ICH Q6(R1) EWG Work Plan
July 11, 2025

Topic Adoption date: *June 2021*

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Regulatory Chair: *Dr. Robin Levis, FDA, United States*

Last Face-to-Face Meeting: *Madrid, Spain, May 2025*

1. Key milestones

1.a. Current status of key milestones

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

1.b. Key Deliverables

MC 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
Jul. 2025	*Nov. 2025*	*Finalize draft text, including annexes*	*Finalize the draft of the Q6(R1) guideline for constituents' review*