ComplianceOnline Hosts ‘Cleanroom, Microbiology & Sterility Assurance Practices Seminar for Drug & Device Manufacturers’

"Cleanroom, Microbiology and Sterility Assurance Practices for Drug and Device Manufacturers" Seminar has been added to ComplianceOnline.com's offering.

Cleanroom, Microbiology and Sterility Assurance Practices for Drug and Device Manufacturers

SAN JOSE, CA, UNITED STATES, April 15, 2021 /EINPresswire.com/ -- ComplianceOnline, the world’s leading provider of regulatory compliance training, is holding a 2-day virtual seminar entitled ‘Cleanroom, Microbiology and Sterility Assurance Practices for Drug and Device Manufacturers’ on May 10-11, 2021 (9:00 AM to 4:00 PM EDT). The seminar will be presented by Charity Ogunsanya, CEO and Founder, Pharmabiodevice Consulting LLC.

This course will educate attendees about various key elements of sterility assurance and contamination control such as Cleanroom Regulations, Classification, Sources and types of particles, Design Requirements, Validation/Qualification, Operations, Environmental Monitoring Program requirements, Excursion investigations, DataTrending, Microbiological processes/methodology, Cleanroom cleaning/disinfection.

The types of micro-organisms, typical mitigation steps in ensuring an effective contamination control through Personnel Training (Aseptic Practices, Cleanroom Behavior and Contamination Control Procedures),Gowning Controls, Personnel Training, Cleanroom Trafficking (Cleanroom Personnel Material, Product and Equipment Transfer Practices and Training (Entry and Exit Policy), Cleanroom Gowning, Contamination Control, Cleaning and Disinfection Program and the Basics of Sterilization Processes- Physical and Chemical Processes will also be discussed.

The various regulatory bodies’ requirements such as 21 CFR Part 211 (mostly relevant 211.113

“Control of microbiological contamination”, ISO 14644 (Various Parts), FDA Guidance for Industry: Sterile Drug Products Produced By Aseptic Processing - Current Good Manufacturing Practice”) amongst others and the criticality of aseptic processing and other key contamination control evaluators during the manufacture and testing of products are important to the quality determination and release of the finished manufactured products.

The seminar will consist of two (2) Parts for a total of 6 Modules.

There are seven (7) key topics that will be discussed on Day 1 and Day 2 of the Seminar are as follows:

- Cleanroom Regulations, Classifications, Basic Background and Design Considerations
- Cleanroom Qualification, Cleaning Validation (IOQ/PQ), Routine Monitoring and Excursion Investigation
- Environmental Monitoring Program (Monitoring, Excursion Investigation and Trending of Data)
- Personnel Training (Aseptic Practices, Cleanroom Behavior and Contamination Control Procedures)
- Cleanroom Trafficking (Cleanroom Personnel Material, Product and Equipment Transfer Practices and Training (Entry and Exit Policy)
- Cleanroom Gowning, Contamination Control, Cleaning and Disinfection Program
- Basics of Sterilization Processes- Physical and Chemical Processes

Attendees will gain an understanding of compliance expectations and learn from FDA Form 483s and case studies as bonus.

Learning Objectives:

- Discuss Cleanroom Classification, Regulations and Guidelines
- Summarize how to Perform Cleanroom Design, Validation/Qualification, Operation, Environmental Monitoring Program and ensuring a state of control
- Describe Aseptic Practices, Personnel Health Practices, Gowning and Trafficking Patterns in a Cleanroom
- Establish and describe the Requirements of Cleanroom Cleaning/Disinfection and Contamination Control Practices
- Summarize various Sterilization Processes, Advantages and Disadvantages –both Physical and Chemical
- Describe the Sterilization Processes and Controls

Who will Benefit:

This training will benefit those involved in the manufacturing, processing, testing and release of sterile and non-sterile products. It will provide the attendee an understanding of the basic

concept of microbiology, microbiological and contamination control practices, cleanroom design, routine testing, qualification/validation and use of cleanrooms as well as the typical sterilization processes (Physical and Chemical) within various industries such as the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Product Manufacturing Industries, especially personnel and management in:

- Quality Assurance
- Quality Control
- Manufacturing
- Validation
- Supplier Quality Assurance
- Regulatory Affairs
- Shipping and Receiving
- Facility and Maintenance
- Engineering
- Materials Management
- Analysts
- Analytical Chemists
- All levels of management
- Microbiologists

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
May 10-11, 2021 (9:00 AM to 4:00 PM EDT)

About the Speaker:
Charity Ogunsanya, is the CEO and founder of Pharmabiodevice Consulting LLC. Ms. Ogunsanya has over 23 years of extensive practical and management experience in various Fortune 100 pharmaceutical, biotechnology, biologics, cell therapy, diagnostics, research and development, radio-pharmaceutical, Contract Manufacturing Organization (CMO) and medical device/IVD companies.

She has been a much sought after SME to assume key roles specifically related to remediation and difficult quality and compliance related deficiencies associated with FDA's Consent Decree, FDA's Warning Letters and other regulatory bodies' inspectional findings. Her remediation work has constantly resulted in several successful national and international regulatory bodies' inspections, re-inspections and new product approvals.
Her technical expertise covers and goes beyond interpretation, administration and set up of quality assurance, quality/compliance, quality engineering, aseptic processing, contamination control, quality control, microbiology, sterility assurance, stability, vaccine development, new product design, product release testing and medical device sterilization (ethylene oxide (EtO), gamma, radiation, VHP sterilization) systems and operations for compliance to various regulations.

She has a keen working knowledge of the requirements and regulations guiding new and existing products from planning through design, proof of concept, research and development, technology transfer, pre-clinical, clinical, commercial manufacturing, supply chain, regulatory filings, pre-approval inspections, licensure, government affairs, commercialization and post-approval inspections.

She is a member of the Parenteral Drug Association (PDA), American Society of Microbiologists (ASM), and other Scientific Forums and Industry Expert Network. She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and she is currently attaining her Masters in Biotechnology (Biodefense Concentration) at the Johns Hopkins University Advanced Academic Program.

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.

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