliance Associates, Inc.*	**Interest Group Description:** The Management of Outsourced Operations Interest Group provides a forum for sharing information among PDA members on management, oversight and regulatory responsibilities of outsourced activities. The meeting is open discussion format with a moderator. The group discussion at PDA annual meeting will focus on the issue of "Customer Concerns Related to Their Relationship with Their Outsourced Service Provider". Some matters we will be discussing: • "If I am only a small volume client of a large CMO, what leverage do I have to negotiate a favorable quality agreement" • "I am a virtual pharma company that relies exclusively on CMOs. In the US there is insufficient manufacturing capacity for a specific pharma product in my portfolio but there is a CMO in Asia that can manufacture the product. o Can anyone comment on the state of the CMO industry in the US in terms of expected future expansion? o Can anyone comment on the use of a CMO in Asia / outside the USA" If you have other related issues or questions you would like to raise you can add new and different ideas to this session.

IG5 - Microbiology/ Environmental Monitoring	**Leader: Julie Barlasov,** Associate Director, Sterile & Microbiology Quality Assurance & Quality Risk Management COE, *Merck & Company /Merck, Sharp & Dohme*	**Interest Group Description:** The Microbiology/Environmental Monitoring Interest Group addresses topics in pharmaceutical microbiology, rapid microbiology, environmental monitoring, and compendial issues. The group typically has a guest speaker followed by a group discussion. If warranted, task forces are established to respond to issues relevant to microbiologists. **Speaker:** **Jette Christensen,** Scientific Director, Compliance, *Novo Nordisk A/S*
IG6- Packaging Science	**Leader: Roger Asselta,** Vice President, Technical Affairs, *Genesis Packaging Technologies*	**Interest Group Description:** The session will provide updates on current activities in the area of parenteral packaging, including Technical Reports, Tasks Forces and regulatory Issues. An area of focus will be change control for packaging system components. Perspectives will be presented by Susan Dounce of Datwyler Pharma and Jennifer Johns of Pfizer. The meeting will provide an open forum for further discussion on this issue and additional topics of interest. **Speakers:** **Susan Dounce, PhD,** Senior Manager, Business Development & Innovation, Injection Systems *Datwyler Sealing Solutions* **Jennifer Johns,** Director, Packaging & Device Services, *Pfizer, Inc.*

5:30 p.m. - 7:00 p.m.
Networking Reception in Exhibit Hall - Sponsored in Part by the *PDA Southern California Chapter*

Tuesday, April 4, 2017

7:00 a.m. - 8:30 a.m.
Continental Breakfast

7:00 a.m. - 5:15 p.m.
Registration Open

7:00 a.m. - 5:15 p.m.
Speaker Ready Room Open

7:15 a.m. - 8:15 a.m.
Concurrent Breakfast Sessions

Breakfast I: Overcoming the Barriers to Technology Implementation & Change Management **Moderator: Tia Bush,** Vice President, Quality, *Amgen, Inc.*	**Breakfast II: Knowledge Management – Q12 Update** **Moderator: Melissa Seymour,** Vice President, Corporate Quality, *Biogen*	**Breakfast III: Business Management of QRM** **Moderator: Ghada Haddad,** Director, Global Quality Risk Management Center of Excellence*, Merck & Company /Merck, Sharp & Dohme*
Session Description: Developing a new therapy requires significant investment and is often marked by lengthy development to commercialization timelines and a high risk of failure. Innovation in the pharmaceutical industry has a dramatic impact on the health and wellness of millions of people and the ability of the company to maintain the solid business results that are expected by shareholders. For many pharmaceutical companies, innovation is the core element of their vision and mission to serve patient needs. Partnering with regulators can ensure that innovative and safe medicines are available to those that need it most. While the regulators' primary role is to ensure patient safety, it is clear that they are playing an active role in promoting innovation. The regulatory framework is	**Session Description:** Knowledge Management is increasingly becoming more and more important to the industry with respect to facilitating product development, continuous improvement across the product lifecycle and post-marketing process control. It is clear, also, that the current regulatory processes are less than optimal for encouraging product and process improvements. The Q12 initiative is driving more intense dialogue on what the most effective KM and regulatory reporting processes could achieve. Knowledge Management and how that information flows both internally and externally to regulators could be a turning point in how Post Approval Changes are managed. This session will focus on integrated use of knowledge	**Session Description:** ICH Q9 (Quality Risk Management), defines harm as damage to health, including the damage that can occur from loss of product quality or availability. At many firms, the principles outlined in ICH Q9 are leveraged in a very detailed, complex manner, to assess the intricate failure modes or hazards associated with specific process steps or equipment within the manufacturing process. While this may be beneficial in understanding and controlling granular risks associated with a specific process step, it does not always lend itself to a strategic landscape. A holistic review of systems, processes, and company strategies is necessary to identify the strategic risks that could potentially have more impact on the overall compliance status, product availability to patients, and strategic direction of the firm. This presentation will discuss the

