
# Speaker Biographies & Abstracts (listed alphabetically)


**Frank Amorese, Jr.**
Senior Vice President, Animal Health
Flavine North America, Inc.
Closter, NJ

Frank is a 34 year veteran of the pharmaceutical industry. He is currently Senior Vice President, Animal Health at Flavine North America, Inc., a company representing small to medium sized API producers located in Europe and Asia. Flavine provides technical, regulatory, development and commercial distribution services to both the companies it represents and the human health and veterinary pharmaceutical drug product manufacturers.

Frank has spent the past 20 years working in the veterinary market. His primary responsibilities have been managing Asian supplier as well as US and Canada customers. Areas of focus have been in project management, business development, and establishing strategies for sales, marketing and new product and supplier selection. Especially with China, Frank has experienced the myriad of changes in this country during this period; from solely State owned factories to private enterprises, the shift in cultural changes, standards of living and the ongoing efforts toward environmental (clean air and water) improvements.

Frank holds a BSc degree in Animal Science from The Ohio State University's College of Agriculture. He lives in New Jersey with his wife, Linda, and a 1 year old calico cat, Lily. Frank and Linda have adult, twin daughters, Bianca, a pediatric nurse practitioner and Dana, a physician assistant that both live in NJ and work in NYC hospitals.

---

**Presentation**
*Drug Shortage/Economic Perspective*
Wednesday, July 18, 2018, 3:45 – 4:45 p.m.

The topic I will be covering is drug shortage caused by API. The scenarios discussed represent actual experiences related to various manufacturers my company represented in the past or at present time. Likewise, certain points I will address correspond to specific market situations that have occurred which I have become aware of during the 21 years I have been serving the veterinary pharmaceutical industry.

I hope that the results of the presentation will create a degree of awareness of the critical importance of API supply to the veterinary drug manufacturers, distributors, veterinarians, farmers and ranchers caring for their animals that provide for our animal based protein sources. Also as many of us are pet parents too, we want to be sure of the supply chain of a range of FDA approved, veterinary labeled drug products to treat our pets, beloved members of our respective families.

The bottom line benefit will be that veterinarians and animal caretakers have at their disposal the right medications in ample supply to provide to their clients. This will help maintain good health, preventing and curing diseases to avoid unnecessary pain and / or suffering.


**Kevin Cheng, Ph.D.**
Staff Fellow
U.S. Food & Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Kevin Cheng received his Ph.D. in synthetic organic chemistry from the University of Pennsylvania in 2013 and his B.S. in chemistry from the University of Buffalo in 2007. His research included developing novel zinc and palladium mediated reactions along with the synthesis of small molecules. Kevin has been a reviewer with the Division of Manufacturing Technologies (DMT) in FDA/CVM since 2016.

---

**Presentation**
*Selection of Active Pharmaceutical Ingredient (API) Starting Materials*
Wednesday, July 18, 2018, 1:00 – 1:45 p.m.

The selection of appropriate starting materials for the manufacture of an active pharmaceutical ingredient is an important part of manufacturing a quality drug. This presentation will use current guidance to explain the selection principles CVM considers when evaluating the appropriateness of proposed starting materials in fermentation, synthetic, and semisynthetic drug substance manufacturing processes.


**George B. Collins, Jr.**
Vice President, Manufacturing
Vanderbilt Chemicals LLC
Clarksville, TN

George's education includes a BS degree in Biochemistry from UCLA. He also served as an Equine Research Animal Attendant at Ft Collins, Colorado Veterinary Teaching Hospital before joining RT Vanderbilt in 1984.

George has been VP and Mgr for the Minerals Division at Vanderbilt Chemicals LLC since 1991. He coordinates and contributes to the various mining and production activities related to producing mineral excipients as Magnesium Aluminum Silicate NF.

On behalf of Vanderbilt Minerals LLC, George has attended IPEC-Americas meetings since 2010 and currently serves as Vice Chair Compendial Review Committee, Executive Committee, and also serves on USP General Notices Team.

George enjoys skiing, taking care of his family's horses, and reading a good mystery.

---

**Presentation**
*Quality and Safety of Inactive Ingredients Critical for Animal Health Drug Products*
Thursday, July 19, 2018, 11:00 a.m – 11:45 a.m.

This presentation will examine the basic principles of pharmaceutical excipients as the in-active ingredients used in medicines. We will describe how excipients are sourced and used in animal health drug products. We will provide an overview of IPEC-Americas (International Pharmaceutical Excipients Council) and how this Council provides leadership for the safe production and use of excipients.

