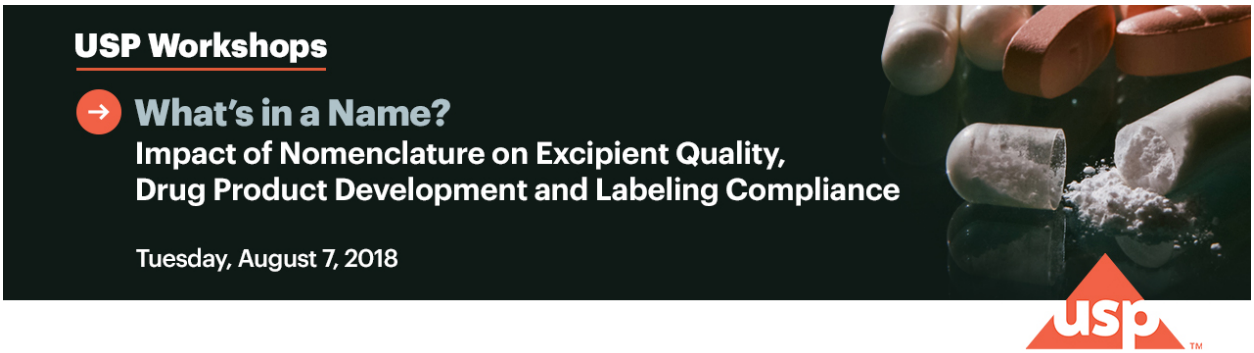
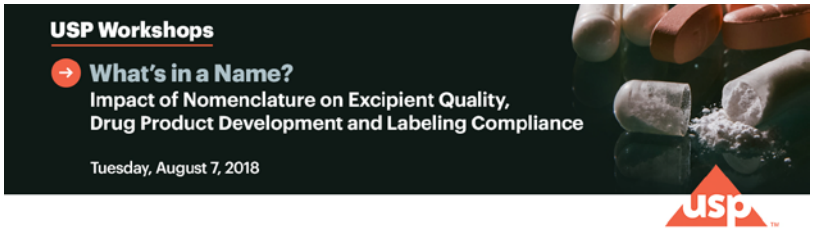


Speaker Biographies & Abstracts

(listed alphabetically)

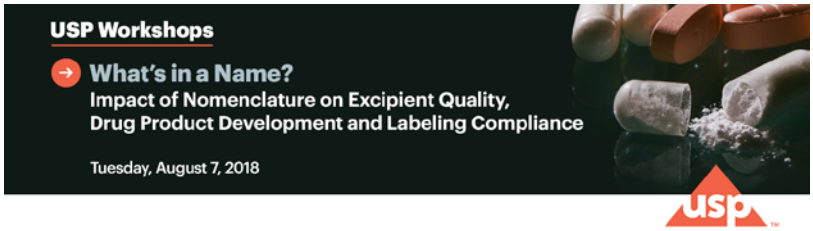


LCDR Jibril Abdus-Samad, PharmD
Policy Lead, Compendial Operations and Standards Branch/DRGS/OPPQ/OPQ/CDER
U.S. Food & Drug Administration
Silver Spring, MD

Lieutenant Commander (LCDR) Jibril Abdus-Samad is a pharmacist in the U.S. Public Health Service. Currently, he works at FDA in the Center for Drug Evaluation and Research (CDER) in the Office of Policy for Pharmaceutical Quality as a member of the Compendial Operations and Standards Branch. More recently, he was the Labeling Reviewer for the Office of Biotechnology Products (OBP) in CDER in which he evaluated labeling for biological products for compliance with labeling regulations. Prior to OBP, LCDR Abdus-Samad served as a Safety Evaluator within the Division of Medication Error Prevention and Analysis at FDA for 6+ years. He practiced in various pharmacy settings within Veterans Affairs and the private sector. LCDR Abdus-Samad received his PharmD from the University of the Sciences in Philadelphia in 2000 and a Graduate Certificate in Patient and Product Safety from the University of Southern California in 2010.

Presentation
Labeling of Inactive Ingredients
Tuesday, August 7, 2018, 9:45 – 10:25 a.m.

Labeling of inactive ingredients is required by the Food, Drug, and Cosmetic Act and the implementing regulations. This presentation will provide an overview of the regulations and a USP General Chapter that address labeling of inactive ingredients in drug and biological products.



Lawrence Callahan, Ph.D.
Chemist
U.S. Food & Drug Administration
Silver Spring, MD

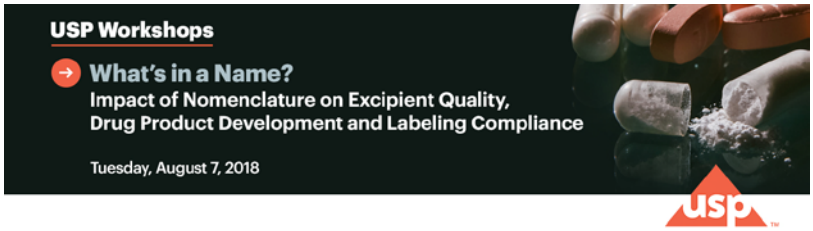
Dr. Lawrence Callahan obtained his Ph.D. in Chemistry from the University of Chicago. He was previously employed at NIH and the United States Pharmacopiea (USP). He has been involved in Nucleic Acid, HIV, and tuberculosis research and was responsible for the development of analytical methods for biotechnology-derived products and numerous USP monographs. Dr. Callahan was also responsible for the management and development of chemical/biological databases for the National Institute of Allergy and Infectious Disease (NIAID), National Library of Medicine (NLM), and National Cancer Institute (NCI).

