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

2 Day virtual Seminar

Course Description

What are U.S. FDA CGMP expectations / requirements for Post Market Surveilance and Complaint Handling.

This seminar will examine Section 522 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as appropriate articles / Annexes of the EU's MDR, which require manufacturers to conduct postmarket surveillance at the time of approval or clearance or at any time thereafter of certain class II or class III devices. Section 522 is implemented in 21 CFR 822. This formal postmarket surveillance is the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device. A more generalized "post market surveillance" / complaint handling is also a requirement under the device CGMPs, 21 CFR 820, -.100 - CAPA, and -.198 - Complaints

Why Should You Attend

Global companies must meet US FDA 21 CFR 820 (The QSR) requirements in order to sell such devices in the US, no matter where they are manufactured . These companies must pass FDA compliance inspections (audits) to 21 CFR 820. One of the key components of these device CGMPs in addrssing post-market use issues and complaints / CAPA. The FDA expects companies to have effective programs in place to caputure post-market problems / non-conformances, react to minimize risk to users / patients, and use such data for product imporvement. With certain devices, the FDA mandates such controls

Who Will Benefit

- Senior management
- Regulatory Affairs
- Quality Assurance
- Production
- R&D and Engineering

Faculty John E. Lincoln

John E. Lincoln, is Principal of J. E. Lincoln and Associates LLC, a consulting company with over 36 years experience in U.S. FDA-regulated industries, 22 of which are as an independent consultant. John has worked with companies from start-up to Fortune 100, in the U.S., Mexico, Canada, France, Germany, Sweden, China and Taiwan

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Training Agenda Day 01

Introduction (personal / course information)

Session 1 – US FD&C Act Section 522 and 21 CFR 822

- "Postmarket Surveillance under Section 522 of the Federal Food, Drug, and Cosmetic Act", Guidance, dated October 2022
- 21 CFR 822 – Implementing Sec. 522 of the FD&C Act – The Law / Requirements – Class II and III Devices

Session 2 -- US FDA's Post Approval Studies (PAS) Requirements

- PAS Requirements and PMAs
- PAS Orders
- PAS Protocols
- Interim and Final PAS Reports
- Report Evaluations

Session 3 -- FDA's Voluntary Summary Malfunction Reports

- Medical Device Reporting / Adverse Events (MDRs)
- The Voluntary Summary Malfunction Reports

Session 4 -- CAPA / Trending

- Internal "Complaints" - NCMRs, OOS'
- External Complaint Handling
- CAPA Documentation
- CAPA Trending

Q&A

End, Day 1

Training Agenda Day 02

IReview of Day 1 – Key Points

Session 5 – Failure Investigation, Root Cause Analysis

- Failure Investigation Tools
- Root Cause Analysis – Methods and Tools
- Communication
- Reports
- CAPA Trending

Session 6 – Risk Management and Human Factors

- Patient Hazard / Risk Management per ISO 14971:2019
- QMS / System Level
- File / Review (Benefit / Risk)
- Narrative / Descriptive Information
- Hazards, FTA, D-, P-, U-FME[C]A + Normal
- FDA Use / Human Factors Requirements
- Use Engineering Process – 9 stages – IEC 62366-1

Session 7 – Cybersecurity, Especially Post-Market

- Cybersecurity Requirements
- Threat Modelling ...
- Post-Market Cybersecurity

Session 8 – Project Management Tools (slides)

Gantt Chart

- CPM Network Diagram
- PERT Network Diagram
- Post-Market Surveillance Usage

Q&A

End, Day 1

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Name **Email**

Organization **Department** **Position**

Phone **Mobile**

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