

# ICH Q3E EWG Work Plan

*July 08, 2025*

**Topic Adoption date:** *June 2019*

**Rapporteur:** *Ms. Patricia Parris, PhRMA*

**Regulatory Chair:** *Dr. Jason Rodriguez, FDA, United States*

**Last Face-to-Face Meeting:** *Madrid, Spain, May 2025*

## 1. Key milestones

### 1.a. Current status of key milestones

<b>Past completion date</b>	<b>Milestone</b>
<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>Sep. 2023</i>	<i>ELSIE MOU Finalized and Signed</i>
<i>Oct. 2023</i>	<i>Threshold Project vendor contracts approved for the development of PDEs Safety and Threshold Project Team met in Prague, Czech Republic for ICH Biannual Meeting</i>
<i>Mar. 2025</i>	<i>PWP Consultation before Step 1 Q3E Topic Leader Sign-off</i>
<i>May. 2025</i>	<i>Q3E EWG met in in Madrid, Spain for ICH Biannual Meeting</i>
<i>Aug. 2025</i>	<i>Step 1 Sign-off by Q3E Topic Leader and Step 2a/b endorsement by ICH Assembly</i>

### 1.b. Key Deliverables

<b>MC commencement of work approval date</b>	<b>Deliverable</b>
<i>Jul. 2020</i>	<i>Q3E Guideline for Extractables and Leachables (E&amp;L).</i>
<i>Jun. 2023</i>	<i>Threshold Project - PDEs Generation</i>

### 1.c. Future anticipated key milestones

Expected future completion date	Milestone
<b>Jan. 2026</b>	<i>Begin addressing public consultation comments (4 months public consultation; 1 month constituent administration; 1 month consolidating comments)</i>
<b>Mar. 2026</b>	<i>Interim F2F Meeting – Safety Team Focus</i>
<b>Sep. 2025</b>	<i>Develop Q3E Training Materials</i>
<b>Jul. 2027</b>	<i>Step 3 sign-off and Step 4 adoption of final guidance</i>

## 2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<b>Jun. 2023</b>	<i>Mar. 2026</i>	<u>Threshold Project</u> <ul style="list-style-type: none"> <li><i>Ongoing peer reviews and EWG adoption of PDEs drafted by internal and external resources</i></li> </ul>	<ul style="list-style-type: none"> <li><i>Critical review of additional PDEs generated by internal and external resources</i></li> <li><i>Real time distribution analysis with peer reviewed PDEs</i></li> <li><i>Draft manuscripts:</i> <ol style="list-style-type: none"> <li><i>Database development and chemical characterization/prioritization;</i></li> <li><i>PDE methodology and QT derivation</i></li> </ol> </li> </ul>
<b>Jul. 2025</b>	<i>May. 2026</i>	<u>Public consultation</u> <ul style="list-style-type: none"> <li><i>Receive public consultation comments and consolidate</i></li> </ul> <u>Technical Document</u> <ul style="list-style-type: none"> <li><i>Address comments</i></li> <li><i>Training materials</i></li> </ul>	<ul style="list-style-type: none"> <li><i>Consolidate public consultation comments and update guideline as appropriate</i></li> <li><i>Continue development of training materials integrated learning from comments</i></li> <li><i>Finalize Threshold Project and outstanding durational QT (&gt;1 month to &lt;1 year)</i></li> <li><i>Drafting Threshold Project manuscript</i></li> </ul>

<b>Mar. 2026</b>	<i>Mar. 2026</i>	<i>Interim F2F Meeting – Safety Team Focus</i>	<ul style="list-style-type: none"><li>• <i>Review Threshold Project Status</i></li><li>• <i>Address QC Review</i></li><li>• <i>Reach consensus on &gt;1 month to &lt;1 year QT</i></li></ul>
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