

# 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



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



## **Draft Agenda** (as of June 4, 2018)

### **DAY ONE: Wednesday, July 18, 2018**

- |                           |   |
|---------------------------|---|
| <b>8:30 – 9:00 a.m.</b>   | <b>Registration &amp; Coffee</b>  |
| <b>9:00 – 9:15 a.m.</b>   | <b>Welcome and Opening Introduction</b><br>Ron Piervincenzi, Ph.D., <i>CEO, USP</i><br>Courtney Tallman, <i>Program Planning Chair, GADA</i>  |
| <b>9:15 – 10:00 a.m.</b>  | <b>Components and Maintenance of Type II VMFs Coupled with Practical issues with eSubmitter in VMF Submissions</b><br>Scott Fontana, Ph.D., <i>Center for Veterinary Medicine, FDA</i><br>Elizabeth Cormier, Ph.D., <i>Center for Veterinary Medicine, FDA</i><br>Trupti Dhami, Ph.D., <i>Center for Veterinary Medicine, FDA</i> |
| <b>10:00 – 10:45 a.m.</b> | <b>Top Type II VMF Deficiencies</b><br>Jason Dreabit, M.A., <i>Center for Veterinary Medicine, FDA</i><br>Greg Hunter, Ph.D., <i>Center for Veterinary Medicine, FDA</i><br>Renée Pietsch, Ph.D., <i>Center for Veterinary Medicine, FDA</i>  |
| <b>10:45 – 11:00 a.m.</b> | <b>Morning Break</b>  |
| <b>11:00 – 11:15 a.m.</b> | <b>CVM Updates, VMF's</b><br>Greg Hunter, Ph.D., <i>Center for Veterinary Medicine, FDA</i>   |
| <b>11:15 – 11:45 a.m.</b> | <b>Foreign Inspections – Compliance and Expectations</b><br>Alonza Cruse, <i>Office of Regulatory Affairs, FDA</i>  |
| <b>11:45 – 12:00 p.m.</b> | <b>Q&amp;A/ Expert Panel Discussion</b> , Moderated by Michael Kerrigan, Ph.D.  |
| <b>12:00 – 1:00 p.m.</b>  | <b>Lunch</b>  |
| <b>1:00 – 1:45 p.m.</b>   | <b>Suitability Assessment of Regulatory Starting Materials (RSMs)</b><br>Dimitrios Zarkadas, Ph.D., <i>Director, Engineering, API Technology &amp; Portfolio Management, Merck</i>  |

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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**  
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## DAY TWO: Thursday, July 19, 2018

<b>8:30 – 9:00 a.m.</b>	<b>Registration &amp; Coffee</b>
	<b>Opening Introduction</b> Courtney Tallman, <i>Program Chair, GADA</i>
<b>9:00 – 9:45 a.m.</b>	<b>Fundamental Principles of Developing and Maintaining Veterinary Master Files within cGMP Compliance for API Manufacturers</b> Herschel Gaddy, Ph.D., <i>President and CEO, Gaddy &amp; Associates</i>
<b>9:45 – 10:30 a.m.</b>	<b>Import Alerts</b> Dillard Woody, Ph.D., <i>Center for Veterinary Medicine, FDA</i> Nawab Siddiqui, Ph.D., <i>Center for Veterinary Medicine, FDA</i>
<b>10:30 – 10:45 a.m.</b>	<b>Q&amp;A/ Expert Panel Discussion</b> , Moderated by Stephanie Batliner
<b>10:45 – 11:00 a.m.</b>	<b>Morning Break</b>
<b>11:00 – 11:45 a.m.</b>	<b>Quality and Safety of Inactive Ingredients Critical for Drug Products</b> George Collins, <i>Vice President Manufacturing, Vanderbilt Chemical</i>
<b>11:45 a.m. – 12:00 p.m.</b>	<b>Q&amp;A/ Expert Panel Discussion</b> , Moderated by Stephanie Batliner
<b>12:00 – 1:00 p.m.</b>	<b>Lunch</b>
<b>1:00 – 1:30p.m.</b>	<b>USP to Present</b> Jennifer Devine, J.D., <i>Vice President, Global Legal Affairs, USP</i>
<b>1:30 – 2:15 p.m.</b>	<b>CVM Interaction with USP</b> Sohail Mosaddegh, <i>Senior U.S. Regulatory Affairs Manager, USP</i> Sarai Obando, Ph.D., <i>Center for Veterinary Medicine, FDA</i>
<b>2:15 – 2:45 p.m.</b>	<b>USP/NF Monographs</b> Morgan Puderbaugh, <i>Senior Scientific Liaison-Chemical Medicines, USP</i>
<b>2:45 – 3:00 p.m.</b>	<b>Q&amp;A/ Expert Panel Discussion</b> , Moderated by Morgan Puderbaugh
<b>3:00 – 3:15 p.m.</b>	<b>Afternoon Break</b>

## USP Workshops

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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**