

Effective Corrective and Preventive Action for FDA Regulated Industries

AGENDA

Day 1

8:00 a.m. Introductions and course objectives

Module 1: Overview

Workshop 1 and feedback

Module 2: Regulatory Requirements

12:00 noon Lunch

1:00 p.m. Workshop 2 and feedback

Module 3: Corrective Action Process

Workshop 3 and feedback

Module 4: Problem Solving and Root Cause Analysis

5:00 p.m. End Day 1

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Day 2

- 8:00 a.m. Case Study 1 and feedback
Module 5: Effectiveness of CAPA
Case Study 2 and feedback
Module 6: Preventive Action
- 12:00 noon Lunch
- 1:00 p.m. Workshop 4 and feedback
Module 6: Preventive Action continued
Workshop 5 and feedback
Module 7: Risk Management
Module 8: Quality System Inspection Technique
Module 9: Business Improvement and Summary
- 5:00 p.m. Course close