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Webinar on

Best Practices And FDA Requirements For A GMP Environment

Webinar Description

In this bundled webinar instructors will describe the importance of classifying computer systems subject to FDA regulations in accordance with GAMP, the regulations associated with the detection, correction and prevention of human errors in GMP manufacturing and laboratory processes, also about FDA Regulations Associated with the Detection, Correction and Prevention of Human Errors in GMP Manufacturing and Laboratory Processes.

The webinar format is 1-1.5 hours of audio-visual presentation, including a brief Q&A session.

This webinar bundle includes below 3 recorded webinars:

Onboarding in a GMP Environment: Best Practices for Foundational Employee Success

FDA Regulations Associated with the Detection, Correction and Prevention of Human Errors in GMP Manufacturing and Laboratory Processes

FDA Compliance and GAMP V Computer System Classification

Onboarding in a GMP Environment: Best Practices for Foundational Employee Success

Presented by Michael Esposito

The FDA's expectations for training new employees are summed up in 21 CFR 211.25(a), i.e., pharmaceutical professionals require the education, training, and experience to complete their job functions. Onboarding new or transferred employees in a Pharmaceutical Good Manufacturing Practices (GMP) environment and ensuring compliance with these requirements create some unique challenges.

Although FDA expectations provide some of the frameworks regarding types and frequency of training, there are decisions that the company will need to make in light of its evaluation of how to best achieve compliance for its employees, maintain a quality culture, and manage the work environment.

Often there are questions regarding how to translate these requirements into the day-to-day operations of the company. Of particular interest are the different perspectives of onboarding from Human Resources and Quality Assurance (particularly Training), each of which has their own priorities. Managers, likewise, are eager to have their employees qualified to perform their job functions as efficiently as possible because of pressure to keep pace with the business, and will communicate their expectations to these two organizations. A successful onboarding strategy will combine the inputs of all these stakeholders and help create a consistent and well-understood process for the company.

FDA Regulations Associated with the Detection, Correction and Prevention of Human Errors in GMP Manufacturing and Laboratory Processes

Presented by Angela Bazigos

We are often quick to ascribe fault to people rather than our systems, facilities, and operations. However, in this class, we will learn how to tell if you are too quick to ascribe guilt to people rather than probe deeper. We will focus on improved techniques to get to the real cause of the problem. With this information, you will be able to develop meaningful CAPAs that have a chance to remedy these problems, the first time. We will focus on how to assess the success of these CAPA's. This will lead to a significant reduction of repeat observations which will lead to improved efficiency and right-first-time operations. This live interactive presentation will also discuss the regulations associated with the detection, correction, and prevention of human errors in GMP manufacturing and laboratory processes.

Analysis of investigation reports reveals that human error is one of the top root causes for deviations, discrepancies and quality incidents in pharmaceutical manufacturing. And when you examine the CAPA's that are developed from these, retraining and rewrite of SOP is top the list. Yet on further re-examination, you find that these problems keep resurfacing again and again. Put in another way, the CAPA's are ineffective. Does it mean that the CAPA's were wrong or is it pointing to another problem? Namely, that the investigation did not pinpoint the root cause of our most probable contributing factors to the problem. Most often "human error" is not really the problem but a symptom of a system or facility or operation that is not designed to be run by humans. Humans do contribute to problems but more often than not, because what we are asking them to do is not designed with humans in mind. So a true CAPA should be developed to solve the problems with the system, facility, and operation rather than focus on remediation of people. This requires investigations to focus on getting to the real root cause and contributing factors.

FDA Compliance and GAMP V Computer System Classification

Presented by Carolyn Troiano

We will discuss the importance of classifying computer systems subject to FDA regulations in accordance with GAMP V. This is critical in order to develop the appropriate validation strategy and achieve the thoroughness required to prove that a system does what it purports to do. It also ensures that you do not go beyond what is required for a specific classification of the system so as to be cost-effective.

Upon completion of this session, attendees will have an understanding of how to classify computer systems in accordance with GAMP V, and develop a sound validation strategy for each system to meet FDA compliance. The attendees will understand the level of testing required for each classification, and the appropriate level of documentation that must be completed to support it. They will also gain an understanding of the training and skills required to both classify systems and work on various classifications of systems to validate or maintain them. The attendees will have a good grasp of how to leverage these practices across all systems by creating a standardized program for classifying systems in accordance with GAMP V.

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