



**2nd Excipient Workshop:  
Focus on Excipient Quality, Compendial Testing, and Regulatory Impact  
November 17-18, 2015  
USP Meetings Center, Rockville, MD USA**

**Preliminary Agenda**

*(Updated November 15, 2015)*

**DAY ONE: Tuesday, November 17, 2015**

8:00 – 8:30 a.m.      **Registration and Coffee**

8:30 – 8:45 a.m.      **Welcome and Introductions**

**SESSION I**

**Strategy to Bring *USP-NF* Excipient Monograph Specifications Up to Date**

**Moderator:** Jeffrey Medwid, Ph.D., *Government Liaison, USP Excipient Monographs 2 Expert Committee*

8:45 – 9:15 a.m.      **Keynote Presentation**  
Joseph Kushner, IV, Ph.D., *Pfizer Inc.*

9:15 – 9:45 a.m.      **Industry Perspective**  
**Presentation 1:** FDA /OPQ IID Issues and Potential Resolutions  
Katherine Ulman, *DOW Corning*

9:45 – 10:10 a.m.      **USP Perspective**  
**Presentation 2:** Challenges and Opportunities in Excipient Monograph Development and Update  
Kate Houck, Ph.D., *Chair, USP Excipient Monographs 2 Expert Committee*

10:10 – 10:40 a.m.      **Break**

10:40 – 11:10 a.m.      **Regulatory Perspective**  
**Presentation 3:** FDA CDER Inactive Ingredient Database: Goals and Progress  
Susan Zuk, *U.S. Food and Drug Administration (FDA)*

11:10 – 11:40 p.m.      **Academic Perspective**  
**Presentation 4:** Global Excipient Databases – NIPTE Overview  
Stephen Hoag, Ph.D., *Member, General Chapters Physical Analysis Expert Committee. University of Maryland, School of Pharmacy*

11:40 – 11:45 a.m.      **PQRI Survey Results on Excipient Variability (poster presentation)**  
Lawrence H. Block, Ph.D., *Vice-Chair, USP Excipient Monographs 2 and General Chapters Physical Analysis Expert Committees*

11:45 – 12:00 p.m.      **Q & A (15 min)**

12:00 – 1:00 p.m.      **Networking Lunch**



## SESSION II

### Challenges and Opportunities in Excipient Monograph Development and Update

**Moderators:** Hong Wang, Ph.D., *USP Senior Scientific Liaison, Excipients* / Kevin Moore, Ph.D., *USP Manager, Pharmacopeial Harmonization*

#### Topic 1: USP Up-to-Date for USP-NF monographs

- 1:00 – 1:30 p.m.      **Regulatory Perspective**  
**Presentation 5 (FDA):** FDA Perspective on Excipient Monograph Up-to-Date  
Steven Wolfgang, Ph.D., *Government Liaison, USP Excipient Monographs 1 Expert Committee*
- 1:30 – 2:00 p.m.      **USP Perspective**  
**Presentation 6:** What Does *USP-NF* Up-To-Date Mean for Excipients?  
R. Chris Moreton, Ph.D., *Vice-Chair, USP Excipient Monographs 1 Expert Committee*
- 2:00 – 2:30 p.m.      **Industry Perspective**  
**Presentation 7:** Challenges and Opportunities in Development of Novel Excipients and Monographs in USP  
Shaukat Ali, Ph.D., *BASF*
- 2:30 – 3:00 p.m.      **Break**

#### Topic 2: Global Harmonization Activities for Excipients

- 3:00 – 3:30 p.m.      **Presentation 8:** USP Update on Pharmacopeial Harmonization Activities  
Lawrence H. Block, Ph.D., *Vice-Chair, USP Excipient Monographs 2 and General Chapters Physical Analysis Expert Committees (USP)*
- 3:30 – 4:00 p.m.      **Presentation 9:** Pharmacopoeial Discussion Group (PDG) Update on Harmonization Activities – Japanese Pharmacopoeia (JP)  
Hiroshi Tokunaga, Ph.D. (PMDA)
- 4:00 – 4:30 p.m.      **Presentation 10:** EP Update on Harmonization Activities – European Pharmacopoeia  
Professor Anne Gayot (EDQM)
- 4:30 – 5:00 p.m.      **Roundtable Discussion / Q & A (30 min)** – Challenges and Opportunities for Harmonization, Update and Development of Excipient Specifications  
Moderator: Jiasheng Tu, Ph.D.
- 5:00 p.m.      **Adjourn**



## DAY TWO: Wednesday, November 18, 2015

8:00 – 8:30 a.m.      **Registration and Coffee**

### SESSION III

#### **Challenges and Opportunities in Development and Update of Excipient Monographs Used for Biologics Drug Applications**

**Moderator:** R. Chris Moreton, Ph.D., *Vice Chair, USP Excipient Monographs 1 Expert Committee* / Catherine Sheehan, MS., MS., *USP Senior Director, Excipients*

8:30 – 9:00 a.m.      **Keynote Presentation: Integrity of Supply – Shifting Paradigms**  
Marla Phillips, Ph.D., *Xavier Health*

#### **USP Perspective**

9:00 – 9:30 a.m.      **Presentation 1:** Understanding USP's Role with Excipients Used in Biologics: Identifying Gaps in Current Excipient Monographs and Developing Monographs for Missing Excipients  
Thiago C Carvalho, Ph.D., *Member, USP Excipient Monographs 1 Expert Committee*

#### **Regulatory Perspective**

9:30 – 10:00 a.m.      **Presentation 2 (FDA):** FDA Review of Excipient Submissions in BLA  
Laurie Graham, *U.S. FDA*

10:00 – 10:30 a.m.      **Break**

10:30 – 11:00 a.m.      **Presentation 3 (FDA):** The Scientific and Regulatory Basis for the Management of Excipient Data During the Review of Biotechnology-Derived Drugs  
Ashutosh Rao, Ph.D., *U.S. Food and Drug Administration (FDA)*

11:00 – 11:30 a.m.      **Q & A (30 min)**

#### **Industry Perspective**

11:30 – 12:00 p.m.      **Presentation 4:** Ensuring an Excipient is Suitable for its Intended End Use; An Excipient Manufacturer's Perspective  
Dora Meissner, M.S., *BioSpectra*

