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Effective CAPA Program, A valuable tool in quality improvement

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Effective Corrective Action and Preventive Action (CAPA) can improve the quality of products and may reduce the compliance risk. FDA warning letters have cited deficient CAPA program as one of the major compliance weak spots. Having an effective CAPA program in place is more important than having a technology for CAPA. CAPA process is a wider term than just an investigation of a complaint, out of specification laboratory results or a manufacturing investigation. However, the root cause of the investigation and implementing CAPA in a timely manner is an underlying key of CAPA process.

In order to reduce compliance risk, pharmaceutical industries need to have effective CAPA process in place. Effective CAPA process is a basic tool that should be used in quality system in every pharmaceutical industry. Quality system is a fundamental entity and rather more formalized process or practice that describes organization's quality management structure, procedures and processes and resources to achieve the goal of effective CAPA program. The purpose of having a CAPA process in place can help in improvement of quality. In addition, the aim of CAPA is to identify and investigate the issue, gather information, analyzed information, well documented evidences, and take proper corrective and preventive action to prevent their reoccurrence. However, final goal of an effective CAPA process is a continuous improvement driven on quality.

Biography

Dharmi Trivedi has Master's degree in science majoring in Chemistry from Saurashtra University, India. Dharmi is currently pursuing a Doctoral Degree in Health Administration from University of Phoenix and is an associate consultant at Lachman Consulting Services, NewYork USA. Dharmi has over 20 years of experience in Pharmaceutical Industries including, Quality and Compliance, Quality Control and Research and Development. During her career she has gained expertise in cGMP areas that include; investigations, CAPAs, change control, validation, stability program, and external/internal audits.

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