

ICH M9 EWG Work Plan

20 July 2018

Topic Adoption date: *June 2016*

Rapporteur: *Dr. Jan Welink (EC, Europe)*

Regulatory Chair: *Dr. Paul Seo (FDA, US)*

Last Face-to-Face Meeting: *Kobe, Japan, June 2018*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>Nov. 2016</i>	<i>Concept Paper endorsement</i>
<i>Nov. 2016</i>	<i>Business Plan endorsement</i>
<i>Jun. 2018</i>	<i>Reaching Step 1 on document</i>
<i>Jun. 2018</i>	<i>Reaching Step 2a/b on document</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Jul. 2018</i>	<i>Public consultation period</i>
<i>May. 2019</i>	<i>Step 4 adoption of the Final Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Sep. 2018</i>	<i>Nov. 2018</i>	<i>Teleconference</i>	<i>Further discussion of additional results of FDA, US experimental data on similarity in composition by reversed engineering (ongoing)</i>

			<p><i>experiments) and experimental data on dissolution testing media volume and coning effects (ongoing experiments).</i></p> <p><i>Discussion on possible issues on dissolution media.</i></p>
Feb. 2019	<i>Feb. 2019</i>	<i>Review of comments received during public consultation</i>	<i>Compilation of all the comments</i>
Mar. 2019	<i>Mar. 2019</i>	<i>Teleconference</i>	<p><i>Discussion on the comments received during public consultation.</i></p> <p><i>Incorporation of the comments in the guideline.</i></p>
Apr. 2019	<i>Apr. 2019</i>	<i>Teleconference</i>	<p><i>Discussion on the comments received during public consultation.</i></p> <p><i>Update guideline.</i></p>
May. 2019	<i>May. 2019</i>	<i>Step 4 Adoption of the Final Guideline</i>	<i>Finalisation of the guideline.</i>