ICH Q6(R1) EWG Work Plan

January 21, 2025

Topic Adoption date: *June 2021*

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Last Face-to-Face Meeting: *Montreal, Canada, November 2024*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Jun. 2021	*Topic adoption by ICH Assembly*
Feb. 2024	*Establishment of Q6(R1) Informal Working Group*
Jun. 2024	*Concept paper endorsed by ICH MC and transition to Expert Working Group (EWG)*

1.b. Key Deliverables

Approval Date	Deliverable
Jun. 2024	*Q6(R1) Guideline*
Jun. 2024	*Q6(R1) Training Material*

1.c. Future anticipated key milestones

Expected future completion date	Milestone
Jan. 2026	*Training material preparation initiated*
Jun. 2026	*Step 1 and 2a/b Sign-off of Q6(R1) draft Technical Document* *Initiate work on training materials*
Jun. 2028	*Step 3 and 4 Sign-off and Adoption of the Q6(R1) Guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details

Nov. 2024	*May 2025*	*General principles draft refinement*	*Update draft text of general principles considering new topics emerged during Montreal meeting and taking into account EWG discussion and comments. Identify new topics for discussion, if any.*
Nov. 2024	*May 2025*	*Drafting of chemical section*	*Provision of draft on the majority of the chemical section for EWG review.*
Nov. 2024	*May 2025*	*Drafting of biological section*	*Development of framework for the biologics section based on the table of content and development of the draft key general sections for biologics for EWG review.*
Nov. 2024	*May 2025*	*Sections drafting and background work*	*Identify which annexes are neededand start drafting*
Nov. 2024	*May 2025*	*Multiple EWG Meetingsvia Teleconference*	*Advance alignment discussions and identify topics of discussion for face-to-face meeting*
April 2025	*May 2025*	*Draft review by EWG*	*EWG to review draft text and provide comments*

Mid-term high-level specific tasks ***between the ICH meeting and reaching steps 1-2****.*

Beginning date	**End date**	**Task / Activity**	**Details**
Nov. 2024	*May 2025*	*Sections drafting*	*Continue drafting all three sections (general principles, chemicals and biologicals)*
May. 2025	*Nov. 2025*	*Completion of drafting sections*	*Complete drafting all sections including annexes*
Jan. 2026	*Feb. 2026*	*Constituency review of the draft guideline*	*Request comments from all constituents*
Feb. 2026	*Jun. 2026*	*Address comments from constituency review*	*Review comments received. Address the comments. Update the guideline*

Jan. 2026	*Feb. 2026*	*Training materials*	*Establish a working plan for the training materials*
Jun. 2026	*Jun. 2026*	*Step 1 and 2a/b Sign-off of Q6(R1) draft Technical Document*	*Submit document to ICH MC for endorsement*
July. 2026	*Jan. 2027*	*Public consultation*	*Provide final draft for public consultation and collect comments*