Workshop: Solubility Criteria for Veterinary Products
Co-sponsored by the American Academy of Veterinary Pharmacology and Therapeutics and USP

November 7–8, 2012
USP Headquarters, Rockville, MD

~ DRAFT AGENDA ~
(As of October 22, 2012 – Subject to Change)

Wednesday, November 7, 2012 (Day 1)

7:30 a.m. Registration and Continental Breakfast

8:30 a.m. Welcome and Introductory Remarks
Mario Gonzalez, Ph.D., Chair, USP Solubility for Veterinary Drugs Expert Panel; P’Kinetics International

8:45 a.m. The USP Revision Process
James De Muth, Ph.D., Chair, USP General Chapters–Dosage Forms Expert Committee; University of Wisconsin–Madison

9:15 a.m. Role of Expert Panels in USP and Comments Received
Margareth Marques, Ph.D., USP

9:45 a.m. Physico-chemical Basis of Drug Solubilization
Raafat Fahmy, Ph.D., U.S. Food and Drug Administration

10:15 a.m. Break

10:30 a.m. Influence of Drug Solubility on Formulation and Oral Drug Bioavailability
Marilyn Martinez, Ph.D., Government Liaison, USP Solubility for Veterinary Drugs Expert Panel; U.S. Food and Drug Administration

11:00 a.m. Influence of Drug Solubility on Formulation and Oral Drug Bioavailability (continued)
Marilyn Martinez, Ph.D.

11:30 a.m. Testing Drug Solubility: Methodological Considerations
Bryan Crist, Member, USP Solubility for Veterinary Drugs Expert Panel; Agilent Technologies

12:00 p.m. Q & A

12:30 p.m. Lunch

1:30 p.m. Solubility Criteria in Human Medicine and Its Application to Drug Development and Regulation
Alan Parr, Pharm.D., Ph.D., Member, USP Solubility for Veterinary Drugs Expert Panel; GlaxoSmithKline
**Wednesday, November 7, 2012 (continued…)**

2:00 p.m. Why We Cannot Simply Use Human Solubility Criteria in Veterinary Species
Marilyn Martinez, Ph.D.

2:30 p.m. Unique Physiological Attributes: Dog
Mark Papich, M.S., D.V.M., Member, USP Solubility for Veterinary Drugs Expert Panel; North Carolina State University

3:00 p.m. Break

3:30 p.m. Unique Physiological Attributes: Bovine
Mike Apley, D.V.M., Ph.D., DACVCP, Member, USP Solubility for Veterinary Drugs Expert Panel; Kansas State University

4:00 p.m. Discussion

5:00 p.m. Reception in Corridor of Volunteers

6:30 p.m. Adjourn for the day

**Thursday, November 8, 2012 (Day 2)**

7:30 a.m. Registration and Continental Breakfast

8:00 a.m. Potential Solubility Criteria
Moderator: Marilyn Martinez, Ph.D.
- Dog
- Discussion

9:15 a.m. Potential Solubility Criteria
Moderator: Marilyn Martinez, Ph.D.
- Bovine
- Discussion

10:30 a.m. Break

11:00 a.m. General Discussion
Moderator: Sanja Modric, D.V.M., Ph.D., Government Liaison, USP Solubility for Veterinary Drugs Expert Panel; U.S. Food and Drug Administration

12:00 p.m. Lunch

1:00 p.m. Presentation of Summaries/Attendee Comments
Moderator: Mario Gonzalez, Ph.D.
- Dog
- Bovine
- Discussion

3:00 p.m. Break

3:15 p.m. Closing Session/Summary/Next Steps

4:00 p.m. Workshop adjourns