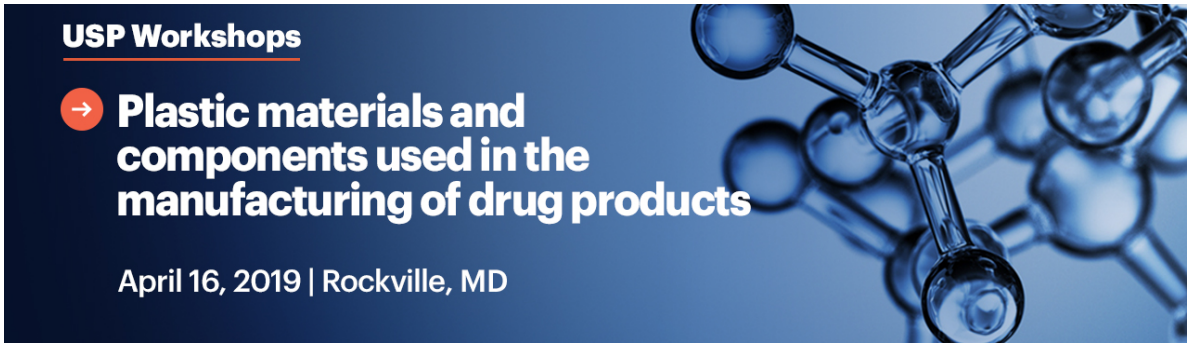

Speaker Biographies & Abstracts (listed alphabetically)

Weibing Ding, Ph.D.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel
Director, GSK
King of Prussia, PA

Weibing Ding is currently a Director at GSK. Since obtained his Ph.D. in Chemical Engineering from the University of Utah, Dr. Ding has spent more than 20 years with both single-use technology provider and drug manufacturers. He has been instrumental in development, manufacturing, qualification and implementation of single-use systems in bioprocesses. Specific to extractables and leachables, Dr. Ding has contributed to designing tests, developing methods, benchmarking industry best practice, and generating compendial standard. Prior to joining GSK, he worked for Pall Life Sciences and Amgen. He is currently an Expert Panel member for USP<665>.

Presentation
<665> and <1665>: Extraction Process for Manufacturing Components and Systems
Tuesday, April 16, 2019, 11:00 – 11:30 a.m.

The presentation will focus on the proper design of extraction processes for the components used in drug manufacturing. The main categories consist of bags, filters, tubing, connectors and other components. The factors affecting extraction thermodynamics and kinetics will be discussed. These include, but are not limited to time, temperature, pre-treatment, agitation as well as chemical incompatibility. It is necessary to scale up/down between test and process conditions. While USP<665> provides a set of standard test conditions, it also allows flexibility for special cases (e.g. surface area to volume ratio for filters and other components). This practice leads to suitable extractables results that are useful to evaluation of leachables from these components used in drug manufacturing processes.

Michael Eakins, Ph.D.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel
Principal Consultant, Eakins and Associates
East Windsor, NJ

Dr. Michael Eakins is the Founder and Principal Consultant of Eakins & Associates with over 35 years' experience in pharmaceutical research and development. At Eakins and Associates, Michael provides experience and advice on parenteral primary packaging, especially on glass delamination and glass defects, the selection and product development in glass and plastic pre-filled syringes, and on extractables and leachables for parenteral packaging and manufacturing components. He regularly lectures on these topics worldwide for the USP.

Michael was responsible for the pharmaceutical development of diagnostic radiology products at E. R. Squibb and Bristol-Myers Squibb and for global packaging initiatives for contrast media at Bracco SpA.

Michael was the Vice-Chair of the USP Packaging, Storage and Distribution Expert Committee in the 2005-2010 and 2010-2015 cycles and is currently a member of the USP Packaging and Distribution Expert Committee for the 2015-2020 cycle. He is an active member of the Parenteral Drug Association, being the co-chair of the Glass Defects Task Force that revised Technical Report 43 and was a member of the Elastomers and Seals Defects Task Force. He obtained his Ph.D. from London University and has contributed to over 60 publications and 8 USA patents.

Presentation
Welcome and Overview of USP's Approach to the Revision of USP <665> and <1665>
Tuesday, April 16, 2019, 8:30 – 8:40 a.m.

James Hathcock, Ph.D.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel
Sr. Director, Regulatory and Validation, Pall BioTech
Port Washington, NY

James Hathcock, PhD is Senior Director of Regulatory and Validation at Pall BioTech, which includes responsibility for the extractables and leachables characterization strategy to support the safe and successful end-user implementation of technologies enabling pharmaceutical manufacturing. He is an active member of ASTM, PDA, ISPE, and BPSA as well a USP <665> expert panel member. Since joining Pall in 2008, James has led chemical and performance characterization of Medical and BioTech components, as well as relevant technical packages supporting regulatory filings. Prior to joining Pall, James was a professor of hematology at the Mt. Sinai School of Medicine in New York City, where he directed the protein purification core laboratory.

