

ICH Q13 EWG Work Plan

September 13, 2020

Topic Adoption date: *November 2018*

Rapporteur: *Dr. Sau Lee - FDA, United States*

Regulatory Chair: *Dr. Yoshihiro Matsuda - MHLW/PMDA, Japan*

Last Face-to-Face Meeting: *Singapore, November 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2018</i>	<i>Concept Paper and Business Plan Endorsement</i>
<i>Nov. 2018</i>	<i>Initiation of consensus building</i>
<i>May. 2019</i>	<i>Outline for technical document developed</i>
<i>Jun. 2019</i>	<i>Face-to-Face Meeting in support of consensus building, outline finalization, and technical document drafting</i>
<i>Nov. 2019</i>	<i>Face-to-Face Meeting in support of development of the technical document</i>
<i>April 2020</i>	<i>Completed draft distributed to individual organizations for feedback</i>
<i>May 2020</i>	<i>Virtual Meeting in support of revisions of the technical document</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2020</i>	<i>Virtual Meeting to continue revisions of the technical document and plan training materials</i>
<i>May 2021</i>	<i>Face to Face Meeting to finalize the technical document and Step 1 sign-off and Step 2 a/b endorsement, and initiate public consultation</i>
<i>Nov. 2022</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>May. 2020</i>	<i>Nov. 2020</i>	<i>Multiple EWG Meetings via Teleconference</i>	<i>Share and revise draft text for the technical document; have internal consultations by each party; review feedback from internal consultations; discuss plans for next virtual EWG meeting</i>
<i>Nov. 2020</i>	<i>Nov. 2020</i>	<i>Virtual EWG Meeting</i>	<i>Continue progress on drafting of the technical document and consensus building; discuss potential regional and/or technical concerns identified through each party's internal consultations</i>