Excipients will be studied to determine how these ingredients are different from APIs from a composition, manufacturing, and GMP perspective. While excipients are not pharmacologically active, they do provide critical functions for medicines.
Excipient perspectives from the USP and IPEC-Americas will be examined. Potential assistance and questions/issues are introduced.

We will see examples of where excipients are used in animal health drug products.
The presentation will provide examples of useful and free guides which are available from IPEC-Americas with a link and information for further contact.


**Elizabeth Pollina Cormier, Ph.D.**
Chemist
U.S. Food & Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Elizabeth Pollina Cormier, Ph.D. is a chemist at the US Food and Drug Administration's Center for Veterinary Medicine where she focuses on the evaluation of various quality aspects of drug manufacturing. Prior to joining FDA, Dr. Cormier received her bachelor's degree with honors in chemistry from Dartmouth College, during which time she conducted research at SUNY Stony Brook and Merck Research Laboratories and was a Howard Hughes Medical Institute Undergraduate Fellow. She received her Ph.D. in organic chemistry from the University of Pennsylvania, where she developed novel synthetic methods using samarium(II) iodide. Dr. Cormier is recognized as an expert in the regulation of active pharmaceutical ingredients, and has served on several FDA-wide committees involved in the development of Agency policies for Good Manufacturing Practices, contract manufacturing, and drug substances. With over twelve years at FDA, she has received numerous awards, including the FDA Centennial Honor Award, for her contributions to FDA and public health.

---

**Presentation**
*Using eSubmitter For Type II VMFs*
Wednesday, July 18, 2018, 9:15 – 10:00 a.m.

This presentation provides an overview of the electronic submission process of Type II Veterinary Master Files (VMFs) to the Center for Veterinary Medicine (CVM). The topics to be discussed include an overview of the electronic submission process, the registration process requirements, how to submit using eSubmitter, and the creation of new VMF via eSubmitter. This presentation will also demonstrate the Question-Based Review template for VMF submissions and examples for various VMF submission types.


**Alonza Cruse**
Director, OPQO
U.S. Food & Drug Administration, Office of Regulatory Affairs
Silver Spring, MD

Alonza Cruse is director of the Office of Pharmaceutical Quality Operations within the Office of Regulatory Affairs (ORA) in the Food and Drug Administration (FDA). His office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research and the Center for Veterinary Medicine. Additionally, Mr. Cruse is leading ORA's pharmaceutical collaboration efforts under our Program Alignment initiative.

From 2013 – 2015, Mr. Cruse served as the acting director of the Office of Medical Products & Tobacco Operations within ORA, overseeing activities such as implementation of the Generic Drug User Fee Amendments, of pharmacy compounding, and of the development of a new inspection protocols program.

Prior to that, Mr. Cruse was the director of the Los Angeles District Office, where his responsibilities included providing executive leadership to implement, manage and evaluate FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his Bachelor of Science degree in medical technology from York College (City University of New York).

---

**Presentation**
*Foreign Inspections – Compliance and Expectations*
Wednesday, July 18, 2018, 11:15 a.m. – 11:45 a.m.

A brief synopsis of some of ORA activities focusing on program alignment, inspections and the Concept of Operations.


**Jennifer Devine, J.D.**
Vice President, Global Legal Affairs
USP
Rockville, MD

Jennifer Devine is Vice President, Global Legal Affairs—Standards, for USP. She serves as legal counsel to the organization's global scientific and standards-setting activities. She provides legal and policy advice and representation to USP management and staff, and the Council of Experts, to help ensure the integrity of USP's standards and standard-setting processes.

Ms. Devine returns to USP after serving in several leadership roles at the United States Food and Drug Administration (FDA)--first in the Center for Drug Evaluation and Research's (CDER) Office of Compliance and then as Deputy Director, Associate Commissioner for Global Regulatory Operations and Policy. In these positions, Jennifer helped to shape and implement FDA's globalization strategy--providing direction and oversight as FDA worked to address the challenges of a global supply chain. Ms. Devine also spent a year at the Agency for Healthcare Research and Quality, where she helped to implement the Patient Safety and Quality Improvement Act. Prior to joining FDA, Ms. Devine spent ten years in USP's Office of General Counsel, working on a variety of scientific, regulatory, international, legislative, and patient-centered issues.

Ms. Devine earned her undergraduate degree at University of Maryland, College Park, and her Juris Doctorate from Widener University Delaware Law School. She also holds a Master of Laws (LL.M.) in International Law from Georgetown University Law Center.

