

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	The revision of ICH Q9 – a framework for inspecting PQS Effectiveness and its role in ICH Q12 implementation	Kevin O'Donnell Market Compliance Manager HPRA Health Products Regulatory Authority, Ireland (remote)
10:30	ICH Q12, Knowledge Management and PQS as well as history and evolution of these concepts	Ingrid Markovic Head of Global RA CMC Policy Novartis Pharmaceuticals Corporation, USA
11:00	Coffee break	
11:30	Continuation: ICH Q12, Knowledge Management and PQS as well as history and evolution of these concepts	Ingrid Markovic
12:00	Use of AI tools in the context of PQS (industry point of view)	Gert Thurau Lead Technology Innovation Manufacturing in CMC Reg Policy F. Hoffmann-La Roche, Switzerland
13:00	Group Photograph	
13:15	Lunch	
14:30	How to inspect AI tools in the context of PQS	<i>tbd</i>
15:10	How to inspect OOS (see also Guidance for industry: Investigation OOS Test Results for Pharmaceutical Production)	Jay Jariwala Founder and President Pharmasure LLC
15:50	Coffee break	
16:20	How to inspect OOT, OOX, Deviations and Management Review	Anna-Maria Kurzreiter Inspector/Senior Expert AGES Austrian Agency for Health and Food Safety
17:00	<i>tbd</i>	<i>tbd</i>
17:30	End of day 1	
	All participants are kindly invited for dinner	
18:30	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? 	Kevin O'Donnell & Ingrid Markovic Jay Jariwala 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? 	Kevin O'Donnell & Ingrid Markovic Jay Jariwala Anna-Maria Kurzreiter
12:00	Lunch	
13:30	Workshops 3rd <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? 	Kevin O'Donnell & Ingrid Markovic Jay Jariwala Anna-Maria Kurzreiter
14:45	<i>tbd</i>	<i>tbd</i>
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	