**Topic Title:** **Performing an Effective, Robust and Compliant Sterility Failure Investigation: How to Avoid Common Mistakes**

**Course Duration: 90 Minutes Q&A Duration: 10 Minutes**

**Date: April 28, 2018**

**Time: 10 am PST (1 pm EST) most preferred.**

**Background:**

Performing an effective, robust, complete and compliant sterility test result failure investigation is an effective tool that helps to prevent future loss of product, regulatory filed complaint and product recalls. Further contamination of subsequently manufactured batches of finished products, raw materials, bulk drug substance or excipient may be prevented if the source of the contaminant is clearly identified at the onset of the initial sterility test failure investigation using an effective and compliant investigational process or tool. Mistakes are often made when corrective and preventative actions are not clearly identified and applied during a manufactured product sterility test failure investigation because an ineffective investigational procedure and tool was used to conduct a sterility test failure investigation. Avoiding such common mistakes will ensure that these types of products meet the sterility requirements USP <71> and other regulatory guidelines applicable to finished products, bulk drug substance, raw materials or excipients.

**Why should you attend?**

This 60-minute training will provide an understanding of the regulations guiding the sterility testing program and the process of conducting an effective, robust and compliant sterility test investigation for various types of sterile products. The attendees will gain an understanding of the step by step investigational tool to apply when conducting a sterility test failure investigation, how to delineate between a probable and an affirmative root cause using the recovered contaminant based on the investigational findings. Possible corrective and preventative actions and how to apply the results of the investigation (investigational findings) to other manufactured batches of products within the same cleanroom will be discussed. Disposition of the manufactured batch of product with a failed sterility test result, regulatory guidelines associated with a *“Retest”* of the affected batch and handling a sterility failure associated with a commercially distributed product under stability testing program will be discussed. The content of a sterility test investigation form to provide robustness to an investigational process will be shared with the attendees as a tool that may be used when designing a sterility failure investigation program.

**Areas Covered in the Session:**

**Module#1 (Requirements of a Sterility Testing Program and Initial Consideration During a Sterility Failure Investigation)**

* Regulations Guiding Manufactured Product Sterility Testing
	+ USP <71> Sterility Testing
* Ensuring Adherence to Program Testing Requirements
	+ Aseptic Processing
	+ Contamination Control
	+ Appropriateness of Testing Facility
	+ Appropriateness of Testing Personnel
	+ Training/Competencies
* Initial Considerations During a Sterility Test failure Investigation
	+ Affected Departments and Roles
		- Role of Quality Control
		- Role of Quality Assurance
		- Role of Manufacturing or Operations
		- Role of Facility or Engineering
		- Role of Regulatory Affairs
	+ The Sterility Failure Notification Process
		- Initial Documentation Process during an Investigation
	+ What Happens to the Affected Product Batch
		- Handling of affected batch(es) of product

**Module#2 (Step by Step Process of Conducting an Effective, Robust and Compliant Sterility Test Failure Investigation)**

* Step by Step Process In Conducting Sterility Test Failure Investigation
	+ What to Look for During the Investigational Process
		- Role of Personnel Handling and Cleanroom Behavior
		- Role of Testing Materials, Equipment and Media
		- Role of Environmental Monitoring or Testing
		- Role of Disinfection and Practices
		- Role of Testing Facility
		- Role of Laboratory Environment (Incubation)
		- Role of Training
		- Role of Environmental Controls
		- Role of Classified Testing Locations
		- Role of Room and Materials Qualification (Various)
		- Role or Microbial Identification
		- Role of Previous Product Sterility Test Failure Trends and Reports
		- Role of Previous Trends and Reports
		- Other Important Aspects
* Role of Contaminant as a Key Tool During Investigational Process
	+ Microbial Identification of Contaminant
		- Important or Not Important? Why or Why Not
	+ Using a Process Map of Contaminant as a Tool for Root Cause Analysis
		- How to Utilize Identified Contaminant to perform a sterility test failure investigation.
		- Root cause analysis process
			* “*Most probable root cause*” versus “*Final root cause*”