---

**Presentation**
*USP to Present*
Thursday, July 19, 2018, 1:00 p.m. – 1:30 p.m.


**Trupti Dhami, Ph.D.**
Staff Fellow
U.S. Food & Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Dr. Trupti Dhami is currently a Review Chemist with the Division of Manufacturing Technologies at CVM. She holds a Ph.D. in Materials Chemistry from National Chemical Laboratory and Rensselaer Polytechnic Institute and was a Post-Doctoral Fellow with the Department of Chemical and Biomolecular Engineering at Johns Hopkins University. She has about 5 years of experience in the pharmaceutical/biotechnology sector. She also held Affiliate Faculty position with the Department of Chemistry and Biochemistry at Loyola University. She has authored several publications in the international journals in the field of analytical and materials chemistry.

---

**Presentation**
*Using eSubmitter For Type II VMFs*
Wednesday, July 18, 2018, 9:15 – 10:00 a.m.

This presentation provides an overview of the electronic submission process of Type II Veterinary Master Files (VMFs) to the Center for Veterinary Medicine (CVM). The topics to be discussed include an overview of the electronic submission process, the registration process requirements, how to submit using eSubmitter, and the creation of new VMF via eSubmitter. This presentation will also demonstrate the Question-Based Review template for VMF submissions and examples for various VMF submission types.


**Jason Dreabit, M.A.**
Chemist
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Jason Dreabit received his B.S. in Chemistry from Drexel University in 1996 and his M.A. in Chemistry from the University of Virginia in 1998. Prior to coming to the FDA, Jason was a medicinal chemist at GlaxoSmithKline Pharmaceuticals where he developed novel peptide deformylase inhibitors as antibacterial agents. Jason has been a reviewer of manufacturing information for animal drug applications at the Center for Veterinary Medicine, U.S. Food and Drug Administration in Rockville, MD since 2010. In addition to reviewing duties, Jason currently serves as the Acting Team Leader for the Drug Substance Matrix Team, within the Division of Manufacturing Technologies and serves as a government liaison to USP's General Chapters Chemical Analysis, Expert Committee.

---

**Presentation**
*Common Type II VMF Deficiencies*
Wednesday, July 18, 2018, 10:00 – 10:45 a.m.

Many FDA and international Guidances include recommendations on the chemistry, manufacturing, and control (CMC) information that could be included in Type II VMF applications; nevertheless, CVM still frequently issues certain comments. This presentation will include examples of commonly issued comments and provide examples of recommended responses and/or references to appropriate Guidances (e.g., FDA, VICH, ICH) or USP General Chapter(s). Comments regarding fermentation and synthetic manufacturing, characterization, specifications, control of drug substance, reference standards, stability, and labeling are covered.


**Scott Fontana, Ph.D.**
Management & Program Analyst
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Scott Fontana earned his Ph.D. in Chemistry from the University of Tennessee in 2005. He joined FDA's Center for Veterinary Medicine in February of 2005 as a chemistry reviewer with the Division of Manufacturing Technologies in the Office of New Animal Drug Evaluation (ONADE). In 2010 Scott transferred to a position on the newly formed Business Informatics team to help develop ONADE's electronic submission and review systems, including the development and deployment of eSubmitter templates for all pre-market submissions in March 2011. In 2014 Scott became the team leader of the Business Informatics team where he continues to support the development of eSubmitter templates as well as system enhancements to ONADE's electronic submission and review systems.

---

**Presentation**
*Using eSubmitter For Type II VMFs*
Wednesday, July 18, 2018, 9:15 – 10:00 a.m.

This presentation provides an overview of the electronic submission process of Type II Veterinary Master Files (VMFs) to the Center for Veterinary Medicine (CVM). The topics to be discussed include an overview of the electronic submission process, the registration process requirements, how to submit using eSubmitter, and the creation of new VMF via eSubmitter. This presentation will also demonstrate the Question-Based Review template for VMF submissions and examples for various VMF submission types.


**Herschel Gaddy, Ph.D.**
President and CEO
Gaddy & Associates
St. Joseph, MO

Herschel J. Gaddy is a Ph.D. prepared biochemist who amassed a 20-year corporate career with ever-increasing responsibilities for the manufacturing, QA/QC, pharmaceutical technology, research and development and U.S. FDA Regulatory Affairs departments of various veterinary pharmaceutical manufacturing companies, whereby his tenure concluded as the Vice President of Pharmaceutical Development.