rigid in order to maintain high standards, but regulators are open to discussion with the industry. This session will focus on the collaborative initiatives that are underway as well as the opportunities that still exist to overcome the barriers of introducing new technology both internal to the company and external with the regulators.	gained during the product lifecycle, including transparency with regulators, to establish and maintain a state of control which could facilitate opportunities for reduced reporting of Post Approval Changes.	connection of risk management (including Quality Risk Management) to business strategy and what tools and methodologies could be used to identify this level of risk. Follow the methodology used in the lifecycle of a risk, how it is communicated and escalated to senior leadership, and how the risk control recommendations are incorporated into business processes, portfolio management, and in decision making principles. The outcome of this process should be a decision focused on ensuring a compliance driven, sustainable business that consistently delivers quality product to patients.
Rapti Madurawe, PhD, Division Director (Acting), Process Assessment I, CDER, *FDA* **Michael Abernathy,** Director, Regulatory Affairs, *Amgen, Inc.*	**Postapproval Change and Knowledge Management – Where are We? Results from the PAC iAM Task Force Survey** **Emma Ramnarine,** Head, Global Biologics Quality Control, *Genentech, Inc., A member of the Roche Group* **The Future State - Knowledge Management and Sharing to Reduce Regulatory Burden** **Ursula Busse, PhD**, Quality Intelligence & External Relations, *Novartis*	**Integration of Risk Management into Product Strategy and Portfolio** **Lori Richter,** Site Risk Manager, *Genentech, Inc., A member of the Roche Group*

8:30 a.m. - 9:30 a.m.
2018 Annual Meeting Exhibit Space Drawing *(Invitation Only)*

8:30 a.m. - 10:00 a.m. **P3 - Next Generation Manufacturing & Facilities** **Moderator: Maik Jornitz,** CEO, *G-Con Manufacturing, Inc.*
Session Description: Capital expenses, invested into rigid production facilities, which are often only designed to facilitate one product, are a high risk. These are highly inflexible, difficult to scale and unable to be divested if the drug target fails. In addition, process intensification due to higher expression rates and continuous processing efforts; require rapidly deployable facilities with a smaller footprint. Production site design and process equipment flexibility is becoming a key element. The session will address modular facilities, production process platforms, single-use equipment, which can be established fast track and with high degree of flexibility.
8:30 a.m. - 9:00 a.m. **Next Generation Biomanufacturing** **Mike Vandiver,** Vice President, Manufacturing & Plant Design, *Just Biotherapeutics* 9:00 a.m. - 9:30 a.m. **Trends in Creating Flexible Clinical and Launch Facilities for Parenteral Products** **Barry Starkman,** Principal Consultant, Parenteral Manufacturing, *DPS Engineering* 9:30 a.m. - 10:00 a.m. **Questions & Answers/ Discussion**

9:45 a.m. - 4:00 p.m.
Exhibit Hall Open

10:00 a.m. - 10:45 a.m.
Refreshment Break & Poster Presentations in Exhibit Hall

The following posters will be presented during refreshment breaks on Tuesday, April 4, 2017.

