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Understanding practical approaches towards FDA investigations

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Key focus will be put on practical examples, implementation & compliance practices



Mumbai based BlueTech Media is organising a training programme on investigation, root cause analysis, risk assessment & CAPA on 23 and 24 June, 2020.

The training will be conducted by Hitendra Kumar Sharma, CEO of NADH+ GXP Compliance Services, a Member of American Society for Quality & Indian Pharmaceutical Association

WORKSHOP OVERVIEW:

It has been observed that one of the most common FDA 483 and Warning Letter citations continues to be inadequate investigations, Root Cause Analysis, CAPA & Risk assessment.

The FDA uses the investigation reports and investigation trends to identify potential quality problems and action plan taken in all areas of the company. Ultimately, inadequate investigations can lead to 483 citations, Warning Letters, release of sub-standard product, or product recall. Furthermore, costly and time-consuming system remediation may be required.

Having a procedure on Investigations, Root Cause analysis, CAPA & Risk assessment is not enough. It is the strategy, content, extent of efforts made and conclusions that truly count.

This training will help attendees understand the fundamental steps, practical approach towards investigations, Root Cause analysis, CAPA and proactive approach as well as reactive approach of risk assessment.

Key focus will be put on practical examples, implementation & compliance practices with respect to current guideline requirements, FDA citations and learning from observations.

BENEFITS OF ATTENDING THE WORKSHOP:

1. Skill shall be developed for formal investigation & risk assessment, how to arrive on root cause, what are the practical approach for CAPA
2. During the course of workshop, participants will understand the easy, pragmatic and cost effective approaches to compliance
3. The attendees will learn what are the current oversight about these topics, how they can be in compliance with respect to different guideline requirement
4. Management and Oversight on the investigation, risk assessment & the CAPA system and its documentation
5. Acquire new and enhanced skills in finding multiple root cause
6. Methods to reduce & avoid human error
7. Attendees will be able to understand the different types of investigations tools
8. To avoid release of sub-standard product & product recall
9. This training would enable attendees to overcome most common FDA 483 and Warning Letter citations caused due to inadequate investigations, Root Cause analysis, CAPA & Risk assessment