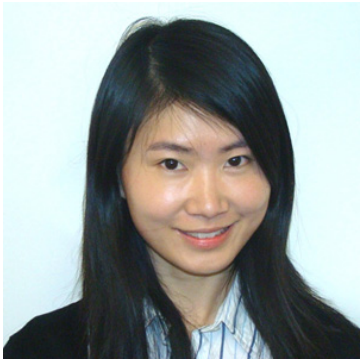
Dr. Callahan is currently responsible for the development and management of the Global Substance Registration System (GSRS). The goal of the GSRS is to define all substances in FDA regulated products, assign a Unique Ingredient Identifier (UNII) and create meaningful relationships between substances. The GSRS also links substances to products, applications, clinical trials and adverse events. The GSRS is a collaborative effort between NIH's National Center for Advancing Translational Sciences (NCATS) and foreign regulatory authorities.

Drs. Callahan, Dr. Frank Switzer and Dr. Herman Diederik were the primary editors of the ISO 11238 Standard for defining substances in medicinal products. Dr. Callahan is also the FDA lead on the Global Ingredient Archival System (GInAS) project, which attempts to integrate regulatory, toxicological, and clinical information on all substances in medicinal products.

Presentation
Introduction and Overview of GSRS and SRS
Tuesday, August 7, 2018, 8:45 – 9:45 a.m.

This presentation will focus on defining excipients according to the ISO 11238 standard and also the use of the Global Substance Registration System (GSRS).



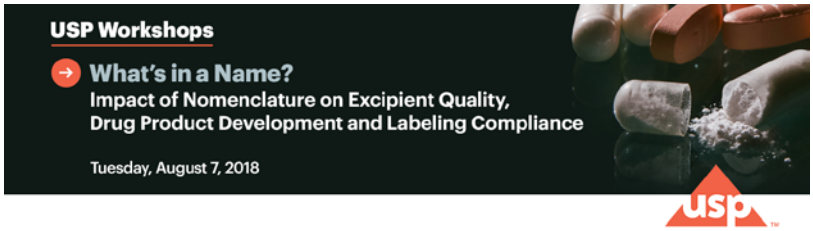


Pervina Kei
Senior Research Associate, Early Stage Pharmaceutical Development
Genentech, Inc.
San Francisco, CA

Pervina Kei has worked 9 years at Genentech. As a member of the pharmaceutical development group, she develops formulation for early stage products. She previously worked at Abbvie in analytical development department. She holds a BA from the University of California at Berkeley.

Presentation
Case Study 4 – Polysorbates: The Complex Composition of Polysorbate 20 and Polysorbate 80
Tuesday, August 7, 2018, 2:45 – 3:45 p.m.

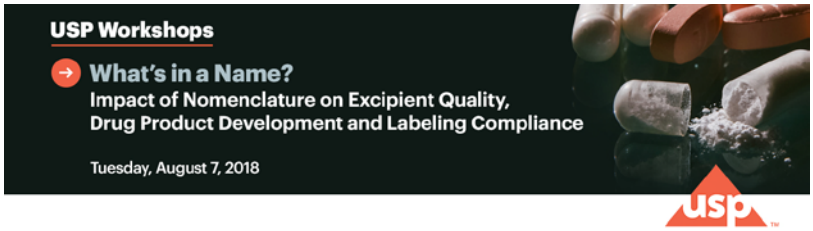
Polysorbate 20 and 80 are commonly used excipients in many dosage forms and the majority of biopharmaceuticals. The composition of polysorbates is only described in the USP in terms of hydrocarbon chain length and number of POE units. There is no description of degree of esterification (mono-, di-, tri, and tetra-ester), variety of head group (sorbitol, POE sorbitan, POE isosorbide) or the presence of un-esterified head group (non-surfactant). In parenteral protein products upon long-term storage, these surfactants can degrade into insoluble products (including free fatty acids), which can lead to increased subvisible and visible particle counts. Studies have also shown that polysorbates, which are made of multiple components, are susceptible to enzymatic degradation in a unique fashion. Different grades and sources of polysorbate can present different outcomes. It is important to fully describe the composition of polysorbates in the USP and develop assays to control polysorbate composition to achieve similar composition among different vendors and polysorbate grades in order to control drug product quality.