12:00 – 1:00 p.m.      **Networking Lunch**

#### **Industry Perspective (Cont'd.)**

1:00 – 1:30 p.m.      **Presentation 5:** Drug Product Manufacturer's Perspective on the Use of Pharmaceutical Excipients in Biologics Finished Final Product / Formulation; Focusing on the Characterization of Surfactants  
Y. John Wang, PhD., *Genentech*

1:30 – 2:00 p.m.      **Presentation 6:** Impact of Raw Material Variability for Upstream Processes to Drug Substance Performance Attributes  
Colleen Alexander, Ph.D., *BMS*



- 2:00 – 3:30 p.m.      **Parallel Breakout Sessions:** Rationalization of Terminology used in the manufacturing of Biologics, including Drug Substance (upstream/downstream processing) and Drug Product (final formulations) aspects. To discuss / understand when compendial grade materials are necessary in the manufacture of Biologics. Parallel breakout sessions will explore and report back on learnings relating to the use of the current terminology and provide recommendations / path forward.  
Moderator: Jiasheng Tu, Ph.D.
- 3:30 – 4:00 p.m.      **Break**
- 4:00 – 4:15 p.m.      **Closing Summary**  
Session I
- 4:15 – 4:30 p.m.      Session II
- 4:30 – 4:45 p.m.      Session III
- 4:45 p.m.              **Workshop Concludes**

**Speaker and Moderator Information  
(alpha order)**



**Colleen M. Alexander, Ph.D.**

Scientist  
Bristol-Myers Squibb  
East Syracuse, NY, USA

Colleen Alexander is a Scientist in the Material Science group within Manufacturing Sciences and Technology (MS&T) at Bristol-Myers Squibb (BMS) in East Syracuse, NY. Colleen focuses primarily on the Raw Materials sub-function within Material Science. In this role, she provides raw materials support to biologics drug substance manufacturing, as well as support in the authoring of regulatory filings and internal documents. Colleen joined BMS in 2014 and has most recently worked as a Postdoctoral Research Associate in the Chemistry Department at the University of Massachusetts at Amherst. Colleen holds a Ph.D. in Chemistry from Syracuse University, a B.S. in Biochemistry from State University of NY at Oswego, and a B.A. in Psychology from McGill University.

---

**Presentation Abstract**

Presentation 6: Impact of Raw Material Variability for Upstream Processes to Drug Substance Performance Attributes  
Wednesday, November 18, 2015, 1:30 – 2:00 p.m.

The impact of raw material variability on the upstream manufacturing of a biologics drug substance (DS) process is discussed in this presentation. Raw material variability is explored within-lot, lot-to-lot, and as a function of time. The impact to DS manufacturing is measured for relevant parameters, including several process performance attributes (PAs). In the first study, metals were quantified using ICP-MS in upstream raw materials, demonstrating both within-lot and lot-to-lot variability of copper content. To further explore the impact of copper content variability, a pilot scale upstream manufacturing study that included 7x and 20x copper supplementation relative to the copper content of the control condition was completed. Viable cell density (VCD) of the cell culture was enhanced 1.4 fold and 1.9-fold relative to the control for the 7x and 20x copper conditions, respectively. Percent viability was enhanced for both high copper conditions. The percent viability remained > 80% for both high copper conditions compared to < 40 % for the control. Titer was also enhanced significantly for both high copper conditions. Furthermore, titer for the 7x copper condition was comparable to manufacturing scale data which utilized a high copper raw material lot.

In a separate study, vitamins and amino acids were quantified in cell culture media using HPLC-MS. Variability of select vitamins and amino acids was demonstrated as a function of media age. For example, folic acid concentration declined over the 12 month media shelf life, ultimately reaching < 12% of its theoretical concentration. In a small scale follow up study, media age and folic acid content were evaluated for their response toward specific PAs: VCD, percent viability, titer, and

glycosylation. At small scale, newer media (1 month) increased VCD, percent viability, titer, and glycosylation relative to old media (11 months). Increased folic acid content (folic acid spiked into old media) increased glycosylation relative to control (aged media). Manufacturing scale data was consistent with the small scale study, and demonstrated a >15% increase in titer using new media compared to aged media. In another retrospective analysis of manufacturing data, the impact of media age and component variability was explored for a different cell culture medium. Lot-to-lot variability of a single media component was identified and was found to correlate with reduced titer. Media age at  $\geq 6$  months correlated with reduced titer.

The results from these studies enhance the knowledge of how raw materials impact manufacturing and are useful for identifying strategic material-related changes to support process improvements.



**Shaukat Ali, Ph.D.**  
Technical Support Manager  
BASF Corporation  
Florham Park, NJ, USA

Shaukat Ali has over 21 years of experience in the pharmaceutical industries including 11 years at BASF, where he supports solubilization, instant and modified release platforms, and APIs. Dr. Ali's areas of expertise include solid dispersions, liposome drug delivery, controlled release, transdermal, and film development technologies.

Dr. Ali is a member of the editorial advisory boards of, American Pharmaceutical reviews, Biopharma Asia, Contract Pharma, Drug Delivery & Development, International Journal of Pharmaceutical Investigation, Journal of Pharmaceutical Sciences and Pharmacology, and Journal of Analytical & Pharmaceutical Research. He is also a member of USP panel of experts for General Chapters-Physical Analysis. He received his Ph.D. in Chemistry from the City University of New York and pursued his postdoctoral training at the University of Minnesota and Cornell University. He has authored over 37 scientific articles and is the inventor in 14 US patents.

---

### **Presentation Abstract**

Challenges and Opportunities in Development of Novel Excipients and Monographs in USP

Tuesday, November 17, 2015, 2:00 – 2:30 p.m.

Compendial requirements of novel excipients and their “first to use” in formulation have been subject of continued interest by both the excipient and drug manufacturers. Such challenges have been underestimated, and thus finding the common solutions at both sides, stemming from excipient's safety or acceptance by the industry, have been unsettled. Coupled with regulatory and FDA requirements, those issues further discouraged innovation by excipient manufacturers, which in turn has slowed down the industry in addressing the challenges either with continued surge in number of poorly soluble compounds, in areas of taste-masking of bitter APIs or finding the appropriate excipients for improving the performance of a desired dosage. Notably, these challenges may not be addressed with the standard excipients and therefore, the pharma industry will continue to depend upon the novel excipients that meet desired safety and performance, and technological adaptable for developing better and smarter medicines for tomorrow. That will inevitably challenge the regulatory agencies.

