

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 <i>Examples from real inspections and lessons learned</i> <ul style="list-style-type: none"> • 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 Zwickovits Jay Jariwala & Sina Berndl Anna-Maria Kurzreiter
10:15	Coffee break	
10:45	Workshops 2nd run <i>Examples from real inspections and lessons learned</i> <ul style="list-style-type: none"> • 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 Zwickovits Jay Jariwala & Sina Berndl Anna-Maria Kurzreiter
12:00	Lunch	
13:30	Workshops 3rd run <i>Examples from real inspections and lessons learned</i> <ul style="list-style-type: none"> • 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 Zwickovits 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	