Otilia Koo, Ph.D.
Member, Excipient Monographs 1 Expert Committee
Director, Integrated Development Team, Bristol-Meyers Squibb
New York, NY

Otilia Koo, PhD, is currently Director, Integrated Development Teams at Bristol-Myers Squibb Company. Her research interests and publications are in excipients characterization, the role of excipients in formulation development and processes and targeted lipid-based drug delivery systems. She serves in the 2015 - 2020 USP Expert Committee for Excipient Monographs and was lead guest editor of themed issues in AAPS Journal and AAPS Pharm SciTech. Otilia Koo is also the sole editor for the book, "Pharmaceutical Excipients: Overview, Functionality, and Applications in Research and Industry" published in 2017. Otilia Koo received her Ph.D. in Pharmaceutics from the University of Illinois at Chicago, and Masters/Bachelor from the National University of Singapore. She also is an adjunct assistant professor at University of Illinois at Chicago.

Presentation
Moderator, Breakout Session 2
Tuesday, August 7, 2018, 2:45 – 3:45 p.m.

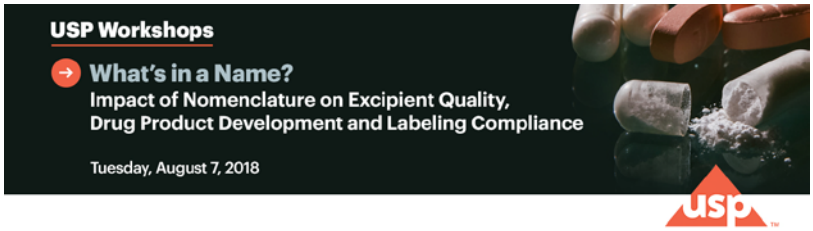


Xiao Ling, Ph.D.
Senior Researcher and Director of Excipient Division
Institute for Drug Control, Shandong Province
Shandong, China

Dr. Xiao Ling is a Senior Researcher in Excipient Division in Institute for Food and Drug Control, Shandong Province. She has over ten years of experience in developing and updating ChP standards. She received her MD in Shandong University prior joining the SDIFDC, and received her Ph.D. in 2012. Also have the one-year experience of working as a Professional Reviewer of pharmaceutical research for IND(investigational new drug) and NDA(new drug application), Division of Antineoplastic Products, Center for Drugs Evaluation, China State Food and Drug Administration(CFDA).

Presentation
Nomenclature of Pharmaceutical Excipients in ChP
Tuesday, August 7, 2018, 11:00 – 12:15 p.m.

To introduce the Nomenclature of Pharmaceutical Excipients in ChP (The second draft for comments), including the General Principles and the Detailed nomenclature of some specific excipients, e.g., Starch, phospholipids, pre-mixed and co-processed excipients.

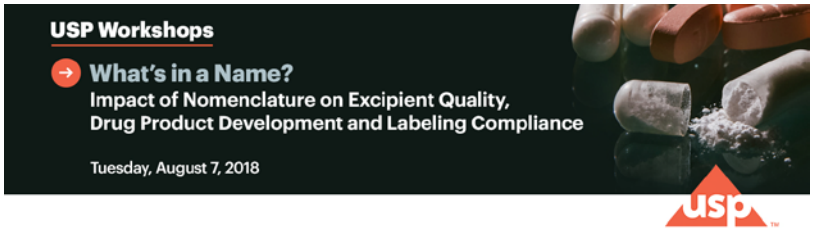


Tamaki Miyazaki, Ph.D.
Senior Researcher, Division of Drugs
National Institutes of Health Sciences, Japan
Kanagawa, Japan

Tamaki Miyazaki is a senior researcher at the National Institute of Health Sciences (NIHS) in Japan. She started her career as scientist at NIHS in 1989 and obtained a Ph.D. in Pharmacy from Hiroshima University in 2002 for her work on the characterization of hyaluronic acid as a raw material for pharmaceutical products. She has over 30 years of experience in regulatory science. Her primary research has been focusing on the stability of pharmaceutical products including raw materials for the products, and the development of test methods for the evaluation of quality characterization of pharmaceutical products. She serves the chair of the Committee on Pharmaceutical Excipients for the Japanese Pharmacopeia since June 2018. She is also a member of the Committee on Physical Methods, several Sub-committees and working groups.

Presentation
Excipient Nomenclature for JP
Tuesday, August 7, 2018, 11:00 – 12:15 p.m.

In this presentation, the overview of pharmaceutical excipients in Japan and nomenclature for JP will be provided. The recent topics of nomenclature in JP will also be given. Further, the differences in excipient monograph structures between JP and USP (individual and family monograph) will be shown in several case studies.



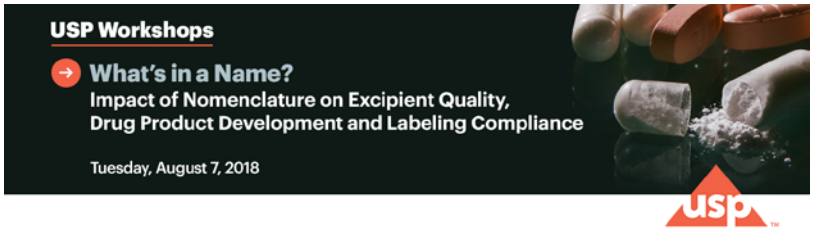
R. Christian (Chris) Moreton, B.Pharm., M.Sc., Ph.D.
Member, Excipient Monographs 1 Expert Committee
Vice President, Pharmaceutical Sciences, FinnBrit Consulting
Waltham, MA

Dr. Moreton is an independent consultant/advisor in the areas of pharmaceutical formulation and excipients. He has over 40 years' experience in the pharmaceutical sector, mainly as a formulation scientist working in both large and small innovator and generic companies, but also in QA, QC and Regulatory Affairs with an excipient and drug delivery company.

