

ICH M9 EWG Work Plan

9 February 2017

Topic Adopted: 14 June 2016

Last Face-to-Face Meeting: Osaka, Japan – November 2016

1. Anticipated Milestones

Completion Date	Deliverable
June 2018	Adoption of <i>Step 2 a/b</i> document
June 2019	Adoption of <i>Step 4</i> document

2. Timelines

Date	Task / Activity	Details
June 2016 - November 2016	E-mail consultation within WG/ EWG	<ul style="list-style-type: none"> ➤ Concept paper and Business plan were established. ➤ Agenda and possible documents for Osaka meeting were prepared.
7-10 November 2016	Face-to-face meeting (Osaka)	<ul style="list-style-type: none"> ➤ In depth discussion on criteria for BCS classification and biowaiving. ➤ Preparation of draft version guideline. ➤ Preparation/consensus on next steps towards face-to face meeting Montreal May 2017.
November-February 2017	Submission by e-mail: Collecting of supporting documents	<ul style="list-style-type: none"> ➤ Tasks have been distributed among members (action plan) to collect supporting documents on open issues as identified during the face to face meeting.
January 2017	Submission by e-mail: new draft version of the guideline	<ul style="list-style-type: none"> ➤ The Rapporteur will prepare a (new) draft version of the guideline based upon the discussions so far.
February 13, 2017	EWG teleconference	<ul style="list-style-type: none"> ➤ Discussion of open issues based upon the collected supportive documents by members. ➤ Drafting new version of guideline.
March - April 2017	EWG teleconference	<ul style="list-style-type: none"> ➤ Update of progress. ➤ Discussion open/controversial issues identified during February 2017 teleconference.

		<ul style="list-style-type: none"> ➤ Drafting new version of guideline. ➤ Preparation second EWG meeting.
May 2017	Face-to-face meeting (Montreal)	<ul style="list-style-type: none"> ➤ Finding consensus on controversial issues. ➤ Update of the draft guideline through face-to-face discussion