Downstream Processing of a Large Live Virus: Challenges in Development and Scale Up for a Sterile Purification Process
Wanli (Justin) Ma, Senior Scientist, Vaccines Process Development, *Merck Research Laboratories*

A Harmonized Approach to Data Integrity
Kimberley Buytaert-Hoefen, PhD, Senior Consultant, *Parexel*

Performance Analysis – Inspiring Innovation for Reliable Supply
Pia Krieger, Performance Analysis Workstream Lead, *Roche GmbH*

Analytical Approach for Implementation of Visual Inspection
MariannNeverovitch, Research Scientist, *Bristol-Myers Squibb*

Operational Excellence: Lean Six Sigma Applied to Analytical Method Transfers
Charlotte Brice, Account Director, *Catalent Pharma Solutions*

Cleaning Validation Concerns for Continuous Manufacturing Processes
Elizabeth Rivera, Technical Services Manager, *Steris Corporation*

A Software System for Next Generation Sequencing Based Detection of Adventitious Agent Contamination
Asa Oudes, PhD, Scientific Account Manager, *Genedata Inc.*

Can Single Use Components be Considered Commodities?
Christopher Smalley, **PhD**, Director, Engineering BioSterile Validation, *Lyophilization Technology, Inc.*

Process Analytical Technology (PAT) in Continuous Bioprocessing
Edita Botonjic-Sehic, PhD, Senior Principal R&D Scientist, *Pall Life Sciences*

Beyond The Count: A Three-Pronged Approach To USP <788> Utilizing Particle Counting, Automated Raman Spectroscopy and Automated SEM-EDS for Source Determination
Emily Landsperger, Scientist II, *Gateway Analytical*

The Future of Outsourcing: How to Ensure a Successful Contract Partner Relationship
Brittany Cloud, Group Leader, Quality Compliance, *Eurofins Lancaster Laboratories, Inc.*

Mold Control and Detection In Biological Drug Substance Manufacturing Facilities: An Industry Perspective
Stephanie Ramsey, Manager II, Global QC Microbiology, *Shire*

Combination Products - Lessons Learned and Case Studies
Steve Coulter, PhD, General Manager, RCA West, *Regulatory Compliance Associates, Inc.*

Usability Formative Study for Risk Mitigation in the Early Development Phase of a full Passive, Integrated Safety System for Prefilled Syringes
Alessandro Artioli, PhD, Core Team Leader, *Nuova Ompi S.r.l.*

Raw Material Management and Product Design Strategy for Enhanced Quality, Assurance of Supply, Validation & Change Control of Single-Use Systems
Paul Preibe, Director, *Product Management, Sartorius Stedim*

Application of Online Process Analytical Technology (PAT) to Evaluate Lyophilized Parenteral Formulations for Process Understanding and Product Quality
Charudharshini Srinivasan, PhD¸ Staff Fellow, CDER, *FDA*

Safe, Reliable Bulk Drug Substance Transfers via Frozen Storage and Logistics in Single-Use Containers
Michael Marciniak, Senior Product Manager, Freeze-Thaw Technologies, *Sartorius Stedim NA, Inc.*

