

ICH Q12 EWG Work Plan

7 March 2017

Topic Adopted: September 2014

Last Face-to-Face Meeting: Osaka, Japan – November 2016

1. Anticipated Milestones

Completion Date	Deliverable
November 2016 – April 2017	Share ICH Q12 version 7 with constituents. 2 EWG meetings, via teleconference to review and finalize examples, and prepare for interim meeting.
April 2017 Interim Meeting	Interim face meeting of EWG, April 4-7 , to review comments, identify and resolve major issues and prepare v8.0 for May/June face-to-face meeting.
May/June 2017	5-day face-to-face meeting to finalize Step 1 Technical Document

2. Timelines

Date	Task / Activity	Details
September 2014 – November 2014	<i>Step 1:</i> Consensus building, reviewing concept paper and business plan, and drafting the agenda for Lisbon meeting	EWG continued regular interactions by email
November 2014 – June 2015	Continue EWG discussion and meetings	<p>The EWG will meet, via teleconference, four times between January and May, 2015, to develop initial draft of guideline chapters, and to prepare for June Meeting:</p> <ul style="list-style-type: none"> ➤ Three sub-teams will be established to prepare proposals for consideration by the entire EWG ➤ January 21, 2015, EWG teleconference to identify key topics for guideline and agree on an integrated approach for the guideline <u>(Progress Report)</u> ➤ February 23, 2015, EWG teleconference to identify key elements of each chapter and agree on outline <u>(Outline of Guideline)</u> and initiate drafting of core guideline chapters ➤ March 31, EWG Teleconference to discuss key issues and agreement on ‘bullet points’ content of guideline chapters, provide

		<p>instructions to drafting teams to convert ‘bullet points’ to text, and to review EWG workplan (First Chapter Draft – Bullet points)</p> <ul style="list-style-type: none"> ➤ May 13, 2015, EWG teleconference to review draft of document, identify major challenges and prepare for June ICH Face to face meeting (Chapters Draft)
June 2015	EWG face-to-face meeting	EWG will meet face-to-face in June 2015, to address major challenges, develop guideline version 1 and agree on future milestones and timelines
June 2015 – December 2015	Continue EWG discussion and meetings	<p>The EWG will meet, via teleconference, four times between June and December 2015 to review version 1, discuss major issues to produce updated Q12 Technical Document, and to prepare for December Meeting:</p> <ul style="list-style-type: none"> ➤ Three sub-teams will continue to draft sections for consideration by the entire EWG ➤ July 8, 2015, EWG teleconference to review Fukuoka progress and identified challenges and agree plan to address ➤ September 9, 2015, EWG teleconference to review drafting teams materials, discuss common issues among drafting teams and address disagreements and concerns: ➤ October 14, EWG Teleconference to review version 2 Technical document ➤ November 19, 2015, EWG Teleconference to review version 2 and agree on agenda for face-to-face meeting in December
December 2015	EWG Face-to-face meeting	<ul style="list-style-type: none"> ➤ Face-to-face meeting to review updated Q12 Technical Document and address disagreements and concerns.
December 2015 – June 2016	Continue EWG discussion and meetings	<ul style="list-style-type: none"> ➤ Four EWG meetings, via Teleconference, to assess progress on major issues, revise current draft, and produce Q12 Technical Document version 4 ➤ Interim informal 2 day meeting of the established conditions team April 6-8, 2016
April 6-8, 2016	Interim Face-to-Face Meeting of Established Conditions (EC) Team	<ul style="list-style-type: none"> ➤ Face-to-face meeting of EC team to advance the development of EC section. EC section is a pre-requisite for enabling further development of other Q12 elements including lifecycle management plans, expectations for life cycle approaches in managing to legacy (currently marketed)

		products and overall role of the PQS
June 2016	EWG face-to-face meeting	<ul style="list-style-type: none"> ➤ Face-to-face meeting, to review Q12 Technical Document version 4, and address disagreements and concerns ➤ Agree on Q12 Technical Document version 5
June 2016 – November 2016	Continue EWG discussion and meetings	<ul style="list-style-type: none"> ➤ Five EWG meetings, via Teleconference, to assess progress on major issues, revise current draft, and produce Q12 Technical Document version 6
November 2016	EWG face-to-face meeting	<ul style="list-style-type: none"> ➤ Face-to-face meeting, to review Q12 Technical Document version 6, and address disagreements and concerns ➤ Agree on Q12 Technical Document version 7 to be shared with ICH parties and stakeholders
November 2016 – June 2017	Continue EWG discussion and meetings	<ul style="list-style-type: none"> ➤ Two EWG meetings, via Teleconference, to review input from ICH parties and stakeholders on issues that must be addressed before moving to <i>Step 1</i> Technical Document
April 2017	Interim face-to-face meeting of EWG	<ul style="list-style-type: none"> ➤ Interim 4-day meeting of EWG week of 3 April 2017 to address comments on v7.0 and prepare v8.0 for May/June face-to-face meeting.
May/June 2017	EWG face-to-face meeting	<ul style="list-style-type: none"> ➤ Face-to-face meeting to finalize <i>Step 1</i> and <i>Step 2a/b</i> Technical Document
June 2017 – June 2018	Continue EWG discussion and meetings	<ul style="list-style-type: none"> ➤ Receive <i>Step 2a/b</i> document comments, triage, and address significant issues
June 2018	EWG face-to-face meeting	<ul style="list-style-type: none"> ➤ Face-to-face meeting to finalize <i>Step 4</i> document