

ICH Q3D (R2) Maintenance EWG Work Plan

31 January 2020

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

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Regulatory Chair: *N/A*

Last Face-to-Face Meeting: *Amsterdam, The Netherlands - June 2019*

1. Key milestones

1.a. Current status of key milestones

Past completion date	Milestone
Q1 2018	Achieve consensus on revision to Cadmium Inhalation PDE
Q3 2018	Publish Step 2 version for public comment on Cadmium Inhalation PDE
Q1 2019	Finalize Step 3/4 revision (Q3D(R1)) to Cadmium Inhalation PDE following review of public comments

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Feb. 2020	Step 1 sign-off of cutaneous PDEs document
Mar. 2020	Step 2a/b endorsement of cutaneous PDEs document
Q2-Q3 2020	Publish for public comment Step 2 cutaneous PDEs document
Nov. 2020	Step 3 document for cutaneous PDEs
Dec. 2020	Step 4 document for cutaneous PDEs

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
<i>Apr. 2017</i>		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>		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>Nov. 2017</i>	<i>Nov 2018</i>	EWG holds monthly teleconferences; subgroups work on key action items identified at 2017 F2F meeting	<ul style="list-style-type: none"> ➤ Sub-groups address key issues including bioavailability assumptions; potential skin toxicity; applicability of limit for nickel; treatment of platinoids. Report back on progress at monthly calls. Initiate drafting of document.
<i>Jun. 2018</i>		Finalize PDE revision to Cadmium Inhalation PDE	<ul style="list-style-type: none"> ➤ Sign off on <i>Step 2</i> document; prepare for release for public comment
<i>Sep. 2018</i>	<i>Nov. 2018</i>	Review public comments on Cadmium PDE revision	<ul style="list-style-type: none"> ➤ Achieve agreement on final text for revision.

<i>February 2019</i>	<i>March 2019</i>	Finalize Cadmium Inhalation PDE revision	➤ Gain agreement on <i>Step 3/4</i> version
<i>Jun. 2019</i>		EWG meets for F2F meeting	➤ Conduct a detailed review of each section of the Addendum and updated text of cutaneous PDE development
<i>Jun. 2019</i>	<i>Nov. 2019</i>	EWG holds monthly teleconferences; work on finalizing of the sections identified at the 2019 F2F meeting as sections requiring further explanation	➤ Achieve agreement on the Addendum document for cutaneous PDEs.
<i>February 2020</i>		Finalize PDEs for cutaneous and transdermal route. Step 1 sign-off	
<i>March 2020</i>		Publish Step 2 for public comment.	➤ Cutaneous PDEs to be published for public comment.
<i>April 2020</i>	<i>July 2020</i>	Review public comments on cutaneous PDEs	➤ Internal/external consultation in ICH regions for cutaneous and transdermal route of administration
<i>Jul. 2020</i>	<i>Oct. 2020</i>	EWG telecon/e-mail consultation	➤ Reviewing and resolving comments received from consultation process; preparing <i>Step 3/4</i> document
<i>November 2020</i>		<i>Step 3</i> signoff	➤ Postal signoff <i>Step 3</i> by the Regulatory Experts.
<i>December 2020</i>		<i>Step 4</i>	➤ Adoption by the Regulatory Members of the Assembly.