Dr. Moreton has been a USP Expert Committee member since 2000, and he is a member of the Excipient Monographs 1 Expert committee (EM1) in the 2015-2020 Revision cycle. He is currently also a member of the USP Excipients Nomenclature Joint Subcommittee, Co-chair of the USP General Chapter <1059> Excipient Performance Expert Panel and Chair of the USP Lactoses Joint Subcommittee.

Dr. Moreton is a Visiting Lecturer at Manchester University, UK in their Pharmaceutical Industry Advanced Training (PIAT) program.

Presentation
Moderator, Breakout Session 1
Tuesday, August 7, 2018, 2:45 – 3:45 p.m.



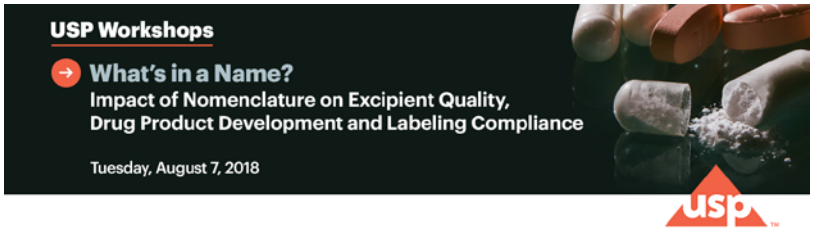
Lisa Parks
Vice President, Sciences & Regulatory Affairs
Association for Accessible Medicines
Washington, DC

Lisa holds a BS in Pharmacy from the Massachusetts College of Pharmacy in Boston, MA. In her current role as the Vice President of Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM), she assists with the development of the Scientific Affairs initiatives and member communications and training opportunities. She is involved with facilitating discussions and efforts on: bioequivalence; research and development of drug substance and drug product; IID; emerging technology; quality metrics; CMC; ICH initiatives; and FDA guidance and policy development with members and industry stakeholders. She also develops, plans, and coordinates AAM's technical conferences. Lisa served as a key member of AAM's negotiating team for the Generic Drug User Fee Amendments (GDUFA II) and the Biosimilar User Fee Act (BsUFA II) with FDA. She currently serves in the same capacity for both user fee programs for the implementation phase of both programs.

Prior to joining AAM, Lisa held crucial positions in various Offices at the FDA's Center for Drug Evaluation and Research (CDER). She began her FDA career at the Office of Generic Drugs (OGD) as a regulatory filing reviewer, where she enhanced the filing review checklist to increase transparency of FDA expectations at the time of filing of generic drug applications to FDA and served as the FDA's point of contact with industry for the IID improvement initiative and PIV website updates. Lisa's ability to drive cross-functional teamwork led to her appointment as a key representative by the Director of OGD for the initial implementation of GDUFA I. She moved on to support the implementation of GDUFA I for CDER and played a key role in the establishment of CDER's Office of Pharmaceutical Quality (OPQ).

Presentation
Excipient Industry Perspective on Excipient Nomenclature-A Generic Sponsors Perspective
Tuesday, August 7, 2018, 1:00 – 2:15 p.m.

Insight into how changes to excipient nomenclature and naming impacts the research and development of generic drug products and the overall quality of Abbreviated New Drug Application (ANDA) submissions to FDA.



David Schoneker, M.S.
Director of Global Regulatory Affairs
Colorcon
Harleysville, PA

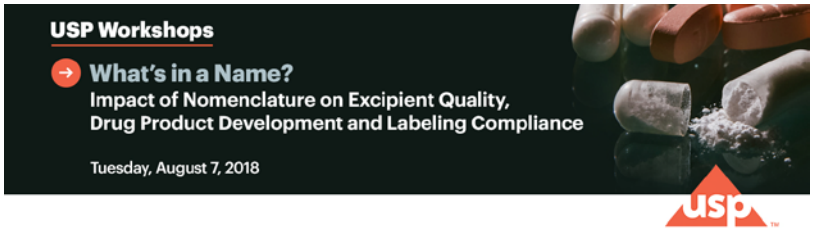
David R. Schoneker is the Director of Global Regulatory Affairs at Colorcon. His responsibilities include global coordination of Colorcon's worldwide regulatory activities and market expansion projects to gain regulatory acceptance of Colorcon's products and components for various target markets.

He received his B.S. degree from Ursinus College and M.S. in Chemistry from Villanova University. His previous position at Colorcon was Director of Quality Assurance and Quality Control. He has been at Colorcon since 1977. Mr. Schoneker has been active in many professional organizations such as AAPS, PQRI, RAPS, ASQ, ACS, AOAC and the Delaware Valley Chromatography Forum. He also is involved with a number of trade organizations such as the International Pharmaceutical Excipients Council (IPEC), the International Association of Color Manufacturers (IACM), the Consumer Health Products Association (CHPA), the International Food Additives Council (IFAC), the Council for Responsible Nutrition (CRN) and the Institute of Food Technologists (IFT).

