ICH Q3D(R2) EWG Work Plan
4 February 2022

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, Netherland - 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*
Aug. 2020	*Step 1 sign-off of cutaneous PDEs document*
Sep. 2020	*Step 2a/b endorsement of cutaneous PDEs document*
Q2 2021	*Publish for public comment Step 2 cutaneous PDEs document*

1.b. Future anticipated key milestones

Expected future completion date	Milestone
Feb. 2022	*Finalize Step 3 document for cutaneous PDEs following review of public comments*
Mar. 2022	*Step 4 document for cutaneous PDEs*

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Apr. 2017	*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.*	➢ *Schedule teleconferences* ➢ *Develop work plan and delegate work*
Aug. 2017		*Initiate discussions regarding error in calculation for Cadmium Inhalation PDE*	➢ *Schedule teleconferences to discuss proposed revision*
Nov. 2017	*Click or tap to enter a date.*	*EWG meets for F2F meeting* *Review PDE revision to Cadmium Inhalation PDE*	➢ *Review progress on cutaneous and transdermal PDE development* ➢ *Achieve agreement on revision to text regarding PDE. Forward revision for public comment.*
Nov. 2017	***Nov. 2018***	*EWG holds monthly teleconferences; subgroups work on key action items identified at 2017 F2F meeting*	➢ *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.*
Jun. 2018	*Click or tap to enter a date.*	*Finalize PDE revision to Cadmium Inhalation PDE*	➢ *Sign off on Step 2 document; prepare for release for public comment*

Sep. 2018	***Nov. 2018***	*Review public comments on Cadmium PDE revision*	➢ *Achieve agreement on final text for revision.*
Feb. 2019	***Mar. 2019***	*Finalize Cadmium Inhalation PDE revision*	➢ *Gain agreement on Step 3/4 version*
Jun. 2019	***Click or tap to enter a date.***	*EWG meets for F2F meeting*	➢ *Conduct a detailed review of each section of the Addendum and updated text of cutaneous PDE development*
Jun. 2019	***Feb. 2020***	*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.*
Mar. 2020	***May. 2020***	*Review PDE revision to Au, Ag, Ni PDEs*	➢ *Correct the errors of the all route of PDEs of Au, the parenteral PDE of Silver and the inhalation PDE of Ni.*
Jun. 2020	***Aug. 2020***	*Finalize PDEs for cutaneous and transdermal route.* *Finalize PDE revision to Au, Ag, Ni PDEs Step 1 sign-off*	
Sep. 2020	***Apr. 2021***	*Publish Step 2 for public comment.*	➢ *Cutaneous PDEs to be published for public comment.*
Jan. 2021	***Apr. 2021***	*Review public comments on cutaneous PDEs*	➢ *Internal/external consultation in ICH regions for the public comments on cutaneous PDEs*
Feb. 2021	***Feb. 2022***	*EWG telecon/e-mail consultation*	➢ *Reviewing and resolving comments received from consultation process; preparing Step 3/4 document*
Feb. 2022		*Step 3 signoff*	➢ *Postal signoff Step 3 by the Regulatory Experts.*
Mar. 2022		*Step 4*	➢ *Adoption by the Regulatory Members of the Assembly.*