In December of 1995, Dr. Gaddy founded a pharmaceutical technology and U.S. FDA Regulatory Affairs consulting firm known as Herschel J. Gaddy & Associates. Dr. Gaddy is the President & CEO of Gaddy & Associates, and he not only serves as the U.S. FDA Regulatory Affairs Agent, but also provides pharmaceutical technology professional consulting services to numerous companies located throughout Europe, Asia, Canada, Mexico and the U.S.

Dr. Gaddy has provided leadership and his pharmaceutical technology and U.S. FDA Regulatory Affairs skill sets to guide a number of troubled and start-up human and veterinary pharmaceutical manufacturers to current Good Manufacturing Practices (cGMP) compliance. Also, Dr. Gaddy has used the above referenced skill sets to engineer hundreds of New Animal Drug Application (NADA), Abbreviated New Animal Drug Application (ANADA) and Supplemental NADA and ANADA product registration approvals at the Center for Veterinary Medicine at the U.S. Food and Drug Administration (CVM/FDA) during his corporate and consulting career.

Meanwhile, Dr. Gaddy has represented the holders of dozens of Drug Master File (DMF) and Veterinary Master File (VMF) product registrations as their US. FDA Regulatory Affairs Agent and pharmaceutical technology consultant, whereby the DMF/VMF product registrations were individually approved by the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (CDER/FDA) and CVM/FDA for use in sponsored New Drug Application and Abbreviated New Drug Application (NDA/ANDA) and NADA/ANADA product registrations.

Dr. Gaddy has been an associate member of the Generic Animal Drug Alliance for many years, where he currently serves as the Treasurer of GADA.

---

**Presentation**
*Fundamental Principles of Developing and Maintaining Veterinary Master Files within cGMP Compliance for API Manufacturers*
Thursday, July 19, 2018, 9:00 – 9:45 a.m.

This presentation explores the fundamental facility, equipment, analytical development and validation, ancillary support services, documentation and personnel requirements for the development and maintenance of Veterinary Master File (VMF) registrations for active pharmaceutical ingredients (APIs) within compliance of current Good Manufacturing Practices (cGMP) to be submitted and held on file at the Center for Veterinary Medicine at the U.S. Food and Drug Administration (CVM/FDA).


**Susan Homire, DVM**
Veterinary Medical Officer
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Dr. Homire is a veterinary medical officer on the Medical Review Team in CVM's Office of Surveillance and Compliance, Division of Surveillance. She has 19 years of varied FDA experien including 10 years at CVM, and currently provides scientific, medical and regulatory support for enforcement actions related to unapproved and compounded animal drugs and conducts evaluati of animal drug shortage situations and medically necessary veterinary product determinations. Dr Homire received her DVM from the University of Missouri-Columbia College of Veterinary Medicin

---

**Presentation**
*Drug Shortages and Medically Necessary Veterinary Products*
Wednesday, July 18, 2018, 3:00 – 3:45 p.m.

CVM's Animal Drug Shortage Management process focuses on actual or potential shortages of FDA-approved animal drug products that could significantly affect public and/or animal health. When appropriate and feasible, CVM attempts to prevent or alleviate shortages of medically necessary veterinary products (MNVPs) by, for example, working with industry to resolve manufacturing issues leading to the shortage; encouraging manufacturers of similar or alternative products to increase production; prioritizing review of pending applications for products that could alleviate the shortage; or temporarily exercising enforcement discretion over the importation of foreign-approved products or distribution of otherwise non-compliant products until the approved product is again available.


**Greg Hunter, Ph.D.**
Chemist
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Greg Hunter received his B.S. in Pharmacy in 1985 and Ph.D. in Biochemistry from the University of Kansas in 1997. Before coming to FDA, Greg was a pharmacist in the retail and hospital settings. Greg has been a reviewer of manufacturing information for animal drug applications at the Center for Veterinary Medicine, U.S. Food and Drug Administration in Rockville, MD since 2001. In addition to reviewing duties, Greg currently serves as a government liaison to USP's Chemical Medicines 3 monograph committee and maintains the content for CVM's Veterinary Master File website.

---

**Presentations**

*Common Type II VMF Deficiencies*
Wednesday, July 18, 2018, 10:00 – 10:45 a.m.

Many FDA and international Guidances include recommendations on the chemistry, manufacturing, and control (CMC) information that could be included in Type II VMF applications; nevertheless, CVM still frequently issues certain comments. This presentation will include examples of commonly issued comments and provide examples of recommended responses and/or references to appropriate Guidances (e.g., FDA, VICH, ICH) or USP General Chapter(s). Comments regarding fermentation and synthetic manufacturing, characterization, specifications, control of drug substance, reference standards, stability, and labeling are covered.