10:45 a.m. - 12:15 p.m.
Concurrent Sessions

Technology Track: Advances in Analytical Sciences & Quality Control Strategies	Science Track: Developments in Patient-Centered Precision Medicine	Processing Track: Next Generation Manufacturing
A2 - Real Time Release Testing **Moderator: Tia Bush,** Vice President, Quality, *Amgen, Inc.*	**B2 - Immunotherapies** **Moderator: Tor Graberg,** Head of External Advocacy Operations, Quality, *AstraZeneca*	**C2 -Manufacturing & Logistics for Personalized Medicine** **Moderator: Maik Jornitz,** CEO, *G-Con Manufacturing, Inc.*
Session Description: Real time release testing (RTRT) and continuous manufacturing are hot topics within industry and regulators alike. ICH defines RTRT as "the ability to evaluate and ensure the quality of in-process and/or final product based on process data, which typically include a valid combination of measured material attributes and process controls." Many companies and academic research centers are making investments in the implementation of continuous manufacturing processes and RTRT. The benefit of increased knowledge of the product and the manufacturing process is a fundamental concept of quality by design (QbD) and the harmonized ICH quality guidelines. Experts believe that RTRT approaches have both economic and quality benefits from manufacturing efficiency to an increased assurance of product quality. However, progress has been slow due to the technical challenges that exist. This session will explore RTRT approaches, benefits, and challenges in a manufacturing environment.	**Session Description**: In the last years we have seen a rapid development of new methods using immunotherapies in treating different types of cancer. By combining immunotherapy with other types of treatment, an increase of the effectiveness may be accomplished. Newer types of immune treatments are now being developed, and they will affect how we treat cancer in the future. This session will explore more about the status of where pharma development is today as well as example of a successful research.	**Session Description:** Gene and cell therapies are rapidly rising therapies with unique processing and logistics needs. These therapies can be patient based, utilize a high standard of aseptic processing due to the lack of a terminal sterilization possibility, require rapid release possibilities to ship the injectable to the patient respectively have a need for robust and secure needle to needle logistics. These are just a few facets of difference in personalized medicine processing compared to traditional therapies. The session will discuss key needs and trends within the personalized medicine area and introduces processing and manufacturing possibilities.
10:45 a.m. - 11:15 a.m. **Real-Time Release Testing: A Case Study on an existing Commercial Product** **Juan Torres, PhD,** Senior Vice President, Global Quality, *Biogen Idec*	10:45 a.m. - 11:15 a.m. **Advances in the Assessment and Control of the Effector Functions of Therapeutic Antibodies** **Xu-Rong Jiang, MD,** Quality &Technical Director, *AstraZeneca*	10:45 a.m. - 11:15 a.m. **Facilities for Personalized Medicine: Today and Tomorrow - When Redoing the Batch is Not an Option** **Henriette Schubert,** Global Technology Partner, Facility & Lab, *NNE* **Mikkel Mohr Madsen,** Engineer, Active Products & Utility, *NNE*
11:15 a.m. - 11:45 a.m. **Predictive Process Analytical Technologies as Enabler of More Efficient Operations Towards Real-time Release** **Cenk Undey, PhD,** Executive Director of Process Development, *Amgen, Inc.*	11:15 a.m. - 11:45 a.m. **Immunotherapies for the Future** **Mark Dudley, PhD,** Senior Vice President, Bioprocessing, *Adaptimmune, Ltd.*	11:15 a.m. - 11:45 a.m. **Manufacturing and Process Systems for Cell Therapies** **Vijay Chiruvolu**, **PhD**, Vice President, Process Sciences & Engineering, *Kite Pharma*
11:45 a.m. - 12:15 p.m. **Questions & Answers/Discussion**	11:45 a.m. - 12:15 p.m. **Questions & Answers/Discussion**	11:45 a.m. - 12:15 p.m. **Questions & Answers/Discussion**

