

ICH Q3E EWG Work Plan

February 08, 2025

Topic Adoption date: June 2019

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Last Face-to-Face Meeting: Montreal, Canada, November 2024

1. Key milestones

1.a. Current status of key milestones

| Past 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>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> |
| <i>Nov. 2024</i> | <i>Quality/Chemistry and Safety subteams topics drafted for training materials</i> |

1.b. Key Deliverables

| Approval Date | Deliverable |
|------------------|---|
| <i>Jul. 2020</i> | <i>Q3E Guideline for Extractables and Leachables (E&L).</i> |
| <i>Jun. 2023</i> | <i>Threshold Project - PDEs generation</i> |

1.c. Future anticipated key milestones

| Expected future completion date | Milestone |
|---------------------------------|---|
| <i>May. 2025</i> | <i>EWG meeting in Madrid to:</i> <ul style="list-style-type: none">• <i>Reach consensus on technical document</i> |
| <i>Mar. 2025</i> | <i>Begin PWP consultation (1 month)</i> |
| <i>Jun. 2025</i> | <i>Step 1 Sign-off, Step 2a/b endorsement</i> |
| <i>Nov. 2025</i> | <i>End of Public consultation period</i> |

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|------------------|---|
| Jun. 2027 | <i>Step 3 sign-off and Step 4 adoption of final Guideline</i> |
|------------------|---|

2. Timeline for specific tasks

| Beginning date | End date | Task / Activity | Details |
|-----------------------|------------------|--|--|
| Jun. 2023 | <i>May. 2025</i> | <u>Threshold Project</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 additional PDEs generated by internal and external resources</i> <i>Real time distribution analysis with peer reviewed PDEs</i> <i>Draft manuscripts:</i> <ol style="list-style-type: none"> <i>Database development and chemical characterization/prioritization;</i> <i>PDE methodology and QT derivation</i> |
| Jun. 2024 | <i>May. 2025</i> | <u>Technical Document</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>Define QT values based on threshold project data</i> <i>Develop content that harmonizes issues raised in the Concept Paper</i> |