# ICH Q9(R1) EWG Work Plan
## *February 24, 2023*

**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:** *Incheon, Republic of Korea, November 2022*

## 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-June 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*<br>*Step 2b – Draft Guideline endorsed by Regulatory Members of the ICH Assembly* |
| ***Dec. 2021*** | *Step 3 - Start of Public Regional Consultation on Draft Guideline and publication of Informational Presentation on Draft Guideline* |
| ***Jul. 2022*** | *Step 3 - End of Public Regional Consultation on Draft Guideline in all regions* |
| ***Nov. 2022*** | *Review by the EWG of the draft training materials on all six revision topics: 1) Product Availability Risks, 2) Risk Review, 3) Hazard Identification, 4) Subjectivity in QRM, 5) Risk-based Decision-making, and 6) Formality in QRM.* |
| ***Nov. 2022*** | *Submission of the Step 3 draft Guideline to the Plenary Working Party* |

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| | *(PWP) for review before the Step 3 Sign-off* |
| ***Jan. 2023*** | *Step 3 Sign-off of the revised Guideline* |
| ***Jan. 2023*** | *Step 4 Sign-off of the revised Guideline* |

### 1.b. Future anticipated key milestones

| Expected future completion date | Milestone |
|---|---|
| ***Mar. 2023*** | *Finalisation and EWG sign-off of the training materials on the following three topics to support the revised guideline: 1) Product Availability Risks, 2) Risk Review, and 3) Hazard Identification.* |
| ***Jun. 2023*** | *Finalisation and EWG sign-off of the training materials on the remaining three topics to support the revised guideline: 4) Subjectivity in QRM, 5) Risk-based Decision-making, and 6) Formality in QRM.* |

## 2. Timeline for specific tasks**

| Beginning date | End Date | Task / Activity | Details |
|---|---|---|---|
| ***Feb. 2023*** | ***Mar. 2023*** | *Continue the development of the training materials (including case studies) on the following three topics to support the revised Guideline: 1) Product Availability Risks, 2) Risk Review, and 3) Hazard Identification.* | *Sub-groups of the EWG were formed in December 2021 to develop the training materials on these topics. These Sub-groups will continue their work and they will present the materials to the full EWG for review in February 2023. The training materials will then be finalized in March 2023.* |
| ***Feb. 2023*** | ***Jun. 2023*** | *Continue the development of the training materials (including case studies) on the remaining three topics to support the revised Guideline: 4) Subjectivity in QRM, 5) Risk-based Decision-* | *Sub-groups of the EWG were formed in December 2021 to develop the training materials on these topics. These Sub-groups will continue their work and they will present the materials to the full EWG for review in April and May 2023. The training materials will then be finalized in June 2023.* |

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| | | *making, and 6) Formality in QRM.* | |
| ***Feb. 2023*** | ***Feb. 2023*** | *Generation of the Step 4 Presentation on the finalised ICH Q9(R1) Guideline.* | *This presentation will provide an overview of the revisions made to the Guideline and it will address implementation considerations.* |