

ICH Q3E EWG Work Plan

March 11, 2024

Topic Adoption date: *June 2019*

Rapporteur: *Ms. Patricia Parris, PhRMA*

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

Last Face-to-Face Meeting: *Prague, Czech Republic, November 2023*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Jun. 2019</i>	<i>Endorsement of Topic</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>All three vendor contracts approved; Safety and Threshold Project Team meet in Prague, CR</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2024</i>	<i>EWG meeting in Fukuoka, Japan to:</i> <ul style="list-style-type: none"> • <i>Integrate the Threshold Project learnings into the Safety section</i> • <i>Integrate Quality and Safety sections</i>
<i>Nov. 2024</i>	<i>Reach consensus on draft Technical Document</i>
<i>Jan. 2025</i>	<i>Begin PWP consultation (Health Canada, 1 month)</i>
<i>Jun. 2025</i>	<i>Step 1 Sign-off and Step 2a/b endorsement by ICH Assembly</i>
<i>Nov. 2025</i>	<i>End of Public consultation period</i>
<i>Jun. 2027</i>	<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
Jun. 2023	<i>May. 2024</i>	<i>Finalization of chemistry/quality sections</i>	<i>Reach consensus on final sections of chemistry/quality sections.</i>
Jun. 2023	<i>Jun. 2024</i>	<i>Finalization of safety section</i>	<i>Finalise the recommendations in the safety section, with exception of those that depend on outcome of threshold project.</i>
Jun. 2023	<i>Nov. 2024</i>	<u><i>Threshold Project</i></u> <ul style="list-style-type: none"> • <i>Ongoing peer reviews and EWG adoption of PDEs drafted by internal and external resources</i> 	<ul style="list-style-type: none"> • <i>Critical review of PDEs generated by internal and external resources</i> • <i>Real time distribution analysis with peer reviewed PDEs</i> • <i>Determine/plan for Phase 3 analysis of PDE dataset</i>
Jul. 2024	<i>Nov. 2024</i>	<u><i>Technical Document</i></u> <ul style="list-style-type: none"> • <i>Integrate learning from Threshold Project into safety assessment strategy</i> • <i>Align all aspects of the integrated draft guideline</i> • <i>Format draft guideline per ICH template</i> 	<ul style="list-style-type: none"> • <i>Conclude QT values based on threshold project data</i> • <i>Develop content that harmonizes issues raised in the Concept Paper</i> • <i>EWG reach consensus and prepare for PWP consultation</i>