



**USP Second Annual Workshop
Evolution and Advances in Compounding**

August 6-7, 2019

**Speaker Biographies & Abstracts
(listed alphabetically)**



John Barickman, BSP Pharm, MBA, FACHE

Omniceil
Philadelphia, PA

John is the Sr. Pharmacist Consultant for the IV Solutions division of Omnicell. John earned a Bachelor degree in the Science of Pharmacy from Ohio State University and a Master degree in Business Administration from Ohio University.

He has written several articles about the importance of automation in IV compounding to improve safety, accuracy, cost and regulatory compliance and have been a speaker for multiple educational sessions and seminars concerning IV workflow management systems and IV robotics.

John has extensive hospital pharmacy and sterile compounding experience having served as the director of pharmacy in multiple hospitals for over 20 years. During the past 5 years, as the Senior IV Pharmacist Consultant for Omnicell, he has focused exclusively on sterile compounding and has consulted with over 100 hospital pharmacy clients to help them meet their IV compounding challenges.

John is a Fellow of the American College of Healthcare Executives (FACHE) and former Chair of the ASHP Informatics Section Advisory Group for Operations and Automation. As a long-standing member of the ASHP Informatics IV workflow committee, he helped develop professional educational programs about IV Workflow and most recently developed guidelines for the selection and use of IV workflow management systems and IV automation, which has been submitted for publication.

Session III: New and Emerging Technologies in Compounding

Using Automation and Process Workflow to Improve Accuracy in Compounding

Tuesday, August 6, 2019, 1:00 – 2:20 p.m.

The safety and compliance gaps in contemporary compounding are reviewed in light of the predominant processes and tools used in compounding practice today. The key technologies which are emerging to support safe and regulatory compliant sterile compounding are discussed with emphasis on the IV workflow management systems.

The workflow management systems, which employ various combinations of software and hardware technology are discussed relative to the problems they solve and their effectiveness in various combinations. Opportunities for application of these systems and strategies for broader adoption are explored.



Danny Barnes, PharmD, RPh

Triangle Compounding Pharmacy
Cary, NC

Danny has spent the last 20 years developing personalized medications, including high risk sterile medications, while being a compounding pharmacist and owner at Triangle Compounding Pharmacy (TCP). Triangle Compounding Pharmacy was the first compounding pharmacy in NC to meet national standards and be accredited by the Pharmacy Compounding Accreditation Board (PCAB). Triangle Compounding Pharmacy was also the first compounding pharmacy to register as a Human Drug Outsourcing Facility (503B) to help physicians and hospitals meet critical patient needs by compounding crucial medications during drug shortages. Danny received his Pharm.D. from Campbell University. Danny also serves as Chief Pharmacy Officer of Panaceutics, an innovative company using robotic automation to bring truly personalized nutrition and personalized medicine to patients. Danny serves his community and the pharmacy community through activities and membership in various organizations.

Session VI: Innovative Approaches to Facility Design of Compounding Areas

Considerations for the Construction of The Compounding

Wednesday, August 7, 2019, 10:35 – 12:00 p.m.

USP, state, and federal standards for personalized compounded medicine have evolved over the years to improve the quality and safety of compounding preparations for the patient and the compounder. Best practices and considerations for designing and building a new facility to meet the relevant standards for compounding sterile, non-sterile, hazardous and non-hazardous medications are reviewed.

From the planning and design phase to the environmental microbial qualification phase, the challenging process of designing and building a new facility or remodeling an existing one will be explored to help participants avoid the many pitfalls of building cleanroom facilities. Innovative designs and technologies will be explored with an emphasis on designing a facility to meet standards and help maintain a state of control for the safety of compounders and patients.



Debbie Barrow, PharmD

Baptist Health
Miami, FL

Debbie Barrow, PharmD, has served as the Director of Pharmacy at two hospitals in the Florida Keys, Mariners Hospital in Tavernier since 1989 and Fishermen's Community Hospital in Marathon since July 1, 2017. She brings more than 30 years of expertise in pharmacy practices. She previously served in management roles in Nuclear Pharmacy and Community Pharmacy practice. She earned her Bachelor of Science in Pharmacy from Mercer School of Pharmacy in Atlanta, Georgia, and her Doctorate of Pharmacy from the University of Florida. In 2009, she was honored with the Stand Up for Patient Safety Management Award for her multidisciplinary approach in reducing the incidence of Contrast-induced Nephropathy in the CT Suite. Her work on this subject has been published by the National Patient Safety Foundation.