BASF continues to take a steeper path and innovate new excipients, knowing that the approval of drugs with novel excipients will take much longer than those developed with the standard excipients. It is challenging but important to address the industry's needs where most desirable. Soluplus® and Kollicoat® Smartseal



were developed to meet exactly those needs in addressing solubility and bioavailability challenges and designing better dosages with taste masked API's, respectively. Both have yet not been approved in drug products.

This presentation will focus on technical understanding of selected innovative excipients and their performances in the desired formulation dosages. The challenges in development of dosage with non-compendial excipients such as Soluplus® and Kollicoat® Smartseal, and their acceptance not only by the industry but also by regulatory agencies, will be discussed with common interests and how to embrace the novel excipients in drug products without being listed in FDA's inactive ingredient database. The presentation will highlight challenges and opportunities with developing NF monographs in USP.





**Lawrence H. Block, Ph.D.**

**USP Affiliation:** Vice-Chair, USP Excipient Monographs 2 and General Chapters  
Physical Analysis Expert Committees

Professor Emeritus of Pharmaceutics  
Duquesne University  
Pittsburgh, PA, USA

Lawrence H. Block, Ph.D., is Professor Emeritus of Pharmaceutics at the Mylan School of Pharmacy and Graduate School of Pharmaceutical Sciences at Duquesne University. Dr. Block was educated at the University of Maryland where he earned his B.S. in Pharmacy, M.S., and Ph.D. degrees. Dr. Block is a Fellow of both the American Association of Pharmaceutical Scientists (AAPS) and the American Pharmacists Association - Academy for Pharmaceutical Research and Science (APhA-APRS). He is a member of AAPS, APhA-APRS, the Controlled Release Society, the New York Academy of Sciences, and the Society of Rheology. Dr. Block is a Past Chair of both the Teachers of Pharmaceutics Section of the American Association of Colleges of Pharmacy and the Basic Pharmaceutical Sciences Section of the APhA-APRS. He currently serves as Co-Chair of the Excipient Monographs 2 Expert Committee of the USP and is also a member of the USP General Chapters - Physical Analysis (GC-PA) Expert Committee. In addition, Dr. Block serves as Chair of the Rheology Subcommittee of the GC-PA. A recipient in 2000 of the Duquesne University President's Award for Excellence in Scholarship, Dr. Block has authored more than 100 publications and mentored more than 70 post-baccalaureate Pharm.D., M.S., and Ph.D. research students in the course of his professional career. His research interests embrace excipient technology, rheology, drug and cosmetic delivery systems, pharmaceutical engineering, biopharmaceutics, and pharmacokinetics. He has served as a Visiting Scholar at Kobe Gakuin University in Kobe, Japan and Visiting Professor of Pharmaceutical Sciences at the Center for Pharmacogenetics at the University of Pittsburgh School of Pharmacy.

---

**Steering Committee Member**

**Presentation Abstract**

PQRI Survey Results on Excipient Variability (poster presentation)  
Tuesday, November 17, 2015, 11:40 – 11:45 a.m.

Excipient variability has long been a topic of concern among pharmaceutical manufacturers and formulators. But, like the weather, " ...everybody talks about it, but nobody does anything about it". But is excipient variability inevitable and irremediable? To explore and understand excipient variability better, PQRI recently initiated a survey of the pharmaceutical industry intended to assess the extent of the problem and its impact on pharmaceutical manufacturing and product performance. Although survey participation was more limited than had been hoped for (n = 49), the results corroborate the expectations of many excipient

experts: Excipient variability issues on a commercial scale have been experienced by many excipient users: In many instances there was a need to reformulate or reengineer the affected product(s). An extensive review of the literature on excipient variability will be the subject of a forthcoming PQRI publication. Subsequently, a PQRI workshop or webinar will provide forums for further discussion and exploration of excipient variability and its ramifications. Ultimately, these activities will facilitate the provision of recommendations for best practices for the pharmaceutical industry, pharmaceutical excipient manufacturers, and regulatory authorities.

Presentation 8: USP Update on Pharmacopeial Harmonization Activities  
Tuesday, November 17, 2015, 3:00 – 3:30 p.m.

This talk will provide an overview of the current of international harmonization from a USP perspective. Global harmonization of pharmacopeial specifications of excipients has been a goal of pharmacopeias, in response to requests from industry to eliminate redundant testing across multiple regions. These efforts began with the Pharmacopeial Discussion Group (PDG), which work on harmonizing selected standards for general chapters and excipient monographs with the USP, European Pharmacopeia, and Japanese Pharmacopeia. USP's current efforts to this end are exemplified in this presentation not only by the formal PDG process but also by collaborations through WHO on the development of the Good Pharmacopeial Practices (GPhP), as well as additional informal prospective harmonization activities with other pharmacopeias



**Thiago Carvalho, Ph.D.**

**USP Affiliation:**

Member, USP Excipient Monographs 1 Expert Committee

Research Investigator  
Bristol-Myers Squibb  
New Brunswick, NJ, USA

Thiago Carvalho, Ph.D., is currently a Research Investigator in Drug Product Science & Technology at Bristol-Myers Squibb. He has over 6 years of experience in the pharmaceutical industry, working with development, tech transfer and manufacturing of protein therapeutics as well as in the drug product development of small molecules. He holds a B.Pharm. Degree from Federal University of Minas Gerais, Brazil, and a Ph.D. degree in Pharmaceutics from the University of Texas at Austin. Dr. Carvalho has published several peer-reviewed manuscripts and organized multiple scientific symposia and webinars. He is the 2015 Past Chair of the AAPS Excipients Focus Group and currently serves at the 2015-2020 USP Excipient Monographs Expert Committee.

---

**Steering Committee Member**

**Presentation Abstract**

Presentation 1: Understanding USP's Role with Excipients Used in Biologics: Identifying Gaps in Current Excipient Monographs and Developing Monographs for Missing Excipients

Wednesday, November 18, 2015, 9:00 – 9:30 a.m.

For the 2015-2020 USP Council of Experts revision cycle, the USP is investing to bring the USP-NF Up to Date. As part of this effort, the USP-NF monographs will be revised to be current, relevant and suitable for their intended use.

The great majority of Biologics products are delivered via injection and thus require bioburden and endotoxin controls with appropriate acceptance limits. Monographs for excipients used in Biologics formulations should thus comply with requirements for parenteral products.

