ICH S5(R3) EWG Work Plan
29 January 2018

Topic Adoption date: April 2014
Rapporteur: Mr. Günter Waxenecker (EC, Europe)
Regulatory Chair: N/A
Last Face-to-Face Meeting: Montreal, Canada – May/June 2017

1. Key milestones

1.a. Current status of key milestones

<table>
<thead>
<tr>
<th>Past completion date</th>
<th>Milestone</th>
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</thead>
<tbody>
<tr>
<td>Jun. 2014</td>
<td>ICH S5 Informal WG meeting in Minneapolis, US; Discussion on the topic and endorsement of Concept Paper within IWG. Post-hoc discussion about the further process.</td>
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<tr>
<td>Nov. 2014</td>
<td>ICH S5 Informal WG meeting in Lisbon, Portugal; Re-discussion on the topic and endorsement of revised Concept Paper within EWG. Definition of work packages for revision ICH S5(R2).</td>
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<tr>
<td>Mar. 2015</td>
<td>Topic endorsed by the ICH Steering Committee.</td>
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<tr>
<td>Apr. 2015</td>
<td>ICH S5(R3) EWG Telecons; Initiation of work on ICH S5(R3) in line with the identified work packages.</td>
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<tr>
<td>Jul. 2017</td>
<td>Step 1 sign-off on the Technical document</td>
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<tr>
<td>Aug. 2017</td>
<td>Step 2a/b Endorsement of the Draft Guideline; Regional public consultation of 6 months</td>
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<tr>
<td>Oct. 2017</td>
<td>Publication of explanatory slides agreed by EWG members</td>
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1.b. Future anticipated key milestones

<table>
<thead>
<tr>
<th>Expected future completion date</th>
<th>Milestone</th>
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<tbody>
<tr>
<td>Mar. 2018</td>
<td>Step 3 regional consultation: The latest regional deadline for comments provided by the ongoing public review period is due by end of March.</td>
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<tr>
<td>Apr. 2018</td>
<td>Start of step 3 discussion of regional consultation comments</td>
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<tr>
<td>Nov. 2019</td>
<td>Step 3 experts sign-off / Step 4 Adoption of the Final Guideline (Face-to-face meeting)</td>
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## 2. Timeline for specific tasks

<table>
<thead>
<tr>
<th>Beginning date</th>
<th>End date</th>
<th>Task / Activity</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sep. 2017</strong></td>
<td>Nov. 2019</td>
<td>ICH S5(R3) EWG Teleconferences</td>
<td>Initiate review of the ICH Reference compounds currently in the list and those submitted through the public notification, as they become available, to double check data, ensure accessibility to source data and identify data gaps. Formation of an ICH S5(R3) EWG subgroup to work on details.</td>
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<tr>
<td><strong>Jan. 2018</strong></td>
<td>May. 2018</td>
<td>ICH S5(R3) EWG and regional Teleconferences</td>
<td>Collate comments and concerns (regional and EWG level)</td>
</tr>
<tr>
<td><strong>Apr. 2018</strong></td>
<td>Jun. 2018</td>
<td>ICH S5(R3) EWG and regional Teleconferences</td>
<td>Organize review of comments, identification of disagreements and concerns by selection of key items received during public review period that must be addressed before moving forward</td>
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