Debbie is dedicated to patient safety. She is scheduled for nursing staff meetings each month for educational presentations. Mariners Hospital has a robust, evidence based clinical practice medication safety committee. The committee publishes a monthly newsletter aptly named "A Shot of Interest". She frequently speaks to community groups.

Enjoys the beautiful Florida Keys, Special interest gardening and ethnobotany

Session VII: Building Quality into the Compounding Process: Perspectives from Compounders

Before and After the Inspection: Perspectives from a Compounder

Wednesday, August 7, 2019, 1:00 – 3:00 p.m.



Gus Bassani, PharmD

Member, USP Compounding Expert Committee
Katy, TX

Gus Bassani, PharmD currently serves as Chief Scientific Officer for PCCA, a Houston based FDA-registered supplier of active pharmaceutical ingredients, excipients and technical consulting to pharmacies, healthcare institutions and outsourcing facilities. He has been with PCCA since 2002. In addition to the scientific and technical responsibilities of his position, Gus is regularly engaged in legislative, regulatory and public affairs activities. Prior to joining PCCA, Gus worked in multiple pharmacy practice and industry settings, and taught extemporaneous compounding principles to pharmacy students in Drake University's Pharmaceutics Laboratory course. Gus received his Doctor of Pharmacy degree from Drake University College of Pharmacy and Health Sciences. He is a member of the 2015 – 2020 USP Compounding Expert Committee, chairs the Compounded Preparation Monograph Subcommittee and has served on the Drake University College of Pharmacy and Health Sciences National Advisory Council.

Session III: New and Emerging Technologies in Compounding

Moderator

Tuesday, August 6, 2019, 1:00 – 2:20 p.m.



Robert Campbell, PharmD

The Joint Commission
Chicago, IL

Robert Campbell, Pharm.D. currently serves as the Clinical Director, Standards Interpretation Group for Hospital and Ambulatory Programs at The Joint Commission. In this role, Dr. Campbell is responsible for providing interpretation of Joint Commission standards in the Hospital, Ambulatory and Office Based Surgery Accreditation programs, with special emphasis on standards issues. He provides direction and leadership to surveyors and Standards Interpretation Group (SIG) staff addressing interpretation of standards. He also participates as a consultant in the development and revision of standards and supports ongoing accreditation services and special projects.

Dr. Campbell also serves as the Director of Medication Management for the Joint Commission Enterprise. In this role, he functions as the subject matter expert for medication management related topics; assists with interpreting the intent of standards, as well as the development and revision of standards; provides guidance to organizations and Surveyors; and supports the accreditation and certification process across the Joint Commission Enterprise. Dr. Campbell continues to function as a Surveyor for The Joint Commission in the Hospital Accreditation and Critical Access Hospital Accreditation Programs, as well as a Reviewer in the Medication Compounding Certification Program to assess compliance with accreditation and certification program standards

Prior to joining The Joint Commission, Dr. Campbell worked in health care organizations and held leadership positions with oversight responsibilities for performance improvement, accreditation readiness, risk management, infection control, medical staff services, and inpatient and outpatient pharmacy services.

Dr. Campbell is currently licensed as a Registered Pharmacist in Florida. In addition, he holds a Green Belt in Six Sigma.

Session IV: Advancing Quality Compounding: Perspectives from Adopting Bodies

Perspectives from Accreditation Organizations

Tuesday, August 6, 2019, 2:30 – 4:30 p.m.

Accrediting organizations have a role in evaluating compliance of sterile medication compounding. The approach is unique in looking at inter-departmental processes providing expertise in key areas ensuring resources such as infection prevention and control activities and facilities management. The Joint Commission has adopted the principles within the applicable accreditation and certification programs to improve patient safety and reduce risk by overlapping these principles in on-site survey activity.



Tiffany Chan, PharmD

USP
Rockville, MD

Tsz “Tiffany” Chan is an alumni from Shenandoah University Bernard J. Dunn School of Pharmacy, where she earned her Doctor of Pharmacy. She has prior experience as a pharmacy technician for a nationally-recognized retail chain of community pharmacies, a community hospital which served as part of a regionally-prominent health system, and an independent compounding pharmacy. She completed post-graduate pharmacy residency training at Johns Hopkins Bayview Medical Center before joining United States Pharmacopeia as an Associate Scientific Liaison for the Compounding Expert Committee.