*CVM's VMF Website*
Wednesday, July 18, 2018, 11:00 – 11:15 a.m.

The Center for Veterinary Medicine (CVM) maintains a public website for Veterinary Master Files (VMFs). The site identifies VMF holdings at CVM as well as information about the content and submission of the files. We will explain the features of this page.


**Frank Jellen, Ph.D.**
Regulatory Affairs
Excella
Feucht, Germany

Frank Jellen is an organic chemist by education and started its career in pharmaceutical industry in R&D and production before changing his responsibilities to regulatory affairs for drug substances, now counting more than 15 year experience in this specific field for all kind of product registrations and markets worldwide including human as well as veterinary drugs. Since 2008 he oversees regulatory affairs drug substance activities of Fareva for in total four API facilities located in Europe, France and Germany. These sites have various types of drug substance activities such as chemical production of sterile and non-sterile APIs for human and veterinary use including physical operations such as milling and micronisation.

Aside its main responsibilities for drug substance regulatory affairs, he is very much involved and experienced in all further drug substance related processes such as supply chain, quality control, chemical production, change and deviation handling, complaints, quality contracts and quality management, sales and marketing, customer support for high potent APIs, sterile APIs, Generics, NCIs, clinical studies, furthermore customer and HA inspections, transfer activities, etc.

Based on his broad experience he collected in the field of pharmaceutical industry, he follows a very practical and scientific approach driven by the pretension to continuously guarantee a safe supply as well as safe drug product for human and animal patients. As a consequence and due to further increasing discrepancies between practice and regulatory requirements worldwide, he is very much engaged to establish and practice a reasonable handling of regulatory and quality procedures necessary for pharmaceutical products on the market. Along with his daily work, he is further engaged to closely cooperate with several Pharmacopoeias such as EP, USP, JP, etc and aside his obligations with Fareva, he recently was announced to join the EDQM commission for Group 10B - Organic chemistry - Synthetic semi-synthetic products as a representative from industry.

---

**Presentation**
*Supply Chain and Regulatory Requirements – An API Manufacturer's Point of View*
Wednesday, July 18, 2018, 3:45 – 4:45 p.m.

Supply Chain is one of many other aspects of Pharmaceutical supply of drug products for patients (human and animal) worldwide. Like others, Supply Chain is very important as there are many risks in Product quality as well as final supply to the market. Nevertheless, the aspect Supply Chain is not less or more important than other topics. We in fact have to understand all of these aspects as an equal brick on the way to a successful task in providing sufficient high quality drugs.

The topic Supply Chain nevertheless combines several important characteristics, quality, supply safety and costs. Furthermore, Supply Chain attributes are part of the registration of a Drug Product which significantly narrows down the flexibility to react on any arising issues. In times of global trade as well as referring back to the increased sharing of obligations within the entire Supply Chain for one and the same Product, the term Supply Chain has to be replaced by "Supply Network" much better describing the complexity we reached today. In this context, never forget the origin of each Supply Chain starting from natural resources such as oil, ore, water etc. There is a basic chemical heavy industry prior dipping into the pharmaceutical Supply Chain. This part of industry does not follow GMP but somewhere, there is an entrance into the pharmaceutical GMP world which makes it sometimes very


difficult especially in case of redefinition of starting material and very small molecules. While Health Authorities strictly requires compliance of the drug application to the manufacture, the flexibility of manufacturers in registering changes in supply chain is getting more and more complicate and lengthy. In case everything remains stable, the implemented regulatory systems work well but in case of changes, the system shows its weakness in missing flexibility and speed. The presentation gives an overview on actions which have to be currently taken in case of changes in supply chain but is also asking for improvements along with showing some possibilities to achieve this. Such improvements are even more necessary and important taking into account the overall physical supply chain situation for raw materials, starting materials and others sourced from China which is currently and in most cases the only sourcing possibility worldwide while China shuts down thousands of chemical facilities thereby significantly impacting the worldwide supply chain safety.

The presentation includes a message for Health Authorities, Industry and all other parties involved and obliged in supplying human and animal patients with high quality drugs to take the freedom putting our implemented strategy and systems in question whether we are on the right way or whether we have to change our strategy to be prepared for future challenges, not only related to supply chain topics.


