MEDICAL DEVICES:
DEVELOPING EFFECTIVE
POST MARKET SURVEILLANCE
AND COMPLAINT HANDLING SYSTEMS

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.
Jonathan Lee has more than 25 years of broad-based medical device experience with extensive Quality System experience encompassing ISO, MDD & GMP standards and regulations, through consulting and senior management positions in QA/RA, R&D, Project Management, Product Management, and Product Introduction disciplines, in both the United States and Australia. A multiple patent holder, Mr. Lee’s prior roles include VP R&D at Cardiac Control Systems, Vice President Quality, Regulatory & Clinical affairs at Medtronic. In addition, his consulting roles supporting implantable bio stimulation telemetry systems, implantable heart sub-system, catheter defibrillation system, surgical tool, vertebral stiffness measuring system, respiratory interfaces, cardiac catheter development, medical device process V&V, quality system development & implementation, and product approvals, have provided for an extensive accumulated experience.

Today, as Principal Consultant and Managing Member of “MedDev Consulting Solutions International” he provides strategic direction and tactical solutions for unique medical device challenges. Including areas such as integration of quality systems with compliance, product performance and elevated stakeholder expectations.

Mr. Lee holds an Electrical Engineering (Biomedical) BE degree from the University of NSW in Australia with post graduate work in Computer Studies at the same University. He has participated in compliance symposia at Harvard University and served as an instructor on quality systems at University of Southern California School of Pharmacy Master’s Degree Program.

### HOTEL INFORMATION

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<tr>
<th>Hotel Name</th>
<th>Location</th>
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<td>The Hilton LAX, Los Angeles, CA</td>
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### FIRST DAY

**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

### SECOND DAY

**Post approval studies:**
- Post approval/conditions of approval studies
- Requirements
- 522 studies (post market surveillance)
- Registries

**Medical device tracking:**
- What needs to be tracked
- Usefulness of tracking
- Requirements for tracking
  - FDA
  - EU

**Quality system considerations:**
- More on the feedback loop to quality system
- Data to monitor, frequency of review
- Links to key QMS processes:
  - Risk management
  - CAPA
  - Management controls
- Escalation
  - Corrections, removals, and recalls
  - Inspections
  - Enforcement actions

**Complaint handling system implementation challenges:**
- Records
- Timeliness
- Decision making – who decides what?
- Field service
- Trending – separating ‘real’ from ‘noise’
- MDR-reporting & second guessing
- Global & multiple site implementation
- International product distribution & reporting

**Related other topics:**
- Pharma & AERS
- HHE’s
- Competitors & complaints
- Inspections: Some do’s & don’ts