Session I: USP Updates

Updates on USP <795>, <797>, and <800>

Tuesday, August 6, 2019, 10:00 – 11:00 a.m.

This presentation will be an overview of USP Compounding Standards. The audience will gain insight on what Compounding General Chapters are currently available, such as the newly revised compounding standards. Additionally, the audience will receive an introduction to the Expert Volunteers that create the standards and the standard-setting process.



Gigi Davidson, BS Pharm, DICVP

Chair – USP Compounding Expert Committee
Pittsboro, NC

Gigi Davidson is the former Director of Clinical Pharmacy Services at the North Carolina State University College of Veterinary Medicine where she practiced veterinary pharmacy for 35 years. Ms. Davidson received her BS in Pharmacy from The University of North Carolina at Chapel Hill in 1983 and subsequently was awarded Diplomate status in the International College of Veterinary Pharmacy in 2001. Gigi is a past President of the Society of Veterinary Hospital Pharmacists and served as the Government and Regulatory Affairs Liaison for that organization for 10 years. Ms. Davidson is also the current President of the American College of Veterinary Pharmacists. Ms. Davidson is the Chair of the United States Pharmacopeia Compounding Expert Committee for the 2010-2020 Cycles and was the first female recipient of the USP Beal Award in 2015. Ms. Davidson has many publications in peer-reviewed scientific journals and her primary area of research interest is quality, stability, safety, efficacy and disposition of compounded preparations in non-human species. In her retirement Ms. Davidson is the owner of Vetpharm Consulting and is a conservationist beekeeper in her spare time.

**Session V: Innovative Approaches to Implementing USP Compounding Standards:
Practitioner Perspective**

Moderator

Tuesday, August 6, 2019, 9:00 – 10:20 a.m.



Gene Decaminada, RPh

Option Care
Ridgefield, CT

Gene Decaminada is the Manager of Compounding Compliance with Option Care. Currently oversees cleanrooms across the United States and is responsible for adherence to SOP's, policies and performs on-site training. Gene is a graduate of St. John's University in New York where he received his B.S. degree. His professional interests include USP 797/800 Standards for Sterile Compounding, Home Infusion Pharmacy and working as a Pharmacist Preceptor for the PGY-1 Residents. He has been a home infusion pharmacist for over 20 years and a member of NHIA since 1999. Gene has held a variety of clinical and leadership positions. His interest areas include clean room guidelines and standards for sterile compounding. Current member of the NHIA Sterile Compounding Committee, the BPS Sterile Compounding Council and most recently the NHIA Standards Committee. Past member of the BPS Sterile Compounding Taskforce.

Session VII: Building Quality into the Compounding Process: Perspectives from Compounders

Before and After the Inspection: Perspectives from a Compounder
Wednesday, August 7, 2019, 1:00 – 3:00 p.m.



Carol Fuller, AIA, LEED AP

Architect, Chartwell
Pittsburgh, PA

Carol Downey Fuller is a Registered Architect and LEED Accredited Professional with 35 years of experience. She received a Bachelor of Environmental Design from Miami University and a Master of Business Administration from the University of Pittsburgh. Over her career she has provided project management services across a variety of fields, including aviation, higher education, museum, sacred and historic properties. Her experience has covered all facets of project development and management; programming through construction administration, including the professional leadership of staff, consultants and contractors.

She has been with the University of Pittsburgh Medical Center for the past 8 years and most recently in the role of providing project planning, design and construction support to Chartwell Pennsylvania, LP. In her current role as Director of Planning, Ms. Fuller has directed the relocation and expansion of a 52,000 SF corporate headquarters and state-of-the-art infusion and specialty pharmacy. Construction was substantially complete in December 2018. She is currently working with Chartwell to expand and relocate branch facilities in both Erie and Altoona, with a third branch in central PA to follow in 2020.

Ms. Fuller has effectively employed her skills and expertise to manage over \$250 million in complex and strategically significant projects over her successful career.

Session VI: Innovative Approaches to Facility Design of Compounding Areas

Perspectives from an Architect

Wednesday, August 7, 2019, 10:35 – 12:00 p.m.