Presentation
Benefits and Examples of Generating <665> Data: Equipment Supplier's Perspective
Tuesday, April 16, 2019, 1:00 – 1:30 p.m.

With the recent publication of the revised USP <665> standard, defining minimum requirements for plastic components used in biologics manufacturing, the path forward regarding what types of data to expect from suppliers becomes the simplest and clearest we have seen in years. The risk-based approach to generating standardized component data, employs the fundamental tenants of ICH Q8 and Q9 to ensure the cost and level of scientifically-justified characterization data align with risk to the drug product, while allowing end users the flexibility to employ already-established, in-house risk models. Moreover, the recently published USP <665> protocol establishes a stepwise approach where the compendia requirements for low, medium and high risk components incrementally build upon one another, and align, now more than ever, with popular market-driven expectations for more expansive data. In this presentation we share examples of how the USP three solvent extraction profiling approach at key timepoints captures the vast majority of extractables seen in other timepoints and solvents relative to typical bioprocessing conditions. In addition experiences and examples of USP <665> low, medium and high risk component datasets for biocontainers, aseptic connectors and filters are presented. With finalization of the revised <665> chapter, expectations amongst suppliers, end users and regulators becomes streamlined and tractable, and today's gaps in minimum supporting component data will soon become a topic of the past.

Desmond Hunt, Ph.D.
Principal Scientific Liaison, USP
Rockville, MD

Dr. Desmond G. Hunt has been with USP since 2005 and holds the position of Principle Scientific Liaison in the Compendial Science Group-General Chapters. He is the scientific liaison to the Packaging and Distribution and Dosage Forms Expert Committees, where he works to develop and revise USP Standards. He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to pharmaceutical packaging, particulate matter in parenteral and ophthalmic dosage forms and good storage and transportation practices. He participates on several industry Working Groups and Technical Committees related to his areas of expertise. Dr. Hunt obtained his M.S. and Ph.D. from the University of Texas at Austin and prior to joining USP, was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA.

Presentation
Top Ten Comments Received from the 2017 PF Proposal: How Comments Were Addressed in Current PF Draft.
Tuesday, April 16, 2019, 8:40 – 9:00 a.m.

Edwin Jao, Ph.D.
Government Liaison, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel
Division Director, Office of Process and Facilities, U.S. Food and Drug Administration
Silver Spring, MD

Edwin Jao is a division director in the Office of Process and Facilities (OPF), which is part of the office of Pharmaceutical Quality (OPQ) of CDER. Edwin has been working with FDA for 16 years, covering various phases of drug product approval process, ranging from IND, NDA, ANDA, and post approval supplement. Prior to joining FDA, Edwin worked for major pharmaceutical companies for 18 years. Edwin holds a PhD in medicinal chemistry from Rutgers University.

Presentation
Equipment Suitability for Manufacturing of Liquid Dosage Forms - FDA/OPF's Perspective
Tuesday, April 16, 2019, 9:00 – 9:30 a.m.

The following topics will be covered in the presentation

- Regulatory requirements for equipment suitability studies
- Issues related to equipment suitability
- General expectations from OPQ review and inspection Team
- Regulatory and compendial documents currently available in the public domain
- Risk-based approach
- Samples of deficiencies and Case studies

Dennis Jenke, MBA, Ph.D.
Chair, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel
Chief Executive Scientist, Triad Scientific Solutions LLC
Hawthorn Woods, IL

Dr. Dennis Jenke is the Chief Executive Scientist at Triad Scientific Solutions, LLC, a consulting organization that provides the pharmaceutical, cosmetic, food and related industries with integrated, science-based, and practical solutions to suitability for use challenges for packaging, manufacturing components and systems, and administration devices. Prior to Triad, Dr. Jenke was a Baxter Distinguished Scientist at Baxter Healthcare Corporation for nearly 35 years where he worked with a team whose primary responsibility includes the chemical assessment of material/product compatibility, specifically with respect to extractables and leachables associated with packaging systems, manufacturing systems and administration devices for pharmaceutical products He has published extensively, with over 160 manuscripts in the areas of analytical chemistry, environmental science and material/solution compatibility, and serves as an expert reviewer for numerous pharmaceutical and analytical journals, He is the author of the book Compatibility of Pharmaceutical Solutions and Contact Materials; Safety Considerations Associated with Extractables and Leachables and a contributing author to the Leachables and Extractables Handbook. Dr. Jenke is a member of industry groups and standards-setting organizations whose charter is to establish standards best demonstrated practices in the area of material/solution compatibility including: ELISE, PQRI, USP, AMMI, etc. Considering USP specifically, Dr. Jenke is chair of the USP Expert Panels responsible for drawing monographs for plastics and polymer used in pharmaceutical packaging and pharmaceutical and biopharmaceutical manufacturing.

