

# ICH Q3C(R8) EWG Work Plan

## 1 February 2019

**Topic Adoption date:** *February 2017*

**Rapporteur:** *Dr. Timothy McGovern - FDA, United States*

**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>
<i>November 2018</i>	<i>Finalisation of Q3C(R7) – error correction for ethylene glycol PDE.</i>

#### 1.b. Future anticipated key milestones

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

## 2. Timeline for specific tasks

<b>Beginning date</b>	<b>End date</b>	<b>Task / Activity</b>	<b>Details</b>
<b><i>Apr. 2019</i></b>		Approval by the Assembly under <i>Step 2</i>	➤ Release for public consultation
<b><i>Apr. 2019</i></b>	<i>Oct. 2019</i>	<i>Step 3</i>	➤ Internal/external consultation in ICH regions
<b><i>Oct. 2019</i></b>	<i>Nov. 2019</i>	EWG telecon/e-mail consultation	➤ Reviewing and resolving comments received from consultation process; preparing <i>Step 3/4</i> document
<b><i>Q4 2019</i></b>		<i>Step 3</i> signoff	➤ Electronic signoff <i>Step 3</i> by the Regulatory Experts.
<b><i>Feb. 2020</i></b>		<i>Step 4</i>	➤ Adoption by the Regulatory Members of the Assembly.