

26 February 2016
EMA/INS/158905/2016
Compliance and Inspections

EU workshop on ICH Q3D from a quality perspective

5-6 April 2016, European Medicines Agency, London

Purpose

The new ICH Q3D guideline for elemental impurities will be the subject of a workshop at the EMA between EU regulators, the European Pharmacopoeia and the pharmaceutical industry. The workshop will focus mainly on the quality aspects of the guideline and its implementation in the European regulatory system.

The training modules developed and endorsed by the Q3D IWG will be used as a basis for the material presented at the workshop.

Topics on the program include:

- Overview of safety aspects;
- Risk assessment of elemental impurities;
- Control of elemental impurities;
- Application of the calculation options;
- Elemental impurities in the Ph.Eur. and implications for CEPs;
- EU regulatory perspective on elemental impurities.

Attendance at the workshop will be by invitation only.