Kevin Hansen, PharmD, MS, BCPS

Moses H. Cone Memorial Hospital
Greensboro, NC

Kevin Hansen, PharmD, MS, BCPS is Assistant Director of Pharmacy at Moses H. Cone Memorial Hospital in Greensboro, N.C. Dr. Hansen provides leadership and operational oversight for pharmaceutical compounding and pharmacy perioperative services. He serves as the Residency Program Director for the Health-System Pharmacy Administration residency program. In addition, Dr. Hansen serves as adjunct faculty for the University of North Carolina Eshelman School of Pharmacy. Dr. Hansen earned his Doctor of Pharmacy degree from Lake Erie College of Osteopathic Medicine (LECOM) in Erie, PA and completed an ASHP-accredited PGY1/PGY2/MS Health-System Pharmacy Administration residency at the University of North Carolina Medical Center. He is board certified in pharmacotherapy through the Board of Pharmacy Specialties. Within Moses H. Cone Memorial Hospital, Dr. Hansen is involved in several committees and initiatives related to his practice interests of pharmaceutical compounding, handling hazardous drugs, medication and compounding safety, drug shortage management, and pharmacy perioperative services. He has taken a lead role in developing multidisciplinary teams, such as the Pharmaceutical Compounding Advisory Council and the Hazardous Drug Committee. He also provides pharmaceutical compounding guidance and standardization across Cone Health, a 6-hospital health system.

**Session V: Innovative Approaches to Implementing USP Compounding Standards:
Practitioner Perspective**

Practitioner from A Hospital/Health System Setting

Tuesday, August 6, 2019, 9:00 – 10:20 a.m.



Alissa Jijon, JD

USP
Rockville, MD

Alissa Jijon is Senior Counsel at the U.S. Pharmacopeial Convention (USP). She advises the organization on issues related to the standards-setting process and the regulatory environment. She also helps articulate the role of USP standards in law. Prior to joining USP, Alissa specialized in FDA regulatory law in private practice in Washington, DC. In that capacity, she advised companies and trade associations in the food, dietary supplement, and pharmaceutical industries on issues related to regulatory compliance and enforcement. She received her BA, magna cum laude, from Yale University and her JD, cum laude, from Harvard Law School.

Session IV: Advancing Quality Compounding: Perspectives from Adopting Bodies

Moderator

Tuesday, August 6, 2019, 2:30 – 4:30 p.m.



Kim Kiefer
Empower Pharmacy
Houston, TX

Kimberly Kiefer is a graduate of the University of South Florida. She began her career in the Compounding industry as the Operations Manager for a compounding only pharmacy in Tampa FL. Ms. Kiefer then served as a Technical Compounding Consultant for several raw material suppliers and as such, provided consultancy to pharmacists and pharmacy technicians across the United State on formulation, physical chemistry, application, clinical data, quality and regulatory for more than 15 years. In addition, Ms. Kiefer has supported the compounding industry through new product R&D, design and direction of analytical studies, and the development of continuing pharmacy education.

Session III: New and Emerging Technologies in Compounding

The Practical Use of USP as a Primary Reference Resource for Compounded Formulations
Tuesday, August 6, 2019, 1:00 – 2:20 p.m.

“The Practical Use of the USP as a Primary Reference Resource in the Formulation of Compounded Preparations” will offer a discussion that describes how most traditional compounders are using the USP as a reference resource when formulating compounded preparation and how the USP monographs supply vital information to the process. The presentation will indicate how Outsourcing Facilities are using the USP in light of their statutory obligation to follow cGMP. Finally, the discussion will consider what resources traditional compounders may desire from USP in the future.



Daniel Kraft, MD

Singularity University/Exponential Medicine
San Francisco, CA

Daniel Kraft is a Stanford and Harvard trained physician-scientist, inventor, entrepreneur and innovator. With over 25 years of experience in clinical practice, biomedical research and healthcare innovation, Kraft has served as Faculty Chair for Medicine at [Singularity University](#) since its inception, and is the Founder and Chair of [Exponential Medicine](#), a program that explores convergent, rapidly developing technologies and their potential in biomedicine and healthcare. Daniel is a graduate of Brown University, Stanford Medical School and completed his residency at the Massachusetts General Hospital. Daniel founded RegenMed Systems, has multiple digital health, medical device, immunology and stem cell related patents and served on faculty at Stanford and UCSF. He is an Aspen Institute Health Innovator Fellow, and a Kauffman Fellow.

Keynote Speaker

Tuesday, August 6, 2019, 9:00 – 10:00 a.m.



