2-day In-person Seminar:
Supplier Management for Medical Device Manufacturers

By: Dan O’Leary, President at Ombu Enterprises, LLC

Location: Boston, MA  |  November 8-9, 2018

SPEAKER
Dan O’Leary, President at Ombu Enterprises, LLC

Daniel O’Leary has more than 30 years’ experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs. He has a Master’s Degree in Mathematics, focusing on logic and number theory. His professional experience relates to quality, regulatory, reliability, and operations management.

Mr. O’Leary is a regular speaker at international conferences including ASQ, ISM, and RAMS. He teaches courses in reliability methods, medical device regulations and practices, statistical methods, management systems (ISO 9001, FDA QSR, & ISO 13485), and project management. Mr. O’Leary is an ASQ certified biomedical auditor, quality auditor, quality engineer, reliability engineer, and Six Sigma black belt; he holds an APICS certification in resource management.

LEARNING OBJECTIVES

Upon course completion, participants will:

- Understand FDA QSR and ISO 13485 requirements for supplier management
- Understand the FDA’s multi-tier supplier classification system
- Understand when suppliers have to register and list with the FDA
- Use an analysis matrix and radar chart to compare suppliers
- Explain the link between design control and purchasing data
- Develop an overall supplier management plan

- Understand how to develop and implement supplier controls
- Create receiving inspection criteria and apply them as part of supplier controls
- Create supplier measurement and monitoring systems
- Create a system for supplier business risk
- Create a system for supplier regulatory risk
- Create a risk based system for supplier audits
- Develop a supplier audit using the backward trace process approach
Supplier selection and management is a fundamental issue faced by medical device manufacturers. Suppliers are critical to the performance and safety of your device as well as your business. Neither the FDA nor your notified body regulates suppliers (with a few exceptions). Instead, they expect you have an effective process that ensures your suppliers perform. The regulators hold you responsible and verify your controls through inspections and audits. Consequently, you need to understand and implement the regulatory requirements for supplier management. You should pass an audit or inspection without any issues.

This course delivers the tools, templates, and methods to help participants implement an effective, efficient, and compliant supplier management program.

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SUPPLIER MANAGEMENT FOR MEDICAL DEVICE MANUFACTURERS

COURSE DESCRIPTION
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This course delivers the tools, templates, and methods to help participants implement an effective, efficient, and compliant supplier management program.

This two-day hands-on workshop provides a clear understanding of the underlying principles of supplier management, using exercises to help illustrate the points and solidify understanding. In addition, the course uses FDA Warning Letters to raise issues and help you learn from others. As part of the practical implementation, the course includes supplier evaluation and selection; measuring, monitoring, and re-evaluation; outsourced processes; supplier auditing techniques; and supplier issues in management review.

The workshop uses the Global Harmonization Task Force (GHTF) framework, but expands it to cover other important issues and techniques. The course includes information from the ISO 13485:2016 Handbook, FDA’s QSIT, and the MDSAP Audit Model.

Multiple exercises, guidance documents, tools, and templates help you implement an effective program.

AGENDA

Day One (8:30 AM - 4:30 PM)
Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

1 Part A – Regulatory Requirements
   - Supplier management in FDA QSR & ISO 13485:2016
   - EU Medical Device Regulation (MDR)
     - Unannounced visits
   - Supplier Evaluation and Selection
     - When suppliers have to register and list with FDA
     - Outsourced processes
   - Purchasing Data
   - Acceptance activities

2 Part B – Planning for Supplier Management
   - Supplier management as a business process
   - The business risk model
   - The regulatory risk model
   - The medical device risk model

3 Part C – Planning for Supplier Selection
   - Identifying what to procure
   - Design control and purchasing data
   - Identify risks (business, regulatory, and device)
   - Identify controls (business, regulatory, and device)
   - Special considerations
     - UDI
     - Control numbers
     - RoHS
     - Conflict Minerals

4 Part D – Potential Suppliers
   - Identify potential suppliers
   - Evaluative business capability
   - Evaluate operational capability
   - Using an analysis matrix and a radar chart

Day Two (8:30 AM – 4:30 PM)

5 Part E – Supplier Selection
   - Sole source v. single source
   - The directed procurement problem
   - Selecting the supplier
   - The Approved Supplier List

6 Part F – Implementing Supplier Controls
   - Building the final control plan
   - Receiving acceptance as a supplier control
   - Developing hidden controls
   - The supplier quality agreement

7 Part G – Monitoring, Measuring, and Evaluation
   - Standard supplier metrics
   - Implementing predictive analysis
   - Developing a supplier audit program
   - Using the supplier’s QMS certificate
   - The backward tracing process audit
   - Supplier management as part of Management Review

8 Part H – Feedback and Communication
   - Supplier scorecards
   - Corrective action requests

9 Part I – Evaluating your program
   - Supplier management maturity models
   - FDA’s QSIT
   - MDSAP Audit Model
   - GHTF guidance on auditing supplier control
   - Case Study and exercise on maturity models

WHO WILL BENEFIT
- Quality Managers
- Supply Chain Managers
- Quality Engineers
- Supplier Quality Engineers
- Purchasing Professionals
- Regulatory Specialists
- Production and Process Engineers
- Design and Development Engineers
- Verification and Validation Specialists