

# ICH Q3C(R7) EWG Work Plan

*21 February 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>Q2 - 2018</i>	<i>Step 2a/b Endorsement of the Draft Guideline</i>
<i>Q2 - 2019</i>	<i>Step 4 Adoption of the final Guideline</i>

## 2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Jun. 2018</i>		<i>Step 2a/b Endorsement of the Draft Guideline</i>	➤ <i>Release for public consultation</i>
<i>Jun. 2018</i>	<i>Dec. 2018</i>	<i>Public consultation</i>	➤ <i>Internal/external consultation in ICH regions</i>

<i>Jan. 2019</i>	<i>Mar. 2019</i>	EWG telecon/e-mail consultation	➤ Reviewing and resolving comments received from consultation process; preparing <i>Step 3/4</i> document
<i>Q2 2019</i>		<i>Step 3</i> Experts sign-off	➤ Electronic sign-off under <i>Step 3</i> by the Regulatory Experts.
<i>May. 2019</i>		<i>Step 4</i> Adoption	➤ Adoption of the Harmonised Guideline by the Regulatory Members of the Assembly.