12:15 p.m. - 1:30 p.m.
Interest Group Leaders Meeting *(Invitation Only)*

12:15 p.m. - 1:30 p.m.
Portfolio Steering Committee Meeting *(Invitation Only)*

12:15 p.m. - 1:45 p.m.
Networking Luncheon & Passport Raffle in Exhibit Hall

1:00 p.m. - 2:00 p.m.
Audit Committee Meeting *(Invitation Only)*

1:45 p.m. - 3:15 p.m.
Concurrent Sessions

Technology Track: Advances in Analytical Sciences & Quality Control Strategies	**Science Track: Developments in Patient-Centered Precision Medicine**	**Processing Track: Next Generation Manufacturing**
A3 - Control Strategies based on Product Characterization **Moderator: Marcia Baroni,** Director, QC Microbiology & EM/Sterility Assurance, *Eli Lilly & Company*	**B3 - Genomic Profiling** **Moderator: Ghada Haddad,** Director, Global Quality Risk Management Center of Excellence*, Merck & Company /Merck, Sharp & Dohme*	**C3 - Selecting and Introducing New Technologies** **Moderator: Susan Schniepp,** Distinguished Fellow, *Regulatory Compliance Associates, Inc.*
Session Description: In the past 5 years, with broader implementation of ICH Q8, 9 and 10, we have seen a drastic increase in the use of Design Space, Risk management and Control Strategies in Pharmaceutical Manufacturing. More robust control strategies can lead to much more capable and in control processes and more effective and efficient manufacturing. Initial applications started with the control of more traditional physical, chemical and microbiological parameters, but have progressively evolved becoming increasingly complex and process/product specific and are now taking advantage of product characterization to further refine control strategies and mechanisms. This session will explore examples of successful applications, the implementation process and its benefits.	**Session Description:** As research on genomic profiling progresses, knowledge is gained on why some individuals are susceptible to certain diseases while others are not and why people have different reactions to the same drug. It can also be used as an innovative approach to diagnose treat or even prevent diseases. This session will address some current uses and future opportunities to use genomic profiling as a tool to improve healthcare.	**Session Description:** The pharmaceutical industry is always looking for new and innovative technologies that will help ensure potential lifesaving medicines are available to patients in a timely manner. This session will discuss the efforts of Advanced Digital Design of Pharmaceutical Therapeutics (ADDoPT) project launched in the UK. This project's mission is to enable digital design of the manufacturing process for innovative medicines. In addition, this session will discuss recent advances in the use of 3-D printing and how it can be used to advance the pharmaceutical industry.
1:45 p.m. - 2:15 p.m. **Using QRM to Determine Critical Process Parameters and the Process Control Strategy** **Kelly Waldron,** Senior Consultant, *ValSource, LLC.*	1:45 p.m. - 2:15 p.m. **Enabling Precision Medicine: The Applications of Genomics in Clinical Drug Development** **Angela Qu**, **MD/PhD,** Scientific Director, Genomic Medicine, *PAREXEL International*	1:45 p.m. - 2:15 p.m. **ADDoPT: Consortium to Enable Digital Design of Drug Manufacturing** **David Royle**, Associate Principal Scientist, Pharmaceutics Project Expert, *AstraZeneca*
2:15 p.m. - 2:45 p.m. **Characterization and Control of Cell and Gene Therapies** **Margit Jeschke, PhD,** Global Head, Analytical Development, Cell and Gene Therapy, *Novartis AG*	2:15 p.m. - 2:45 p.m. **Metabolic Profiling** **Sandra Merkel DeJames, PhD,** Director, Commercial Strategy & Execution, Precision Medicine, *Metabolon*	2:15 p.m. - 2:45 p.m. **Emerging Technologies** **Laurie Graham,** Biologist (Team Leader), CDER, *FDA*
2:45 p.m. - 3:15 p.m. **Questions & Answers/Discussion**	2:45 p.m. - 3:15 p.m. **Questions & Answers/Discussion**	2:45 p.m. - 3:15 p.m. **Questions & Answers/Discussion** **Panelists:** **Tia Bush,** Vice President, Quality, *Amgen, Inc.* **Tor Graberg,** Head of External Advocacy Operations, Quality, *AstraZeneca*

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

4:00 p.m. - 5:15 p.m.
Concurrent Interest Group Sessions

IG7 - Process Validation	**Leaders: Scott Bozzone, PhD**, Principal, *Pharm Lifecycle Validation &* **Vijay Chiruvolu**, **PhD**, Vice President, Process Sciences & Engineering, *Kite Pharma*	**Interest Group Description:** We will have a brief presentation by Vijay Chiruvolu, Ph.D. of Kite Pharma, on "The Challenges of Establishing a Control Strategy for Autologous Cell Therapy Product". Establishing a robust control strategy is essential and fundamental to successful process validation. Cell therapy manufacturing process present unique challenges. This presentation will highlight some of the known unknowns of building a control strategy for manufacture of autologous cell therapy products. Also, we will discuss what's new in process validation such as the PDA TR on Oral Solids/Semisolids, new FDA warning letters, inspection observations, and regulations. Challenges that face these new technologies (e.g. continuous manufacturing) may be discussed in an open forum. Please bring your questions and share your thoughts.
IG8 - Quality Risk Management	**Leader: Magaly Aham,** Vice President of Compliance & US Operations, *PharmaBioServ, Inc.* **Amanda McFarland,** Consultant *Concordia ValSource, LLC.* **Emma Ramnarine,** Head, Global Biologics Quality Control, *Genentech, Inc., A member of the Roche Group*	**Interest Group Description:** We are very excited to be meeting again at the 2017 Annual PDA meeting. We welcome all current members and potential new members to join us in the QRM Interest Group (IG) session. The mission of our QRM IG is to learn, promote, share best practices within our interest group community that can help us incorporate and advance QRM practices in our respective organizations and QRM implementation journeys. The Pharma industry is facing a significant increase of QRM-related tasks at any stage of a product/process lifecycle, driven by regulatory pressure, business-related reasons and the agility required by both. Most companies have tackled these challenges so far without an integrated approach. Overall that makes knowledge management and integrated QRM activities very difficult in terms of consistency and efficiency. In this session, we will query and drive a discussion with the QRM-IG audience on the requirements and expectations that need to be realized in QRM activities to support an agile life cycle management and continual improvement of products and processes. We will capture the audience experiences with different approaches and facilitate a discussion on best practices that could be adopted.
IG9 - Sterile Processing	**Leader: Vanessa Vasadi-Figueroa,** Partner/Microbiologist, *Quality Executive Partners, Inc.*	**Interest Group Description:** Complex and changing regulations, supply chains, markets, technology and product portfolios and new dimensions to familiar and continued challenges in the manufacture, control and assurance of sterile products. This session will offer participants the opportunity to develop their know-how in applied solutions through real-life examples, case-studies and shared best practices.

