

ICH Q3C(R8) EWG Work Plan

19 October 2018

Topic Adoption date: *February 2017*

Rapporteur: *Dr. Timothy McGovern, (FDA, US)*

Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *none (written procedure)*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
<i>May 2017</i>	<i>Achieved consensus on three solvents develop PDEs to include tert-butanol, 2-methyltetrahydrofuran, cyclopentylmethylether.</i>

1.b. Future anticipated key milestones

Expected future completion date	Milestone
<i>Q1 2019</i>	<i>Step 2a/b Endorsement of the Draft Guideline</i>
<i>Q3 - 2019</i>	<i>Step 4 Adoption of the final Guideline</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Mar. 2019</i>		Approval by the Assembly under <i>Step 2</i>	➤ Release for public consultation
<i>Mar. 2019</i>	<i>Sep. 2019</i>	<i>Step 3</i>	➤ Internal/external consultation in ICH regions

Sep. 2019	Nov. 2019	EWG telecon/e-mail consultation	➤ Reviewing and resolving comments received from consultation process; preparing <i>Step 3/4</i> document
Q4 2019		<i>Step 3</i> signoff	➤ Postal signoff <i>Step 3</i> by the Regulatory Experts.
May. 2020		<i>Step 4</i>	➤ Adoption by the Regulatory Members of the Assembly.