

ICH Q9(R1) EWG Work Plan

August 01, 2021

Topic Adoption date: *May 2020*

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

Last Face-to-Face Meeting: *None*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2020</i>	<i>Concept Paper endorsement</i>
<i>Nov. 2020</i>	<i>Business Plan endorsement</i>
<i>Dec. 2020</i>	<i>EWG held its first meeting (via telecon)</i>
<i>May 2021</i>	<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>
<i>May-June 2021</i>	<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 significant issues with the draft text or critical areas that were missing prior to the EWG proceeding to the Step 1 Sign-off.</i>

1.b. Future anticipated key milestones

Expected future completion date*	Milestone
<i>Oct. 2021</i>	<i>Step 1 – Technical document sign-off by all Topic Leaders</i>
<i>Nov. 2021 – Dec. 2021</i>	<i>Step 2a/2b – Final Technical Document endorsed by all members of the Assembly and Draft ICH Q9(R1) guideline endorsed by Regulatory members of the Assembly</i>

Dec. 2021	<i>Step 2 – Informational Presentation approved by all Topic Leaders</i>
Jan. 2022 – Mar. 2022	<i>Step 3 – Regional Regulatory Consultation on Draft Guideline</i>
Aug. 2022	<i>Step 3 – Draft Guideline sign-off by all Regulatory Topic Leaders</i>
Oct. 2021 – Aug. 2022	<i>Development of training materials</i>
Aug. 2022	<i>Finalization and endorsement of the training materials</i>
Sep. 2022	<i>Step 4 – Adoption of the final ICH guideline</i>

* The ongoing COVID-19 pandemic introduced significant uncertainty regarding the timeframe of the project. A zero ability to meet in person due to travel restrictions as well as unforeseen increases in the workload of EWG members required an extension of the milestones documented in the January 29th 2021 workplan by approximately 3 months. (Note: The endorsed Business Plan for the revision work had identified the potential need to extend the milestone dates by 6 months as a result of the Covid-19 pandemic. If required, the additional three month extension cited in the endorsed business plan may be considered in case of unexpected delays, and if that happens, this workplan will be revised accordingly.)

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
Jul. 2021	Oct. 2021	<i>Taking the comments of the aforementioned May/June 2021 informal consultation into account, work to agree within the EWG the Step 1 draft guidance text for Q9(R1).</i>	<i>Sub-groups of the EWG were formed in June and July 2021 to work on the comments received during the May/June 2021 informal consultation and to make the necessary changes to the draft guideline text.</i>
Jul. 2021	Jul. 2021	<i>In relation to the development of training materials to support the revised guideline, agree within the EWG the learning goals that will be associated with the training materials.</i>	<i>Work to draft the various learning goals started in January 2021 and it continued through July 2021. By the end of July 2021, it is anticipated that the EWG will have agreed the learning goals associated with the training materials on each of the six revision topics that are the subject of the guideline revision.</i>

Aug. 2021	Aug. 2021	<i>Issue an invitation to stakeholders for the submission of case studies (and other training materials) for the consideration by the EWG on each of the six revision topics that are of concern for the revision of ICH Q9.</i>	<i>The stakeholders will be provided with the EWG-agreed learning goals for the training materials in relation to each of the six revision topics so that they may tailor their submitted case studies and other suggested training materials to address those learning goals.</i>
Sep. 2021	Sep. 2021	<i>Deadline for the receipt of case studies (and other training materials) from stakeholders for consideration by the EWG on each of the six revision topics of concern to the revision of ICH Q9.</i>	<i>Stakeholders will be given 8 weeks to submit suggested case studies and other training materials. The deadline for the submission of those materials will be September 30th 2021.</i>
Oct 2021	Oct 2021	<i>Step 1 Sign-off of the draft Technical Document ICH Q9(R1)</i>	<i>Note that a pre-Step 1 Sign-off version of the consensus draft Technical Document will be provided to the Plenary Working Party (PWP) in September 2021 for comment. Any comments made by the PWP will be considered by the EWG during October 2021.</i>
Oct. 2021	Aug. 2022	<i>Work on developing the training materials to address the 6 topics of concern in the revision of ICH Q9.</i>	<i>Note: The training materials will be completed and agreed within the EWG before the Step 4 Sign-off of the revised Guideline in September 2022.</i>