IG10 - Technology Transfer	**Leader: Melissa Seymour,** Vice President, Corporate Quality, *Biogen*	**Interest Group Description:** The Technology Transfer IG was launched in 2016 and has as its main objective to capture the opportunity given by benchmarking industry experience in Technology Transfer in order to provide useful information through Technical Reports, articles, position papers, training sections, deliverable templates and lectures. As part of this meeting we will provide an overview of the IG including, history, current goals and opportunities, as well as the strategic plan for the coming years. Additionally, the IG has developed a TT Matrix which provides a framework on the knowledge transfer needs and required activities based on current regulatory guidance for commercial to commercial Technology Transfer. This matrix is broken into the five main stages or technical transfer associated with the organizational functions typically involved in a technical transfer. Additionally the team has started a library of industry Guidances, References, Articles, Books, and Position Papers. We will take the opportunity of the IG meeting to: Review the proposed matrix of activities/deliverables, Expand the benchmarking on the time/resources required for TT activities, and Continue Development of the TT library. This IG will be an active discussion between presenters and the audiences with a key goal of benchmarking. **Speaker:** **John Wass,** Consultant, *Commissioning Agents, Inc.*
IG11 - Visual Inspection of Parenterals / Lyophilization	**Leaders: John Shabushnig, PhD,** Principal Consultant, *Insight Pharma Consulting, LLC &* **Edward Trappler,** President, *Lyophilization Technology, Inc.*	**Interest Group Descriptions:** With the publication of USP <790>, which became official on August 1, 2014 and USP <1790> which will become official on August 1, 2017, there has been significant discussions within the industry on considerations for application of these chapters to difficult to inspect products. This includes issues of sampling, testing and interpretation of the results. This joint interest group session will focus on considerations in utilizing the information embodied within these chapters for lyophilized products. The session will begin with review of the information provided within chapters <790> and <1790>, and current industry trends in their application. As lyophilized preparations are one of those products that are difficult to inspect, and for which <1790> provides supporting information, the joint session will focus on visual inspection of lyophilized products. The focus of this joint interest group session will be on these USP chapters, however, discussions on current topics brought to the session by participants on visual inspection and lyophilization are also welcome. Topics discussed in past sessions have included technical and operational aspects, quality and regulatory expectations, as well as the latest trends throughout our industry, both domestic and international. This open forum is structured so that topics of current interest are identified at the onset of the meeting for open discussions among participants. The informal forum provides a unique opportunity to learn from a variety of experiences and perspectives and provides an excellent benchmark for current industry practices. Bring your experience and questions in applying the information within USP <790> and <1790>, along you're your current topics of interest for discussion with your peers at this upcoming session.

IG12 - Pre-filled Syringes	**Leader: Olivia Henderson, PhD,** Principal Engineer, *Amgen, Inc.*	**Interest Group Description:** The Prefilled Syringe Interest Group provides a forum for discussions of actual topics related to pre-fillable injection system components such as cartridges or syringes and combinations thereof with injection and safety devices. Members come together to exchange in an open discussion latest information about technological improvements in the universe of pre-fillable syringes and injection devices, covering production, filling, handling and regulatory aspects. The format of the Interest Group meetings includes formal presentations of experts from industry and government as well as open discussion forums and preparation of upcoming conferences to related topics. **Speaker:** **Polymer Syringes: Market Trends and Growth Drivers** **Patrick Gallagher,** Business Development Manager, Syringes, *Schott North America, Inc.*

