

ICH Q13 EWG Work Plan

February 21, 2019

Topic Adoption date: *November 2018*

Rapporteur: *Dr. Sau (Larry) Lee – FDA, United States*

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

Last Face-to-Face Meeting: *Charlotte, NC, USA, November 2018*

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>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jun. 2020</i>	<i>Step 1 sign-off and Step2 a/b endorsement, and initiate public consultation</i>
<i>Nov. 2021</i>	<i>Step3 sign-off and Step 4 adoption of final guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2018	<i>May. 2019</i>	<i>Multiple EWG Meetings via Teleconference</i>	<i>Develop outline for technical document; initiate drafting process; identify sub-teams if required; identify potential sites for visits; discuss plans for face-to-face meeting</i>
Jun. 2019	<i>Jun. 2019</i>	<i>Face-to-Face EWG Meeting</i>	<i>Continue progress on drafting of technical document and consensus building; presentations on technical approaches/perspectives</i>
Jun. 2019	<i>Nov. 2019</i>	<i>Multiple EWG Meetings via Teleconference</i>	<i>Share and revise draft text for technical document; sub-team reports, if appropriate; discuss plans for next face-to-face meeting</i>
Nov. 2019	<i>Nov. 2019</i>	<i>Face-to-Face EWG Meeting</i>	<i>Continue progress on drafting of technical document and consensus building; discuss identified regional and/or technical concerns identified between face-to-face meetings</i>