

ICH Q6(R1) EWG Work Plan

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Topic Adoption Date: *June, 2021*

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

Last Face-to-Face Meeting: *Rio, May-June, 2026*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>Jul. 2021</i>	<i>Topic adoption by ICH Assembly</i>
<i>Feb. 2024</i>	<i>Establishment of Q6(R1) Informal Working Group</i>
<i>Jul. 2024</i>	<i>Concept paper endorsed by ICH MC and transition to Expert Working Group (EWG)</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>Jul. 2024</i>	<i>Q6(R1) Guideline</i>
<i>Jul. 2024</i>	<i>Q6(R1) Training Materials</i>

1.3 Future Anticipated Milestones



Expected future completion date	Milestone
<i>May-Nov, 2026</i>	<i>Finalise Step 1/2 document and develop Step 2 presentation</i>
<i>Sep-Oct, 2026</i>	<i>Targeted Constituency Review for new content</i>

Nov, 2026	<i>Step 1 and Step 2a/b sign-off of Final Technical Document and Step 2 Presentation</i>
Dec, 2026- May, 2027	<i>Public consultation</i>
Dec, 2026- May, 2027	<i>Initiate training materials preparation</i>
Jun, 2027-Jan, 2028	<i>Review of comments from public consultation and update the guideline</i>
Feb, 2028	<i>Additional Constituent Review(s)</i>
Mar-May, 2028	<i>Finalised guideline and develop Step 4 Presentation</i>
Jun, 2028	<i>Step 3 and Step 4 sign-off of Final draft Guideline Document and Step 4 Presentation</i>
TBC	<i>Finalise Training Material</i>

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
<i>Jun. 2026</i>	<i>Oct. 2026</i>	<i>Assessment of comments from constituency review and text update</i>	<i>Analyse comments from constituents and update the guideline accordingly</i>
<i>Jun. 2026</i>	<i>Sep. 2026</i>	<i>Finalise new content</i>	<i>Finalise the content that was not reviewed by constituents</i>
<i>Sep. 2026</i>	<i>Oct. 2026</i>	<i>Targeted constituency review</i>	<i>Circulate the new content for a targeted constituency review</i>
<i>Oct. 2026</i>	<i>Nov. 2026</i>	<i>Finalise the draft Guideline</i>	<i>Address the last comments and finalise the text for a line-by-line review in Prague</i>