International Reference Standards Symposium
November 3-4, 2016
USP Meetings Center, Rockville, MD USA
Preliminary Agenda-- *Updated October 27, 2016*

DAY ONE: Thursday, November 3, 2016	
8:00 – 8:45 a.m.	**Registration**
8:45 – 9:00 a.m.	**Welcome by EDQM and USP** **Andrea Lodi and Jaap Venema**
9:00 – 10:45 a.m.	**Topic I – Characterization of Reference Standards** • USP Perspective – Steve Rau and Fabian Jameison, USP • Industry Perspective – Iffaaz Salahudeen, BMS • Allergens Reference Materials – Martin Chapman, INDOOR • Panel Q&A
10:45 – 11:15 a.m.	**Break**
11:15 – 12:45 p.m.	**Topic II –Traceability and Calibration Against Higher Order Standards** • European Pharmacopoeia Perspective – Andrea Lodi, EDQM • Industry Perspective – Anne Jespersen, NovoNordisk • Certification of Reference Standards – Dmytro Leontiev, Ukrainian Pharmacopeia • Panel Q&A
12:45 – 1:45 p.m.	**Lunch**
1:45 – 3:30 p.m.	**Topic III –Reference Standards for Impurities** • EDQM Perspective – Stefan Almeling, EDQM • USP Perspective – Ren-Hwa Yeh, USP • Industry Perspective – Marion King, Ipsen • Non-Compendial Reference Standards for Impurities – Christian Zeine, LGC • Panel Q&A
3:30-3:45 p.m.	**Break**
3:45 – 4:30 p.m.	**Panel Discussion**
4:30 -5:30 p.m.	**Reception and Poster Sessions**

DAY TWO: Friday November 4, 2016	
8:30 – 9:00 a.m.	**Plenary Session:** Role of Public Standards in Quality Assessment of Biologics – Tina Morris, USP
9:00 – 10:30 a.m.	**Topic IV- Reference Standards for Biologics** • Evolution of Potency Standards – Sandra Prior, NIBSC • Monoclonal Antibody Reference Material – Mike Tarlov, NIST • RS for Monoclonal Antibodies – Uma Sreenivasan, Cerilliant • Panel Q&A
11:00 a.m. – 12:30 p.m.	**Topic V - Best Practices in Material Management: Packaging, Storage, Inventory Management and Transportation** • USP Perspective – Andrea Iwanik, USP • Pharmaceutical Industry Best Practices – Teresa Bowlby, Lilly • Developing a Strategy for Shipping Temperature Sensitive Materials Internationally – Anthony Leone, World Courier • Panel Q&A
12:30 – 1:00 p.m.	**Topic VI – Regulatory Expectations** • Reference Standards: An Inspector's Viewpoint – Sotirios Paraschos, EDQM
1:00 – 1:45 p.m.	**Lunch**
1:45 -2: 15p.m.	**Evaluation**
2:15 – 3:15 p.m.	**Topic VI – Regulatory Expectations *(Continued)*** • Use of Reference Standards in Investigations – Bruce Harris FDA/ORA • Japan Regulatory Expectations – Hiroko Shibata, National Institute of Health Science • Panel Q&A
3:15 – 4:15 p.m.	**General Panel Discussion**
4:30	**Adjourn**