5:30 p.m. - 7:30 p.m.
Red Carpet Reception

Wednesday, April 5, 2017

7:00 a.m. - 8:30 a.m.
Continental Breakfast

7:00 a.m. - 12:00 p.m.
Registration Open

7:15 a.m. - 8:15 a.m.
Concurrent Breakfast Sessions

Breakfast IV: Data Integrity **Moderator: Ursula Busse, PhD**, Quality Intelligence & External Relations, *Novartis*	**Breakfast V: Applying Phase-Appropriate GMPs in Personalized Medicines - Development and Manufacturing** **Moderator: Veronique Davoust, PharmD,** Senior Manager, Global Quality Intelligence, *Pfizer, Inc.*	**Breakfast VI: PDA Manufacturing Initiative** **Moderator**: **Maik Jornitz,** CEO, *G-Con Manufacturing, Inc.*
Session Description: This session will include updates from Data Integrity Working Group member the latest activities from a on the latest developments and trends in the world of DI.	**Session Description:** A few of the core challenges with GMPs lie within the structure of an organization's research and development. Advances in personalized medicin may require the application of a different approach to manufacturing. This session will address challenges and potential solutions to meet GMP standards.	**Session Description:** Manufacturing sites and processes are changing rapidly to more flexible, smaller systems to be implemented in new sites. Older or aging sites require to modernized and optimized to still fulfill the manufacturing and regulatory requirements. These are just two aspects of the need for a PDA Manufacturing Initiate to support the industry and be an interface between end-users and regulatory authorities. The session will give an update of the Manufacturing Initiative and invites discussions and input to further this project.
Anil Sawant, PhD, Vice President, Global Quality Management Systems & External Affairs, *Merck & Company/Merck, Sharp & Dohme*	**John Geigert**, **PhD,** President, *BioPharmaceutical Quality Solutions*	**Hal Baseman**, Chief Operations Officer, *ValSource, LLC.*

8:30 a.m. - 10:00 a.m.
P4 - Application of Big Data for Manufacturing Process Design and Optimization
Moderator: Aaron Goerke, PhD, Associate Director/Head of Downstream Global Manufacturing Science & Technology, *Genentech a Member of the Roche Group*

Session Description: 'Big data' is a topic with a lot of potential. The potential is not merely the collection of data but includes the analysis combined with the knowledge to answer complex questions. This creates new possibilities for the pharmaceutical industry to drive operational and business performance to higher levels. Industry success stories will be presented with concepts being discussed that will provide unique opportunities for your organization. New strategies, processes, mindsets and skills are key takeaways. The important question is: Can you afford not to adapt to the big data era?

8:30 a.m. - 9:00 a.m.
Big Data to Optimize Manufacturing
Michele D'Alessandro, Vice President & Chief Information Officer, *Merck & Company/Merck, Sharp & Dohme*

9:00 a.m. - 9:30 a.m.
Practical 'Big Data' Insights for R&D and Commercial Manufacturing Organizations
Adam Fermier, PhD, Scientific Director, PDMS, *Janssen Pharmaceuticals R&D*

9:30 p.m. - 10:00 a.m.
Questions & Answers/ Discussion

10:00 a.m. - 10:30 a.m.
Refreshment Break

10:30 a.m. - 12:00 p.m.
P5 - Industry Response to Emerging Healthcare Needs for Uninterrupted Medicine Product Supply
Moderator: Morten Munk, Global Technology Partner, *NNE*

Session Description: New threats to our global health seem to surface more and more frequently. Diseases like Ebola and the Zika virus, which were unknown or only a local problem just few years ago, have begun to spread rapidly causing a global threat. The pharmaceutical industry is a key player in resolving this crisis and faces a major challenge to move potentially lifesaving products faster through the development pipeline test them in clinical studies and deliver them to the market ready to be distributed to the patients. An important tool to prioritise this effort is the generation and sharing of valid knowledge globally.

10:30 a.m. - 11:00 a.m.
Trends in the Global Burden of Disease: Results from the GBD 2015 Study and Forecasts to 2040
Christopher Murray, MD, Professor, Global Health, *University of Washington* & Director, *Institute for Health Metrics & Evaluation*

11:00 a.m. - 11:30 a.m.
Challenges After the Finish Line – How Can We keep a Product in Supply after its Initial Approval?
Anders Vinther, PhD, Chief Quality Officer, *Sanofi Pasteur*

11:30 a.m. - 12:00 p.m.
Questions & Answers/Discussion

12:00 p.m.
Closing Remarks & Adjournment
Ghada Haddad, Director, Global Quality Risk Management Center of Excellence, *Merck & Company/Merck, Sharp & Dohme* and **Morten Munk,** Global Technology Partner, *NNE*, Co-Chairs, 2018 PDA Annual Meeting Program Planning Committee