

ICH Q1 EWG Work Plan

July 10, 2026

Topic Adoption Date: *November 2022*

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

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

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

1 Key Milestones

1.1 Current Status of Key Milestones

- List key **past milestones** in the table for context.
- Key Milestones Include:
 - Concept Paper endorsement,
 - Completion of PWP Consultation (if applicable)
 - ICH *Step* sign-off (*Guidelines, Q&As, Implementation Packages*)
 - Completion of *Step 3* Public Consultation,
 - *Step 2* and *Step 4* Presentations
 - Stakeholder Engagement Activities
 - Training materials developed.
- Choose only the most relevant achievements.

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

1.2 ICH MC Key Deliverables

- The table records **all deliverables** that the ICH MC has approved for development, either:
 - those listed in the **Concept Paper**, or

- additional deliverables **approved later** by the MC.
- **“Approval Date”** = the date the MC approved starting work on that deliverable (either the Concept Paper approval date or a later time point based on MC approval).

MC Approval Date	Deliverable
November 2022	Q1 Guideline and Training Materials

1.3 Future Anticipated Milestones

Please provide in the table below the main deliverable(s) to be achieved in the next year(s):

Dates or expected timeline (e.g. Q1 2026 etc.) should be provided for:

- PWP engagement (if applicable) ahead of Step 1 and Step 3 Sign off
- Step 1 sign-off and Step 2a/b endorsement and delivery of the Step 2 Presentation
- Step 3 sign-off and Step 4 adoption and delivery of the Step 4 Presentation
- Any other relevant high-level deliverables (finalised documents, public consultation period, special actions to advance the topic through ICH, e.g. stakeholder engagement or training, etc.)

Expected future completion date	Milestone
Sept. 2026	Plenary Working Party engagement ahead of Step 3 sign-off
Nov. 2026	EWG consensus towards Step 3 sign-off
Dec. 2026	Step 3 sign-off and Assembly review for Step 4 (after Prague). A 1-month delay allows for additional time to complete any remaining corrections, capture signatures and sharing the document for MC regulators review towards Step 4.
Jun. 2027	Delivery of training material

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 biannual meeting (recommended 4 – 10 tasks).

Beginning date	End date	Task / Activity	Details
Jul. 2025	Oct. 2026	Revision based on Public Consultation	Resolve all Major and Standard comments and reach EWG consensus on comments that warrant further Q1 revisions.

Mar. 2026	Oct. 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> <i>Review comments received from PWP and ICH Secretariat and align on the final guidance.</i>
Jun. 2025	Jun. 2027	<i>Training Material</i>	<i>Align upon and complete core training materials and case studies.</i>