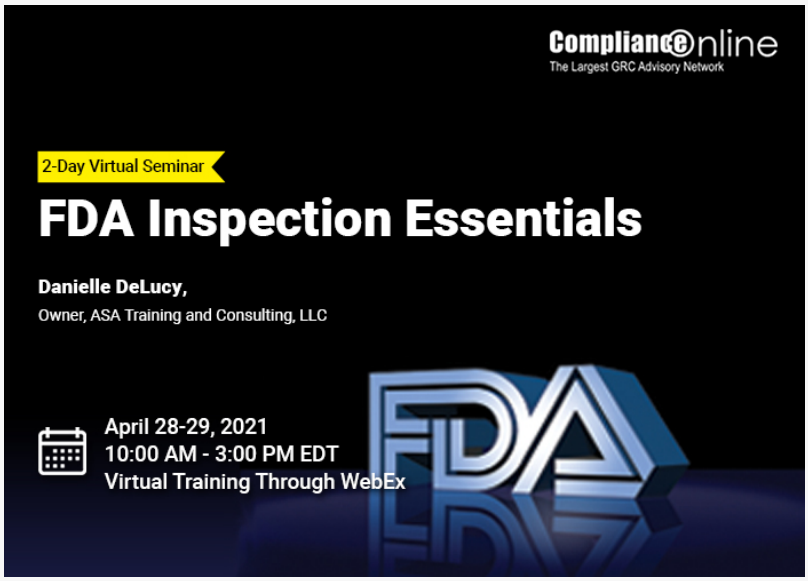
ComplianceOnline Launches FDA Inspection Essentials Seminar for FDA Regulated Companies

"FDA Inspection Essentials" Seminar has been added to ComplianceOnline.com's offering.



FDA Inspection Essentials

SAN JOSE, CA, UNITED STATES, April 1, 2021 /EINPresswire.com/ -- ComplianceOnline is holding a 2-day virtual seminar entitled "FDA Inspection Essentials" on April 28-29, 2021 (10:00 AM - 3:00 PM EDT). The seminar will be presented by Danielle DeLucy, owner of ASA Training and Consulting, LLC.

The purpose of the Regulatory inspection is an activity that should demonstrate that your company is operating according to the proper CFR requirements and maintaining a state of compliance. The key to a successful audit is being able to communicate how your quality systems assure this state of control.

Many times, the arrival of a Regulatory Investigator is a daunting experience for some. This seminar, you will learn how to properly alert key members that an investigator has arrived, the proper protocol for setting up the Inspection room and any associated “war” rooms that will support the inspection, and how to manage requests from the investigators in a timely and accurate manner. This preparation minimizes stress and disorder during the inspections.

Working in a highly regulated industry, we know our firms need to be “inspection-ready” at all times. This is not only to maintain a good rapport with the Regulators, but also as a commitment to quality for our customers, the patients who use our products.

Regulatory inspections should be a time to demonstrate the high level of compliance your firm has to the regulations, and to customer safety and quality. The purpose of a regulatory inspection is to ensure that your facility is in compliance with FDA rules and regulations.

Investigators want to know that product was manufactured appropriately and that the current Good Manufacturing Practices are up to FDA standard. An inspection can be very intimidating to all involved, but it is vital if you want an inspection that results in a satisfactory report.

The inspection management plan should provide for, Response to the arrival of the investigators, Guidance of the inspectors' activities, Procedure for working with the investigators, and Documentation of the inspection. The management plan or SOP should spell out all of the procedures that you will follow during an investigation. Personnel training is one key variable that should be looked at prior to any inspection. Educate personnel about the inspection process so they can be prepared. Train individuals to interface with FDA investigators. Verify that training has been provided for the personnel on their current job functions, and that supporting records are on file. The goal is to minimize the opportunity for incorrect answers provided to the inspectors, or providing too much information. Have a list of what to do and what not to do when speaking to the inspectors as well.

Why Should You Attend:

FDA inspections have revealed some trends in recent years. The agency is taking a tougher stand on Quality Systems and using a risk-based approach. Inspectors usually review at least two (2) systems in depth. QA is their number one concern in recent years. They may also look at another system, such as facilities and equipment, materials, production, packaging and labelling or laboratory controls.

FDA does not expect your facility to be perfect. They expect all companies to have some issues. What they really want to see is how you address the problems. The FDA tends to view companies that control these issues to have a high standard of quality. This seminar will help you use the FDA inspection as a learning tool, not as a negative or adversarial experience.

Upon completion of this session, you will learn the proper way to set up for a Regulatory Inspection, ensuring the inspection flows smoothly throughout the duration, and the proper way to speak to inspectors while they are performing the audit.

Learning Objectives:

Upon completion of this session, attendees will:
- Learn Pre-planning and preparation activities
- Know What to do when the investigator arrives
- Know What documents to have ready and on hand
- Develop Assignments and responsibilities for the inspection
- Be Aware of Inspection Do's and Don'ts

Who will Benefit:

- Quality Control Personnel & Management
- Manufacturing Personnel & Management
- Senior Management
- Regulatory Affairs Personnel & Management
- Quality Assurance Personnel & Management

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: April 28-29, 2021 (10:00 AM - 3:00 PM EDT)

About the Speaker:
Danielle DeLucy, MS, is owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance. Prior to this role, Danielle has been in the industry for 15 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations. Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Danielle assists companies who are faced with warning letters, consent decrees and those wishing to improve compliance establish more robust quality systems so that the company can succeed.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is headquartered in Palo Alto, California, and can be reached at http://www.complianceonline.com. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality Management Solutions for global corporations.

For more information on ComplianceOnline or to browse through our training programs, please visit our website

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