

ICH Q12 EWG Work Plan

July 27, 2018

Topic Adoption date: *September 2014*

Rapporteur: *Ms. Ashley Boam (FDA, US)*

Regulatory Chair: *Ms. Nanna Kruse (EC, Europe)*

Last Face-to-Face Meeting: *Montreal, Canada, May 2017*

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>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Dec. 2018</i>	<i>Complete public consultation period.</i>
<i>Jun. 2019</i>	<i>Step 4 adoption and initiation of training activities</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Feb. 2018</i>	<i>Sep. 2018</i>	<i>3 EWG meetings via teleconference</i>	<i>Review revised workplan; discuss each region's plans and timing for public consultation; regional updates; discuss plans for next F2F meeting; establish sub-teams to discuss plans for training and to</i>

			<i>develop additional examples.</i>
Sep. 2018	Oct. 2018	<i>EWG meeting via teleconference</i>	<i>Sub-team reports; develop agenda for interim F2F meeting in January or February 2019.</i>
Jan. 2019	Feb. 2019	<i>Face-to-face EWG interim meeting</i>	<i>Interim F2F meeting prior to June 2019 F2F meeting to begin discussion of comments received during the public consultation period.</i>
Feb 2019	June 2019	<i>2 EWG meetings via teleconference</i>	<i>Continue discussion of any significant public comments not addressed at interim F2F meeting and plans for training. Plan agenda for June F2F meeting.</i>