PDA® Parenteral Drug Association	Training Course Agenda
	PDA 576 Root Cause Investigation for CAPA

DAY 1

8:30 — **Welcome and Introductions**

9:00 — Step 1: Describe the Performance Problem
- Introduce instructor case study
- Problem statement
- Problem description (Is/Is Not Diagram)
- Flow chart process(es)
- Timeline of events
- Team charter

10:30 — **Break**

10:45 — Step 2: Collect Data
- Determine data needed
- Data collection tools and techniques
- Data measurement plan
- Workshop

12:00 — **Lunch**

13:00 — Step 3: Identify Possible Causes
- Timeline of changes
- Differences between Is and Is Not facts
- Changes associated with any differences between Is and Is Not facts
- Risk analysis
- Brainstorming techniques (flow diagram, fishbone, group, individual, etc)

14:30 — **Break**

14:45 — Step 4: Test Possible Causes
- Test possible causes against facts
- Summarize testing leveraging contradiction matrix
- Historical perspective of investigations

16:00 — **End of Day 1**

DAY 2

8:30 — **Recap Day 1**

9:00 — Step 5: Identify Technical and Systemic Root Cause(s)
- Verify assumptions
- Studies/experiments
- Identify technical root cause(s)
- Identify systemic root cause(s)

10:30 — **Break**

10:45 — Step 6: Determine Corrective/Preventive Actions
- Mistake proofing techniques
- Variation reduction and optimization techniques
- Corrective/preventive action(s)
- Acceptance criteria
- Risk mitigation
- Control plan

12:00 — **Lunch**

13:00 — Step 7: Verify Corrective/Preventive Actions
- Implement and measure effectiveness of corrective/preventive actions
- Evaluate control plan

14:30 — **Break**

14:45 — Second Participant Real Life Case Study

16:00 — **End of Training Course**