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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<th>Time</th>
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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)  |
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 – 1:30 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

3:00 – 3:15 p.m.  **Afternoon Break**
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<td>3:15 – 4:00 p.m.</td>
<td>USP Reference Standards</td>
<td>Doreen McDonald, Director, Reference Standards Planning and Management, USP</td>
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<td>4:00 – 4:45 p.m.</td>
<td>USP-NF New Platform/Subscription Models</td>
<td>Frank (Trey) White, III, Ph.D., Senior Director, Strategic Marketing &amp; Program Operations-Documentary Standards, USP</td>
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