

Root Cause Analysis

Getting to the Bottom of a Problem

This book explains the importance of root cause analysis (RCA) to globally-regulated industries (pharmaceutical, medical device, dietary supplements), the common and easy-to-learn tools, team approaches, documentation, and how to institutionalize RCA into a company's culture. The material is presented as a practical narrative based on the author's actual experiences, successes and failures, in real world, less than ideal, environments. With this book the reader learns how to approach a problem, how to select the RCA tools, when and how to use them, verification and validation activities for products and processes, and how to document progress to final conclusion. Case studies demonstrate successful implementation of root cause analysis, and highlight pitfalls, false steps, and causes of failures.

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