

13A - A Unified Approach to Complaints, Servicing, and FDA Reporting

Presenter

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Session Summary

Medical device manufacturers have interlocking regulatory requirements. This presentation explains how to create unified systems that brings together servicing, complaints, corrective action, and other processes. Session participants learn the regulatory requirements for both record keeping and reporting to the FDA.

This presentation provides you with the information you need to implement an effective system for managing and reporting adverse events. During the session, we break down the regulatory requirements into plain English, and describe them using common quality tools such as flow diagrams and fault tree analysis. Using this approach helps you understand the essential parts of the regulations.

The session provides complete descriptions of the interlocking systems that the FDA requires you to implement. These systems include:

- Complaint Management
- Medical Device Reporting
- Corrections and Removals Management and Reporting
- Corrective Actions
- Corrective Action Statistical Analysis
- Risk Management
- Service Reports
- Service Report Statistical Analysis

This presentation unites the systems to make their implementation easier and more effective. You learn:

- When written procedures are required
- When (and how) to name designated individuals
- When (and how) to formally designate units
- What records you must keep
- When you must report to the FDA
- What statistical techniques to use to analyze corrective actions and service reports

These techniques include histograms, scatter plots, check sheets, Pareto charts, and cause-and-effect diagrams. Because these regulations may also span your organizational structure, this is especially suited for cross-functional and cross discipline teams.

About the Presenter – Dan O'Leary

Dan O'Leary, President, Ombu Enterprises, LLC has more than 30 years of experience in quality, operations, and program management in regulated industries that include aviation, defense, medical devices, and clinical labs. He has a Masters Degree in Mathematics, focusing on logic and number theory. His professional experience relates to quality, reliability, and operations management. Dan's company, Ombu Enterprises, LLC, offers training and execution in Operational Excellence by helping companies to achieve efficient and effective processes and regulatory compliance.

Dan is a regular speaker at international conferences including ASQ, ISM, and RAMS. Dan also teaches courses in reliability methods, medical device regulations and practices, statistical methods, management systems (ISO 9001 & ISO 14001), and project management. His professional affiliations include membership in the American Mathematical Society, the American Statistical Association, the Society of Industrial and Applied Mathematicians, the Institute for Supply Management, the Project Management Institute, and APICS; Dan is a Senior Member of the American Society for Quality as well, and has held

leadership positions in ASQ sections. He is an ASQ Certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, Six Sigma Black Belt, and is certified by APICS in Resource Management.