

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. **Adjourn**