PROBLEM SOLVING & DECISION MAKING FOR INVESTIGATIONS AND CAPAs

ACCELERATE & IMPROVE INVESTIGATIONS AND CAPAs

KT's systematic approach to handling and responding to regulatory issues, quality problems, validations, complaints and recalls is used by life science organizations worldwide to meet the challenges of operating in a regulated environment efficiently and economically.

DESCRIPTION

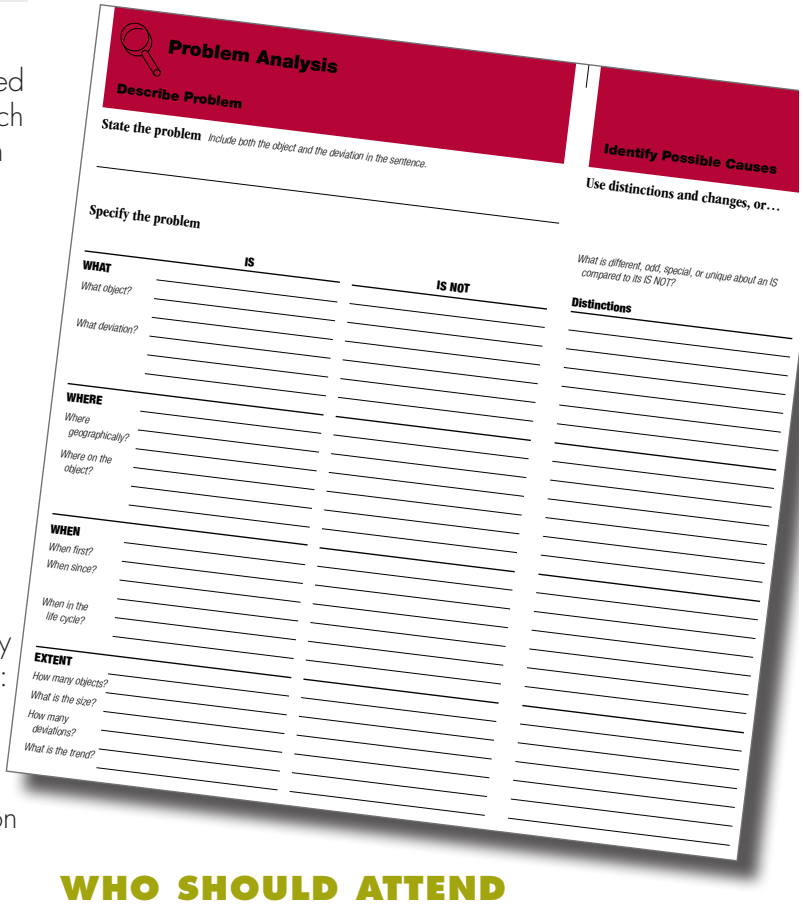
In this three-day work session, you will learn our acclaimed process approach to respond to deviations, an approach that is focused, rapid, and fully documented. Cut through the complexity of compliance by setting priorities, troubleshooting issues, and taking the most effective and efficient corrective and preventive actions. Learn to control risk and recognize opportunities for ongoing improvement. Using our FDA-recognized, step-by-step approach, learn to close out these issues with complete and well-documented investigations. Using the KT approach in investigations will dramatically reduce the cycle time for approval and the number of open investigations.

HOW YOU WILL BENEFIT

By using KT's standard, best-practice approach for every non-conformance, you will remarkably improve the quality of your investigations and reduce approval cycle time by:

- Assessing complex issues and breaking them down systematically to correctly create and support investigations
- Listing and prioritizing issues relevant to the investigation
- Using a logical and systematic process to find and confirm true and root causes
- Finding the true cause of a problem before investing in expensive CAPAs
- Accessing relevant information by using incisive questioning techniques
- Dealing rationally and constructively with emergency situations
- Demonstrate structured thinking when closing investigations

USE THE ACCLAIMED KT PROCESSES TO ADDRESS THE DEVIATIONS AFFECTING COMPLIANCE, PRODUCTION, AND QUALITY ISSUES



WHO SHOULD ATTEND

Anyone involved with writing, approving, or providing input to investigations in the areas of quality assurance, quality control, regulatory, audit, compliance or manufacturing in a regulated environment.

700-10-P336308 KL723

WWW.KEPNER-TREGOE.COM INFO@KEPNER-TREGOE.COM

KT Kepner Tregoe