

Designing a CAPA System

Client

Qualitest

Industry

Pharmaceutical

Business Challenge

To improve corrective and preventive action (CAPA) systems.

Background

Qualitest, a leading developer and manufacturer of affordable, high-quality generic pharmaceuticals, wanted to improve their system for corrective and preventive action (CAPA).

Solution

Qualitest engaged Regulatory Compliance Associates® Inc. (RCA) to improve their CAPA System. RCA brought a wealth of knowledge by providing tools, advice and best practices for incorporation into the new draft standard operating procedure (SOP).

Result

Qualitest is implementing the new SOP and capturing CAPAs in their software tool which collects and analyzes data. The company plans to pursue CAPA certification after obtaining new equipment for the automated software system.

“RCA understood our needs and helped design a CAPA process that aligns with industry best practices and takes us to the next level.”

