ICH Q9(R1) EWG Work Plan
January 24, 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: *None*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2020	*Concept Paper and Business Plan endorsement*
May 2021	*Completion of a pre-Step 1 Sign-off draft of the ICH Q9(R1) Technical Document as agreed within the Expert Working Group (EWG)*
May – Jun. 2021	*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.*
Oct. 2021	*Step 1 Sign-off on the consensus draft Technical Document*
Nov. 2021	*Step 2a - Final Technical Document endorsed by all members of the ICH Assembly* *Step 2b – Draft Guideline endorsed by Regulatory Members of the ICH Assembly*
Dec. 2021	*Start of three-month Public Regional Consultation on Draft Guideline and publication of Informational Presentation on Draft Guideline*

1.b. Future anticipated key milestones

Expected future completion date*	Milestone
Mar. 2022	*Step 3 – End of Public Regional Consultation on Draft Guideline and start of Discussion and Review of Comments*
Aug. 2022	*Step 3 – Draft Guideline sign-off by all Regulatory Topic Leaders*
Jan. 2022 – Aug. 2022	*Development of training materials (including case studies) to support the revised Guideline*
Aug. 2022	*Finalization and endorsement of the training materials*
Sep. 2022	*Step 4 – Adoption of the final ICH guideline*

* 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
Jan. 2022	***Aug. 2022***	*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.*	*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 consult with the full EWG periodically on the training materials that are developed.*

Mar. 2022	***Jul. 2022***	*Review of, and discussion on, the comments received in the Step 3 consultation and update of the draft Guideline*	*The review of the Step 3 comments will begin in March 2022 and it will continue until July 2022, at which stage a draft updated version of the Guideline will be developed.*
Jul. 2022	***Jul. 2022***	*Plenary Working Party (PWP) review of the Draft Guideline following the Step 3 discussion and updates.*	*It is anticipated that the updated draft Guideline will be sent to the PWP for review in July 2022 and that any comments made by the PWP will be considered by the EWG during August 2022.*
Aug. 2022	***Aug. 2022***	*Finalization and endorsement by the EWG of the training materials.*	*It is anticipated that the training materials will be endorsed by the full EWG during August 2022, just before initiation of Step 4 for the revised Guideline.*
Sep. 2022	***Sep. 2022***	*Step 4 – Adoption of the ICH Harmonised Guideline.*	*It is anticipated that adoption of the revised Guideline by the Regulatory Members of the Assembly will occur in September 2022.*