Agenda GMP-Training 2026

Inspecting PQS Maturity and the Use of Artificial Intelligence in Pharmaceutical Quality Systems

5-6 May 2026, Hotel Eden Palace, Montreux, Switzerland

Day 1: Tuesday, 5 May 2026

Time	Topics	Speakers
09:00	***Registration & Welcome Coffee***	
09:30	**Welcome address**	
	Introduction of the topic	**Barbara Herzog** Swissmedic
09:45	**Operationalizing ICH Q12** Global Experience, PQS Enablement and Lessons Learned	**Ingrid Markovic** Head of Global RA CMC Policy **Socrates Kyritsis** Cardio Renal Metabolic Area Head, GRA CMC Novartis Pharmaceuticals Corporation, USA
10:35	**ICH Q12:** Implementation in the EEA – Pilot Project and implications for inspections going forward	**Kevin O'Donnell** *(remote)* Market Compliance Manager HPRA Health Products Regulatory Authority, Ireland
11:00	***Coffee break***	
11:30	**ICH Q12:** Implementation in the EEA – Pilot Project and implications for inspections going forward (cont)	**Kevin O'Donnell** *(remote)*
12:00	**Introduction of AI and use of AI tools in the context of PQS** (industry point of view)	**Marcin Chojecki** Global AI Engineering Lead **Christian Stock** Site Quality Head F. Hoffmann-La Roche, Switzerland
13:00	Group Photograph	
13:15	***Lunch***	
14:30	**Current OOS inspection trends**	**Jay Jariwala** Founder and President Pharmasure LLC
15:10	**How to inspect OOT, OOX, Deviations and Management Review**	**Anna-Maria Kurzreiter** Inspector/Senior Expert AGES Austrian Agency for Health and Food Safety
15:50	***Coffee break***	
16:20	**How to inspect AI tools**	**Sina Berndl** GMDP Inspector, Swissmedic
17:00	**AI inspection technique**	**Jay Jariwala**
17:30	***End of day 1***	
18:30	***All participants are kindly invited for dinner*** ***Meeting at the Hotel du Grand Lac Excelsior*** *Rue de Bon-Port 27, Montreux*	

Day 2: Wednesday, 6 May 2026

Time	Topics	Workshop Moderators
09:00	**Workshops 1st run** *Examples from real inspections and lessons learned* - **Workshop 1: How to inspect PQS in the light of ICH Q12** - **Workshop 2: How to inspect AI in PQS** - **Workshop 3: How to inspect OOS, OOT, OOX**	**Ingrid Markovic, Kevin O'Donnell** *(remote)* **& Michael Zwitkovits** **Jay Jariwala & Sina Berndl** **Anna-Maria Kurzreiter**
10:15	*Coffee break*	
10.45	**Workshops 2nd run** *Examples from real inspections and lessons learned* - **Workshop 1: How to inspect PQS in the light of ICH Q12** - **Workshop 2: How to inspect AI in PQS** - **Workshop 3: How to inspect OOS, OOT, OOX**	**Ingrid Markovic, Kevin O'Donnell** *(remote)* **& Michael Zwitkovits** **Jay Jariwala & Sina Berndl** **Anna-Maria Kurzreiter**
12:00	*Lunch*	
13:30	**Workshops 3rd run** *Examples from real inspections and lessons learned* - **Workshop 1: How to inspect PQS in the light of ICH Q12** - **Workshop 2: How to inspect AI in PQS** - **Workshop 3: How to inspect OOS, OOT, OOX**	**Ingrid Markovic, Kevin O'Donnell** *(remote)* **& Michael Zwitkovits** **Jay Jariwala & Sina Berndl** **Anna-Maria Kurzreiter**
14:45	**The revision of ICH Q9 and the EU GMP Guides – key points for inspectors to consider**	**Kevin O'Donnell** *(remote)*
15:15	*Coffee break*	
15:45	**Summary of the Workshops**	Workshop moderators and participants
16:15	**Panel discussion on the most debated topics/questions**	
16:45	*Closing and End of Training*	