

ICH Q12 EWG Work Plan

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Topic Adoption date: September 2014

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Last Face-to-Face Meeting: Amsterdam, The Netherlands, June 2019

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Sep. 2014</i>	<i>Concept Paper endorsement</i>
<i>Jun. 2017</i>	<i>Step 1 for Q12 Technical Document, consisting of Core Guideline and associated Annex</i>
<i>Nov. 2017</i>	<i>Steps 2a and 2b reached</i>
<i>Dec. 2018</i>	<i>End of public consultation period</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Nov. 2019</i>	<i>Step 3 Experts Sign-off</i>
<i>Nov. 2019</i>	<i>Step 4 adoption</i>
<i>Spring 2020</i>	<i>Initiation of training activities</i>

2. Timeline for specific tasks

Beginning date	End Date	Task / Activity	Details
<i>Jun. 2019</i>	<i>Jun. 2019</i>	<i>EWG meeting via teleconference and exchange of proposed text revisions via email</i>	<i>Continue discussion of any outstanding text from June 2019 meeting; discuss plans for training.</i>
<i>Jul. 2019</i>	<i>Jul. 2019</i>	<i>EWG meeting via teleconference and exchange of proposed text revisions via email</i>	<i>Discussion of proposed revised text for Chapter 1.</i>
<i>Sep. 2019</i>	<i>Sep. 2019</i>	<i>EWG meeting via teleconference to discuss proposed text revisions</i>	<i>Example and training sub-teams to report out. Continue discussion of examples (ECs for analytical methods, ECs for manufacturing process, PLCM) and plans for training.</i>
<i>Oct. 2019</i>	<i>Oct. 2019</i>	<i>EWG meeting via teleconference to discuss proposed text revisions and plan agenda for November F2F meeting</i>	<i>Continue discussion plan to development of training materials. Finalize agenda for Nov 2019 meeting.</i>