

## 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

<b>Time</b>	<b>Topics</b>	<b>Speakers</b>
09:00	<b>Registration &amp; Welcome Coffee</b>	
09:30	<b>Welcome address</b>	
	<b>Introduction of the topic</b>	<b>Barbara Herzog</b> Swissmedic
09:45	<b>The revision of ICH Q9</b> – a framework for inspecting PQS Effectiveness and its role in ICH Q12 implementation	<b>Kevin O'Donnell</b> Market Compliance Manager HPRA Health Products Regulatory Authority, Ireland (remote)
10:30	<b>ICH Q12, Knowledge Management and PQS</b> as well as history and evolution of these concepts	<b>Ingrid Markovic</b> Head of Global RA CMC Policy Novartis Pharmaceuticals Corporation, USA
11:00	<b>Coffee break</b>	
11:30	<b>Continuation: ICH Q12, Knowledge Management and PQS</b> as well as history and evolution of these concepts	<b>Ingrid Markovic</b>
12:00	<b>Use of AI tools in the context of PQS (industry point of view)</b>	<b>Gert Thurau</b> Lead Technology Innovation Manufacturing in CMC Reg Policy F. Hoffmann-La Roche, Switzerland
13:00	Group Photograph	
13:15	<b>Lunch</b>	
14:30	<b>How to inspect AI tools in the context of PQS</b>	<i>tbd</i>
15:10	<b>How to inspect OOS</b> (see also Guidance for industry: Investigation OOS Test Results for Pharmaceutical Production)	<b>Jay Jariwala</b> Founder and President Pharmasure LLC
15:50	<b>Coffee break</b>	
16:20	<b>How to inspect OOT, OOX, Deviations and Management Review</b>	<b>Anna-Maria Kurzreiter</b> Inspector/Senior Expert AGES Austrian Agency for Health and Food Safety
17:00	<i>tbd</i>	<i>tbd</i>
17:30	<b>End of day 1</b>	
18:30	<b>All participants are kindly invited for dinner</b>  <b>Meeting at the Hotel du Grand Lac Excelsior</b> Rue de Bon-Port 27, Montreux	

**Day 2: Wednesday, 6 May 2026**

<i>Time</i>	<i>Topics</i>	<i>Workshop Moderators</i>
09:00	<b>Workshops 1<sup>st</sup> run</b> <i>Examples from real inspections and lessons learned</i> <ul style="list-style-type: none"> <li>• Workshop 1: How to inspect PQS in the light of ICH Q12?</li> <li>• Workshop 2: How to inspect AI in PQS?</li> <li>• Workshop 3: How to inspect OOS, OOT, OOX?</li> </ul>	Kevin O'Donnell & Ingrid Markovic  Jay Jariwala  Anna-Maria Kurzreiter
10:15	<b>Coffee break</b>	
10:45	<b>Workshops 2<sup>nd</sup> run</b> <i>Examples from real inspections and lessons learned</i> <ul style="list-style-type: none"> <li>• Workshop 1: How to inspect PQS in the light of ICH Q12?</li> <li>• Workshop 2: How to inspect AI in PQS?</li> <li>• Workshop 3: How to inspect OOS, OOT, OOX?</li> </ul>	Kevin O'Donnell & Ingrid Markovic  Jay Jariwala  Anna-Maria Kurzreiter
12:00	<b>Lunch</b>	
13:30	<b>Workshops 3<sup>rd</sup></b> <i>Examples from real inspections and lessons learned</i> <ul style="list-style-type: none"> <li>• Workshop 1: How to inspect PQS in the light of ICH Q12?</li> <li>• Workshop 2: How to inspect AI in PQS?</li> <li>• Workshop 3: How to inspect OOS, OOT, OOX?</li> </ul>	Kevin O'Donnell & Ingrid Markovic  Jay Jariwala  Anna-Maria Kurzreiter
14:45	<i>tbd</i>	<i>tbd</i>
15:15	<b>Coffee break</b>	
15:45	<b>Summary of the Workshops</b>	Workshop moderators and participants
16:15	<b>Panel discussion on the most debated topics/questions</b>	
16:45	<b>Closing and End of Training</b>	