
	<h1>Training Course Agenda</h1>
	<p>PDA 576.1 Root Cause Investigation for CAPA</p>

DAY 1	
8:30	<p>Welcome and Introductions</p> <ul style="list-style-type: none"> Overview of methodology and when to use Introduce first participant real life case study
8:40	<p>Step 1: Define the Performance Problem</p> <ul style="list-style-type: none"> Introduce instructor case study Problem statement (investigation focus) Problem description (investigation scope) Workshop Flow chart with key inputs of process(es) within scope of investigation (what will be reviewed)
10:30	<p>Break</p>
10:45	<p>Step 2: Collect Data</p> <ul style="list-style-type: none"> Determine data needed (verify and narrow investigation scope) Identify methods for collecting data Consider tools and techniques for analyzing data Workshop
12:00	<p>Lunch</p>
13:00	<p>Step 3: Identify Possible Causes</p> <ul style="list-style-type: none"> Timeline of changes Differences and Changes Risk analysis review Brainstorming techniques (gemba, fishbone, group, individual, etc.) <p>Step 4: Test Possible Causes</p> <ul style="list-style-type: none"> Challenge possible causes against data Define “reasonable” assumptions Document testing process results Summarize testing leveraging contradiction matrix Workshop
14:30	<p>Break</p>
14:45	<p>Step 5: Identify Technical and Systemic Root Cause(s)</p> <ul style="list-style-type: none"> Verify assumptions Studies/experiments Identify technical root cause(s) Identify systemic root cause(s) <p>Step 6: Determine Corrective/Preventive Actions</p> <ul style="list-style-type: none"> Mistake proofing (poke-yoke) vs. variation reduction and optimization techniques Corrective/preventive action(s) Risk mitigation Control plan Acceptance criteria Workshop <p>Step 7: Verify Corrective/Preventive Actions</p> <ul style="list-style-type: none"> Implement corrective/preventive actions Evaluate effectiveness (control plan) Determine additional preventive actions Disseminate knowledge gained

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Finale

- Compare/contrast this investigation methodology with other approaches
 - Shortcuts
 - Simple investigations
 - Investigation report
 - Return on investment
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16:00

End of Training Course
