Speaker Profile

Add to cart

Product code: WEB175

DOWNLOAD CATALOG (https://worldcompliancesseminars.com/assets/images/admin.jpg)

20-Jun,2017

Attend Live Online Training

☐ $179 One Dial-in One Attendee

Group

☐ $395 Multiple locations upto 5 dial in

Recorded Version Only

☐ $249 Available within 24 hrs after completion of live Webinar. Unlimited viewing for 3 Months

CD/DVD Version Only

☐ $295 CD/DVD will be dispatched after 72 hrs on completion of live Webinar

Live Webinar Medical Devices - International Regulatory Compliance & Regulatory Affairs

01:00 PM EDT | 10:00 AM PDT | 12:00 PM CDT Duration 90 Minutes

Webinar Includes : All the training handouts , certificate ,Q/A and 90 mins Live Webinar

Description

Add to cart

Medical device manufacturers are not only self-regulated, but are also regulated by numerous local and national governmental agencies.
As such, medical device manufacturers are regulated by various laws, regulations, standards, and guidelines written and adopted by industry and governmental agencies.
Medical device regulations in the US and the EU are foundational to the remainder of the regulations that are applied to medical devices throughout the world.
An inspection by a representative of a regulatory body or a complaint from the market could uncover regulatory violations that may result in sanctions of various levels of seriousness.
These sanctions could result in diminished reputation, device recalls, extended intrusive monitoring, and/or civil and criminal penalties.

Why should you attend :

It is important to understand how regulatory agencies in both the US and the EU are structured and function and the specific medical device regulations within each jurisdiction that apply to maintain sound medical device compliance.
Today, with the EU's new Medical Device Regulation of over 400 pages soon to be law and the complexities of medical device regulations in the US, it is critical to effective regulatory compliance that all levels of management all along the supply chain, understand how the process works and have at least a basic understanding of the key regulations and their contents.

Areas Covered

This webinar will provide basic information concerning the structure of both US and EU regulatory bodies. The regulatory content common to all regulations will be addressed to create a foundation for understanding the basics of medical device compliance regulations.
We will then discuss the meaning of regulatory compliance from both an internal – company, and external – regulatory body standpoint.
To establish clarity and common understanding, we will discuss and define the differences between the common regulatory terms – law, regulation, directive, standard, and guideline and explore their impact upon compliance.
21CFR 820 the Quality System Regulation is an essential part of the entire medical device regulatory portfolio and is critical to any discussion of medical device regulations. We will discuss the key components of this regulation and how the regulation relates to the "Total Quality System Concept."
We will complete the webinar with a discussion of the EU Medical Device Directives and how they compare to the new Medical Device Regulation.

Who will Benefit

Anyone involved in medical device design and development. To include compliance, engineering, regulatory affairs

Industries who can attend

This 90-minute online course is intended for professionals in the Medical Device, Biotechnology,Pharmaceutical Industry. Although not presently stated in the draft , the same guide could be used by FDA Regulated Industries personnel

Back to Top

Speaker Profile

(https://worldcomplianceseminars.com/user/cart) 0

Charles H Paul

Charles H. Paul is the President of C. H. Paul Consulting, Inc. – a regulatory, manufacturing, training, and technical documentation consulting firm – celebrating its twentieth year in business in 2017. Charles has been a regulatory and management consultant and an Instructional Technologist for 30 years and has published numerous white papers on various regulatory and training subjects. The firm works with both domestic and international clients designing solutions for complex training and documentation issues.

Add to cart

He has held senior positions in consulting and in corporate training development prior to forming C. H. Paul Consulting, Inc.. He also worked for several years in government contracting managing the development of significant Army-wide training development contracts impacting virtually all of the active Army and changing the training paradigm throughout the military.

He has dedicated his entire professional career explaining the benefits of performance-based training