

ICH Q12 EWG Work Plan

February 25, 2019

Topic Adoption date: September 2014

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Regulatory Chair: Ms. Nanna Kruse – EC, Europe

Last Face-to-Face Meeting: Tokyo, Japan, February 2019 (Q12 interim meeting)

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>Jun. 2019</i> | <i>Step 3 Experts Sign-off</i> |
| <i>Second half 2019</i> | <i>Step 4 adoption</i> |
| <i>Second half 2019</i> | <i>Initiation of training activities</i> |

2. Timeline for specific tasks

| Beginning date | End Date | Task / Activity | Details |
|-----------------------|------------------|---|--|
| Mar. 2019 | Mar. 2019 | <i>EWG meeting via teleconference and exchange of proposed text revisions via email</i> | <i>Continue discussion of any significant public comments not addressed at interim F2F meeting, discuss proposed text revisions developed by subgroups and plans for training.</i> |
| Mar. 2019 | Apr. 2019 | <i>Continue to exchange proposed text revisions via email</i> | <i>Where possible, agree upon revised text to address minor comments.</i> |
| May. 2019 | May. 2019 | <i>EWG meeting via teleconference to discuss proposed text revisions and plan agenda for June F2F meeting</i> | <i>Continue discussion of proposed revisions developed by subgroups. Plan agenda for June F2F meeting</i> |