Final Agenda

DAY ONE: Wednesday, July 18, 2018

8:30 – 9:00 a.m. Registration & Coffee

9:00 – 9:15 a.m. Welcome and Opening Introduction
Ronald T. Piervincenzi, Ph.D., CEO, USP
Courtney Tallman, Program Planning Chair, GADA

9:15 – 10:00 a.m. Using eSubmitter For Type II VMFs
Scott Fontana, Ph.D, Center for Veterinary Medicine, FDA
Elizabeth Pollina Cormier, Ph.D., Center for Veterinary Medicine, FDA
Trupti Dhami, Ph.D., Center for Veterinary Medicine, FDA

10:00 – 10:45 a.m. Common Type II VMF Deficiencies
Jason Dreabit, M.A., Center for Veterinary Medicine, FDA
Greg Hunter, Ph.D., Center for Veterinary Medicine, FDA
Renée Pietsch, Ph.D., Center for Veterinary Medicine, FDA

10:45 – 11:00 a.m. Morning Break

11:00 – 11:15 a.m. CVM’s VMF Website
Greg Hunter, Ph.D., Center for Veterinary Medicine, FDA

11:15 – 11:45 a.m. Foreign Inspections – Compliance and Expectations
Alonza Cruse, Office of Regulatory Affairs, FDA

11:45 – 12:00 p.m. Q&A/ Expert Panel Discussion
Moderated by Michael Kerrigan, Ph.D., CVM, FDA

12:00 – 1:00 p.m. Lunch

1:00 – 1:45 p.m. Selection of Active Pharmaceutical Ingredient (API) Starting Materials
Michael Kerrigan, Ph.D., Center for Veterinary Medicine, FDA
Kevin Cheng, Ph.D., Center for Veterinary Medicine, FDA
Anna Kooser, Ph.D., Center for Veterinary Medicine, FDA
John Stanko, Ph.D., Center for Veterinary Medicine, FDA
1:45 – 2:30 p.m.  
Suitability Assessment of Regulatory Starting Materials (RSMs)  
Dimitrios Zarkadas, Ph.D, Director, Engineering, API Technology & Portfolio Management, Merck

2:30 – 2:45 p.m.  
Q&A/ Expert Panel Discussion  
Moderated by Brian Wachter, MBA, Boehringer-Ingelheim

2:45 – 3:00 p.m.  
Afternoon Break

3:00 – 3:45 p.m.  
Drug Shortages and Medically Necessary Veterinary Products  
Susan Homire, DVM, Center for Veterinary Medicine, FDA

3:45 – 4:45 p.m.  
Supply Chain and Regulatory Requirements – An API Manufacturer’s Point of View  
Frank Jellen, Ph.D., Regulatory Affairs, Excella

Drug Shortage / Economic Perspective  
Frank Amorese, Senior Vice President, Animal Health, Flavine North America Inc.

4:45 – 5:00 p.m.  
Q&A/ Expert Panel Discussion  
Moderated by Brian Wachter, MBA, Boehringer-Ingelheim

5:00 p.m.  
Day One Workshop Adjournment

5:00 – 6:00 p.m.  
Networking Reception  
Sponsored by Generic Animal Drug Alliance (GADA)
DAY TWO: Thursday, July 19, 2018

8:30 – 9:00 a.m. Registration & Coffee

Opening Introduction
Courtney Tallman, Program Chair, GADA

9:00 – 9:45 a.m. Fundamental Principles of Developing and Maintaining Veterinary Master Files within cGMP Compliance for API Manufacturers
Herschel Gaddy, Ph.D., President and CEO, Gaddy & Associates

9:45 – 10:30 a.m. Import Alerts: An Overview of the Import Process
Dillard Woody, Center for Veterinary Medicine, FDA
Nawab Siddiqui, MS, MPA, Center for Veterinary Medicine, FDA

10:30 – 10:45 a.m. Q&A/ Expert Panel Discussion
Moderated by Stephanie Batliner, Bimeda Inc.

10:45 – 11:00 a.m. Morning Break

11:00 – 11:45 a.m. Quality and Safety of Inactive Ingredients Critical for Animal Health Drug Products
George B. Collins, Jr., Vice President, Manufacturing, Vanderbilt Chemicals LLC

11:45 a.m. – 12:00 p.m. Q&A/ Expert Panel Discussion
Moderated by Stephanie Batliner, Bimeda Inc.

12:00 – 1:00 p.m. Lunch

1:00 – 1:30 p.m. USP to Present
Jennifer Devine, J.D., Vice President, Global Legal Affairs, USP

1:30 – 2:15 p.m. CVM Interaction with USP
Sohail Mosaddegh, Senior U.S. Regulatory Affairs Manager, USP
Sarai Obando, Ph.D., Center for Veterinary Medicine, FDA

2:15 – 2:45 p.m. USP/NF Monographs
Morgan Puderbaugh, Senior Scientific Liaison-Chemical Medicines, USP

2:45 – 3:00 p.m. Q&A/ Expert Panel Discussion
Moderated by Morgan Puderbaugh, USP
3:00 – 3:15 p.m.  Afternoon Break

3:15 – 4:00 p.m.  USP Reference Standards
Doreen McDonald, Director, Reference Standards Planning and Management, USP

4:00 – 4:45 p.m.  USP-NF New Platform/Subscription Models
Frank (Trey) White, III, Ph.D., Senior Director, Strategic Marketing & Program Operations-Documentary Standards, USP

4:45 – 5:00 p.m.  Q&A/ Expert Panel Discussion
Moderated by Morgan Puderbaugh, USP

5:00 p.m.  Day Two Workshop Adjournment