

The Difference Between Compliance and Quality (Live Webcast)

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Unit	Each
Deliverydetails	No Dangerous Good

Description

Course Description: Our journey from compliance to quality is rooted in deep traditions, but are those traditions helping us or hurting us? Focusing solely on inspecting for compliance is not sufficient to prevent drug shortages nor ensures drug quality. This talk discusses the quality management maturity (QMM) model / how to move to a culture of quality / common areas of improvement / what to expect. /// Duration: 8/10/2022, 11:00 AM EDT - 8/10/2022, 12:00 PM EDT

1- The regulatory push (CDER/ CBER/FDA/FDASIA).

Through dialogue with industry, the agency knows the challenge of producing metrics on the global scale. The quality management maturity model (QMM) and rating system constitute an agreement between industry and the future, with a focus on quality for drug manufacturers to have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement. This evolution began in compliance. The future, however, is quality criteria driven.

2- How to move from quality metrics to a culture of quality. Too many times, metrics programs focus on making or keeping a dashboard green instead of using the data to understand improvement opportunities and drive the organization toward their quality goals. A strong quality culture is the foundation that drives improved performance, through efficient processes that people can follow, and investment in analysis and impact from data.

3- Quality attributes and quality behaviors.

What does an organization with a mature quality management model look like? How do we shift the mindset? These are common questions that pharmaceutical manufacturers ask. We discuss techniques to shift the conversation. For many companies that struggle with a healthy quality maturity model, we examine where you are on the spectrum of evolution. Starting from a narrow metrics focus to finding common themes in areas of improvement, we discuss what to expect, and what to look forward to.

Compliance is demonstrating an organization's ability to meet regulatory requirements, while quality refers to the condition and functionality of products and services to consistently deliver intended performance, and it is dynamic.

Who should participate:

Drug manufacturing, pharmaceutical manufacturing, biologics organizations; Job function: quality assurance (QA), quality control (QC), operations managers, quality management, pharmaceutical quality directors, MHA, MPH.