

ICH Q3E EWG Work Plan

January 16, 2023

Topic Adoption date: *June 2019*

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

Last Face-to-Face Meeting: *Incheon, Republic of Korea, November 2022*

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>Sep. 2022</i>	<i>Interim meeting, Washington DC, United States focus group on safety issues</i>
<i>Dec. 2022</i>	<i>Draft guideline with key sections progressing toward harmonization</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Mar. 2023</i>	<i>Submit proposal on threshold project for ICH funding</i>
<i>Jun. 2023</i>	<i>Reach consensus on Technical Document</i>
<i>Aug. 2023</i>	<i>Complete PWP consultation</i>
<i>Nov. 2023</i>	<i>Step 1 Sign-off, Step 2a/b endorsed</i>
	<i>End of Public consultation period</i>
<i>Nov 2025</i>	<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
<i>Jan. 2023</i>	<i>Jun. 2023</i>	<ul style="list-style-type: none"> • <i>Continue with content development for Technical Document</i> • <i>Reach consensus on Technical Document</i> 	<ul style="list-style-type: none"> • <i>Develop content that harmonizes the issues raised in the Concept Paper</i> • <i>EWG reaches consensus and prepares for any potential PWP concerns</i>
<i>Jul. 2023</i>	<i>Aug. 2023</i>	<i>PWP consultation</i>	<i>Address PWP comments</i>
<i>Sep. 2023</i>	<i>Nov. 2023</i>	<i>Step 1 sign-off, Step 2 a/b endorsed</i>	