As users and regulatory agencies are becoming less ‘tolerant’ of medical device failure, regulatory agencies are placing greater emphasis on post market surveillance as a way to improve risk management and protect public health. This course will review the regulatory expectations for post market surveillance and outline how to apply the requirements to medical devices. Topics include: complaint handling & vigilance systems, Medical Device Reports (MDR), implementation challenges, medical device tracking, impact of post approval studies, compliance requirements & meeting them, and complaint systems inspections. Throughout the course, examples and case studies will help participants apply the concepts being covered.
What is post market surveillance?
- Terminology: Surveillance, complaint, adverse event...
- Lifecycle of a medical device
  - Importance of risk assessment & risk management
  - Medical device design and manufacture:
    - Relationships with surveillance & complaint handling
- Conditions of approval & post approval studies
- Adverse event & vigilance reporting
- What is a medical device report?
  - GHTF SG2 guidelines

Requirements and effective strategies for surveillance & complaint handling:
- Is there a difference between post market surveillance & complaint handling?
- What is complaint handling?
  - Parsing complaints from:
    - Enhancement requests
    - Personal preferences
    - Service
    - Business practices
  - When does a complaint become a reportable event?
- Build your business case to management
- What is post market surveillance if NOT complaint handling?
- Managing complaints and looking at trends
- Feedback loop to quality system
- Escalation & evaluation for field action
  - Risk assessment/management
  - HHE

Requirements and effective strategies for medical device reporting:
- US requirements for reporting
  - Who does it apply to? Who is exempt?
  - What is a reportable event?
  - Reporting timelines
  - MedWatch, MedSun & MAUDE
    - Forms 3500, 3500A
- European (EU) requirements
  - MDD, AIMD
  - What is an event?
  - Reporting timelines
  - EC Guidelines & vigilance systems
  - EU: Eudamed & NCAR

HOTEL INFORMATION
The Hilton LAX, Los Angeles, CA (CPPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CPPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CPPIE room rate of $255/night if booked 4 weeks in advance).
DoubleTree by Hilton London - Victoria (CPPIE room rate of £199.00/night if booked 4 weeks in advance).