Joint EDQM-USP Hybrid Symposium on Pharmaceutical Reference Standards

Hosted by the

European Directorate for the Quality of Medicines & HealthCare (EDQM),

Council of Europe

23-24 September 2026

TENTATIVE PROGRAMME *(subject to change)*

Day 1: 23 September 2026

8:00 - 9:00	*Participant Registration*	

Opening Session		
9:00 - 9:15	Welcome addresses	EDQM and USP Speaker

Session 1: Good Practices for the Establishment of Small Molecule Reference Standards		
9:15 - 10:00	Common presentation by EDQM & USP - Pharmacopeial Reference Standards: Principles, Challenges, and Practical Approaches	EDQM and USP Speaker
10:00 - 10:35	An industry perspective on reference materials for small molecules – case studies	Industry Speaker
10:35 - 11:00	*Coffee break*	
11:00 - 11:35	Best practices for establishing reference standards when no pharmacopoeial standard is available	Industry Speaker
11:35 - 12:10	Expectations of the regulator for marketing dossier / general expectations in an audit	Regulatory Speaker
12:10 - 13:15	*Lunch break*	

Session 2: Good Practices for the Establishment of Reference Standards for Biological Products		
13:15 - 13:50	USP Standards to support therapeutic mAbs	USP Speaker
13:50 - 14:35	Ph. Eur. approach to performance- and potency reference standards: insights from monoclonal antibody case studies	EDQM Speaker
14:35 - 15:10	General Principles for Reference Standards Life-Cycle Management – An Industry perspective	Industry Speaker
15:10 - 15:40	*Coffee break*	
15:40 - 16:15	Ensuring Quality and Consistency: An Industry Perspective on Reference Materials for Biopharmaceuticals	Industry Speaker
16:15 - 16:50	Reference materials for biologicals – an EU regulatory view	Regulatory Speaker
16:50 - 17:25	WHO International Standards for Biotherapeutics	Regulatory Speaker
	End of Day 1	

Day 2: 24 September 2026

Session 3: New Developments and Challenges related to Pharmaceutical Reference Standards		
8:30 - 9:05	Regulatory talk (FDA perspective)	Regulatory Speaker
9:05 - 9:40	Reference Standards for commercial and clinical ADC programs	Industry Speaker
9:40 - 10:15	Navigating the Analytical Road from mAbs to rAAV: Key differences, challenges, and value of Pharmaceutical Reference Standards	Industry Speaker
10:15 - 10:40	*Coffee Break*	
10:40 - 11:15	Total protein determination of biological standards	Industry Speaker
11:15 - 11:40	Digital Standards	USP Speaker
11:40 - 12:15	An industry perspective to manage E2E Reference Standard Implementation	Industry Speaker
12:15 -12:50	Use of Accelerated Stability Assessment Program (ASAP) approach in RS stability monitoring	EDQM Speaker
12:50 - 14:00	*Lunch break*	

Session 4: Q&A Sessions and Poster Award		
14:00 - 14:30	Q&A Session on 'Small molecular reference standards'	EDQM/USP
14:30 - 15:15	Q&A Session on 'Biological reference standards'	EDQM/USP
15:15 - 15:45	Poster Award Ceremony	Poster Pannel
15:45 - 16:15	Report summarising the key points and outcomes from the breakout session discussions.	

Closing Session		
16:15 - 16:30	**Closing remarks**	EDQM/USP speaker
End of the symposium		

Note: *Recorded sessions will be made available to support virtual participants who may not be able to attend the entire event due to time differences.*

For further information, please contact: events@edqm.eu