Mr. Schoneker was the Chairman of IPEC-Americas during the period 2007-2009 and is currently a member of the Executive Committee. He is now serving as the Vice Chair for Science and Regulatory Policy where he is actively involved with the development of Regulatory, Safety, Excipient GMP and Supplier Qualification related guidelines to improve Excipient Acceptability, Safety and Global Supply Chain Security. Mr. Schoneker also Co-Chairs IPEC's QbD/Product Development Committee, Composition Committee and IID Working Group. He also is a member of the Board of Directors of the IPEC Foundation. He is the Global Expansion Coordinator for the IPEC Federation and has been critically involved in the development of many of the IPEC groups and Partnerships around the world.

He has acted as an interface with many international regulatory agencies and pharmacopeias for the organization. He previously was the USP Liaison for IPEC-Americas and represented them as a member of the United States Pharmacopeial Convention for many years. Mr. Schoneker previously coordinated International Harmonization efforts for IPEC-Americas and participated in the development of IPEC's Good Manufacturing Practices Guide and Auditing Guide for Bulk Pharmaceutical Excipients. He has also led IPEC's efforts in developing guidelines for excipient qualification, significant change notification and the appropriate use of certificates of analysis. Additionally, Mr. Schoneker chairs a number of harmonization working groups on various excipients and has been chairing the Coalition for Rational Implementation of the Elemental Impurity Requirements since 2010.

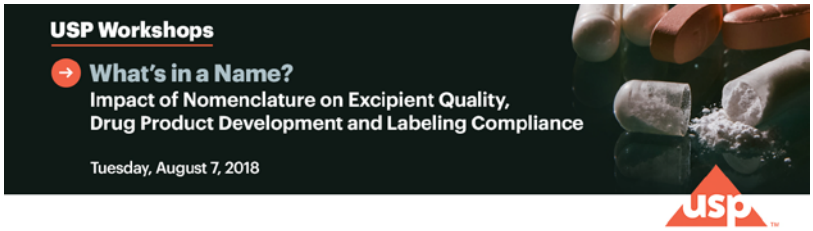
Mr. Schoneker has participated in the area of Color Science for many years and is author of the chapter "Coloring Agents for Use in Pharmaceuticals" in the 4th edition of the *Enclyclopedia of Pharmaceutical Technology* which was published in 2013. He has



also authored many other excipient quality and safety related papers in various journals and trade magazines.

Presentation
Case Study 1 – Glyceryl Caprylocaprate Type I and II: Confusion Regarding What Really Was Covered With the Existing NF Monograph
Tuesday, August 7, 2018, 2:45 – 3:45 p.m.

On November 1, 2015 a NF monograph titled “Glyceryl Monocaprylocaprate” (GMCC) was published in the United States Pharmacopeia-National Formulary (USP-NF) which covered both Type I and Type II GMCC. These materials have also been referenced in various places such as the FDA’s Substance Registration System (SRS) and Inactive Ingredient Database (IID), NDAs and ANDAs, however these excipients have been called caprylic/capric mono/diglycerides, mono-di-glycerides of caprylic/capric acid, mono-di-glycerides of glycerol monocaprylocaprate, and glycerol monocaprylocaprate, EP Type I in the drug labeling which shows up in DailyMed. This has led to great confusion about what actually is covered by the monograph and what has actually been used in previously approved drug products. This presentation will discuss the history of these nomenclature issues and what is being done to clarify the situation both in the USP and in the IID so that drug sponsors will be able to provide accurate information in their drug submissions to FDA going forward.

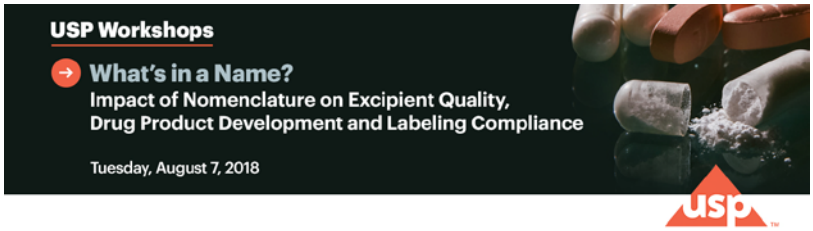


Catherine Sheehan, M.S., M..S.
Senior Director, Science-Excipients
USP
Rockville, MD

Ms. Sheehan joined USP in 2001. She is currently the Senior Director, Science-Excipients, United States Pharmacopeia Convention, Rockville, MD. In her current role, she supports excipients standard setting activities of the USP Council of Experts for two Excipient Monograph Expert Committees. Her responsibilities include working with stakeholders on the development and update of excipient monographs and related general chapters including the update of high priority excipients as part of USPs collaboration with the FDA Monograph Modernization Task Group. She is also responsible for the harmonization activities of excipient monographs and general chapters through the Pharmacopeial Discussion Group and is part of the USP delegation to the Pharmacopeial Discussion Group.