Presentations
<665> and <1665>: A Standardized Extraction Solution Protocol for Manufacturing Components and Systems (Presented by Michael Eakins, Ph.D.)
Tuesday, April 16, 2019, 9:30 – 10:30 a.m.

Polymeric components of drug product manufacturing systems will contact the manufacturing process stream, including process solutions, production intermediates, or the API, DS, or DP themselves, during manufacturing. During contact, process equipment-related leachables (PERLs) could leach from the component and accumulate in the process stream, potentially impacting a quality attribute of the process stream and affecting manufacturing process efficiency. If the PERLs persist through manufacturing, they could accumulate in the pharmaceutical product, potentially affecting product quality attributes such as stability and patient safety.

USP Chapter <665>, Polymeric Components and Systems Used in the Manufacturing of Pharmaceutical and Biopharmaceutical Drug Products addresses this situation via a risk-based approach for chemically characterizing polymeric materials and components used to manufacture pharmaceuticals/ biopharmaceuticals. USP chapter <1665>, Characterization of Polymeric Components and Systems used to Manufacture Pharmaceutical and Biopharmaceutical Drug Products) communicates the key concepts behind <665> and addresses the applicability and the application of <665>.

An important aspect of chapter <665> is establishing the chemical and biological testing requirements for materials and components used in manufacturing systems. This presentation will discuss the USP's testing philosophy, will establish the required testing for materials and will present the risk-based approach for testing components. The presentation will specifically focus on the Standard Extraction Protocol, SEP, which establishes the testing methodology required for high risk manufacturing components.

<1665> Example of a Risk Evaluation Protocol (Presented by Michael Eakins, Ph.D.)
Tuesday, April 16, 2019, 2:50 – 3:20 p.m.

Polymeric components of drug product manufacturing systems will contact the manufacturing process stream, including process solutions, production intermediates, or the API, DS, or DP themselves, during manufacturing. During contact, process equipment-related leachables (PERLs) could leach from the component and accumulate in the process stream, potentially impacting a quality attribute of the process stream and affecting manufacturing process efficiency. If the PERLs persist through manufacturing, they could accumulate in the pharmaceutical product, potentially affecting product quality attributes such as stability and patient safety.

USP Chapter <665>, Polymeric Components and Systems Used in the Manufacturing of Pharmaceutical and Biopharmaceutical Drug Products addresses this situation via a risk-based approach for chemically characterizing polymeric materials and components used to manufacture pharmaceuticals/ biopharmaceuticals. USP chapter <1665>, Characterization of Polymeric Components and Systems used to Manufacture Pharmaceutical and Biopharmaceutical Drug Products) communicates the key concepts behind <665> and addresses the applicability and the application of <665>.

An important foundation of chapter <665> is that the degree of testing required for characterizing manufacturing components should depend on the risk that the component could contribute PERLs to the manufactured drug substance or product. Establishing this risk for components is typically accomplished via application of a Risk Evaluation Matrix, which is a mathematical means of establishing the risk of PERLs based on certain dimensions of the manufacturing situation such as nature of the contacting process stream, temperature and duration of contact, contact stoichiometry (e.g., surface area/volume ratio) and others.

This presentation will discuss the requirements, contained in <665>, for a Risk Evaluation Matrix that can be employed in the context of a <665> risk assessment and will present a science-based example of such a Matrix, which is contained in <1665>.

Ken Wong, M.S.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel
Deputy Director, Process, Technology, Sanofi Pasteur
Swiftwater, PA

Ken Wong is serving as the Sanofi Pasteur's extractables and leachables (E&L) SME based on Swiftwater, PA but also provide E&L supports to all Sanofi sites and lead Sanofi global E&L Community of Practice. His 19-year in biopharma professional career has ranged from R&D to development and commercialization to cGMP manufacturing support. For the last 18 years, he has specialized in E&L in wide range of packaging systems (including lyophilized powders, oral liquids, creams, ophthalmic solutions, transdermal, bio-surgical delivery systems, injectable devices, and inhalation devices for aerosol, solutions and powders). In the last 12 years, he has been heavily involved with Single-Use Technology and actively participating in Disposable workstreams of BioPhorum Operations Group (BPOG), the USP <665> Expert Panel and the ELSIE material working group.

Presentation
Utility of Generating <665> Data: Drug Manufacturer's Perspective
Tuesday, April 16, 2019, 1:30 – 2:00 p.m.

Present case studies on disposable components risk assessment based on route of administration. Discuss the values of USP <665> data and the applicability such data to satisfy E&L qualification of disposable components. Provide case studies where additional studies will be necessary beyond USP <665>.