Event Agenda

Quality Management Systems for Drug Manufacturing Facilities (PDA 813)

DAY 1	
8:00	**Welcome and Introductions**
8:15	Introduction to the Course
8:30	Introduction to QMS and Regulatory Framework
8:45	Foundations of an Effective QMS: Quality Culture and People
9:45	**Break**
10:00	Foundations of an Effective QMS: Documentation
10:30	Foundations of an Effective QMS: Processes
11:30	Case Study Exercises
12:00	**Lunch**
12:45	Supplier and Contractor Controls: Quality Agreements
13:15	Documentation for Batch Release
14:00	The Role of Training in the Organization
14:30	**Break**
14:45	Audits and Inspections
15:15	The Role of the Consultant in the Organization
15:30	Case Study Exercises
16:45	Daily Wrap Up and Questions & Answers (Q&A)
17:00	**End of Day 1**

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DAY 2	
8:00	Recap Day 1
8:15	Understanding, Assessing, and Improving Quality Culture in an Organization
9:30	Data Integrity and Data Governance
10:00	**Break**
10:15	Quality Culture – Activity
11:00	Dissection of a Form FDA 482, Form FDA 483, and a Warning Letter
11:15	Responding to a Form FDA 483 and a Warning Letter
12:00	**Lunch**
12:45	Days 1 & 2 Questions and Recap
13:15	Case Study Exercises (Part 1)
14:00	Case Study Exercises (Part 2)
14:45	**Break**
15:00	Case Study Exercises (Part 3)
15:15	Teach Back
16:15	Course Wrap-up, Q&A, and Closing Remarks
16:30	**End of Event**