Tom Kupiec, PhD
ARL BioPharma
Oklahoma City, OK

Dr. Thomas Kupiec is CEO of ARL Bio Pharma and DNA Solutions. Dr. Kupiec received his Ph.D. in Pharmaceutical Sciences from the University of Oklahoma Health Sciences Center College of Pharmacy. He currently serves on the Oklahoma Center for the Advancement of Science and Technology (OCAST) Board of Directors, the National Safety Council Alcohol, Drugs and Impairment Division Board, and the Foundation Board of Trustees at the University of Central Oklahoma. He is a graduate faculty member at the OU Health Sciences Center and has held teaching appointments at several universities. He has published numerous articles and abstracts in a variety of fields including pharmaceutical sciences, forensic sciences, and pharmacogenomics. Dr. Kupiec is often requested as a guest lecturer and a speaker at national and regional pharmaceutical conferences.

Dr. Kupiec's vision of entrepreneurial research is manifested by his responsibilities at ARL Bio Pharma and DNA Solutions as a technical and business development leader in the pharmaceutical and forensic fields. Additionally, Dr. Kupiec provides consultation and expert witness testimony in the fields of forensic toxicology and pharmaceutical sciences including litigation, patent infringement and medication errors. Testified in over 100 cases in state and federal courts involving both civil and criminal issues, for prosecution as well as defense.

Session II: The Era of Precision Medicine – Implications for Compounders

Pharmacogenomics: Precision Pharmacy in 503a Compounding

Tuesday, August 6, 2019, 11:00 – 12:10 p.m.



Matthew Olson, PE

AMC Engineers
Anchorage, AK

Matt Olson, PE, is a Senior Mechanical Engineer with AMC Engineers (AMC), specializing in healthcare facilities design. Matt has worked on numerous complex healthcare projects over his 12-year career at AMC. AMC is a consulting engineering firm providing mechanical, electrical and plumbing (MEP) systems engineering for various sectors including universities, schools, laboratories, museums and libraries, sports arenas, transportation, correctional, industrial, and healthcare facilities.

Matt has recently been involved in several hospital and outpatient healthcare facility pharmacy renovation and expansion projects for compliance with the new USP-795, 797, and 800 standards. These projects include design of sterile compounding cleanroom suites for both hazardous and non-hazardous drugs, hazardous drug storage rooms, non-sterile hazardous drug containment segregated compounding areas (C-SCA's), as well as general pharmacy and support areas. Matt's expertise includes assessment of existing HVAC systems for compliance with codes and standards. His expertise has allowed for significant cost savings on pharmacy renovation projects where existing HVAC systems were able to be retrofitted and reused.

Matt is a member of the American Society of Healthcare Engineering (ASHE), the Alaska Society of Healthcare Managers and Engineers (ASHME), and the American Society of Heating Refrigeration and Air Conditioning Engineers (ASHRAE). Matt is actively involved in the local ASHME chapter where he recently presented on Pharmacy Design for USP-797 & USP-800 Compliance at their Annual Conference, highlighting critical mechanical systems design criteria for a successful healthcare pharmacy project.

Session VI: Innovative Approaches to Facility Design of Compounding Areas

Perspectives from an Engineer

Wednesday, August 7, 2019, 10:35 – 12:00 p.m.



Rick Rhoads, PharmD
University Compounding Pharmacy
San Diego, CA

Rick Rhoads is the Director of Compounding at University Compounding Pharmacy in San Diego, CA, where he oversees quality and regulatory compliance. During his 12 years of compounding experience, he has implemented USP standards for USP <795>, <797>, and <800>. In 2017 he obtained the QP503A certification from CriticalPoint, and in 2018 he received 40 hours of Aseptic GMP training from the Parenteral Drug Association. He has participated in numerous regulatory inspections, including two from the FDA.

Rick is passionate about improving the compounding profession through enhanced standards and pharmacist collaboration. He has recently published an article about lessons learned from his experience performing a stability study on a CSP. He also has a forthcoming article in AJHP about demystifying smoke studies for compounding pharmacists.

When he is not working in the pharmacy, Rick enjoys fishing with his family in the lakes near his home.

Rick will be presenting from a community pharmacy perspective about innovative approaches to implementing USP standards and maintaining quality control in a fast-paced setting.

Session V: Innovative Approaches to Implementing USP Compounding Standards: Practitioner Perspective

Practitioner from A Community Pharmacy
Tuesday, August 6, 2019, 9:00 – 10:20 a.m.

