ICH M9 EWG Work Plan
14 February 2018

Topic Adoption date: *14 June 2016*

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

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

Last Face-to-Face Meeting: *Geneva, Switzerland, November 2017*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Nov. 2016	*Concept Paper and Business Plan endorsement*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Jun. 2018	*Step 1 Experts Sign-off of the Technical Document*
Jun. 2018	*Step 2 a/b Endorsement of the Draft Guideline*
Aug. 2018	*Public consultation period*
May. 2019	*Step 4 Adoption of the Final Guideline*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Mar. 2018	*Mar. 2018*	*Teleconference*	*Discussion of unresolved issues regarding composition similarity, dissolution media, Caco2 cell data.* *Submission and discussion of first results of FDA, US experimental data on similarity in composition by reversed engineering (ongoing experiments).* *Submission and discussion of first results of FDA, US experimental data on dissolution testing media volume and coning effects (ongoing experiments).* *Drafting new version of guideline.*
May. 2018	*May. 2018*	*Teleconference*	*Update results on experimental data FDA, US* *Preparation and action steps Face to Face meeting Kobe, Japan*
Jun. 2018	*Jun. 2018*	*Face to Face meeting Kobe, Japan*	*Final discussion of FDA, US experimental data* *Discussion and finalizing issues regarding composition similarity, dissolution media, Caco2 cell data.* *Finalization guideline.*