

ICH Q5E Annex EWG Work Plan

07 July 2026

Topic Adoption Date: May 2025

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Last Face-to-Face Meeting Rio de Janeiro, Brazil June 2026

1 Key Milestones

1.1 Completed Key Milestones

Completion date	Milestone
June 2026	ICH MC endorsement of Concept Paper
May 2025	ICH Assembly endorsement of Outline of Concept Paper

1.2 ICH WG Key Deliverables

MC Approval Date	Deliverable
May 2025	The ICH MC endorsed development of the ICH Q5E Annex, "Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their Manufacturing Process (Annex to ICH Q5E)".

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
November 2026	Draft Technical Document (Annex) Outline
August 2027	Step 1 sign-off of ICH Q5E Annex Draft Technical Document by EWG Topic Leaders/ Step 2 a/b Assembly endorsement of draft ICH Q5E Annex Guideline and release for public consultation
February 2028	Step 4 sign-off of ICH Q5E Annex Final Guideline

2. Timeline for Specific Tasks

Beginning date	End date	Task / Activity	Details
May 2026	<i>June 2026</i>	<i>Review of current guidance</i>	<i>Review of parent ICH Q5E Guideline and current regional regulatory Guidelines on ATMP comparability.</i>
May 2026	<i>June 2026</i>	<i>Review ATMP-specific comparability considerations.</i>	<i>Discuss special considerations in ICH CGTDG Recommendation Paper and regional Guidelines.</i>
May 2026	<i>June 2026</i>	<i>Initiation of technical document drafting</i>	<i>Form drafting subgroup; Align on format of technical guidance/annex.</i>
May 2026	<i>Nov 2026</i>	<i>Approach to identify Q5E gaps for various ATMP modalities.</i>	<i>Align on general ATMP product types to identify Q5E gaps and scientifically justified risk-based fit-for-purpose approaches.</i>
July 2026	<i>Nov 2026</i>	<i>Prepare outline of technical document</i>	<i>Outline of draft technical document.</i>