**Michael Kerrigan, Ph.D.**
Chemist
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Originally from West Chester, PA, Mike graduated from Saint Joseph's University, Philadelphia, PA, in 2003 with a B.S. in Chemistry. He then moved across town to study organic and organometallic chemistry at the University of Pennsylvania under the supervision of Prof. Patrick Walsh. His thesis was titled "One-Pot Multicomponent Coupling Methods for the Synthesis of Chiral (Z)-Trisubstituted Allylic Alcohols and a Novel Addition/Oxidative Rearrangement in the Synthesis of 2-Substituted-3-Furaldehydes." After receiving a Ph.D. in 2008, he began his career at FDA as a chemistry, manufacturing, and controls (CMC) reviewer on the Chemotherapeutics Team (HFV-143) within the Division of Manufacturing Technologies (DMT).

Since joining DMT, Mike has primarily worked on the review of pioneer oral dosage forms and drug substance manufacturing information found in Type II DMFs and VMFs. Over the past 9 years, he has regularly served as the acting Master File Group I leader.

---

**Presentation**
*Selection of Active Pharmaceutical Ingredient (API) Starting Materials*
Wednesday, July 18, 2018, 1:00 – 1:45 p.m.

The selection of appropriate starting materials for the manufacture of an active pharmaceutical ingredient is an important part of manufacturing a quality drug. This presentation will use current guidance to explain the selection principles CVM considers when evaluating the appropriateness of proposed starting materials in fermentation, synthetic, and semisynthetic drug substance manufacturing processes.


**Anna Kooser, Ph.D.**
Staff Fellow
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Anna Kooser earned her B.S. in Biology and Music from Indiana University, Bloomington, and Ph.D. in Human Genetics and Molecular Biology from Johns Hopkins University School of Medicine. She has been a reviewer of chemistry, manufacturing, and control information at the Center for Veterinary Medicine (CVM) at FDA since 2016. At CVM, Anna reviews Type II Master Files and the generic versions of Type A Medicated Articles and Soluble Powders. Anna also serves as a Government Liaison to USP for the *Chemical Medicines Monographs 1* Expert Committee.

---

**Presentation**
*Selection of Active Pharmaceutical Ingredient (API) Starting Materials*
Wednesday, July 18, 2018, 1:00 – 1:45 p.m.

The selection of appropriate starting materials for the manufacture of an active pharmaceutical ingredient is an important part of manufacturing a quality drug. This presentation will use current guidance to explain the selection principles CVM considers when evaluating the appropriateness of proposed starting materials in fermentation, synthetic, and semisynthetic drug substance manufacturing processes.


**Doreen McDonald**
Director, Reference Standard Plan & Management
USP
Rockville, MD

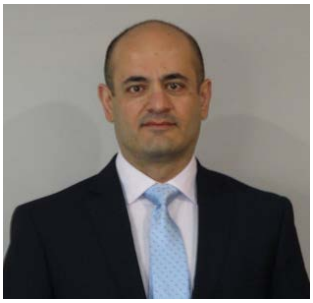
Doreen McDonald has nearly 20 years of experience working at USP in the Reference Standards and Strategic Marketing and Program Operations areas. After several years managing RS Procurement and Planning, she joined what is now USP's Global Strategic Customer Development team where she worked to improve and develop relationships between USP and our customers. She returned to Global Laboratory Operations in late 2016 to lead the newly established Reference Standards Planning and Management group.

Prior to joining USP, Ms. McDonald ran a temporary scientific staffing agency, developed and validated HPLC methods at a specialty chemicals company, and taught high school chemistry. She holds a bachelor's degree in Chemistry, Secondary Education.

---

**Presentation**
*USP Reference Standards*
Thursday, July 19, 2018, 3:15 – 4:00 p.m.

USP Reference Standards are integral to compliance with USP compendial standards. This presentation will provide an overview of USP Reference Standards: regulatory significance, development process, proper use, and future developments.

**Sohail Mosaddegh**
Senior U.S. Regulatory Affairs Manager
USP
Rockville, MD

---

**Presentation**
*CVM Interaction with USP*
Thursday, July 19, 2018, 1:30 – 2:15 p.m.


**Sarai Obando, Ph.D.**

U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Sarai Obando obtained her Ph.D. in Chemistry from Georgetown University. After graduate school, she joined FDA CVM in the Fall of 2008. Sarai is a reviewer on Generic Team II, within the Division of Manufacturing Technologies. Team II reviews solid oral dosage forms and topical products, as well as API master files and facility inspection reports. In addition to review work, Sarai is a government liaison on the USP CHM3 since January 2017.

---

**Presentation**
*CVM Interaction with USP*
Thursday, July 19, 2018, 1:30 – 2:15 p.m.

This talk will provide a summary of the collaboration between CVM and USP. The role and responsibility of the government liaisons, within expert committees and panels, will be explained. In addition, the talk will address how the CHM1 and CHM3 government liaisons monitor the PF for potential impact to animal drug products.


