

*Webinar on*

# **Medical Device Cyber security and FDA Compliance**

# Learning Objectives

- *Provide an overview of cyber security and guidance on device software*
- *Provide an overview of the most common problems faced by the industry in terms of medical device security, efficacy, and safety*
- *Provide a set of best practices and industry standards to meet the challenges of cyber security and other threats to devices and software*
- *Q&A*

This webinar will detail some of the threats and ways to mitigate them to protect consumers from harm.

**PRESENTED BY:**

*Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, animal health, tobacco, e-cigarette/e-liquid and other FDA-regulated industries. She is currently an independent consultant, advising companies on computer system validation and large-scale IT system implementation projects.*

On-Demand Webinar

Duration : 90 Minutes

Price: \$200

# Webinar Description

In this webinar, you will learn just how cyber attacks threaten medical devices and how the industry is currently responding to them. We will discuss the many ways of preventing and mitigating the cyber security risk, and about the industry best practices that can help your company do the same.

This webinar will focus on cyber security of medical devices, a key concern for those who develop, manufacture, test, and distribute these products. Protecting medical devices from hacking where someone can alter the actual code embedded in the device could result in injury or death to a patient or consumer. A serious threat, it must be dealt with at all levels to make sure the end product being used by a patient or consumer is perfectly safe and delivers the effective treatment required.

This session will provide some insight into current trends in cyber security threats to medical devices and how to follow industry best practices to prevent and/or mitigate these threats.



Cybersecurity is a serious concern for medical device safety and effectiveness. Without protection, software running on a medical device could cause severe injury or death to a patient.

*There are many forms of cybersecurity and many remedies for thwarting attempts to penetrate medical device software. Most of these are based on physical and logical security practices that are becoming the best industry practices.*

*This webinar will detail some of the threats and ways to mitigate them to protect consumers from harm.*

*Providing safe and effective medical devices is in the best interests of all those involved in the development, manufacturing, testing, and distribution of these products. One of the largest current threats to these devices working safely and effectively is cyber attacks that can wreak havoc on code and device functionality. Preventing these attacks by identifying sources of threats and rooting them out before they can take effect is of the utmost concern.*



# Who Should Attend ?

*Manufacturing, Testing, Packaging and Distribution companies in the following industries that are regulated by FDA are required to follow GxPs:*

*Pharmaceutical (where drugs are incorporated into medical devices)*

*Medical Device*

*Biologicals (where biological are incorporated into medical devices)*

*Tobacco (based on the Tobacco Control Act of 2009)*

*E-Liquid/Vapor (based on the “Deeming” Act of 2016)*

*E-Cigarette (based on the “Deeming” Act of 2016)*

*Cigar (based on the “Deeming” Act of 2016)*

*Third-Party companies that support those in the above industries*



*Personnel in the following roles will benefit:*

*Information Technology Analysts*

*QC/QA Managers*

*QC/QA Analysts*

*Clinical Data Managers*

*Clinical Data Scientists*

*Analytical Chemists*

*Compliance Managers*

*Laboratory Managers*

*Automation Analysts*

*Manufacturing Managers*

*Manufacturing Supervisors*

*Supply Chain Specialists*

*Computer System Validation Specialists*

*GMP Training Specialists*

*Business Stakeholders responsible for computer system validation planning, execution, reporting, compliance, maintenance, and audit*

*Consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance*

*Auditors engaged in the internal inspection of labeling records and practices*





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