USP Workshops

A focus on the science of veterinary drugs

Understanding Veterinary Active Pharmaceutical Ingredients (APIs): A Guide to Navigating Regulatory and Pharmacopeial Standards—July 18–July 19, 2018

GADA *Co-sponsored by:* **Generic Animal Drug Alliance (GADA)**

Draft Agenda

(as of June 4, 2018)

DAY ONE: Wednesday, July 18, 2018

8:30 – 9:00 a.m.	**Registration & Coffee**
9:00 – 9:15 a.m.	**Welcome and Opening Introduction** Ron Piervincenzi, Ph.D., *CEO, USP* Courtney Tallman, *Program Planning Chair, GADA*
9:15 – 10:00 a.m.	**Components and Maintenance of Type II VMFs Coupled with Practical issues with eSubmitter in VMF Submissions** Scott Fontana, Ph.D, *Center for Veterinary Medicine, FDA* Elizabeth Cormier, Ph.D., *Center for Veterinary Medicine, FDA* Trupti Dhami, Ph.D., *Center for Veterinary Medicine, FDA*
10:00 – 10:45 a.m.	**Top 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 Updates, VMF's** 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
12:00 – 1:00 p.m.	**Lunch**
1:00 – 1:45 p.m.	**Suitability Assessment of Regulatory Starting Materials (RSMs)** Dimitrios Zarkadas, Ph.D, *Director, Engineering, API Technology & Portfolio Management, Merck*

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1:45 – 2:30 p.m.	**Starting Materials and Critical Intermediates (Regulatory Issues and Master File Requirements)** 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*
2:30 – 3:15 p.m.	**Medically Necessary API's, Drug Products and Drug Shortages** Susan Homire, Ph.D., *Center for Veterinary Medicine, FDA*
3:15 – 3:30 p.m.	**Q&A/ Expert Panel Discussion,** Moderated by Brian Wachter, MBA
3:30 – 3:45 p.m.	**Afternoon Break**
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* **Economic Impact Drug Shortages** 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
5:00 p.m.	**Day One Workshop Adjournment**
5:00 – 6:00 p.m.	**Networking Reception** Sponsored by Generic Animal Drug Alliance (GADA)

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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** Dillard Woody, Ph.D., *Center for Veterinary Medicine, FDA* Nawab Siddiqui, Ph.D., *Center for Veterinary Medicine, FDA*
10:30 – 10:45 a.m.	**Q&A/ Expert Panel Discussion,** Moderated by Stephanie Batliner
10:45 – 11:00 a.m.	**Morning Break**
11:00 – 11:45 a.m.	**Quality and Safety of Inactive Ingredients Critical for Drug Products** George Collins, *Vice President Manufacturing, Vanderbilt Chemical*
11:45 a.m. – 12:00 p.m.	**Q&A/ Expert Panel Discussion,** Moderated by Stephanie Batliner
12:00 – 1:00 p.m.	**Lunch**
1:00 – 1:30p.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
3:00 – 3:15 p.m.	**Afternoon Break**

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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
5:00 p.m.	**Day Two Workshop Adjournment**