

**MEDICAL DEVICE SUPPLIER
QUALITY MANAGEMENT**
ARE YOU AND YOUR SUPPLIERS COMPLIANT?

JUNE 20-21, 2017

AMA EXECUTIVE CONFERENCE CENTER
ARLINGTON, VA (WASHINGTON, DC)

AN INTERACTIVE WORKSHOP PRESENTED BY FDANEWS

AGENDA

Day 1

- 8:00 a.m. – 9:00 a.m.** Registration and Continental Breakfast
- 9:00 a.m. – 9:45 a.m.** Introductions: Setting expectations for course work
Discuss the pre-assignment that is given to each attendant
- 9:45 a.m. – 10:15 a.m.** Introduction: Why do we need this?
- Fundamentals of supplier quality and industry trends
 - Basics of FDA and ISO requirements
 - Determine need for progressive supplier management
- 10:15 a.m. – 10:30 a.m.** Break
- 10:30 a.m. – 12:00 p.m.** ISO 13485:2106: Review of changes regarding supplier quality
Planning: What do we need?
- Charter, business needs and quality requirements
- 12:00 p.m. – 1:00 p.m.** Lunch Break
- 1:00 p.m. – 2:30 p.m.** Selecting Suppliers: Whom do we need?
- Selection process using the *Total Risk Factor* model
- 2:30 p.m. – 2:45 p.m.** Break
- 2:45 p.m. – 4:30 p.m.** **INTERACTIVE EXERCISE**
Groups work together to evaluate case studies and benchmark their own companies and share best practices
- 4:30 p.m.** Session wrap-up, end of day one
Assignment for day two

Day 2

- 8:00 a.m. – 8:30 a.m.** Continental Breakfast
- 8:30 a.m. – 10:15 a.m.** Review the assignment from day one
Evaluation: Do suppliers meet our needs?
- Assess need for on-site or desk top audit
- 10:15 a.m. – 10:30 a.m.** Break
- 10:30 a.m. – 12:00 p.m.** Supplier Controls Part I: Are suppliers still meeting what we need?
Building an Effective Control Plans
- Receiving, source inspection, manufacturing quality plans, sampling plans
 - Report cards/Business Review
 - Communication and escalation plan
- 12:00 p.m. – 1:00 p.m.** Lunch Break
- 1:00 p.m. – 2:00 p.m.** Supplier Controls Part II: What are the contractual requirements?
- Developing supplier quality agreements
 - Conducting unannounced audits
- 2:00 p.m. – 2:30 p.m.** **INTERACTIVE EXERCISE**
Groups work together to evaluate case studies and benchmark their own companies and share best practices
- 2:30 p.m. – 2:45 p.m.** Break
- 2:45 p.m. – 4:00 p.m.** End of Relationship: Do we still need them?
- Consolidation, de-activation, termination and risk mitigation for ending the relationship
 - Using the *Total Cost of Ownership* model
- 4:00 p.m. – 4:30 p.m.** Summary of day two
- 4:30 p.m.** Adjournment