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