

ICH Q9(R1) EWG Work Plan

August 01, 2022

Topic Adoption date: *May 2020*

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

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

Last Face-to-Face Meeting: *Athens, Greece, May 2022*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2020	<i>Concept Paper and Business Plan endorsement</i>
May. 2021	<i>Completion of a pre-Step 1 Sign-off draft of the ICH Q9(R1) Technical Document as agreed within the Expert Working Group (EWG)</i>
May.-Jun. 2021	<i>Informal consultation with the organisations represented on the EWG on the initial draft of the ICH Q9(R1) Technical Document – this informal consultation was performed to identify any significant issues with the draft text or critical areas that were missing prior to the EWG proceeding to the Step 1 Sign-off.</i>
Oct. 2021	<i>Step 1 Sign-off on the consensus draft Technical Document</i>
Nov. 2021	<i>Step 2a - Final Technical Document endorsed by all members of the ICH Assembly</i> <i>Step 2b – Draft Guideline endorsed by Regulatory Members of the ICH Assembly</i>
Dec. 2021	<i>Start of three month Public Regional Consultation on Draft Guideline and publication of Informational Presentation on Draft Guideline</i>
Apr. 2022	<i>End of three month Public Regional Consultation on Draft Guideline in all regions with the exception of the USA</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
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Jul. 2022	<i>End of Step 3 Public Regional Consultation in the USA on the draft Guideline and start of review by the EWG of the USA Comments</i>
Sep. 2022*	<i>Completion of review of the Step 3 comments from the USA</i>
Oct. 2022*	<i>Generation of updated Step 3 draft Guideline</i>
Nov. 2022*	<i>Submission of the Step 3 draft Guideline to the Plenary Working Party (PWP) for its one month review before the Step 3 Sign-off</i>
Nov. 2022	<i>End of the development phase of the training materials (including case studies) to support the revised draft Guideline and review of those draft training materials by the EWG at the face-to-face meeting in the Republic of Korea in mid-Nov. 2022</i>
Dec. 2022*	<i>EWG Review of the PWP comments on the Step 3 draft Guideline</i>
Feb. 2023*	<i>Generation of a revised version of the Step 3 draft Guideline following review of the PWP comments</i>
Feb. 2023	<i>Sign-off on the training materials by the EWG</i>
Feb. 2023*	<i>Step 3 Sign-off on the revised Guideline</i>
Mar. 2023	<i>Step 4 – Adoption of the final revised ICH Guideline</i>

* Please note that these milestone timelines are estimates – they may occur earlier than indicated here, depending on the number and type of *Step 3* comments that are received from the US public consultation and from the Plenary Working Party (PWP). It is possible also that the *Step 3* review by the PWP will begin earlier than indicated above – i.e. earlier than November 2022. In the event that all of the comments from the US and from the PWP can be addressed by mid-November 2022 (i.e. by the time of the face-to-face EWG meeting at Incheon in the Republic of Korea), it may be possible to reach the *Step 3* sign-off milestone at that November 2022 meeting.

2. Timeline for specific tasks**

Beginning date	End Date	Task / Activity	Details
Jul. 2022	Nov. 2022	<i>Development of training materials (including case studies) to support the revised Guideline. These will seek to address the learning goals that were agreed within the EWG for the training materials.</i>	<i>Two Sub-groups of the EWG were formed in December 2021 to develop the training materials. Sub-group 1 was tasked with addressing the following topics – Risk-based Decision Making, Formality in QRM and Risk Review. Sub-group 2 was tasked with addressing the following topics: Subjectivity in QRM, Product Availability Risks and Hazard Identification. The Sub-groups will</i>

			<i>consult with the full EWG periodically on the training materials that are developed.</i>
Jul. 2022	Sep. 2022	<i>Review of, and discussion on, the comments received from the USA in the Step 3 consultation and update of the draft Guideline</i>	<i>The review of the Step 3 USA comments will begin in late July (or early August) 2022 and will continue until end September 2022</i>
Oct. 2022	Oct. 2022	<i>Generation of an updated version of the Step 3 draft Guideline for review by the Plenary Working Party</i>	<i>The updated Step 3 draft guideline will be prepared and agreed within the EWG before sending it to the PWP for its review.</i>
Nov. 2022	Nov. 2022	<i>Plenary Working Party review of the Draft Guideline following the Step 3 updates.</i>	<i>It is anticipated that the updated draft Guideline will be sent to the PWP for review at the start of November 2022 and that any comments from the PWP will be received by the EWG at the end of November 2022.</i>
Nov. 2022	Nov. 2022	<i>Review of the draft training materials at the face-to-face EWG meeting in the Republic of Korea</i>	<i>This will be the first opportunity for the full EWG to review the draft training materials that have been developed by the aforementioned training sub-groups of the EWG. After this review, the work on the training materials will continue until February 2023, at which stage they should be finalised.</i>

**** Note:** As indicated in Section 1.b, the above timelines in relation to the guideline revision work are estimates – they may occur earlier than indicated, depending on the number and type of **Step 3** comments that are received from the US public consultation and from the Plenary Working Party (PWP). It is possible also that the **Step 3** review by the PWP will begin earlier than indicated above – i.e. earlier than November 2022. In the event that all of the comments from the US and from the PWP can be addressed by mid-November 2022 (i.e. by the time of the face-to-face EWG meeting at Incheon in the Republic of Korea), it may be possible to reach the **Step 3** sign-off milestone at that November 2022 meeting.