Joint USP-EDQM Symposium on Pharmaceutical Reference Standards

Hosted by United States Pharmacopeial Convention

12601 Twinbrook Pkwy., Rockville, MD 20852

Format: In-person and virtual

27 to 28-SEP-2023

PROGRAM

27-SEP-2023		
8:00 AM onwards	Registration	Participants
8:20 to 8:35 AM	Welcome	Fouad Atouf, USP Petra Dörr, EDQM, Council of Europe

Session 1: Role of RS in Medicinal Products Lifecycle Including Pre-clinical, Clinical, and Commercial **Moderator: Wes Workman, Workman Biotech Consultants, LLC**		
Time US EST	Topic	Speaker
8:35 to 9:10 AM	Reference Standards: Common Practices and Challenges	Ken Miller, BioMarin Pharmaceutical, Inc.
9:10 to 9:45 AM	Pharmaceutical Reference Standards for Early Phase Bioproduct Clinical Development – Industry Best Practices	Kim Dancheck, Eli Lilly
9:45 to 10:20 AM	Management of Biological Reference Materials to prevent potency drift	John Hogwood, MHRA
10:20 to 10:50 AM	Coffee Break	
10:50 to 11:25 AM	Expectations of Reference Standards and Materials for Biotechnology Products in Regulatory Submissions	Rong Wang, US-FDA
End of Session 1		

Session 2: Scientific aspects to be addressed in Characterization Moderator: Stefan Almeling, EDQM, Council of Europe		
11:25 to 12:00 PM	The Use of NMR and qNMR for the Characterization of Pharmacopeial Reference Standards	Matthias Weber, EDQM, Council of Europe
12:00 to 1:00 PM	**Lunch**	
1:00 to 1:35 PM	USP Standards and Tools to Support Multi-Attribute Method for Therapeutic Proteins	Li Jing, USP
1:35 to 2:10 PM	Predictive stability assessment of small molecule RS: case studies	Philippe Duret EDQM, Council of Europe
2:10 to 2:45 PM	Assessing the Continued Suitability of Use Small Molecules USP Reference Standards	Jeffrey Palombo, USP
2:45 to 3:20 PM	Stability Monitoring of Biological Reference Standards	Nadine Ritter, Global Biotech Experts, LLC
End of Session 2 and End of Day 1		
Reception On-site from 3:30 to 5:00pm		

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Session 3: Role of Compendial RS **Moderator: Ravi Reddy**		
8:30 to 9:05 AM	Use of compendial standards fin the USP-NF for Compliance	Deborah Biswas, USP
9:05 to 9:40 AM	Use of compendial standards for non-compendial purpose	Jason Starkey, Pfizer
9:40 to 10:15 AM	Standards and Analytical Reference Materials to support Residual Host Cell Protein Measurement in Biopharmaceuticals	Kevin Carrick, USP
10:15 to 10:40 AM	Coffee Break	
10:40 to 11:15 AM	Reference Standards in Ph.Eur. General Chapters	Stefan Almeling, EDQM, Council of Europe
11:15 to 11:55 AM	Secondary Standards – Considerations in Traceability to Pharmacopoeial Standards	Christian Zeine, USP Stefan Almeling, EDQM, Council of Europe

Session 4: Reference Standards and Regulatory Perspective Moderator: Seth Foltz, Eli Lilly		
11:55 to 12:30 PM	Impurity Reference standards expectations during dossier submission for marketing authorisation (MAA) submissions	Marcus Savsek, BfArM
12:30 to 1:30 PM	Lunch	
End of Session 4		

Session 5: Round table Discussion Breakout Session with USP/EDQM Moderator: Kevin Carrick		
1:30 to 2:30 PM	Q & A on Small Molecule Reference Standards	Ravi Reddy, USP Stefan Almeling, EDQM, Council of Europe
1:30 to 2:30 PM	Q & A on Biological reference standards	Kevin Carrick, USP Sylvie Jorajuria, EDQM, Council of Europe
2:30 to 3:00 PM	Report from breakout sessions Based on the discussions	
End of Session 5		

3:00 to 3:10 PM	Closing remarks	Fouad Atouf, USP Stefan Almeling EDQM, Council of Europe
End of IRSS		

25 Minutes Presentation and 10 minutes for Questions/Discussion

Note: Recorded sessions are planned to be provided for the benefit of virtual participants unable to stay the entire day due to time difference

For further information, please contact
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