New compounding standards create an opportunity for the compounding industry to improve the quality of preparations dispensed to patients. This opportunity also presents a challenge to compounders who must implement change in a diverse and complicated operation. This presentation will discuss implementing these changes from a practitioner perspective in a community pharmacy setting. The areas of focus will be centered on innovative solutions to challenges encountered during implementation of USP <795> and <797>. Specifically, the subjects covered are: assignment of Beyond Use Dates, smoke pattern tests in clean rooms, and aspects of quality assurance and quality control. The assignment of Beyond Use Dates for CSPs and CNSPs is an important part of quality for compounded preparations. Revised USP requirements state that BUDs must be assigned conservatively based on factors including but not limited to the chemical and physical properties, container closure, and antimicrobial effectiveness. This has led to more interest in performing stability studies to accurately assess these factors. Practical lessons for stability studies will be discussed based on the speakers experience performing them on CSPs and CNSPs. Additionally, the requirement for smoke pattern tests under dynamic conditions for sterile compounders will be presented. These smoke studies may be underutilized by compounding staff for process validation and personnel training. They are a valuable tool to reduce risk of CSP contamination when performed under truly dynamic conditions. Lastly, aspects of quality assurance and quality control have become an issue for compounders struggling to consistently meet the standards and maintain control of the operation. When quality issues inevitably arise, the compounder must be prepared to accurately identify and correct the underlying root cause. Quality management systems and root cause analysis are beneficial tools that may aid the compounder in this objective. This section represents an emerging need for the compounding community. USP standards are extremely important for nonsterile and sterile compounders alike due to the diverse and complicated nature of the operations. Implementing these standards is exceptionally challenging and must be approached with determination and innovation based on the unique demands of each pharmacy. Finding solutions to USP compliance can greatly benefit compounding pharmacies and the patients they serve.



Abby Roth, BSc

Member, USP Compounding Expert Committee
Macungie, PA

Abby Roth is the Director of Learning and Development at CriticalPoint, LLC®, a health care training and development company. In her current role, she develops curriculum for CriticalPoint's elearning modules and live training classes. She is also a faculty member for the Sterile Compounding Boot Camp Live Training Series which includes but is not limited to environmental monitoring programs, contamination control practices and sanitization programs. Prior to joining CriticalPoint, Abby served as the Director of Microbiology for Kastango Consulting Group®, and as a Quality Director at a contract microbiology laboratory specializing in environmental monitoring and product testing.

Abby has over 14 years of experience in supporting the testing and consulting needs of the pharmaceutical, medical device and compounding industries. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring, including program development, sampling technique, sample analysis, and data trending. Abby also has experience in consulting on microbial contamination sources and remediation. She holds a Bachelor of Science degree in Biology and a minor in Chemistry from York College of Pennsylvania. In 2014, she became a Certified Manager of Quality/Organizational Excellence through the American Society of Quality.

She is currently serving as an expert committee member of the 2015 to 2020 USP Compounding Committee and is an involved member of the Controlled Environment Testing Association (CETA), speaking at their annual meeting and participating in the revision of their CETA Application Guides. Additionally, she has been invited to speak at the state and national level.

Session VII: Building Quality into the Compounding Process: Perspectives from Compounders

Moderator

Wednesday, August 7, 2019, 1:00 – 3:00 p.m.



Sara Rothman, MPH

Member, USP Compounding Expert Committee
Bethesda, MD

Sara Rothman is a Senior Policy Advisor with FDA's Office of Unapproved Drugs and Labeling Compliance in the Center for Drug Evaluation and Research, Office of Compliance. Sara leads policy development initiatives for FDA's compounding program and works on other regulatory projects. She holds a Master's Degree in Public Health from the University of Massachusetts.

Session IV: Advancing Quality Compounding: Perspectives from Adopting Bodies

FDA Perspective

Tuesday, August 6, 2019, 2:30 – 4:30 p.m.

FDA's human drug compounding program is comprised of policy development, inspections and enforcement, and stakeholder outreach and engagement. This presentation will highlight key elements from each of those areas that illustrate federal requirements and policies relating to the quality of drugs produced by compounders.



Anthony Rubinaccio
NJ State Board of Pharmacy
Newark, NJ

Anthony Rubinaccio joined the New Jersey Department of Law and Public Safety, Division of Consumer Affairs, as Executive Director of the State Board of Pharmacy in December of 2011. Mr. Rubinaccio began his career as a pharmacist in northern New Jersey in 1977, including a five-year period in which he owned and operated a pharmacy in Bloomfield, NJ. He then moved into the field of corporate information technology and was responsible for enterprise-wide application development for two large financial institutions. He returned to the active practice of pharmacy in 2011. A native of New Jersey, Mr. Rubinaccio earned a Bachelor of Science degree at Rutgers College of Pharmacy in 1977, and a Master of Science degree in Management Information Systems from Stevens Institute of Technology in Hoboken in 1992.