**Module#3 (Effective a Robust Corrective Actions, Preventative Actions, Sample of Investigation Forms, Product Disposition Process and Avoiding Common Mistakes)**

* Sample of Sterility Failure Investigation Forms
	+ Important Sections
	+ Effective investigational tools
* Performing a Product Retest During a Sterility Failure Investigation
	+ Regulatory Requirements applicable to Product Retest
		- When to Perform a Product Retest
		- When not to perform a Product Retest
* Applying Corrective and Preventative Action Based on Findings of a Sterility Failure Investigation
	+ Appropriateness of the corrective action
	+ Appropriateness of the preventative action
	+ Examples of corrective and preventative actions
* Disposition of the Products Based on Investigational Findings
	+ How to determine a “False positive” result.
	+ Dispositioning products after a sterility failure investigation
	+ Avoiding common mistakes during product disposition
		- Role of QA
		- What happens after product disposition
* Impact of Sterility Failure for Commercially Distributed Products under a Stability Testing Program
	+ Commercial Impact-Product out in the market
	+ What happens next if a true contamination or failure is discovered?
	+ Role of Regulatory Affairs
	+ Agency Notification Process
* Avoiding Common Mistakes during
	+ When not to ignore an early warning sign of a systemic issue
	+ When not to ignore an effective implementation of adequate corrective action and preventative action.

**Question and Answer Session**

Open questions and answers

**Learning objectives: (Optional)**

1. Discuss the regulations guiding manufactured product sterility testing such as USP <71> *Sterility Testing”* and how to ensure adherence to program testing requirements.
2. Step by step process in conducting sterility test failure investigation and what to look for during the entire investigation process.
3. Discuss the role of contaminant as a key tool during investigational process such as microbial identification of contaminant and if it is important or not important? Why or Why Not
4. Performing a product retest during a sterility failure investigation and how to apply corrective and preventative action based on the findings of a sterility failure investigation
5. How to disposition impacted products based on investigational findings while avoiding common mistakes during product disposition.
6. Impact of sterility failure investigation for commercially distributed products under a stability testing program.

**Target audience/Who will benefit:**

This webinar will provide a great resource to personnel involved within the following departments in the Pharmaceutical, Biotechnology, Diagnostics, Drugs, Cell Therapy, Biologics, Raw Material, Excipients, Chemicals and API Suppliers, and Medical Device industries:

* Quality Control
* Sterility Assurance
* Manufacturing/Production
* Senior Management
* Raw Materials Tester
* Supplier Quality
* Regulatory Affairs
* Quality Assurance
* Compliance
* Design Engineers
* Facility, Maintenance and Engineering
* Contract Manufacturing Organizations (CMO)
* Active Pharmaceutical Ingredients Suppliers
* Chemical Suppliers
* Excipient Suppliers

However, if you are already familiar with how to achieve an effective, robust and compliant sterility failure investigation process you may recommend this webinar to anyone in your company that may require additional knowledge about this subject.

Target Companies/Industries:

1. Pfizer
2. Amgen
3. Johnson and Johnson
4. GSK
5. MedImmune
6. Roche
7. Sanofi Pasteur
8. Genzyme (Roche)
9. Abbott Laboratories
10. Pharmaceutical
11. Biotechnology
12. Biologics (Vaccine)
13. Cell Therapy
14. Diagnostics
15. Medical Device
16. Drugs
17. Radio-pharmaceuticals
18. Raw Material Suppliers
19. Chemical Suppliers
20. Active Pharmaceutical Ingredients Suppliers
21. Excipient Suppliers
22. Contract Manufacturing Organizations (CMO)

**Keywords: (optional)**

Facility, Validation, Cleanroom, Technology, Design, Environmental Monitoring, Aseptic Processing, Classified Areas, Contamination Control, Clean Room Technology, Disinfection, Facility Validation

