

ICH Q1 EWG Work Plan

February 11, 2026

Topic Adoption Date: *January 2026*

Rapporteur/s: *Dr. Ashutosh Rao, FDA, United States*

Regulatory Chair *Ms. Ana Cerúlia Moraes do Carmo, ANVISA, Brazil*

Last Face-to-Face Meeting *Singapore, Singapore, November 2025*

1 Key Milestones

1.1 Current Status of Key Milestones

Completion date	Milestone
<i>Nov. 2022</i>	<i>Concept paper endorsement</i>
<i>Nov. 2022</i>	<i>Business plan endorsement</i>
<i>Nov. 2022</i>	<i>Establishment of EWG</i>
<i>Apr. 2025</i>	<i>Step 1 sign-off by Q1 EWG and Step 2a/b endorsement by ICH Assembly and Regulatory Members of the ICH Assembly</i>
<i>Apr. 2025 -Sep. 2025</i>	<i>Step 3 Public Consultation Period</i>

1.2 ICH MC Key Deliverables

MC Approval Date	Deliverable
<i>Nov. 2022</i>	<i>ICH MC endorsed development of the ICH Q1/Q5C Targeted Revisions of the ICH Stability Guideline Series and related Training materials</i>
<i>Feb. 2025</i>	<i>ICH MC approved a title change to ICH Q1 Stability Testing of Drug Substances and Drug Products</i>

1.3 Future Anticipated Milestones

Expected future completion date	Milestone
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Sept. 2026	<i>Plenary Working Party engagement ahead of Step 3 sign-off</i>
Nov. 2026	<i>Step 3 sign-off/ Step 4 adoption and delivery of the Step 4 Presentation</i>
Jun. 2027	<i>Delivery of training material</i>

2. Timeline for Specific Tasks

*Please provide in the table below short-term high-level specific tasks for work to be done within the Working Group **between now and the next ICH meeting** (recommended 4 – 10 tasks).*

Beginning date	End date	Task / Activity	Details
Jul. 2025	Sep. 2026	<i>Revision based on Public Consultation</i>	<i>Resolve all Major and Standard comments and reach EWG consensus on comments that warrant further Q1 revisions.</i>
Mar. 2026	Sep. 2026	<i>Revision based on Public Consultation</i>	<i>Resolve all Minor comments and reach EWG consensus on comments that warrant further Q1 revisions.</i>
Sep. 2026	Nov. 2026	<i>Revision based on Public Consultation</i>	<i>Share document with PWP and Clearance Officials (if applicable). Send document to ICH Secretariat.</i>
Jun. 2025	Jun. 2027	<i>Training Material</i>	<i>Align upon and complete core training materials and case studies.</i>