PLIANCED

REGULATORY COMPLIANCE
MASTER PROGRAMS

Complaint Management and Reportable Events: Compliant Practices that Satisfy Customer Satisfaction

MASTERS PROGRAM IN Complaint Management and Reportable Events

Duration	: 9 Hrs. 30 Mins		
No of modules	: 4 modules	CEU	: 9
Mode of delivery	: Online		

Regulatory compliance is increasingly visible in healthcare compliance, clinical research compliance, and in all Life Science industries, including pharmaceutical, food, and medical device industries.

Plianced brings Master programs, which allow learners to attend live classes, complete assignments at their convenience.

ABOUT THE PROGRAM:

Complaint handling is likely one of the more cross-functional parts of your quality system: Customer Service may receive your customer complaints, Sales and Marketing may need to reach out to the customer for additional information, Regulatory Affairs may determine whether the complaint is reportable, QA may perform the root cause investigation, R&D or Manufacturing Engineering may need to be involved in the corrective action, and Quality Engineering may need to trend the complaints! This session will include the requirements for all of the above responsibilities, which will include defining, documenting, and implementing a complaint-handling system, the requirements for complaint review, investigation, and corrective action, as well as ISO-specific implications. Also covered will be a discussion of what constitutes a complaint, and recommended practice on how to handle "non-complaint" feedback. The application of risk management to a complaint handling system and a specific risk management system will be explained.

This master program contains a streamlined review of the regulations, allowing the majority of time to be spent on a detailed focus on critical process requirements for compliance with the regulations. Jeff will also call from his 30+ years of experience in this area to put forth recommendations for methods of documentation that are straightforward and compliant. Among these recommendations are contents of complaint records, root cause investigations, and corrective actions. This webinar also covers the application of risk management principles to a complaint investigation.

PROGRAM OBJECTIVES:

Many complaints include terminology that is unlikely to withstand an FDA or ISO audit, such as “isolated occurrence” and “low risk.” Further, from a business perspective, how do you let your customers know that you received their complaint when you know that their next question may be the dreaded “What did you find out?” A compliant quality system has, as one of its supports, a robust complaint system that is both compliant and business-savvy. This session will address these issues and more.

LEARNING METHODOLOGY:

Topic	Delivery mode	Presented By	Date	Time	Duration
Module 1: Complaint Handling (Part 1)	Live class	Plianced Expert	1st May 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Module 2: Complaint Handling (Part 2)	Live class	Plianced Expert	8th May 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Module 3: Adverse Event Reporting	Live class	Plianced Expert	15th May 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Module 4: Recalls / Field Corrective Actions	Live class	Plianced Expert	22nd May 2020	12.00 pm ET	2 hrs
Q&A Session					15 mins
Online Assessment Final assessment and certificate	Online test	Online Quiz	22nd May 2020	2.15pm	30 mins

DETAIL COURSE CONTENT:

Module 1: Complaint Handling (Part 1)	- Regulatory Overview: FDA, ISO 13485 - Definitions - Application of Definitions - The Value of "Non-complaints" - Complaint Triage and Handling - Complaint Investigations - "Closing" Complaints
Module 2: Complaint Handling (Part 2)	- Contents of Complaint Form - Complaint Review and Trending - Implementation of Risk Management into Complaint Handling - Common Pitfalls, How to Overcome Them - Complaint or Non-complaint? - Benefits/Detriments of a Reply to the Customer
Module 3: Adverse Event Reporting	- Regulatory Overview: FDA, ISO 13485 - MDRs: Reporting Process and Requirements - Vigilance Reports: Reporting Process and Requirements
Module 4: Recalls / Field Corrective Actions	- Regulatory Overview: FDA, ISO 13485 - Recall/FCA Classifications - Corrections and Removals - Market Withdrawal and Stock Recovery
Online Assessment	Final assessment and CCU certificate

Who will benefit:

- Customer Service (your "complaint taker")
- Regulatory personnel
- Quality Engineering personnel
- Sales and Marketing personnel
- Customer Service personnel
- R&D personnel
- Manufacturing Engineering
- Executive Management
- Consultants
- Quality system auditors

What will you get?

1) Course Material/Slide deck
2) Access to the recorded version of the entire 9 hours session
3) Certificate of participation with Plianced CEU Credits

Speaker: Jeff Kasoff,

Jeff Kasoff, RAC, is the Director of Quality at Medivators, a leading manufacturer of endoscopy consumables and instrumentation. In this position, Jeff is responsible for oversight of the quality system, including the CAPA program, and is the liaison with FDA. For the previous 13 years, Jeff served as Director of Regulatory Affairs at Life-Tech, Inc., in which capacity he was similarly responsible for quality system oversight. Jeff began his regulatory career as the first full-time employee of Optex Biomedical, a device start-up, where he initiated their regulatory policies and procedures and prepared their submissions. Jeff received his Regulatory Affairs Certification in 1996.