Ms. Sheehan holds both an M.S. Regulatory Science degree and M.S. Molecular Biotechnology degree from The Johns Hopkins University, Baltimore, USA.

Presentation
Workshop Goals and Anticipated Outcomes
Tuesday, August 7, 2018, 8:35 – 8:45 a.m.

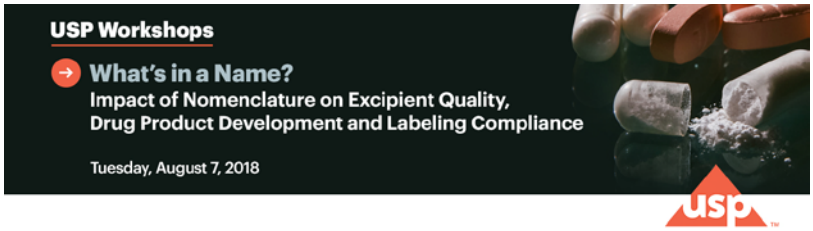


Frank Switzer, Ph.D.
Chemist
U.S. Food & Drug Administration
Silver Spring, MD

Dr. Frank Switzer is a chemist in the Office of Health Informatics at the FDA where he manages the Unique Ingredient Identifier (UNII) substance terminology. Dr. Switzer was co-editor of the ISO 11238 substance standard published in 2012. Before joining the FDA in 2008, Dr. Switzer was a college professor teaching all levels of college chemistry and introductory astronomy.

Presentation
Introduction and Overview of GSRS and SRS
Tuesday, August 7, 2018, 8:45 – 9:45 a.m.

This presentation will focus on defining excipients according to the ISO 11238 standard and also the use of the Global Substance Registration System (GSRS).

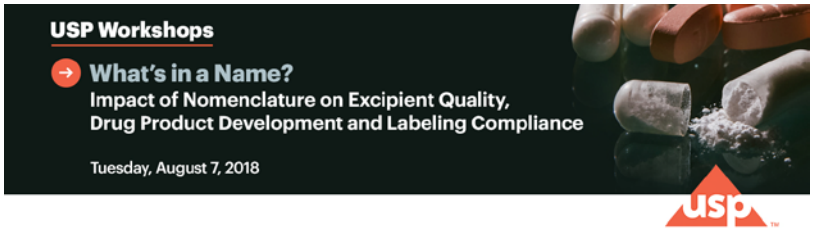


Katherine Ulman
Primary
KLU Consulting, LLC
Sanford, MI

Katherine Ulman retired from Dow Corning Corporation, now a wholly owned subsidiary of The Dow Chemical Company, after more than 40 years of employment. While at Dow Corning, she held positions as a global regulatory compliance manager for their Healthcare business as well as regulatory manager of the Dow Corning Healthcare Industries Materials Site. In addition to her regulatory role, she was an associate scientist at Dow Corning where she worked in the development and characterization of pharmaceutical excipient and medical device raw materials/components. Much of her early career was dedicated to the synthesis of novel silicone monomers and polymers/copolymers. Ulman has been a member of the ACS, AAPS, and CRS. She is currently an active member and vice chair of the Regulatory Committee for IPEC-Americas. She has published and presented several papers in her field, developed and taught a college course in Organosilicone Polymer Chemistry and Technology through SDSM&T, and taught international courses on silicones for pharmaceutical/biomedical applications and medical adhesives through Technomic Publishing Co. Ulman earned her Bachelor of Science degree in chemistry from the South Dakota School of Mines and Technology in 1976.

Presentation
Case Study 2 – Silicone: The Challenges in Aligning USP, SRS and IID Nomenclature of Specialized Excipients
Tuesday, August 7, 2018, 2:45 – 3:45 p.m.

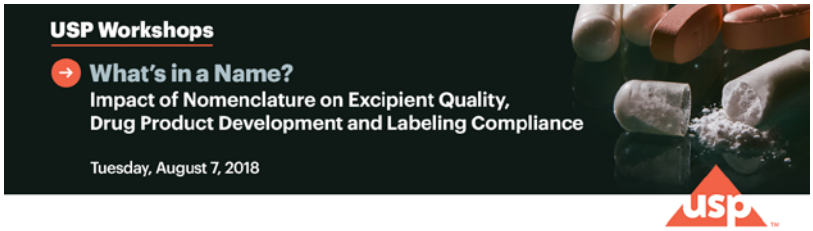
Silicones comprise a class of specialty materials that find use in drug products, cosmetics and medical devices. Silicone excipients are typically comprised of a polymer or oligomer with an inorganic (Si -O -Si) backbone and organic pendant groups. As a result, the chemical name for even the simplest polymer can be complex, lengthy and unfamiliar. In an attempt to simplify the name while describing the general polymer chemistry, the industry has adopted shorthand nomenclature for these materials. Furthermore, depending on their chain length, degree of substitution, substitution type, cross-link density, etc., silicones can come in many forms such as fluids, gums, resins, powders and elastomers. These forms often become part of their commercial names, and colloquial nomenclature is quite commonly used to simplify naming silicone materials. Partially based on this, historical issues exist with IID (listings), SRS (mapping) and USP monograph (references) that will be highlighted during this breakout presentation. Part of the challenge in aligning USP, SRS and IID nomenclature for this class of specialty materials will be defining criteria for a universal naming strategy that will acceptable to stakeholders globally.



