USP WORKSHOP ON QUALITY ATTRIBUTES OF DRUG PRODUCTS APPLIED TO THE SKIN
September 21-22, 2015
USP Meetings Center, Rockville, MD USA

Preliminary Agenda

Updated September 16, 2015

DAY ONE: Monday, September 21, 2015

7:45 – 8:30 a.m.	**Registration & Coffee**
8:30 – 8:45 a.m.	**Welcome and Overview of the USP Process** James De Muth, Ph.D., R.Ph., *Chair, USP General Chapters–Dosage Forms Expert Committee*
8:45 – 9:30 a.m.	**Introduction into Transdermal Systems (TDS) Manufacturing** Patrick Mohr, Ph.D., *LTS Lohmann Therapie-Systeme AG, Germany*
9:30 – 10:15 a.m.	**Quality by design for TDS** Michael Houghton, *Member, USP General Chapters–Dosage Forms Expert Committee*
10:15 – 10:30 a.m.	**Break**
10:30 – 11:15 a.m.	**Particularities of TDS analytics** Michael Komenda, *LTS Lohmann Therapie-Systeme AG, Germany*
11:15 a.m. – 12:00 p.m.	**Procedural and Statistical Considerations for Measurement of Cold Flow in Transdermal Systems** Janelle Gunther, Ph.D., *Janssen Research and Development, LLC*
12:00 – 12:30 p.m.	**Panel Discussion**
12:30 – 1:30 p.m.	**Lunch**
1:30 – 2:15 p.m.	**Using Dynamic Shear to Test Adhesive Properties in Transdermal Systems** Janelle Gunther, Ph.D., *Janssen Research and Development, LLC*
2:15 – 3:00 p.m.	**Predictive Power of In Vitro Drug Release** Isadore Kanfer, Ph.D., *University of Toronto, Canada*
3:00 – 3:15 p.m.	**Break**
3:15 – 4:00 p.m.	**EMA Guideline on Quality of Transdermal Patches** Sean Jones, M.S., *Medicines & Healthcare Products Regulatory Agency (MHRA), United Kingdom*

4:00 – 4:45 p.m.	**Establishing High Quality Transdermal Products** Caroline Strasinger, Ph.D., *U.S. Food and Drug Administration*
4:45 – 5:15 p.m.	**Panel Discussion**
5:15 – 6:15 p.m.	**Networking Reception**

DAY TWO: Tuesday, September 22, 2015

7:45 – 8:30 a.m.	**Registration & Coffee**
8:30 – 9:05 a.m.	**Development and Manufacture of Semisolid Products** Serap Ozelkan, Ph.D., RAC, *Fougera Pharmaceuticals, Inc. – A Sandoz Company*
9:05 – 9:40 a.m.	**Quality by Design for Semisolid Products** Gregory Fieldson, Ph.D., *Mylan Technologies, Inc.*
9:40 – 10:15 a.m.	**Rheological Properties of Products Applied to the Skin** Ahmad Rahman, *Mylan Pharmaceuticals*
10:15 – 10:45 a.m.	**Break**
10:45 – 11:20 a.m.	**Uniformity in Containers 1** Paul Curry, Jr., *Member, USP General Chapters–Dosage Forms Expert Committee*
11:20 – 11:55 a.m.	**Uniformity in Containers 2** Steven Brennan, *Fougera Pharmaceuticals, Inc.*
11:55 a.m. – 12:30 p.m.	**Panel Discussion**
12:30 – 1:30 p.m.	**Lunch**
1:30 – 2:05 p.m.	**In Vitro Drug Release Testing of Patches** Holger Schnabel, Ph.D., *LTS Lohmann Therapie-Systeme AG, Germany*
2:05 – 2:40 p.m.	**Challenges in Developing Methodologies of In Vitro Percutaneous Absorption for Topically Applied Formulations** Theo Kapanadze, Ph.D., D.Sc., *Diteba, Canada*
2:40 – 3:10 p.m.	**Break**
3:10 – 3:40 p.m.	**Challenges in Developing Drug Release Methodologies for Topically Applied Formulations** Danna Mattocks, *Tergus Pharma*
3:40 – 4:10 p.m.	**Topical Drug Delivery: US Regulatory Perspectives from Biopharmaceutics and Related Disciplines** Tapash Ghosh, Ph.D., *USP Performance Test for Semisolid Dosage Forms Expert Panel Government Liaison (U.S. Food and Drug Administration)*

4:10 – 4:40 p.m.	**Characterizing Critical Quality Attributes for Topical Semisolid Dosage Forms** Sam Raney, Ph.D., *USP Performance Test for Semisolid Dosage Forms Expert Panel Government Liaison (U.S. Food and Drug Administration)*
4:40 – 5:10 p.m.	**Panel Discussion**
5:10 – 5:25 p.m.	**Closing Remarks & Wrap-Up** James De Muth, Ph.D., R.Ph., *Chair, USP General Chapters–Dosage Forms Expert Committee* *&* Michael Houghton, *Member, USP General Chapters–Dosage Forms Expert Committee*
5:25 p.m.	**Workshop Adjourns**