GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

Disaster Recovery And Business Continuity Planning For Computer Systems Regulated By FDA

This course will focus on the key aspects of Disaster Recovery and Business Continuity Planning efforts, including best practices and principles for handling this type of work in an FDA-regulated environment.

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.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

FDA guidelines are very specific in terms of how computer systems are to be managed, and each company should have a specific strategy and methodology, along with a set of rigorous tactical processes and procedures that prescribe how Disaster Recovery and Business Continuity Planning should be carried out. This is necessary to protect against the onslaught of threats and attacks, both from natural disasters and as a result of cyber-warfare.

This course will focus on the key aspects of Disaster Recovery and Business Continuity Planning efforts, including best practices and principles for handling this type of work in an FDA-regulated environment (i.e., the system “touches” product during the manufacturing, testing or distribution of the product, or during any other functional activity). The material will include the various aspects of system and data related concerns, and the result will be a prescriptive approach to helping teams and individuals mitigate risk and reach a higher level of security and compliance.

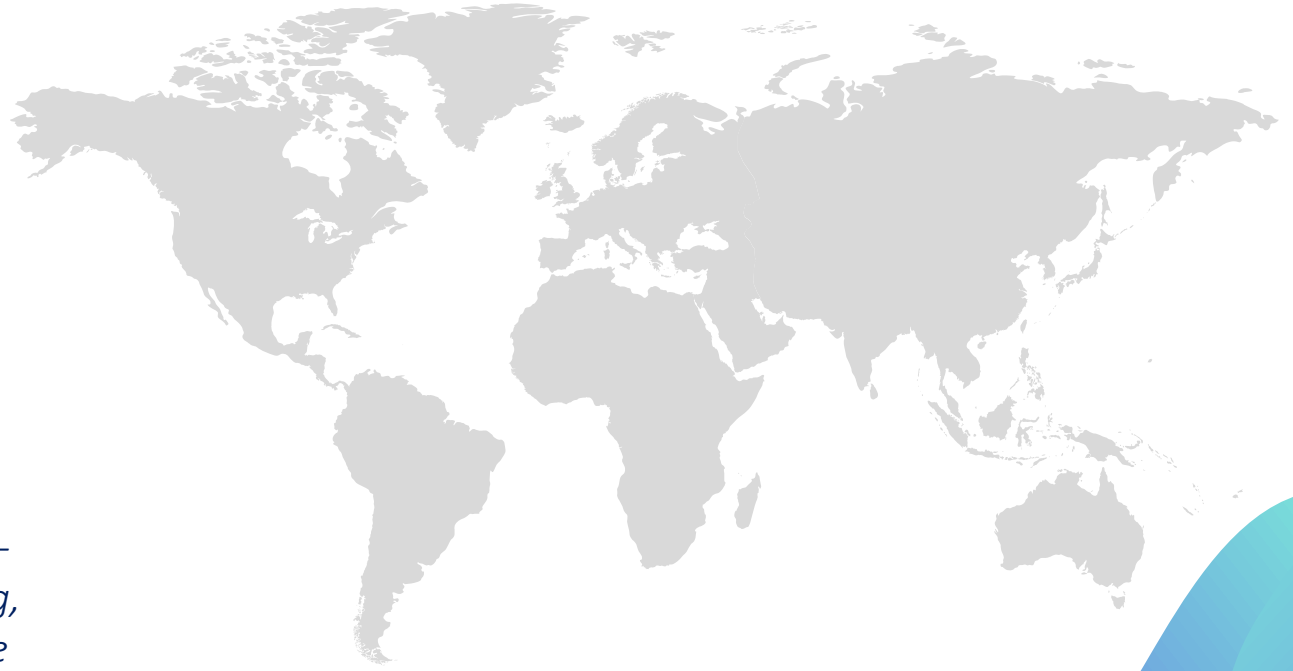
Computer system validation has been regulated by FDA for more than 30 years, as it relates to systems used in the manufacture, testing, distribution and management of a product in the pharmaceutical, biotechnology, medical device, tobacco and other regulated industries. Disaster recovery activities often include efforts to deal with both system functionality and data integrity, quality, accessibility, and accuracy. The specific tasks and deliverables must be completed with care toward maintaining a compliant environment.

Business Continuity Planning activities involve the development of a backup plan for continuing business operations uninterrupted, despite losing the use of computer systems. There are best practices used for establishing good Disaster Recovery and Business Continuity Planning programs for systems operating in the FDA-regulated arena, and these can be leveraged to develop a standard and consistent approach within a company.