**Renée Pietsch, Ph.D.**
Staff Fellow
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Renée Pietsch received her B.S. in biology in 2009 from Liberty University, her M.S. in biomedical engineering in 2012 from Mississippi State University, and her Ph.D. in biological sciences in 2016 from Virginia Tech. In her masters, she studied the mechanical properties of muscle tissue. Her Ph.D. research focused on the aerosolization of microorganisms from aquatic systems. In 2016, Renée started working at the Center for Veterinary Medicine, U.S. Food and Drug Administration in Rockville, MD. She reviews the manufacturing information for generic animal drug applications as well as drug substance information.

---

**Presentation**
*Common Type II VMF Deficiencies*
Wednesday, July 18, 2018, 10:00 – 10:45 a.m.

Many FDA and international Guidances include recommendations on the chemistry, manufacturing, and control (CMC) information that could be included in Type II VMF applications; nevertheless, CVM still frequently issues certain comments. This presentation will include examples of commonly issued comments and provide examples of recommended responses and/or references to appropriate Guidances (e.g., FDA, VICH, ICH) or USP General Chapter(s). Comments regarding fermentation and synthetic manufacturing, characterization, specifications, control of drug substance, reference standards, stability, and labeling are covered.


**Morgan Puderbaugh, B.Sc.**
Senior Scientific Liaison, Chemical Medicines
USP
Rockville, MD

Mr. Puderbaugh joined USP in 2007 to support the development of public standards. In 2010, Mr. Puderbaugh became the primary scientific liaison responsible for veterinary monographs in USP-NF and has been actively working to promote USP to the Animal Health Industry. In 2015, Mr. Puderbaugh's scope widened to include antibiotics monograph development in addition to his role working with veterinary monographs.

Before joining USP, Mr. Puderbaugh worked for Biovail Technologies Ltd. in Chantilly, VA and then for Middlebrook Pharmaceuticals, Inc (formally Advancis Pharmaceutical Company) in Germantown, MD where he was involved in analytical method development and validation as well as quality control and stability testing for several drug substances, excipients and drug products.

Mr. Puderbaugh received a B.Sc. degree in Biology from Southwestern College in Winfield, KS.

---

**Presentation**
*USP/NF Monographs*
Thursday, July 19, 2018, 2:15 – 2:45 p.m.


**Nawab Siddiqui, MS., MPA**
Consumer Safety Officer
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

Nawab has over fifteen years of experience working at various positions at FDA. He is currently working in post-market drug compliance team. Nawab holds a M.S. in Medical Biology from Long Island University, New York and a M.P.A. Health Services Management from New York University.

---

**Presentation**
*Import Alerts: An Overview of the Import Process*
Thursday, July 19, 2018, 9:45 – 10:30 a.m.


**John Stanko, Ph.D.**
Chemist
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

John was raised in northeastern Pennsylvania. He attended Moravian College and graduated with a B.S. in Chemistry in 2003. After completing his Ph.D. in organic chemistry at Duke University under Dr. Steven W. Baldwin, John pursued post-graduate studies at Harvard Medical School and Massachusetts General Hospital under the direction of Drs. Peter Caravan and Bruce Fischl where he investigated synthesizing MR-sensitive fluorescent compounds for *ex vivo* neuroanatomical studies.

John began his professional career working as a patent scientist for a Midwest lawfirm before joining the FDA as a chemistry, manufacturing, and controls reviewer on the Generic II Team (HFV-146) within the Division of Manufacturing Technologies (DMT) in 2013. Over the past five years, John has reviewed generic drug applications covering all types of dosage forms (e.g., tablets, injectables, Type A medicated articles) as well as the drug substance manufacturing information found in Type II veterinary and drug master files (VMFs and DMFs).

---

**Presentation**
*Selection of Active Pharmaceutical Ingredient (API) Starting Materials*
Wednesday, July 18, 2018, 1:00 – 1:45 p.m.

The selection of appropriate starting materials for the manufacture of an active pharmaceutical ingredient is an important part of manufacturing a quality drug. This presentation will use current guidance to explain the selection principles CVM considers when evaluating the appropriateness of proposed starting materials in fermentation, synthetic, and semisynthetic drug substance manufacturing processes.


**Frank (Trey) White, III, Ph.D.**
Senior Director, Strategic Marketing & Program Operations-Documentary Standards
USP
Rockville, MD

Frank (Trey) White joined USP 2 ½ years ago, and brings more than 25 years of diverse experience and expertise to his role as Senior Director, SMPO – Documentary Standards at USP.