Session IV: Advancing Quality Compounding: Perspectives from Adopting Bodies

State Perspective

Tuesday, August 6, 2019, 2:30 – 4:30 p.m.



Brian Serumaga, PhD

USP
Rockville, MD

Brian Serumaga is a Scientific Liaison for the Compounding Expert Committee at USP. He also works on the USP Compounded Preparation Monograph Donation Program. Prior to joining USP, Brian worked as a pharmaceutical policy expert in international development. He also carried out research and teaching as Research Fellow in pharmaceutical policy at the Department of Population Medicine at Harvard Medical School and the WHO collaborating center on medicines policy. After Pharmacy school, Brian worked as a compounding pharmacist in a hospital for geriatric care in Nottingham, UK. Kingdom. He has a Pharmacy degree, a Master's in Public Health and Ph.D in Pharmaceutical Policy from the University of Nottingham, UK.

Workshop Goals and Anticipated Outcomes

Clinical Informatics at the FDA

Tuesday, August 6, 2019, 8:45 – 9:00 a.m.

Session I: USP Updates

CPMs and Other Updates

Tuesday, August 6, 2019, 10:00 – 11:00 a.m.

Session VIII: Debrief and Next Steps

Moderator

Wednesday, August 7, 2019, 3:00 – 3:30 p.m.



Bob Shrewsbury, PhD

Member, USP Compounding Expert Committee
Chapel Hill, NC

Robert Shrewsbury, Ph.D., received his BS in pharmacy from the University of Oklahoma in 1972 and his PhD from the University of Kentucky in 1977. His background training is in basic and applied biopharmaceutics and pharmacokinetics and in drug-interaction mechanisms. His current research interests have focused on classroom and laboratory instructional methodologies using Web-based or technology-based formats. He has authored over 150 book chapters, numerous online education courses and continuing education seminars, and national certification examination study guides for pharmacy professionals, pharmacy students, and pharmacy technicians. He built and maintains an internationally utilized open website for pharmacy compounding where 40 percent of the users are from outside the United States. He was elected as member of the USP Expert Committee on Compounding in 2010 and again in 2015.

Session II: The Era of Precision Medicine – Implications for Compounders

Evolution of Pharmaceutical Dosage Forms – What is On the Horizon for Compounders?

Tuesday, August 6, 2019, 11:00 – 12:10 p.m.

The world of precision medicine is molding and sculpting the future of compounding practice from the formulation-to-delivery of preparations. Most practitioners recognize genomics will be a major driving force in this evolution. However, this presentation offers an insight to an emerging engine that when combined with genomics will change the fundamental responsibilities of not only compounders, but dispensers, industry, and clinical practitioners in the U.S. healthcare system. As a result of these structural changes, compounding practice will emerge as a larger provider of patient care.



Connie Sullivan, B.S.Pharm

Member, USP Compounding Expert Committee
Alexandria, VA

Connie Sullivan, B.S.Pharm., is the President and Chief Executive Officer of the National Home Infusion Association (NHIA). Sullivan has over 25 years of home infusion industry leadership, management, and clinical practice experience. Sullivan is responsible for NHIA's legislative and regulatory advocacy initiatives and developing resources that support the infusion industry in order to foster innovation and promote the delivery of high-quality patient care. Sullivan also oversees the National Home Infusion Foundation, a not-for-profit subsidiary of the association devoted to research, leadership development, and education programs. Sullivan is the current Vice Chair of the United States Pharmacopeia (USP) Sterile Compounding Expert Committee, and a member of the Parenteral Nutrition Expert Panel. Prior to joining NHIA, Sullivan served for 15 years as the National Director of Infusion for a national home health and skilled nursing provider. Sullivan earned her bachelor's in pharmacy from The Ohio State University College of Pharmacy in 1994.

Session II: The Era of Precision Medicine – Implications for Compounders

Moderator

Tuesday, August 6, 2019, 11:00 – 12:10 p.m.



Dennis Tribble, PharmD, FASHP

BD Medication Management Medical Affairs
Daytona Beach, FL

Dr Dennis Tribble is a Director of Medical Affairs for the Medication Management Systems business at BD.

