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CAPA program management via the DMAIC methodology

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Life sciences companies are facing increasing pressure from regulatory bodies, to take a proactive approach for managing non-conformity, process deviations, and critical observations in relation to their defined quality procedures. Approximately 30% to 50% of all FDA-483 citations in FDA regulated industries are related to problems with corrective action & preventive action (CAPA) processes.

CAPA is one such process that has become a formal requirement by regulatory authorities for categorizing the various types of issues a life sciences company may encounter. The CAPA process presented here is based on the define, measure, analyze, improve, and control (DMAIC) framework, which can improve quality systems performance.

DMAIC refers to a data-driven improvement cycle used for improving, optimizing and stabilizing business processes and designs. The DMAIC improvement cycle is the core process used to drive six sigma projects. The DMAIC framework is a business methodology that helps track down and mitigate the root causes of defects. Using DMAIC, you define a problem, measure performance of an area or process, analyze the process, make improvements based on the analysis, and control the amended process.

A DMAIC based CAPA system must contain critical and key functionality, which individually and collectively, must be used to properly manage all deviations or non-conformities while helping the company to manage, monitor and document its efforts to comply with FDA regulations as well as international regulatory authorities, and to help solve the CAPA processes conundrum, which is how to maximize efficiencies and minimize costs while continuously increasing product quality.

Biography

Roger E Gould is the regional director for Compliance Technology Group-South (CTG-South), an engineering services firm with a 15 year history of proven success. Roger earned his BS in applied science technology from Thomas Edison state university in 1985. He is an active six sigma master black belt with a proven track record as an agent of organizational change. Throughout his career, Roger has demonstrated an expert knowledge of quality processes and programs including Corrective and Preventive Action (CAPA), Failure Mode and Effects Analysis (FMEA), and Root Cause Analysis (RCA). Roger possesses an expert level of understanding of GxP and validation requirements for computer systems in regulated (GMP, GLP, GCP) environments.

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