Dr. White received his PhD in Molecular and Cell Biology from The Pennsylvania State University. His research focused on gene expression analysis of the human pathogen, JC virus.

He spent 10 years in the laboratory, developing PCR-based viral diagnostics and gene expression assays, and overseeing DNA sequence analysis projects. He transitioned from the laboratory to a bioinformatics role while at Berlex Biosciences, assisting researchers in analyzing their sequence and expression data, and implementing a number of bioinformatics tools for their use.

Transitioning to business roles in the informatics industry, his areas of responsibility have included strategy, marketing, communications, product development, and running an inside sales team. He has worked at a wide range of organizations ranging from small software companies developing sequence analysis software, to IBM, Ogilvy, and Booz Allen Hamilton. Most recently, he ran product marketing for multiple informatics software products at Elsevier.

His role at USP includes the development, coordination, and oversight of the strategy for the delivery of our documentary standards to customers and stakeholders through new platforms and business models.

---

**Presentation**
**USP-NF New Platform/Subscription Models**
Thursday, July 19, 2018, 4:00 – 4:45 p.m.


**Dillard Woody, Ph.D.**
Supervisory Biologist
U.S. Food and Drug Administration, Center for Veterinary Medicine
Silver Spring, MD

---

**Presentation**
*Import Alerts: An Overview of the Import Process*
Thursday, July 19, 2018, 9:45 – 10:30 a.m.


**Dimitrios Zarkadas Ph.D.**
Director, Engineering, API Technology & Portfolio Management
Merck
Rahway, NJ

Dimitrios Zarkadas is a Director in the API Technology & Portfolio Management group in Merck Animal Health. He is a Chemical Engineer by training holding a PhD degree from New Jersey Institute of Technology. He is also a PMP (Project Management Professional) from 2012. In his current role Dr. Zarkadas is responsible for all facets of commercialization of New Chemical Entities (NCEs) as well as lifecycle management of in-line APIs.
Dr. Zarkadas has 13 years of experience in API development and lifecycle management, 10 in human health and the last three in Animal Health. He was responsible for the commercialization of Boceprevir, a first-in-class HCV protease inhibitor and more recently for the launch of Grazoprevir, one of the two active pharmaceutical ingredients in the Zepatier® HCV treatment. Dr. Zarkadas is currently leading API late stage development for the Merck Animal Health R&D portfolio and lifecycle management activities for in-line products. He is also very active in a number of operational excellence initiatives. He led the design and implementation across Merck Animal Health of the NCE development roadmap, an integrated and systematic framework for developing NCEs from discovery to filing and launch. He was also instrumental in the formulation of the regulatory starting material suitability assessment best practices, which are the topic of his presentation in this workshop. He is the holder of 4 patents and authored a number of journal and conference papers in the area of small molecule development and chemical engineering in general.

---

**Presentation**
*Suitability Assessment of Regulatory Starting Materials (RSMs)*
Wednesday, July 18, 2018, 1:45 – 2:30 p.m.

Selection of regulatory starting material is one of the most important decisions in NCE (New Chemical Entity) development. It defines the GMP envelope and hence affects the overall API COGs, the scope of process and analytical development and the number of steps described in the regulatory filing. In addition, RSM pushback from the regulatory authorities can result in launch delays of up to 1-2 years depending on the severity of the situation. For in-line drug substances, RSM pushback can result in loss of revenue and share market with negative financial implications. Therefore, best practices and tools that can help development or lifecycle management teams in the designation of regulatory starting materials or the evaluation of RSM pushback risk and its successful mitigation when implementing post approval variations is of utmost importance.

In this presentation, the best practices and tools developed and implemented across Merck (Animal and Human Health) are presented. In the heart of this framework, the RSM suitability assessment tool provides a systematic and objective way to evaluate starting material in a number of different dimensions, which are important to regulators and may lead to RSM pushback. Examples of its implementation for NCEs and in-line active pharmaceutical ingredients (APIs) are provided to illustrate the application of the tool, its scoring criteria and the way API teams can use it to mitigate the identified risks and maximize the probability of success in interactions with the regulatory agencies. The workflows for RSM evaluation of NCEs and in-line APIs that complement the RSM suitability tool are also presented. The results from implementing this framework were very encouraging. The rejection rate for NCEs was reduced to zero from 20% and 50% for FDA and EMA respectively, while the limited number of post approval variations completed showed similar success for in-line APIs.