

Root Cause Analysis – A Systematic Approach



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Abstract

A systematic approach to root cause analysis based on process and systems thinking and the DMAIC problem solving and improvement framework is presented, discussed and illustrated. The focus is on getting to root cause and putting permanent fixes in place so that the problems do not occur again. Corrective and Preventive Action are an integral part of the DMAIC framework. The concepts and methods involved are illustrated with pharmaceutical and biotech case studies and examples.

Importance of Getting to Root Cause

Problem solving is critical to successfully maintaining and improving pharmaceutical and biotech processes. Processes are dynamic and as predicted by the second law of thermodynamics will deteriorate over time if left alone. Federal Regulation Title 21 requires that an organization's quality system include a process for Corrective and Preventive Action (CAPA, Lewandowski-Walker 2012, Rodriguez-Perez 2011). Central to an effective CAPA system is the identification of root causes of problems. Systematic approaches for problem solution have been called for but few appear to be used in practice. The frequent result is root causes are not identified and the problems reoccur.

This article begins by discussing root cause analysis and how it differs from just treating problem symptoms. Some common occurring root causes of problems are introduced as way helping one see where to start problem solving activities. The importance of collecting and analyzing data as a route to root cause is also addressed. This discussion creates a list of characteristics a problem solving approach needs to effective. It is argued that the DMAIC framework (Define, Measure, Analyze, Improve, Control) has these characteristics (Snee and Hoerl 2003). The article concludes with a case study illustrating the use of DMAIC in getting to root cause and how the DMAIC framework includes CAPA.

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