Hong Wang, Ph.D.
Senior Manager, Science-Excipients
USP
Rockville, MD

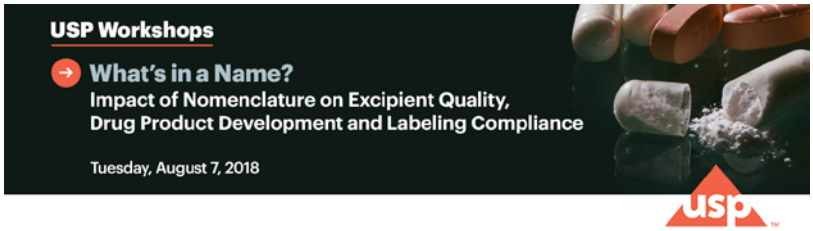
Dr. Hong Wang is a Senior Scientific Liaison in Science—Excipients at U.S. Pharmacopeial Convention. She has over ten years of experience in developing and updating USP-NF public standards. She received her Ph.D. in physical chemistry from the University of Basel, Switzerland. Prior to joining USP, she worked at Bioprocess and Bioanalytical Research department in Merck Research Laboratories, West Point, PA for seven years. Before starting an industrial career at Merck, Dr. Wang worked as a postdoctoral research fellow at Brandeis University, Waltham, MA, for about two years.

Presentation
USP Perspective: Excipients Nomenclature-Overview and Updates
Tuesday, August 7, 2018, 11:00 – 12:15 p.m.



Andrzej Wilk, Ph.D.
Senior Scientific Liaison, Healthcare Quality Standards
USP
Rockville, MD

Presentation
USP Perspective: Excipients Nomenclature-Overview and Updates
Tuesday, August 7, 2018, 11:00 – 12:15 p.m.



Priscilla Zawislak
Chair, IPEC Americas
Global Regulatory Affairs Advocacy Manager, The Dow Chemical Company
Collegeville, PA

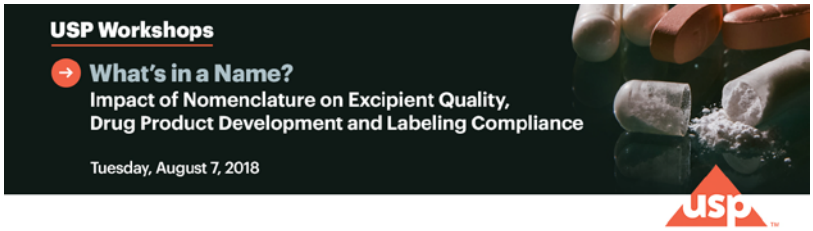
Priscilla has over 30 years' experience in Regulatory Affairs and Quality for excipients, food additives and ingredients for personal care products. Currently with The Dow Chemical Company, she is the Global Regulatory Affairs Advocacy Manager for Dow's Food, Pharma and Medical Solutions business and is responsible for regulatory advocacy for excipients, APIs and food additives. Prior positions included Global Regulatory Affairs Manager for Ashland Inc.'s Pharmaceutical and Nutrition business where she was responsible for regulatory compliance for food additive and excipient products, and Quality Manager at FM Health and Nutrition.

Priscilla is the current Chair of IPEC-Americas and has been an active member of IPEC Americas committees since 2001 and a member of the IPEC Americas Executive Committee. She is also the President of the IPEC Federation, a global organization consisting of regional IPECs in the US, Europe, Japan, China and India. Priscilla is also the co-leader of the Atypical Actives Coalition organized by IPEC-Americas.

Through IPEC Priscilla has been involved in a number of projects with the USP and the PDG. She is a member of the USP General Notices Project Team, the Compendial Process Improvement Team and a delegate to the USP Convention.
Priscilla earned her degrees in Biological Sciences and Chemistry from the University of Delaware.

Presentation
Excipient Industry Perspective on Excipient Nomenclature-IPEC Perspective
Tuesday, August 7, 2018, 1:00 – 2:15 p.m.

Excipient nomenclature, especially with regard to consistency and accuracy, is vital to excipient manufacturers and users in the industry. This presentation will explore some of the current challenges with nomenclature in the Global Substance Registration System (GSRS), the Inactive Ingredient Database (IID), UNII Codes and monographs and the impact these have on industry with regard to drug development and regulatory filings.



Joseph Zeleznik
Manager, Technical & Regulatory Affairs
MEGGLE USA, Inc.
Pawling, NY

Joseph Zeleznik is currently Manager, Technical and Regulatory Affairs at MEGGLE USA, Inc. In this role, he is responsible for providing formulation and product application guidance as well as having quality and regulatory oversight for MEGGLE USA's North American lactose manufacture.

