Webinar

Elemental Impurities (ICH Q3D): Training & Case Studies

October 19th 2017 (Thursday); Starting at 15:00 CEST (Spain)

***Duration: 60 minutes** (The attendance is free, online and previous registration in the form of the bottom)*

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Pablo Cobo

(Biopharma Testing Manager at Kymos Pharma Services)

Summary of the content

- The implementation of the ICH Q3D requirements is already ongoing for finished drug products. In this Webinar, we will highlight the key-points of the normative: scientific risk assessments and methods for analytical testing. The different implementation approaches (component approach and product approach) will be reviewed and analyzed and the webinar will conclude with a case study.

- We intend to cover all possible questions coming from a broad audience using the expertise of Azierta with scientific risk assessments, and the specialist knowledgde of Kymos with analytical testing.

Webinar modules

1. **Background of ICH Q3D**
2. **Introduction, objective, important dates**
3. **Key aspects for the implementation**
4. **How to do a risk assessment; component approach vs product approach**
5. **Analytical testing: Techniques and methodologies suitable for EI analysis**
6. **Analytical testing: Development and validation of analytical methods**
7. **Analytical testing: Project strategies**
8. **Case study: a real example**
9. **Questions**

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