

Changes in Post-market Surveillance in Europe

A Strategy for Post-Market Surveillance

Recent changes to the European Medical Devices Directives, to be implemented by March 2010, require that, in most circumstances, a technical risk assessment alone will no longer be a sufficient basis for a risk assessment. Instead, the acceptability of the risk to patients must be evaluated from a clinical risk assessment, i.e. one based on clinical data. This has an impact, not only on the need for clinical studies as a route to market, but also in the requirement for an ongoing clinical evaluation in the post-market phase. Knowledge of the origins of this requirement, arising from the fundamental principles on which the European Directives were built, helps in the development of a compliant and cost effective post-market risk management plan.

(One-day course)

Course content:

1. Where are we in the regulatory landscape and what are we trying to do?
 - Origin and principles of European regulations
 - Essential Requirements – what are they?
 - Risk Management: ISO 14971 principles and post-market requirements
 - Distillation of requirements in the post-market phase
2. Development of a PMS plan: what are the options?
 - Components of post-market surveillance : prospective studies and reactive data
 - Objectives and requirements of PMS, PMCF & Vigilance
 - What vigilance can do : Advantages and pitfalls
 - Conducting a Clinical Literature Review
 - PMCF: what is it, how does it fit in and when is it necessary?
 - Cost effectiveness considerations
3. Planning for risk management and product support
 - Integration of Vigilance into a post-market surveillance plan
 - Prospective post-market clinical studies
 - Device registries: requirements, advantages and pitfalls
4. The Value of Vigilance and PMCF
 - Examples
5. Conclusion
 - The role of vigilance, surveys and PMCF in a PMS plan
 - A strategy for Post-Market Surveillance