Currently, there are monographs for excipients used in parenteral formulations with considerable gaps. Some examples for monographs requiring modernization are: inconsistencies with regards to bioburden and endotoxin limits; existing excipients being recently used in injectable dosage forms; obsolete technologies to detect impurities; and need to add tests for newly found impurities that may affect data analysis and/or product quality. In addition, some excipients used in Biologics formulations are missing monographs.

The objective of this talk is to bring some of these gaps to light and to initiate a



discussion on how to approach modernizing these monographs.



**Anne Gayot, Ph.D.**

Professor  
University of Lille2 Faculty of Pharmacy  
European Pharmacopoeia  
Lille, France

Professor Anne Gayot is in co-charge of the Pharmaceutical Industry Laboratory at the University of LILLE-France.

- This laboratory, beyond its teaching activities in the field of the development and production of pharmaceutical products, studies the solid state properties and properties of the particulate solid of the raw materials used in the formulation of drugs.
- It studies the physical properties of excipients and active substances with respect to the functionality characteristics.

Professor Anne Gayot was until reorganization of the French agency member and vice-president of the French Marketing authorization committee She is now member of the French Pharmaceutical and Generic working group at the French Agency.

She participates to the writing of the guideline on Pharmaceutical Development of Medicines for Pediatric use.

Professor Anne Gayot has been involved in the French Pharmacopoeia then the European Pharmacopoeia since 1980.

As an expert of powder technology at the European Pharmacopoeia, she was very active in the elaboration of monographs concerning the particle – size, the surface area determinations. She was nominated as a member of the French Pharmacopoeia Commission and belongs now to the Pharmaceutical preparations – Industrial Pharmacy group. She was a member of the cellulose group and a member of the P.A.T. Group of the European Pharmacopoeia from 2008 – 2012.

Since 2005, she has been a member of the functionality related characteristics group. She has been chairman of this group since 2007.

She prepared her Ph.D. at the University of Lille (1981). It concerns microcapsules of activated charcoal for renal patients.

Her scientific work concerns cauterization of solid particles, extrusion - spheronisation, powder for inhalation.

She uses as an invited speaker to give conferences on the pharmaceutical development, the process validation, the powders for inhalation.

She is in charge of the master in industrial pharmaceuticals at the Univ. of Lille 2.

---

### **Presentation Abstract**

Presentation 10: Update on Harmonization Activities – European Pharmacopoeia  
Tuesday, November 17, 2015, 4:00 – 4:30 p.m.

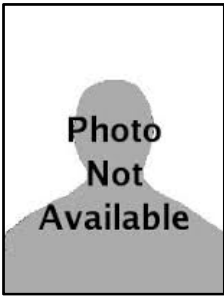
The author presents the European Directorate for the quality of Medicines and Healthcare (EDQM) of the Council of Europe. It supports the Commission in the elaboration and revision of texts of the European Pharmacopoeia.

The Pharmacopoeia European is engaged in a process of harmonization with the Japanese Pharmacopoeia and the United States Pharmacopoeia within an informal structure referred to as the Pharmacopoeial Discussion Group (PDG).

The cellulose derivatives are part of the program of harmonization. The polymers have complex rheological properties. The viscosity can be determined with different apparatus, giving an absolute or relative value.

The harmonization of the determination of the viscosity, especially of cellulose derivatives, is an important subject. Very often, the viscosity is relevant as F.R.C. for some functions of these polymers. The interests of the F.R.C. in a quality by design pharmaceutical development are outlined.

The present work of the F.R.C. group of the Pharmacopoeia European relative to surfactants is presented.



**Laurie Graham**

Lead Biologist  
U.S. Food and Drug Administration (FDA)  
Silver Spring, MD, USA

Biography forthcoming.

---

**Presentation Abstract**

Presentation 2 (FDA): FDA Review of Excipient Submissions in BLA  
Wednesday, November 18, 2015, 9:30 – 10:00 a.m.

Abstract forthcoming.



**Stephen W. Hoag, Ph.D.**

**USP Affiliation:**

Member, General Chapters Physical Analysis Expert Committee

Professor

University of Maryland, School of Pharmacy

Baltimore, MD, USA

Stephen W. Hoag is a professor at the University of Maryland, Baltimore School of Pharmacy. His primary research interests are tablet compaction, dosage form development, controlled release polymers, excipient functionality, excipient testing, formulation of nutritional supplements, botanical products and NIR spectroscopy applications in PAT. Working with the FDA, NIPTE he was a co-principle investigator of the team that created the excipient database on pharmahub.org. Dr. Hoag is a member of NIPTE, USP Counsel of Experts, Steering Committee for the Handbook of Pharmaceutical Excipients, the editorial board of the journal of Pharmaceutical Development Technology and an AAPS Fellow.

---

**Presentation Abstract**

Presentation 4: Global Excipient Databases – NIPTE Overview

Tuesday, November 17, 2015, 11:10 – 11:40 a.m.

Successful manufacturing of pharmaceutical dosage forms and the resultant therapeutic efficacy depends on the physical, chemical and mechanical properties of the drug substance and excipients. Physical properties are linked to final product quality attributes such as purity, uniformity, dissolution, stability, appearance and mechanical durability. Despite awareness of the importance of physical and mechanical properties, many fundamental questions about excipient functionality still need to be answered. To begin answering these questions, an excipient database was created to consistently catalog and organize excipient properties. Databases of material properties are very common in other fields of engineering, and these standardized and reliable material properties are indispensable to engineers who are designing products and industrial processes. In addition, excipients can be variable, because they are derived from natural products or synthetically modified natural products and are available from multiple vendors; as a result, their physical properties may vary from lot-to-lot and vendor-to-vendor, and if this natural variability is not accounted for, it can cause manufacturing problems that seemingly appear unpredictably throughout the life cycle of a drug product. Thus, another goal of the database is to catalog the intrinsic variability of excipients from vendor-to-vendor and lot-to-lot. This will make it easier for formulations to determine the intrinsic variability in their excipients and how this variability could impact product quality. The overall goal of the excipient database is to catalog material properties and usage information that would be useful for formulation development and the evaluation of





formulations by regulators. In this presentation the structure and features of the database will be discussed.



