

ICH Q3E EWG Work Plan

July 21, 2026

Topic Adoption Date: *June 2019*

Rapporteur/s: *Dr. Dan Mellon, FDA, United States*

Regulatory Chair: *Dr. Katrin Buss, EC, Europe*

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
<i>Jun. 2019</i>	<i>Topic was endorsed</i>
<i>Jul. 2020</i>	<i>Final Concept Paper and Business Plan Endorsed</i>
<i>Jun. 2023</i>	<i>ICH funding approved for Threshold Project and 1-year extension from vendor contract approval</i>
<i>Oct. 2023</i>	<i>All three vendor contracts approved; Safety and Threshold Project Team meet in Prague, CR</i>
<i>Jul. 2025</i>	<i>Threshold Project (ICH funded): All vendor draft PDEs received (including additional PDEs requested)</i>
<i>Aug. 2025</i>	<i>Step 1 sign-off by the Q3E EWG and Step 2a/b endorsement of the Q3E draft Guideline by the ICH Assembly</i>
<i>Jan. 2026</i>	<i>Step 3 Public Consultation period for all regions</i>
<i>Mar. 2026</i>	<i>Begin drafting of Threshold Project Manuscript</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
Jul. 2020	ICH MC endorsed development of the ICH Q3E Guideline for Extractables and Leachables (E&L) and potential Q3E Training materials
Jun. 2023	ICH MC endorsed the Q3E Threshold Project for the development of Permitted Daily Exposure (PDE) Monographs by 3 external vendors.

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
Jan. 2027	Revised Step 3 draft Guideline
Feb. 2027	Constituent Review of Guideline and draft threshold project manuscript
Mar. 2027	Finalise Threshold Project Manuscript
Mar. 2027	PWP Review and draft Guideline submitted to Secretariat for editorial review
Jun. 2027	Finalise EWG edits to Guideline for Step 3
Jun. 2027	Develop Step 4 Presentation
Jul. 2027	Step 3 and Step 4 sign-off email submission of Final draft Guideline Document and Step 4 Presentation – 3-4 weeks approximate
Nov. 2027	Finalise Training Materials

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
Feb. 2026	Nov. 2026	<u>Threshold Project</u>	• Critical review of key PDEs generated by internal and external resources to reach alignment on final QTs for Step 4 • Quality Control Assessment of Threshold Project PDE review effort and data analysis • Identify key/common leachables for future PDE monograph finalisation and publication in future revisions.
Mar. 2026	Mar. 2027	<u>Threshold Project Manuscript</u>	• Begin to draft Threshold Project manuscript • Compile database statistics • Identify key lessons learned • Identify and discuss data gaps
Feb. 2026	Sept. 2026	<u>PDE Development Best Practices</u>	• Continue to discuss lessons learned and best practices for PDE development
Feb. 2026	Jan. 2027	<u>Analysis and Discussion of Public Comments</u>	• Consolidate public comments from all regions • Categorise comments • Prioritize comments for discussion in Face-to-Face meeting in June 2026 • Begin to make any necessary updates to Guideline as appropriate
Jul. 2025	Nov. 2027	<u>Training materials</u>	• Continue development of training materials integrated learning from comments