Deviation Management - Why Have We Not Solved the Problem?

By David W. Husman Jan 23, 2018 8:00 am PST

Abstract

Deviations occur across the pharmaceutical and device industries nearly every day. Companies have spent hundreds of hours and thousands of dollars to investigate deviations, identify their causes and implement corrective actions to prevent their recurrence. Yet with all of the investment we continue to frustrate both our personnel and our management as the same problems continue to recur.

FDA and other regulators routinely request to see lists of deviations, non-conformances, CAPAs, complaints, and out of specification investigations during inspections. For nearly 20 years, failure in these systems has been in the top 5 of all observations issued. So what are we doing wrong? This article attempts to explore the issues and provide some possible solutions and paths forward to eliminate the problems routinely documented as deviations within our manufacturing and testing environments. Although the examples focus on U.S. FDA, the problems and solutions are applicable worldwide.

I. Introduction

Numerous articles, seminars, regulations, and guidance documents have been generated in an attempt to address the problems observed by regulators, auditors and quality assurance departments. Despite all the attention and the abundance of available resources to address problems, the FDA and other regulators continue to cite failures with deviations and non-conformances, CAPAs, complaints, and out of specifications. These failures to adequately address management of deviations to ensure they are appropriately investigated, analyzed to determine the reasons for their occurrence and actions taken to eliminate their causes have become a bane to the regulated industry. We continue to spend extensive time in dealing with backlogs, recurring problems, audit findings and regulatory citations.

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