**Kate Houck, Ph.D.**

**USP Affiliation:**

Chair, USP Excipient Monographs 2 Expert Committee

Associate Director, Analysis and Technology  
Astellas Pharma Technology  
Norman, OK, USA

Dr. Kate Houck is the chair of the Excipient Monograph 2 committee and the Associate Director of Analysis and Technology at Astellas Pharma Technologies in Norman Oklahoma where she directs the Analytical Development, Quality Control, Stability and Microbiology groups. She has over 25 years of experience in the pharmaceutical industry with experience in a wide range of pharmaceutical dosage forms as well as drug substances and excipients. Dr. Houck has also worked at The Dow Chemical Company, Syntex Chemicals (now Roche Colorado), Cell Therapeutics, Schein Pharmaceutical, Alkermes and PPD. She has worked as a volunteer for the United States Pharmacopeia on the expert committee for excipient monographs for the last 10 years and has volunteered for a number of local and national organizations.

Dr. Houck earned a B.S. in Chemistry from Creighton University and a Ph.D. in Analytical Chemistry from the University of Arizona.

---

**Steering Committee Member**

**Presentation Abstract**

Presentation 2: Challenges and Opportunities in Excipient Monograph Development and Update

Tuesday, November 17, 2015, 9:45 – 10:10 a.m.

As we near the celebration of 200 years of the USP, it is important that we are looking not only at the past but also at the present and future needs of the healthcare industry. Bringing the existing excipient monographs to up-to-date, in addition to the development of monographs for new excipients is important to providing a stable supply of quality pharmaceutical products to a global marketplace. Changes in the pharmaceutical industry such as increased generics, shift toward biologics, and increased outsourcing demand that the USP-NF standards are maintained to current state of technology. As the pharmaceutical industry finds new uses for existing excipients, the up-to-date excipients monographs must contain certain critical quality attributes that support the new uses. New monographs should be developed for novel excipients that are needed to support emerging technologies. In this changing environment, the role of the inactive ingredient database (IID) in determining what monographs require changes and what new monographs should be developed is crucial to maintaining



the USP-NF standards. Additionally, the IID has the potential to be a great resource of information helping users determine whether a newly added excipient or a change to an existing excipient impacts dosage forms/routes of administration or dosage amounts. This talk will cover a background of the requirements for developing new monographs and updating existing monographs, the impact of the IID nomenclature, functionality, and completeness on excipients monograph development and update, and finally discuss the changes required from the IID to better support the maintenance of USP-NF compendial standards.



**Joseph Kushner, IV, Ph.D.**

Senior Principal Scientist  
Pfizer, Inc.  
Groton, CT, USA

Dr. Kushner received a B.S. in Chemical Engineering from Arizona State University and completed a M.S. and Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology, conducting research in the field of ultrasound-mediated transdermal drug delivery. Since joining Pfizer in 2006 as a research scientist in the Drug Product Design group, Dr. Kushner has led research efforts to better understand the role of excipient variability on small molecule drug product robustness, as well as to progress modeling of the lubrication blending process. These research efforts have led to novel methods for assessing excipient lot-to-lot variability and the development of a lubricant blending process scale-up model, both of which have been used to support the development of Pfizer drug products. Dr. Kushner has authored several publications and presentations in the fields of transdermal drug delivery and solid oral dosage form design and development, including lubrication understanding and excipient variability. Previously, he has given invited talks on excipient variability concepts at workshops hosted by NIPTE, Patheon, and the AAPS Chicagoland Regional Group. He is also currently involved with the International Pharmaceutical Excipient Council (IPEC) QbD and Excipient Composition committees. Through this involvement, he has provided perspectives on excipient variability in drug product manufacturing from an excipient user perspective during IPEC-led training sessions with the FDA Office of Generic Drugs and an IPEC-sponsored Webinar series on Excipient Variability and Quality-by-Design drug product development. Dr. Kushner is a member of both AIChE and AAPS, and also serves as a Scientific Advisor for the Journal of Pharmaceutical Sciences.

---

**Presentation Abstract**

Keynote Presentation

Tuesday, November 17, 2015, 8:45 – 9:15 a.m.

Excipients are an essential component of robust, commercial pharmaceutical drug products. Therefore, understanding the potential impact of variability in excipient material attributes on drug product manufacture and performance is an integral part of drug product design and development. Case studies incorporating excipient variability understanding into the drug product design and development process will be reviewed. These case studies are intended to highlight the challenges drug product developers may encounter while evaluating the impact that excipient variability may play in the performance of drug products and justifying excipient-related aspects of the drug product control strategy.



**Jeffrey Medwid, Ph.D.**

**USP Affiliation:**

Government Liaison, USP Excipient Monographs 2 Expert Committee

Senior CMC Review Chemist

U.S. Food and Drug Administration (FDA)

Silver Spring, MD, USA

Jeffrey B. Medwid, Ph.D., has over 35 years' experience in the pharmaceutical industry. Jeff moved to New York in 1980 to join American Cyanamid (Lederle), which became Wyeth and is now part of Pfizer where he made his career in pharmaceutical development there for over twenty-seven years.

Dr. Medwid retired from Wyeth (now Pfizer) as a Director in Analytical R&D in March 2007 to form CMC Pharmaceutical Consultants, LLC. As president, he consulted for a number of pharmaceutical companies, including a notable trip to China for on-site facility evaluations in 2008. Jeff joined the FDA in October 2008. In his current position as a Senior CMC Quality Reviewer, Jeff's primary role is reviewing the CMC sections for New Drugs. He is also very involved with AAPS, IPEC, and USP (FDA Liaison to USP) in learning and helping to present the FDA perspective on the role of Excipients from a QbD point of view.

---

**Steering Committee Member**

**Moderator**

Session 1: Strategy to Bring USP-NF Excipient Monograph Specifications Up to Date  
Tuesday, November 17, 2015, 8:45 a.m. – 12:00 p.m.



**Dora Meissner, M.S.**

Director of Regulatory Affairs  
BioSpectra  
Bangor, MS, USA

Dora Meissner is the Director of Regulatory Affairs for BioSpectra which is headquartered in Bangor, PA. She received her B.S. in Chemistry from the University of Pittsburgh and is currently pursuing a Master's Degree in Quality Assurance and Regulatory Affairs from Temple University. Dora began working at BioSpectra as a Quality Control Analyst in 2004. She has dedicated her professional career to understanding and advancing the quality and regulatory standards of BioSpectra, a leading manufacturer of Excipients and Active Pharmaceutical Ingredients. During her eleven years at BioSpectra, Dora has been responsible for the Quality, Safety and Regulatory aspects of the company's operations at three different manufacturing facilities. In her current role as Director of Regulatory Affairs, Dora is responsible for managing Quality Control, Quality Assurance, Environmental Health and Safety, Information Technology and Information Systems. Additionally, Dora is responsible for the management of BioSpectra's global raw material supply chain.

