

Clinical Investigation and Evaluation

Literature Review

A critical and indispensable component of any Technical Dossier

With greater emphasis being placed on clinical evaluation at all stages of the medical device life cycle, and restrictions being placed on the use of non-clinical data in conformity assessment, the subject of literature review has emerged into the limelight from its undeserved backwater.

This course will present literature review in the context of the current regulatory framework for clinical evaluation in the EU and the likely impact of the changing expectations from Competent Authorities and Notified Bodies. Advice on how to put together a scientifically robust literature review will be given, based on personal experience writing systematic reviews for Government bodies and on guidance from ISO 14155 and GHTF.

(½ day course)

Course content:

1. Where are we?
 - The regulatory landscape
 - Why carry out a literature review?
2. What is a literature review for?
 - The role of literature review in clinical evaluation
 - What is a clinical evaluation?
 - When is a clinical evaluation required?
 - The place of clinical evaluation in risk management and regulatory compliance
 - The role of literature review in a clinical investigation
 - The role of literature review in post-market surveillance
3. What goes into a literature review?
 - Scientific principles of systematic review
 - Guidance from ISO 14155 and GHTF documents
 - Search and review techniques
 - What is equivalence and how do you demonstrate it?
 - Examples and practical hints