**Tuition and Registration**

**TUITION\*– Single Rate:** U.S. **$295.00 per person Group Rate:** U.S. **$245.00 per person\*\***

Register at www.pharmabiodeviceconsultant.com. For Questions and Information call Customer Service at 240-678-2020.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. Pharmabiodevice Consulting LLC reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

System Requirements: PC-based attendees: Windows(R) 7, Vista, XP or 2003 Server/Macintosh(R)-based attendees: Mac OS(R) X 10.4.11 (Tiger(R)) or newer

**Online Training Course/Courses of interest**

1. Basic Requirement of the Bacterial Endotoxin Testing (BET) or LAL Program–An Online Course. The course ID# 2567
2. CAPA: A Critical Quality System Requirement–An Online Course. The course ID# 2570
3. Clean Room Operations in a Nutshell–An Online Course. The course ID# 2662
4. Designing an Effective Environmental Monitoring Program–An Online Course. The course ID# 2765
5. Environmental Monitoring (EM) Program Basics–An Online Course. The course ID# 2663
6. Out-of-Specification (OOS) Result Investigation–An Online Course. The course ID# 2581
7. Performing an Effective, Robust and Compliant Sterility Failure Investigation: How to Avoid Common Mistakes–An Online Course. The course ID# 2766
8. Standard Operating Procedure (SOP) and Standard Test Method (STM) Requirements–An Online Course. The course ID# 2584

**Instructor Profile:**



**Charity Ogunsanya (CEO, Pharmabiodevice Consulting LLC**

Charity Ogunsanya has over 26 years of extensive experience within the Pharmaceutical, Biotechnology, Biologics, Cell-Therapy, Diagnostics, Research and Development, Radio-pharmaceutical, Contract Manufacturing Organization (CMO) and Medical Device companies.

Throughout her corporate career within these diverse industries, she held various high visibility and business critical roles within the Quality and Compliance division in major Fortune 100 companies both as a Subject Matter Expert (SME), Site Manager, Multi-site Manager and Director Levels receptively.

She has been a sought after expert and have been consistently hired after several competitive efforts by major fortune 100 companies 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 difficult regulatory bodies inspectional findings which is always achieved with a successful outcome. She has also been a sought after expert by various companies requesting her expertise as a known industry expert to specifically assume roles in order to perform a total overhaul, restructure, compliance remediation, re-organization, start-up processes related to Quality Systems improvements and/or enhancements. In all cases, her remediation work resulted in several successful National and International regulatory bodies’ inspections, re-inspection and new product approvals.

Her technical expertise are not limited to the 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.

Ms. Ogunsanya is vast in 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. Her expertise has been sought after by several Fortune 100 Pharmaceutical, Biotechnology, Biologics and Medical Device companies as a Quality and Compliance SME during critical national and international regulatory bodies’ routine and new product approval inspections.

She is the CEO of Pharmabiodevice Consulting LLC (www.pharmabiodeviceconsultant.com) targeted towards Quality and Compliance related remediation, enhancements and consultant services for various companies within the industry. She is a well sought after high level consultant for several international professional expert networks such as Gerson Lehrman Group, Zintro Expert Network and Intota Expert Network. She is a member of the Parenteral Drug Association (PDA), American Society of Microbiologists (ASM), and other Scientific Forums and Industry Expert Network.

Ms. Ogunsanya’s technical industry expertise is recognized based on numerous invitations that she receives to speak at national and international conferences, seminars and webinars hosted by very reputable conference and seminar organizations such as Center for Professional Advancement (www.cfpa.com), Institute for Validation Technology (http://www.ivtnetwork.com), Compliance Online (http://www.complianceonline.com), International Pharmaceutical Academy (IPA) and others.

She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and Masters in Biotechnology (Biodefense Concentration) at the Johns Hopkins University Advanced Academic Program.