ICH Q3D(R1) Guideline for Elemental Impurities – Cadmium Inhalation PDE

Early June 2018 the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) has reached step 2b with revision R1 of its quality guideline Q3D - *Guideline for Elemental Impurities*.

The guidance established permitted daily exposures (PDE) measured in µg/day to evaluate elemental impurities in pharmaceutically manufactured drugs - administered orally, via parenteral and inhalation routes of administration. Differences in absorption between the dermal and oral routes are known for several compounds. Because of that, dermal absorption data may allow re-evaluations (increase or decrease) of some oral PDEs.

Since June 2016 new developed drugs must be risk-evaluated for possible metallic contaminations. From end of 2017 all pharmaceutically manufactured drugs must be tested. The guideline lists 24 elemental impurities and divides these into four risk classes due to their toxicity. Cadmium is together with Mercury, Lead and Arsenic in the highest class 1.

Expert Working Groups (EWG) have been (re-) evaluating the data supporting the Cadmium inhalation PDE and found that a modifying factors approach, like that used to calculate oral and parenteral PDEs was appropriate for the inhalation PDE. Q3D Revision 1 is focused on the error correction. It has reached step 2b in May 2018 and is now open for consultation till 16th of August 2018.

ICH Quality Guidelines – Q3D(R1) Revision of Q3D Cadmium Inhalation PDE
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html