

ICH Q9(R1) Training Group Work Plan

July 22, 2025

Topic Adoption date: *June 2024*

Rapporteur: *Dr. Kevin O'Donnell, EC, Europe*

Regulatory Chair: *Dr. Alex Viehmann, FDA, United States*

Last Face-to-Face Meeting: *Fukuoka, Japan, June 2024*

1. Key milestones

1.a. Current status of key milestones

Note: This workplan relates to the ICH Q9(R1) Training Group, which was set up in June 2024 at Fukuoka, Japan, in order to complete the work of the ICH Q9(R1) IWG, which had run from September 2023 to July 2024. The work of the Training Group relates to completing an update of the 24 presentations in the ICH Q9 Briefing Pack training materials from 2006, in light of the revision of the ICH Q9 guideline which reached Step 4 in January 2023. The work also relates to reviewing and commenting on, from a quality risk management and ICH Q9(R1) perspective, a number of draft presentations (referred to as lessons 3, 5, 6, 7 & 8) which had been developed by a Training Associate tasked by ICH to develop new training materials in relation to ICH Q8/9/10/11.

Past completion date	Milestone
Jul. 2024	<i>Finalisation of an Introductory Presentation on Quality Risk Management and ICH Q9(R1) for the ICH Q9 Briefing Pack on the ICH website. This new presentation was developed and agreed by the ICH Q9(R1) IWG and it replaced six unofficial presentations which had been in the ICH Q9 Briefing Pack since 2006. The new presentation incorporated certain elements of those 2006 presentations.</i>
Jul. 2024	<i>Finalisation of a new presentation on ICH Q8(R2), ICH Q9(R1) and ICH Q10 for the ICH Q8/9/10 Training Materials. This new presentation was developed and agreed by the ICH Q9(R1) IWG and it replaced the unofficial presentations on ICH Q8/9/10 which had been on the ICH website since 2010. The new presentation incorporated certain elements of the 2010 presentations.</i>
Jul. 2024	<i>Generation of a revised version (no. 5) of the Questions and Answers (Q&A) document (revision no. 4) on ICH Q8/9/10 which had been on the ICH website since 2010. The revision was performed to bring the document up-to-date following the revision of ICH Q9 which reached Step 4 in January 2023. This revised version of the Q&A document was routed via the ICH</i>

	<i>Minor Revision Procedure for review, and the updated version, no. R5, was approved on October 30th, 2024.</i>
Sept. 2024	<i>Development of an agreed plan and work schedule within the Training Group for how the remaining 18 presentations from 2006 that are in the ICH Q9 Briefing Pack would be updated. Co-leads were assigned within the Training Group for those 18 presentations.</i>
Jan. 2025	<i>A priority listing of the most important presentations from the aforementioned 18 presentations was agreed within the Training Group. A total of 7 presentations were prioritized; this meant that the updating work on those presentations would be completed by the Training Group before the work on the remaining 11 presentations.</i>
Feb. 2025	<i>Completion of reviews (from a quality risk management and ICH Q9(R1) perspective) of 5 draft training presentations (referred to as lessons 3, 5, 6, 7 & 8) developed by a Training Associate tasked by ICH to develop new training materials in relation to ICH Q8/9/10/11. (Note: Lessons 1, 2 and 4 had been reviewed by the Training Group in 2023/2024).</i>
July 2025	<i>Revision work on the aforementioned 7 prioritised presentations from the ICH Q9 Briefing Pack from 2006 was completed; the revised presentations were sent to the ICH Secretariat for editorial review prior to their publication on the ICH website. (Note: Revision work continued on the remaining 11 presentations in the Briefing Pack.)</i>

1.b. Key Deliverables

Approval Date	Deliverable
Jun. 2024	<ul style="list-style-type: none"> <i>Revised versions of the remaining 18 presentations in the ICH Q9 Briefing Pack from 2006 that have substantial content gaps. (Nine of the presentations relate to the Quality Risk Management methods and tools that are referred to in Annex I of ICH Q9(R1), and nine relate to the potential applications of Quality Risk Management that are referred to in Annex II of ICH Q9(R1).)</i> <i>The revised 18 presentations should be finalised by September 2025. Note: A number of those presentations will have been prioritised for updating before then.</i>

1.c. Future anticipated key milestones

Expected future completion date	Milestone
Sep. 2025	<i>Complete the updating work on 5 of the outstanding 11 presentations from 2006 that are in the ICH Q9 Briefing Pack, to address the substantial content</i>

	<p>gaps in those presentations. These presentations relate to the following topics:</p> <ul style="list-style-type: none"> - Hazard Operability Analysis (HAZOP) - Supporting Statistical Tools - Quality Risk Management as part of Regulatory Operations - Quality Risk Management as part of Materials Management - Quality Risk Management as part of Supply Chain Control
Sep. 2025	The updated 5 presentations will be sent to the ICH Secretariat for editorial review. Any required edits will be addressed and the updated presentations will be published on the ICH website thereafter.
Dec. 2025	<p>Complete the updating work on the final 6 presentations from 2006 that are in the ICH Q9 Briefing Pack, to address the substantial content gaps in those presentations. These presentations relate to the following topics:</p> <ul style="list-style-type: none"> - The Combination of Quality Risk Management Tools - Quality Risk Management as part of Facilities, Equipment and Utilities - Quality Risk Management as part of Development - Quality Risk Management as part of Production - Quality Risk Management as part of Laboratory Control and Stability Studies - Quality Risk Management as part of Packaging and Labelling
Dec. 2025	The updated 6 presentations will be sent to the ICH Secretariat for editorial review. Any required edits will be addressed and the updated presentations will be published on the ICH website thereafter.

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
Jul. 2025	Sep. 2025	Complete the required updating work on the 5 presentations listed on the right that are in the ICH Q9 Briefing Pack from 2006. This revision work will address the significant content gaps in those presentations, and it will bring the	<p>The 5 presentations relate to:</p> <ul style="list-style-type: none"> - Hazard Operability Analysis (HAZOP) - Supporting Statistical Tools - Quality Risk Management as part of Regulatory Operations - Quality Risk Management as part of Materials Management - Quality Risk Management as part of Supply Chain Control

		<i>presentations into line with ICH Q9(R1).</i>	
Sep. 2025	<i>Sep. 2025</i>	<i>Send the updated 5 prioritised presentations to the ICH Secretariat for an editorial review.</i>	<i>Any required edits will be addressed and the updated presentations will be published on the ICH website thereafter.</i>
Oct. 2025	<i>Dec. 2025</i>	<i>Complete the required updating work on the 6 presentations listed on the right that are in the ICH Q9 Briefing Pack from 2006. This revision work will address the significant content gaps in those presentations, and it will bring the presentations into line with ICH Q9(R1).</i>	<p><i>The 6 presentations relate to:</i></p> <ul style="list-style-type: none"> - <i>The Combination of Quality Risk Management Tools</i> - <i>Quality Risk Management as part of Facilities, Equipment and Utilities</i> - <i>Quality Risk Management as part of Development</i> - <i>Quality Risk Management as part of Production</i> - <i>Quality Risk Management as part of Laboratory Control and Stability Studies</i> - <i>Quality Risk Management as part of Packaging and Labelling</i>
Dec. 2025	<i>Dec. 2025</i>	<i>Send the updated 6 presentations to the ICH Secretariat for an editorial review.</i>	<i>Any required edits will be addressed and the updated presentations will be published on the ICH website thereafter.</i>