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