---

**Presentation Abstract**

Presentation 4: Ensuring an Excipient is Suitable for its Intended End Use; An Excipient Manufacturer's Perspective  
Wednesday, November 18, 2015, 11:30 a.m. – 12:00 p.m.

An understanding of the quality, identity, purity and grade of an excipient is essential to assure its suitability for the intended end use. There are many parameters, controls and analytical tests necessary to verify and prove that an excipient is manufactured in accordance with desired quality, uniformity and compliance. These parameters allow an ingredient to consistently meet the defining specifications for use in the manufacture of a drug product. Information provided through resources is available to manufacturers and end users to aid in harmonizing expectations, testing criteria and compliance requirements. Resources, such as the USP Monograph, are used to provide guidelines for qualifying and approving the quality and end use of an ingredient. This presentation will discuss the information and tools that an excipient manufacturer should use to support the intended end use of an excipient. This presentation will also provide a broad overview of how an excipient manufacturer can ensure its products are supplied with the necessary attributes for their intended use. Specific case studies will also be discussed during this presentation.



**Kevin Moore, Ph. D.**

Manager, Pharmacopeial Harmonization  
USP  
Rockville, MD, USA

Kevin is the Manager, Pharmacopeial Harmonization with responsibilities as the USP technical lead for all of USP's global harmonization activities. This includes leading the US delegation to the Pharmacopeial Discussion Group, which works to harmonize General Chapters and Excipient Monographs with representatives from the United States Pharmacopeia, the European Pharmacopeia, and the Japanese Pharmacopeia. In addition, Kevin works to coordinate the technical activities within USP for USP's prospective harmonization initiatives for drug substance, drug product, and excipient monographs, as well as support USP activities in collaboration with WHO in the development of the Good Pharmacopeial Practices (GPhP). Kevin holds a Ph.D. in Inorganic Chemistry from the University of Pennsylvania and a B.S. in Chemistry and Biology from LeMoyne College.

---

**Moderator**

Session 2: Challenges and Opportunities in Excipient Monograph Development and Update  
Tuesday, November 17, 2015, 1:00 – 2:30 p.m.



**R. Chris Moreton, Ph.D.**

**USP Affiliation:**

Vice-Chair, USP Excipient Monographs 1 Expert Committee

Partner  
FinnBrit Consulting  
Waltham, MA, USA

Dr. Moreton is a formulation scientist with over 30 years pharmaceutical industry experience. He has formulated a wide range of different drug products, both for clinical and commercial use, including tablets, capsules, injections, creams, ointments, suppositories and pessaries and has taken products from preformulation through to commercial manufacture. In addition he has worked in QA, QC and Regulatory Affairs for an excipient and drug delivery company.

Dr. Moreton has worked with IPEC over many years, initially in Europe and later in the US. He was a member of the IPEC Team that prepared the initial IPEC Guide on Good Manufacturing Practices for Bulk Pharmaceutical Excipients, and has also helped draft several other IPEC Guides. He is a past Chair of IPEC-Americas.

Dr. Moreton is a member of the Editorial Advisory Board for Pharmaceutical Technology and also for the Journal of Excipients and Food Chemicals. He has authored and co-authored scientific papers, articles and book chapters, and lectured extensively in the areas of excipients, drug delivery, preformulation and formulation at universities, training courses and symposia in the U.S., Europe and Japan.

---

**Steering Committee Member**

**Presentation Abstract**

Presentation 6: What Does *USP-NF* Up-To-Date Mean for Excipients?  
Tuesday, November 17, 2015, 1:30 – 2:00 p.m.

Under the 'USP-NF up to date' initiative the EM1 Expert committee will be working to ensure that new and existing monographs are current, relevant and suitable for their intended use. This presentation will review how this impacts excipient monographs and then focus on monograph updating activities, and how the Committee will be looking to update monographs. In addition the likely impact of new analytical technologies will also be discussed.

**Moderator**

Session 3: Challenges and Opportunities in Development and Update of Excipient Monographs Used for Biologics Drug Applications  
Wednesday, November 18, 2015, 8:30 – 3:30 p.m.





**Marla Phillips, Ph.D.**

Director, Xavier Health  
Xavier University  
Cincinnati, OH, USA

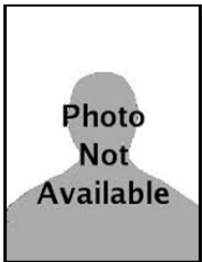
Marla joined Xavier University in 2008 as the Director of Xavier Health, where she leads initiatives with FDA officials and Pharmaceutical and Medical Device professionals. Marla began working in the pharmaceutical industry for Merck in 1996 as a Senior Project Chemist in the Analytical Methods Development group, became Manager of the Quality Control Laboratory for the Philadelphia plant site, and ultimately served as the Head of Quality Operations at the Merck North Carolina facility. She holds a B.S. in Chemistry from Xavier University, and a Ph.D. in Organic Chemistry from the University of North Carolina – Chapel Hill.

---

**Presentation Abstract**

Keynote Presentation: Integrity of Supply – Shifting Paradigms  
Wednesday, November 18, 2015, 8:30 – 9:00 a.m.

Xavier University has been leading the Integrity of Supply initiative since 2012 with representation from FDA, pharmaceutical and medical device manufacturers, and suppliers. The goal of this work is to increase the reliability of the supply chain and to increase product confidence. Major paradigm shifts have been discovered through these initiatives that are resulting in the development of impactful solutions. Attendees will understand how the paradigm shifts can alter current practices in their companies today.