He is a pharmacist with twelve years of hospital pharmacy management experience between two hospitals in the Chicago area before going into industry, first with a hospital information systems company, and then into the medication management automation industry.

He is an inventor with over 30 patents in healthcare automation, including the development of the first IV robotic device as well as the first IV workflow software.

He is a featured blogger on technology and pharmacy practice for ASHP Connect, a past President of the Illinois Council of Health-System Pharmacists, a past Chair of the ASHP Section on Pharmacy Informatics and Technology, and a Fellow of the American Society of Health System Pharmacists.

Session III: New and Emerging Technologies in Compounding

Gravimetrics – Application in Compounding

Tuesday, August 6, 2019, 1:00 – 2:20 p.m.

Gravimetrics is the use of changes in mass to evaluate the volumetric delivery of medication. It was first used in TPN compounders as early as 1989, and is currently used in that role today, along with being found in most (if not all) current IV robotic products to verify product deliver.

Gravimetrics requires knowing the density of the fluid being measured, which means that it can detect over- or under- delivery but cannot detect selection of the wrong product. It therefore must operate in the context of other systems to verify ingredient identity.

Gravimetrics systems do not directly measure fluid volume, but rather detect whether or not such measurements are within tolerance. Such tolerances are dictated by a number of factors, primarily the accuracy limits of the actual measurement device, typically a sterile disposable syringe. Those limits are discussed in depth.

There are other analytic technologies become available that can directly measure final concentration of a preparation. Those technologies are discussed along with the need for use of the USP monographs on the source ingredients to compute appropriate tolerances. An example is presented.



Jaap Venema, PhD

Executive Vice President/Chief Science Officer
USP
Rockville, MD

Jaap Venema, Ph.D., is Executive Vice President and Chief Science Officer (CSO) for USP. He leads the organization's scientific strategy and is responsible for the development of quality standards for medicines, dietary supplements, food ingredients and healthcare, including collaborations with other pharmacopeia and scientific groups. Dr. Venema guides USP's exploration of emerging technologies that may inform future quality standards and oversees USP's Up-to-Date program, which continuously evaluates and revises standards to reflect current and best practice. Dr. Venema also serves as Chair of the Council of Experts, spearheading USP's work developing science-based standards. This body guides and approves the draft standards developed by USP's numerous expert committees, comprised of nearly a thousand scientific experts from academia, industry, healthcare, as well as government agencies.

Dr. Venema's more than 25 years' experience in global research and development, as well as academic research, informs his scientific leadership at USP. Dr. Venema previously served in a variety of scientific leadership positions at Solvay and AbbVie (formerly Abbott Laboratories), where he held various roles in drug discovery and development in vaccines, pain care and immunology, and developed and implemented a global scientific and medical strategy for biotherapeutics. Before his transition to industry, Dr. Venema was a post-doctoral fellow at the European Molecular Biology Laboratory (EMBL) in Heidelberg, Germany, and a Fellow of the Netherlands Academy of Sciences at the Free University of Amsterdam.

A native of the Netherlands, Dr. Venema earned his Master's degree in Chemistry from the Free University of Amsterdam, and his Ph.D. in Biochemistry and Molecular Biology from Leiden University in the Netherlands.

Welcome and Introduction

Tuesday, August 6, 2019, 8:30 – 8:45 a.m.



James Wagner

Member, USP Compounding Expert Committee
Center Valley, PA

Jim Wagner, the president of Controlled Environment Consulting (CEC), has been involved in the Controlled Environment performance evaluation industry since 1979. His consulting includes design and evaluation of sterile compounding facilities, containment facilities and other engineering controls. Jim conducts international training on cleanroom and containment device certification. Prior to founding CEC, Jim was the President of Micro-Clean, a certification and validation company. Jim led the Controlled Environment Testing Association's (CETA) efforts to develop guidance documents for compliance with USP Chapter 797. He was a member of the USP Council of Experts for Compounding and an expert panel member for USP <800>. Jim is a current member of the USP Compounding Expert Committee responsible for revisions to USP <797> and <795>. Jim is a steering committee member for NSF/ANSI standard 49 Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. Jim was a two-time president of the Controlled Environment Testing Association including being CETA's first president in 1991-92. Jim was awarded CETA's Mel First award for outstanding contributions to the advancement of certification and testing of controlled environments.

Session VI: Innovative Approaches to Facility Design of Compounding Areas

Moderator

Wednesday, August 7, 2019, 10:35 – 12:00 p.m.