PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements – Recent Experience and Plans for Full Implementation in 2018

Breakout Session #: 1

Update on Recent US/EU/JP Regulatory Guidance and Further ICH EI Initiatives

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Breakout Session 1: Update on Recent US/EU/JP Regulatory Guidance and Further ICH EI Initiatives

1. Are there any areas in current guidelines that need further clarification?

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    a. If EIs in the drug product are <PDEs based on the risk assessment or testing, what will you do if an individual ingredient monograph has specifications for individual elements?
    b. How should other routes of administration be handled, e.g. dermal, hair/scalp, broken skin vs. normal?

2. Global status of EI/heavy metals requirements outside US/EU

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   a. How are companies planning to manage existing HM/USP <231> requirements in countries that have not planned to implement ICH Q3D and methods (e.g. USP <233>)?
   b. For countries that do not permit skip lot testing, will companies test every lot even if there is sufficient EI data to confirm compliance to the HM limit specs/test?
   c. How do companies plan to address requirements in countries where they have adopted lower limits for specific elements (e.g. India – Hg) than listed or may not be aligned with ICH Q3D?
   d. The same product may be regulated as a drug in one country and a cosmetic in another. How do companies plan to manage this relative to EIs?

3. What happens after Day 1?

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    a. What plans does your company have for reviewing risk assessments or conducting on-going monitoring? At what frequency?
    b. Are pharmaceutical companies 'owning' this process?
        i. Did you receive the necessary information from suppliers?
        ii. Are you putting pressure on suppliers to provide information now/on-going?
        iii. How are you handling contract manufacturers?
        iv. Have you included exchange of EI information in quality agreements?

4. What challenges have you encountered for veterinary drugs or in using ingredients that come from food/cosmetic/industrial suppliers?

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   a. Have you had an particular challenges in collecting the information or doing risk assessments related to animal drugs?
   b. Have you had challenges with suppliers who do not often sell into the veterinary or pharmaceutical market, e.g. food, cosmetic or industrial grade products
      i. Are they familiar with ICH Q3D?
      ii. Are you getting information from them?

5. New drug submissions – have any specific regulatory agency questions or concerns been raised during the review process?

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   a. Are there differences in how specific countries (e.g. US, EU, others) are implementing ICH Q3D?
   b. Are there issues that need further clarity or guidance (e.g. FDA's final guidance has not been published yet)?