**Ashutosh Rao, Ph.D.**

Chief, Laboratory of Applied Biochemistry  
U.S. Food and Drug Administration (FDA)  
Silver Spring, MD, USA

Dr. Ashutosh Rao is the Acting Chief of the Laboratory of Applied Biochemistry and Supervisory Drug Quality Reviewer in the Division of Biotechnology Review and Research, Office of Biotechnology Products at OPQ/CDER/FDA. Dr. Rao received his B. Pharm from the University of Bombay and Ph.D. in molecular pharmacology from the University of Texas M.D. Anderson Cancer Center in Houston, TX. Prior to joining the FDA in 2006, Dr. Rao completed post-doctoral fellowships in biochemistry and molecular biology at the National Cancer Institute in Bethesda, MD. Dr. Rao is currently responsible for the regulation of therapeutic proteins such as enzymes, monoclonal antibodies, and cytokines, and serves as an expert reviewer for biomarkers related to oncology or neuromuscular indications. He also serves on FDA working groups to develop regulatory policy on the development and validation of analytical methods during manufacture, novel excipients, reference standards, and on surrogate markers for accelerated approval. Dr. Rao also directs a laboratory research program that investigates the structure-activity relationship between protein oxidation and drug safety and efficacy. He has authored several peer-reviewed articles on drug development, metal-catalyzed oxidation of therapeutic proteins, biomarkers of cancer chemotherapy, and FDA regulatory guidances.

---

**Presentation Abstract**

Presentation 3: The Scientific and Regulatory Basis for the Management of Excipient Data During the Review of Biotechnology-Derived Drugs  
Wednesday, November 18, 2015, 10:30 – 11:00 a.m.

Abstract forthcoming.



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

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.

---

**Moderator**

Session 3: Challenges and Opportunities in Development and Update of Excipient Monographs Used for Biologics Drug Applications  
Wednesday, November 18, 2015, 8:30 a.m. – 3:30 p.m.



**Hiroshi Tokunaga, Ph.D.**

Technical Expert

Pharmaceuticals and Medical Devices Agency

Tokyo, Japan

He had thirty-six years' experience in the National Institute of Health Sciences and worked at quality control of pharmaceuticals and excipients. After retiring, he starts to work in Pharmaceuticals and Medical Devices Agency. He is one of JP Expert Committee on Excipient and one of the representatives of JP in PDG. He leads actively the quality control of excipients and the International harmonization.

---

**Presentation Abstract**

Presentation 9: Pharmacopoeial Discussion Group (PDG) Update on Harmonization Activities – Japanese Pharmacopoeia (JP)

Tuesday, November 17, 2015, 3:30 – 4:00 p.m.

In this presentation, the activities of PDG are reported from the past to the near future. PDG has three Pharmacopoeial bodies as EP, USP, and JP and WHO as observer. PDG has been established in 1989 and continues to work for 26 years. The first sign-off of the harmonized document was SDS-PAGE. ICH approved the ICH Q6A Agreement for the Specifications for new drugs on 1999 and also established the ICH Q4B for evaluating for inter-regional regulatory acceptance on 2003. ICH Q4B activities stopped to work on 2011. PDG has the Working Procedures from Stage 1 to Stage 6; Stage 1 is the Identification of monograph, Stage 2 is its Investigation, Stage 3 is the Proposal for Expert Committee Review, Stage 4 is its official Inquiry, Stage 5 is its consensus of sign-off, and Stage 6 is its regional adoption and implementation. ICH nominated 15 general chapters on the program of ICH Q6A. When having discontinued the ICH Q4B on 2011, ICH adopted 14 general chapters except “color” on Pharmacopoeia.

PDG Tokyo meeting was hosted by JP in Tokyo, Japan, 30 June – 1 July, 2015. PDG selected 36 general chapters and 62 excipient's monographs. At present, 29 of the 36 General Chapters and 48 of the 62 excipient monographs on the current work programme have been harmonised. Sign-offs at this meeting included a revised monograph on “Povidone” in order to refine conditions for impurity testing of monomers (1- vinyl-2-pyrrolidone and 2-pyrrolidone) and to add identity testing by infrared spectroscopy as a harmonised attribute. In-depth discussions on a number of additional items currently on the work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off. With regard to “Chromatography chapter”, as a follow-up from recent PDG decisions on PDG process improvement, a teleconference with experts from the 3 regions had taken place in May and allowing significant progress to be made in the resolution of major sticking points. The coordinating pharmacopoeia will work on the resolution of a number of other items with the aim of finalising a Stage 4 draft for

public inquiry for the next PDG meeting. With regard to “Copovidone”, the coordinating pharmacopoeia will send out a draft for public consultation in July for the three pharmacopoeias to publish according to their respective schedules. The three pharmacopoeias exchanged information on their respective approaches for the implementation of the ICH Q3D guideline. In addition, PDG confirmed their commitment to harmonise the general chapter on testing procedures for elemental impurities.



**Jiasheng Tu, Ph.D.**

**USP Affiliation:**

Member, USP Excipient Monographs 2 Expert Committee

Professor

China Pharmaceutical University

Nanjing, China

Jiasheng Tu is the professor of pharmaceutics of China Pharmaceutical University, a supervisor of doctorate students. Dr. Tu has also served as the deputy chair of CHP pharmaceutical excipient committee, an expert committee member of CHP, an expert committee member of pharmaceutical excipient of USP, consultant of CDE of CFDA, a reviewer of national award of China, co-editor of Pharmaceutical Biotechnologies.

Dr. Tu graduated from Beijing Medical University. He was awarded Ph.D. of pharmaceutics in China Pharmaceutical University at 1992 and did postdoctoral researches in University of the Pacific, CA, during 2001-2003. Dr. Tu also served as joint-professor in University of the University and Jiangnan University in Wuxi, China.

---

**Steering Committee Member**

**Moderator**

Roundtable Discussion /Q & A (30 min) – Challenges and Opportunities for Harmonization, Update and Development of Excipient Specifications  
Tuesday, November 17, 2015, 4:30 – 5:00 p.m.

Parallel Breakout Sessions: Rationalization of Terminology used in the manufacturing of Biologics, including Drug Substance (upstream/downstream processing) and Drug Product (final formulations) aspects. To discuss/understand when compendial grade materials are necessary in the manufacture of Biologics. Parallel breakout sessions will explore and report back on learnings relating to the use of the current terminology and provide recommendations/path forward.  
Wednesday, November 18, 2015, 2:00 – 3:30 p.m.



