

ICH IQDG Work Plan

April 08, 2019

Topic Adoption date: November 2018

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Last Face-to-Face Meeting: NA

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Oct. 2018</i>	<i>Remit of the Informal Quality Discussion Group (IQDG)</i>
<i>Nov. 2018</i>	<i>IQDG Remit endorsement by Management Committee</i>
<i>Mar. 2019</i>	<i>First IQDG telecon</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Mar. 2019</i>	<i>IQDG draft Workplan</i>
<i>Apr. 2019</i>	<i>IQDG prioritization and recommendations for new ICH Guideline topic proposals (i.e. Q5A, Extractables and Leachables (E&L), Q9, Oligonucleotides...)</i>
<i>Apr. 2019</i>	<i>IQDG Work Plan for MC consideration</i>
<i>Jun. 2019</i>	<i>Agree IQDG Assessment Process establishing criteria to review/triage existing ICH Q & relevant M Guidelines, ICH Guidelines in progress (Steps 1-3) & newly proposed ICH Q topics/Guidelines.</i>
<i>Jun. 2019</i>	<p><i>Preliminary report to MC on:</i></p> <ul style="list-style-type: none"> • <i>IQDG future vision for integration & scope ICH Quality Guidelines</i> • <i>Plans for assessment & prioritization of existing ICH Quality Guidelines that warrant possible revision, updates, annexures, clarifications, Q & A, a potential new guideline, implementation plans &/or training in accordance with the ICH Quality Vision.</i>

Oct. 2019	<i>Assessment of any other new/revised <u>ICH Quality topic proposals</u> & priority recommendations to the MC for consideration & disposition.</i>
Nov. 2019	<i>IQDG Status report to MC on assessment & prioritization of existing ICH Quality guidelines that warrant possible revision, updates, annexures, clarifications, Q & A, a potential new guideline, implementation plans &/or training in accordance with the ICH Quality Vision</i>
Jun. 2020	<i>IQDG Status report to MC on assessment & prioritization of existing ICH Quality guidelines that warrant possible revision, updates, annexures, clarifications, Q & A, a potential new guideline, implementation plans &/or training in accordance with the ICH Quality Vision</i>
Nov. 2020	<i>IQDG Recommendation & Prioritization Report on assessment of ICH Q & relevant M Guidelines that warrant revision, updates, annexures, clarifications, Q & A, a new potential guideline, implementation plans &/or training in accordance with the ICH Quality Vision.</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Feb. 2019	<i>Feb. 2019</i>	<i>Inaugural Meeting</i>	<ul style="list-style-type: none"> • <i>Review of Reflection Paper and Remit</i> • <i>Assess & prioritize proposals for new ICH Q topics</i> • <i>Develop list of priorities for subsequent IQDG assessment</i>
Feb. 2019	<i>Mar. 2019</i>	<i>Draft workplan. Teleconference to meet and align on workplan</i>	<i>Align on tasks necessary to meet milestone activities.</i>
Mar. 2019	<i>Apr. 2019</i>	<i>Submit workplan to MC for consideration</i>	NA

