

ICH Q3D(R1) EWG Work Plan

21 February 2018

Topic Adoption date: *October 2009 (Maintenance for Cutaneous and Transdermal Routes approved September 2016)*

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

Regulatory Chair: *N/A*

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

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Q1 2018	Achieve consensus on revision to Cadmium Inhalation PDE

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Q2 2018	<i>Step 1 and Steps 2a/b on the revision to the Cadmium Inhalation PDE, Regional public consultation period on the Cadmium Inhalation PDE</i>
Q4 2018	<i>Steps 3 and 4 on the revision to Cadmium Inhalation PDE, following review of public comments Step 1 and Steps 2a/b on the cutaneous and transdermal PDEs</i>
Q1 2019	<i>Regional public consultation period on cutaneous and transdermal PDEs</i>
Q4 2019	<i>Steps 3 and 4 on the cutaneous and transdermal PDEs, following review of public comments</i>

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Apr. 2017</i>	Click or tap to enter a date.	Initiate development of permitted daily exposures for the cutaneous and transdermal routes of administration. Define whether cutaneous and transdermal PDEs are necessary for all or some of the 24 elements in the ICH Q3D Guideline.	<ul style="list-style-type: none"> ➤ Schedule teleconferences ➤ Develop work plan and delegate work
<i>August 2017</i>		Initiate discussions regarding error in calculation for Cadmium Inhalation PDE	<ul style="list-style-type: none"> ➤ Schedule teleconferences to discuss proposed revision
<i>Nov. 2017</i>	<i>Click or tap to enter a date.</i>	EWG meets for F2F meeting Review PDE revision to Cadmium Inhalation PDE	<ul style="list-style-type: none"> ➤ Review progress on cutaneous and transdermal PDE development ➤ Achieve agreement on revision to text regarding PDE. Forward revision for public comment.
<i>Feb. 2018</i>	<i>Click or tap to enter a date.</i>	Finalize PDE revision to Cadmium Inhalation PDE	<ul style="list-style-type: none"> ➤ Sign off on <i>Step 1</i> Technical document and Endorsement under <i>Steps 2a/b</i>; prepare for release for public comment
<i>Jun. 2018</i>	<i>Aug. 2018</i>	Review public comments on Cadmium PDE revision	<ul style="list-style-type: none"> ➤ Gain agreement on the revision
<i>December 2018</i>		Finalize PDEs for cutaneous and transdermal route of administration. Publish for public comment.	<ul style="list-style-type: none"> ➤ Sign off on <i>Step 1</i> Technical document and Endorsement under <i>Steps 2a/b</i>; prepare for release for public comment

		Finalize Cadmium Inhalation PDE revision	➤ Electronic sign-off under <i>Step 3</i> by the Regulatory Experts, Adoption under <i>Step 4</i> by the Regulatory Members of the Assembly.
<i>January 2019</i>	<i>May 2019</i>	Public consultation	➤ Internal/external consultation in ICH regions for cutaneous and transdermal route of administration
<i>Jun. 2019</i>	<i>Oct. 2019</i>	EWG telecon/e-mail consultation	➤ Reviewing and resolving comments received from consultation process; preparing <i>Step 3/4</i> document
<i>November 2019</i>		<i>Step 3</i> Sign-off	➤ Electronic sign-off under <i>Step 3</i> by the Regulatory Experts.
<i>December 2019</i>		<i>Step 4</i> Adoption	➤ Adoption under <i>Step 4</i> by the Regulatory Members of the Assembly.