

ICH Q3E EWG Work Plan

September 15, 2022

Topic Adoption date: *June 2019*

Rapporteur: *Dr. Kim Li, PhRMA*

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

Last Face-to-Face Meeting: *None; all meetings have been virtual*

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. 2022</i>	<i>Quarterly EWG meetings (virtual) since 2020</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Sep. 2022</i>	<i>F2F interim meeting with Founding members to build consensus on safety issues</i>
<i>May 2023</i>	<i>Step 1 Sign-off, Step 2a/b endorsed</i>
<i>Nov. 2023</i>	<i>Public consultation period</i>
<i>May 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. 2022</i>	<i>Nov. 2022</i>	<i>Continue with content development for Technical Document Development</i>	<i>Develop content that harmonizes the issues raised in the Concept Paper</i>
<i>Nov. 2022</i>	<i>Feb. 2023</i>	<i>Reach consensus on Technical Document (Step 1)</i>	<i>EWG reaches consensus prior to PWP consultation</i>
<i>Mar. 2023</i>	<i>Apr. 2023</i>	<i>PWP consultation</i>	
<i>Apr. 2023</i>	<i>May 2023</i>	<i>Step 1 sign-off, Step 2 a/b endorsed</i>	