**Katherine Ulman**

Associate Scientist  
Global Regulatory Compliance Manager  
Dow Corning Healthcare  
Midland, MI, USA

Katherine Ulman has been employed with Dow Corning Corporation for 40 years. She is currently a global regulatory compliance manager for Dow Corning Healthcare, as well as a Dow Corning associate scientist. She has worked in the development and characterization of pharmaceutical excipient and medical device raw materials/components for nearly 27 years. She is a member of the ACS, AAPS, and CRS and vice chair of Science and Regulatory Policy for IPEC-Americas. She has published and presented several papers in her field as well as developed and taught courses in Organosilicon Polymer Chemistry and Technology. Ulman earned her Bachelor of Science degree in chemistry from the South Dakota School of Mines and Technology in 1976.

---

**Presentation Abstract**

Presentation 1: FDA /OPQ IID Issues and Potential Resolutions  
Tuesday, November 17, 2015, 9:15 – 9:45 a.m.

The International Pharmaceutical Excipients Council of the Americas (IPEC-Americas) is an industry association that develops, implements, and promotes global use of appropriate quality, safety, and functionality standards for pharmaceutical excipients and delivery systems.

FDA created a working group with IPEC-Americas, including a representative from GPhA to address IID issues. This group has been meeting quarterly with members of the FDA IID Excipient Working Group (EWG) since they first formed in the fall of 2011.

Although the Agency has resolved several historical concerns/issues raised by IPEC-Americas and GPhA, including but not limited to IID content and use, the team continues to work with the Agency as they strive to re-design and maintain IID information while enhancing the utility and usability of the database.

This talk is intended to provide an overview of discussion topics covered by the team, as well as highlight their current status and ongoing activities.



**Hong Wang, Ph.D.**

Senior Scientific Liaison, Excipients  
USP  
Rockville, MD, USA

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.

---

**Moderator**

Session 2: Challenges and Opportunities in Excipient Monograph Development and Update  
Tuesday, November 17, 2015, 1:00 – 2: 30 p.m.





**Y. John Wang, Ph.D.**

Principal Scientist  
Genentech  
San Francisco, CA, USA

Dr. Y. John Wang is a Fellow of American Association of Pharmaceutical Scientists (AAPS). He has been working over 11 years in the Late Stage Pharmaceutical Development at Genentech, a member of the Roche Group. He received his B.S. Pharmacy and, from the University of Michigan, Ph.D. in Pharmaceutical Chemistry. Prior to Genentech, he worked in the formulation department at Squibb, Ortho, Scios and Bayer. His areas of expertise are stability of drug product, autoclave cycle development, protein formulation and stabilizers, deamidation, oxidation of peptides and proteins. He authored or coauthored over 60 peer-reviewed articles, a number of book chapters and two PDA Technical Reports and co-edited two books titled Formulation, Characterization and Stability of Protein Drugs. He was a member of the Board of Directors of the Parenteral Drug Association and, in 1992, Chair of AAPS Biotec Section.

---

**Presentation Abstract**

Presentation 5: Drug Product Manufacturer's Perspective on the Use of Pharmaceutical Excipients in Biologics Finished Final Product / Formulation; Focusing on the Characterization of Surfactants  
Wednesday, November 18, 2015, 1:00 – 1:30 p.m.

Polysorbate 20 and 80, and poloxamer 188 are used extensively in drug products of biologics. Recently the instability of polysorbate has been noticed in development or market products. In some occasions, insoluble particles were observed. The compositions of polysorbate are much more complex than what are defined by pharmacopeia which includes only hydrocarbon chain length and number of POE. Variation in head group, sorbitol, sorbitan, or isosorbide, in order of esterification, mono, di-, tri-, or tetra-esters, and the presence of un-esterified head group (non-surfactant), were not described nor controlled. For polysorbate, new assay method may be developed. By using lipase to generate hydrolyzed polysorbate, all laurate polysorbate 20 was found not to produce insoluble particles. Based on this observation, composition of fatty acids in polysorbate 20 may be revised. We also propose to reduce the unsaturation specification to zero for poloxamer.



**Steven Wolfgang, Ph.D.**

**USP Affiliation:**

Government Liaison, USP Excipient Monographs 1 Expert Committee

Chemist

U.S. Food and Drug Administration (FDA)

Silver Spring, MD, USA

Dr. Wolfgang received his Ph.D. in Inorganic Chemistry from the City University of New York in 1983. He joined FDA in 2005 after spending 15 years as a technical support chemist for a manufacturer of APIs and excipients. Dr. Wolfgang started as a CMC reviewer for new drugs and moved over to the Office of Compliance in 2007. Dr. Wolfgang is an FDA liaison to the USP Excipient Expert Committee and to expert panels for the modernization of the Povidone and Talc monographs and remains active in research at FDA.

---

**Steering Committee Member**

**Presentation Abstract**

Presentation 5: FDA Perspective on Excipient Monograph Up-to-Date  
Tuesday, November 17, 2015, 1:00 – 1:30 p.m.

Abstract forthcoming.



**Susan Zuk, M.S.**

Lead Chemist

U.S. Food and Drug Administration (FDA)

Silver Spring, MD, USA

Susan holds a BS in Chemistry from Syracuse University and a MS in Biotechnology from Johns Hopkins University. During her 15 years with the FDA, she has served as Chemistry Reviewer, Team Leader and Acting Deputy Director in the Office of Generic Drugs and as Acting Branch Chief of the Division of Internal Policies and Procedures (DIPAP) in the OPQ Office of Policy for Pharmaceutical Quality (OPPQ). She is the current leader of the FDA CDER Excipient Working Group. In this role, she is responsible for overseeing the IID project. Susan has served on many FDA committees and working groups related to product safety and quality.

---

**Presentation Abstract**

Presentation 3: FDA CDER Inactive Ingredient Database: Goals and Progress

Tuesday, November 17, 2015, 10:40 – 11: 10 a.m.

The FDA Inactive Ingredient Database (IID) plays a central role in daily decisions made by FDA and the pharmaceutical industry. For FDA, the IID is referenced during all stages of the application process, from filing through chemistry, bioequivalence, toxicology, and clinical reviews of both generic and new drug product applications. It is used as the basis for acceptance of inactive ingredients in generic drug product formulations. For industry, the IID guides many product development decisions. This list, which provides the maximum approved level of each inactive ingredient per unit dose, dosage form and route of administration, is periodically updated as the FDA approves products containing new ingredients and higher levels of existing ingredients. But the IID in its present form has limitations. In this presentation, the progress of FDA's efforts to develop a better, more functional IID will be discussed. The presentation will also describe FDA's vision for the future of the IID.