Mar. 2019	Apr. 2019	<p>Teleconferences –</p> <ul style="list-style-type: none"> • Agree to Process • Advise on the newly proposed ICH quality topics <p>(Q5A, Oligonucleotide, E&L, Q9, M4Q(R1), BE for IR dosage forms)</p>	<ul style="list-style-type: none"> • Develop <u>process</u> / develop criteria to review/triage the existing ICH Q and M Guidelines, new guidelines under review and newly proposed topics/guidelines • Consider new <u>ICH Quality Topic proposals</u> envisioned under the ICH Quality Vision that have not been endorsed by the ICH with the goal of assessing how the proposal could be strengthened for reconsideration. • Prioritize and understand linkages/relationships to existing ICH Guidelines.
Apr. 2019	Apr. 2019	<p>Provide final recommendations for newly proposed ICH quality Topics</p>	<p>Provide the IQDG's final recommendations to ICH MC on the assessment and prioritisation of newly proposed 2018/2019 Quality topics (Q5A, Oligonucleotide, E&L, Q9, M4Q(R1), BE for IR dosage forms)</p>
Apr. 2019	Jul. 2019	<p>Teleconferences –</p> <p>Assessment of ongoing ICH quality Topics</p> <p>In Step 2: M9, Q3D(R1),</p> <p>In step 4: Q12, M7(R2), Q3C(R8), Q3D(R2)</p> <p>Other :</p> <p>M4Q(R1), Q13-, Q2(R2)/Q14</p>	<ul style="list-style-type: none"> • Assess impact of <u>ongoing ICH Quality Topics</u> on future ICH Quality harmonization work envisioned under the ICH Quality Vision. • Identify gaps: what guidelines require further evaluation /updating and why? • Understand linkages/relationships to other ICH Guidelines. • If relevant, suggest procedure /mechanism to update, i.e. Maintenance procedure (preferred as allows opening single chapters), Q&A, additional training • Update and compare activities, prioritizations, and progress with guideline evaluations.

Jun. 2019	<i>Jun. 2019</i>	<i>Discuss proposal for ICH new topics process for 2019/2020 with MC</i>	<ul style="list-style-type: none"> • <i>Discuss ICH new topics process with MC for 2019/2020, i.e. all new Q topics should be progressed via the mechanism of the IQDG.</i>
Jul. 2019	<i>Nov. 2019</i>	<p><i>Monthly Teleconferences</i></p> <p><i>Evaluate current ICH Quality and Multidisciplinary Guidelines</i></p> <p><i>ICH Q1 – Q11</i></p>	<ul style="list-style-type: none"> • <i>Assess impact of <u>current ICH Quality Guidelines</u> on future ICH Quality harmonization work (I.e. Q12) envisioned under the ICH Quality Vision.</i> • <i>Identify gaps: what guidelines require further evaluation /updating and why?</i> • <i>Understand linkages/ relationships to other ICH Guidelines.</i> • <i>If relevant, suggest procedure /mechanism to update, i.e. Maintenance procedure, Q&A, additional training</i> • <i>Update and compare activities, prioritizations, and progress with guideline evaluations</i>
Nov. 2019	<i>Nov. 2019</i>	<i>Teleconference with Informal Generic Drug Discussion Group</i>	<ul style="list-style-type: none"> • <i>Provide feedback on the Informal Generics Drug Discussion group plan.</i>

Nov. 2019	Nov. 2019	<i>If requested and approved, attend F2F ICH meeting.</i>	<ul style="list-style-type: none"> • <i>Provide update of IQDG activities and progress to ICH MC and ICH Assembly at f2f meeting:</i> <ul style="list-style-type: none"> ○ <i>Update ICH Quality vision</i> ○ <i>Propose prioritised list of new guidelines and guideline updates</i> ○ <i>Provide recommendation to the training subcommittee</i>
Nov. 2019	Nov. 2020	<p><i>Monthly Teleconferences</i></p> <p><i>Continue tasks to complete assessment and attend f2f ICH meetings to present final recommendations on any proposed revisions to ICH Guidelines.</i></p>	<ul style="list-style-type: none"> • <i>Assess impact of <u>all ICH Quality Guidelines</u> on future ICH Quality harmonization work envisioned under the ICH Quality Vision.</i> • <i>Identify gaps: what guidelines require further evaluation /updating and why?</i> • <i>Understand linkages/ relationships to other ICH Guidelines.</i> • <i>If relevant, suggest procedure /mechanism to update, i.e. Maintenance procedure, Q&A, additional training</i> • <i>Prioritize and triage recommendations.</i> • <i>Provide update of IQDG activities and final recommendations to ICH MC and ICH Assembly at f2f meeting</i>