Who Should Attend ?

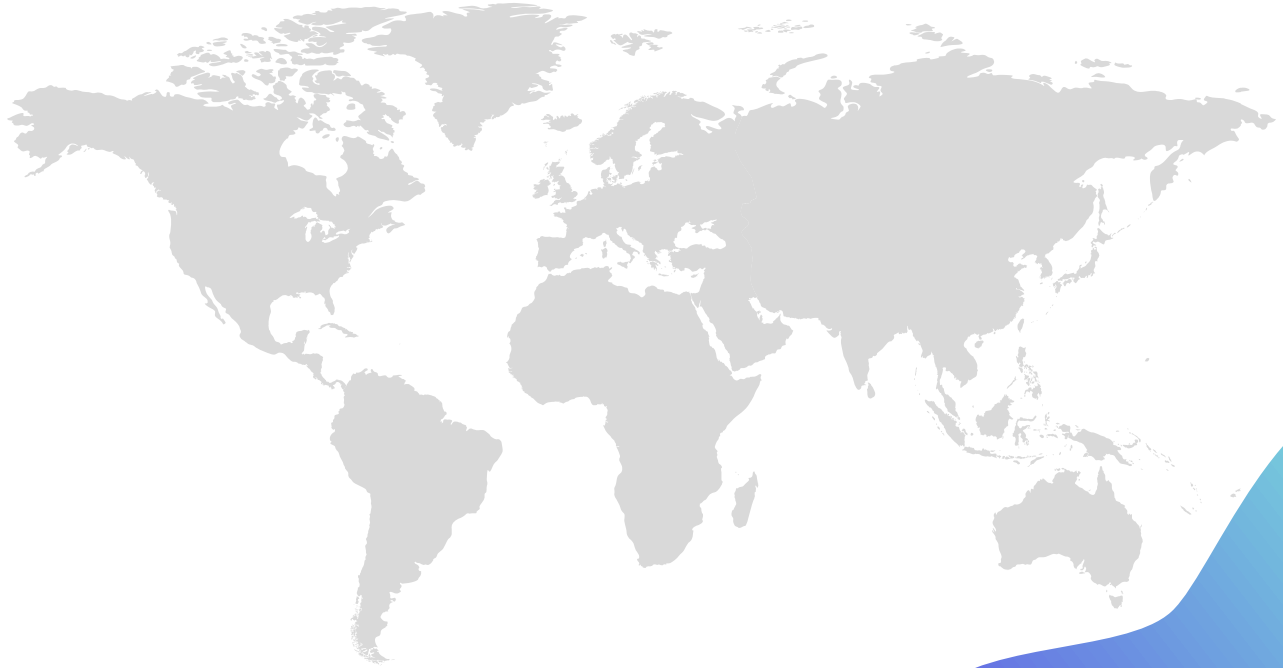
There is an enormous body of documentation and information available that can be overwhelming. This course will provide a condensed overview of the practices that deliver the best results by directing the attendees to the most critical and cost-effective of methods, techniques, and tools available to assure a compliant validation process.

Effective and compliant computer system validation, particularly as it relates to managing the event of a disaster that disrupts operations, is critical to any FDA-regulated organization, including those manufacturing, testing and distributing regulated products. During the past 30 years, best practices that have been developed will ensure that the cost of building and managing a computer system disaster recovery and business continuity program for this purpose, along with the necessary policies and procedures, will be minimized.



GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

You should attend this webinar if you are responsible for planning, executing or managing the validation of a system governed by FDA regulations, specifically in relation to pharmaceutical, medical device, biologics, tobacco and related products. This includes cigarettes, as well as the more recently developed e-cigarette products and smokeless tobacco products.



Manufacturing Analysts and Supervisors
Marketing Analysts and Managers
Information Technology Professionals
QC/QA Analysts and Managers
Laboratory Analysts and Managers
Compliance and Audit Managers
Automation Analysts and Managers
GMP Training Specialists
Computer System Validation Specialists
Business Stakeholders/Subject Matter Experts
Business System/Application Testers
Warehouse Managers
Legal and Regulatory Affairs professionals

Finally, anyone who is acting as a consultant or contractor to a company in an FDA-regulated industry should attend to ensure they are able to bring the most current knowledge and expertise to their assignment.

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321