

## Comparison between IDE studies and CE-marking studies

### An Efficient Strategy for Route to Market

Medical device companies are increasingly trying to optimise clinical trial resources and improve speed of market entry by developing clinical investigation programmes that meet regulatory requirements in both the USA and the European Union. An understanding of the inherent differences between relevant regulations either side of the Atlantic leads to an understanding of their common denominators. With such knowledge, it is possible to design one international, multicentre study that meets all the relevant requirements.

(Half-day course)

#### Course content:

1. Origin of the differences
  - 1906 Food and Drugs Act *et seq.*
  - The New Approach
  - Implications for the basis of market approval
2. Side-by-side comparison of the basic differences
  - Objectives
  - Methodology
  - GCP requirements
  - Duration and numbers
3. Planning studies for the worldwide market
  - Objectives
  - Methodology
  - GCP requirements
  - Duration and numbers
4. How it works in practice
  - Case study
5. Conclusion
  - A strategy for a one-step route to market