ICH Q3D(R1/R2) EWG Work Plan
01 February 2019

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: *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
Q3 2018	Publish Step 2 version for public comment on Cadmium Inhalation PDE
Q4 2018	Receive and review public comments on Step 2 document.

1.b. Future anticipated key milestones

Expected future completion date	**Milestone**
Q1 2019	Finalize Step 3/4 revision to Q3D(R1) - Cadmium Inhalation PDE following review of public comments
Q2 2019	Finalize Step 2 Q3D(R2) cutaneous and transdermal PDEs document Publish for public comment Step 2 cutaneous and transdermal PDEs document
Q4 2019	Review public comments, revise document and finalize Step 4 document for Q3D(R2) cutaneous and transdermal PDEs

2. Timeline for specific tasks

Beginning date	End date	Task / Activity	Details
Nov. 2017	*July 2019*	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		Finalize PDE revision to Cadmium Inhalation PDE	➢ Sign off on *Step 2* document; prepare for release for public comment
Sep. 2018	*Jan. 2019*	Review public comments on Cadmium PDE revision	➢ Gain agreement on *Step 3/4* version
Feb. 2019		Finalize Cadmium Inhalation PDE revision	
July 2019		Finalize Step 2 PDEs for cutaneous and transdermal route of administration. Initiate procedure to publish for public comment.	➢ PDEs to be published for public comment.
August 2019	*November 2019*	*Step 3*	➢ Internal/external consultation in ICH regions for cutaneous and transdermal route of administration
Dec. 2019	*Mar. 2020*	EWG telecon/e-mail consultation	➢ Reviewing and resolving comments received from consultation process; preparing *Step 3/4* document

April 2020		*Step 3* signoff	➢ Postal signoff *Step 3* by the Regulatory Experts.
May 2020		*Step 4*	➢ Adoption by the Regulatory Members of the Assembly.