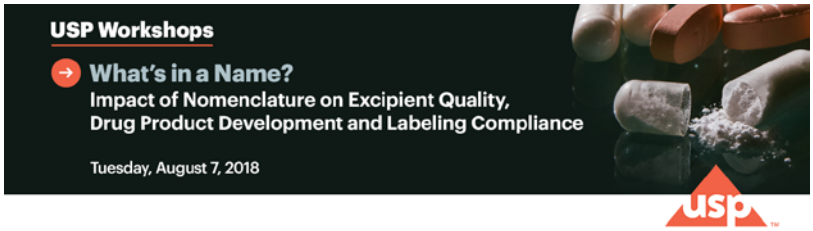
Mr. Zeleznik received his B.S. and M.A. degrees in Chemistry from the State University of New York, College at New Paltz with a focus on instrumental analysis. Prior to joining MEGGLE USA, Mr. Zeleznik was Associate Director, R&D with JRS PHARMA and Research Manager with Penwest Pharmaceuticals Co. Mr. Zeleznik has over 20 years experience in the pharmaceutical industry, having specialized in the development and application of high functionality excipients, and in particular, co-processing applications for the performance enhancement of excipients and pharmacologically active ingredients. Currently a member of IPEC-Americas' Executive Committee, he also serves as Chairman of IPEC-Americas' Quality by Design/Excipient Composition (QbD/EC) committee and has assisted in the development of several IPEC Guides including the newly introduced Co-processed Excipients Guide.

Mr. Zeleznik has authored or co-authored multiple articles published across various industry journals. He was a contributing author to the Handbook of Pharmaceutical Excipients, 8th Ed. published in 2017 and participated in the development of the NF co-processed excipient monograph, Silicified Microcrystalline Cellulose.

Mr. Zeleznik is an avid outdoorsman, enjoying camping, hiking, biking, and wildlife photography and has been active as a cub scout and boy scout leader with Boy Scouts of America for many years.

Presentation
Case Study 3 – Co-processed Excipients: The Challenges in Developing Nomenclature for Co-processed Excipients
Tuesday, August 7, 2018, 2:45 – 3:45 p.m.

Co-processed excipients (CPEs) are not new in pharmaceutical use nor is their inclusion in the United States Pharmacopeia's National Formulary and FDA's Inactive Ingredients Database (IID); however, inconsistencies exist in nomenclature with no established terminology guidance. Further, for co-processed excipients having monographs, monograph nomenclature is not always reflected in the IID. In some instances, IID listings may not even reflect any reference to co-processed excipient inclusion. The speaker will discuss some of the challenges with co-processed excipient nomenclature and provide examples where inconsistencies exist and the issues that may result. Some suggestions regarding nomenclature will be offered for contemplation and consideration.



Susan Zuk, MS
Branch Chief, Office of Policy for Pharmaceutical Quality, OPQ, CDER
U.S. Food & Drug Administration
Silver Spring, MD

Susan holds a BS in Chemistry from Syracuse University and a MS in Biotechnology from Johns Hopkins University. During her 19 years with the FDA, she served in the Office of Generic Drugs as Chemistry Team Leader for many years, specializing in antibiotics. She joined the Office of Policy for Pharmaceutical Quality in 2015 and is currently Branch Chief of the Division of Regulations, Guidance and Standards. She is the lead for the FDA's Inactive Ingredient Database (IID). In this role, she is responsible for overseeing IID improvements. Susan has served on many FDA committees and working groups related to product safety and quality. She is currently a member of the FDA's Center for Drug Evaluation and Research (CDER) Excipient Working Group.

Presentation
FDA's Inactive Ingredient Database: How Does It Work?
Tuesday, August 7, 2018, 9:45 – 10:25 a.m.

Excipients, the inactive ingredients in pharmaceutical products, are essential drug product components that facilitate drug delivery, promote solubility, improve taste and, in general, allow active pharmaceutical ingredients to be transformed into useable dosage forms. FDA's assessment of drug applications includes not only assessment of the active pharmaceutical ingredient (API), but also evaluation of the safety of the proposed pharmaceutical excipients under the conditions of use of the drug product. One of the ways applicants provide evidence of excipient safety is by demonstrating that the excipient has been safely used in previously approved drug products. This is where the FDA's Inactive Ingredient Database (IID) fits into the regulatory submission process. The IID provides information on excipients present in FDA-approved drug products, including the routes of administration and dosage forms of the approved drugs in which they were used. A listing for an excipient in the IID may be referenced in a drug product application to support the safety of the excipient in a new or generic drug product that is used in a similar manner. The IID is, therefore, beneficial to the pharmaceutical industry, especially the generic drug industry.

This presentation will explain how the IID works; how excipients are entered into the IID, sources of excipient nomenclature and units of potency for different dosage forms. It will also touch on specific topics of interest to pharmaceutical manufacturers and excipient suppliers such as the impact of FDA's Global Substance Registration System (GSRS) changes on IID nomenclature and planned changes to the IID as a result of the 2017 passage of the Generic Drug User Fee Amendments (GDUFA II). FDA is currently updating the IID to meet GDUFA II commitments. The presenter invites workshop participants to share their experiences with the IID to help FDA build an optimal system.