# Topic: Effectively Addressing and Remediating FDA's Form 483 Findings, Warning Letters and Consent Decree Compliance Issues

**An FDA News Virtual Conference**

**Date: January 11 and 12, 2019**

**Time: 10:00 a.m. – 4:00 p.m.**

**Background:**

This Live Virtual Interactive Conference/Webinar will guide the attendee in effectively handle, addressing and remediating FDA’s and other related compliance issues associated such as FDA's Form 483, Warning Letter and Consent Decree Compliance Findings. An effective handling and resolution of Compliance issues will prevent further disciplinary actions such as an FDA’s Warning Letter or a formal Consent Decree which ends with a costly impact, fines and possible injunctions by the FDA. Because the impact of non-compliance and remediation of compliance issues are very costly, time consuming and impacting to a business and associated manufactured product including an increasing severity of disciplinary action by the FDA, understanding the triggers, effective preventative and corrective actions and an effective and expedient resolution of such compliance issues will assist a manufacturer of product in preventing expensive remediation of compliance issues, delays to product launch, impact on current commercially available product, overall business reputation, product recall, Fines, loss of impacted Product, loss of business licensure and/or prosecution by the FDA.

**Importance/Learning Objectives of Conference Topic:** Understanding the various implications of not adhering to the rules and regulations of the specific requirements guiding each product types and observed mistakes made by some manufacturers of products that led to the closure of several manufacturing site through an FDA injunction and further bankruptcy of a cGMP product manufacturer will be discussed. This will help in preventing a similar mistake or further detrimental actions from happening or progressing into even more difficult ones. The difficulties and cost associated with remediating an FDA’s Consent decree is very high and most manufacturers of a cGMP drug product have found it very difficult to come out of a consent decree due to the difficulties associated with remediation. Preventing the initiation and progression of compliance related issues and then instituting an appropriate way to address these issues effectively and expeditiously before they become impacting will be discussed. This webinar enhance the attendees’ knowledge as follows:

1. A description of what constitutes an FDA’s Form 483 Compliance Findings, Warning Letter or Consent Decree.
2. The progression and severity of the various FDA compliance findings, triggers of the various progression of the compliance related disciplinary issues and criticality of each type.
3. Discuss what companies are doing ***“Right”*** and ***“Wrong”*** when they have compliance related findings and letters such as FDA's form 483 Findings, Warning Letter or Consent Decree.
4. Discuss the reasons why some companies with recurrent unresolved FDA’s Form 483 findings end up with further progressive compliance issues such as a subsequent FDA’s Warning Letter and/or a Consent decree.
5. Effective Steps in resolving FDA’s Form 483 Findings, Warning Letter and Consent Decree. The importance of expediting a company’s response to each type of compliance citation from by FDA.
6. Discuss the entire process of Consent Decree and various scenarios and players in the process through remediation.
7. Discuss several damaging effects arising from unresolved and difficult compliance related issues such as FDA’s Form 483 Compliance Findings, FDA’s Warning Letter and Consent Decree.
   1. The cost and other impact associated with resolving compliance Remediation Costs.
   2. The overall impact on manufactured products, regulatory filings, employees, product filing, and the overall business and its reputation.
8. The most effective ways in addressing, handling and resolving or remediating compliance issues associated with FDA 483, Warning Letter and Consent Decree issues.
9. Discuss several case studies of companies with progressive compliance issues that ended up in Consent Decree.

**Areas within the 4 Sessions:**

The criticality adhering to the requirements of the Code of Federal Regulations (CFR) and other associated guidelines and best practices cannot be over emphasized. The attendees of this one day virtual conference will be provided a great resource in understanding the various stages of compliance issues and the resulting impact on the manufactured product and business.

A step by step process and description of the various levels of compliance issues and the progressive discipline issued by the FDA such as an FDA’s Form 483 Findings through Warning Letters and into a Consent Decree will be addressed. Discussions of what some companies are doing *“Right”* and *“Not Right”* in addressing and resolving compliance related issues and triggers of a severe action by the FDA will be discussed in detail.

Attendees will be able to understand the most effective and cost efficient ways in handling, resolving and/or preventing recurring future difficult compliance related, appropriate remediation process, timelines, overall cost implications associated with unresolved compliance issues.

Several case studies will be discussed on the progression that occurred with some companies that ended up in a Consent Decree situation and how their compliance issues would have been most effectively resolved will be discussed. Learning from past mistakes and preventing further compliance mistakes as observed by these companies with current Consent Decree will be discussed as case studies.

**Detailed Agenda:**

**10:00 a.m. – 10:15 a.m. Regulations Guiding the Manufacture of cGMP Products and/or Services**

1. Understanding the Importance and Criticality of the Code of Federal Regulations (CFR) Guiding the Various Products, Industries and Processes
2. Description of the Various Parts of the CFR
3. Compliance Expectations, Requirements and Specific Roles of Manufacturers of Products Regarding Compliance.
4. Other National and International Regulations Guiding the Manufacture of Various Products and their Relationship and Importance.

**10:15 a.m. – 11:15 am - Session 1:**

**Topic: Types and Levels of FDA’s Regulatory Findings and Disciplinary Actions Relating to Various Compliance Issues**

**Knowledge Base:** Attendees will gain an understanding in the following key areas:

1. Summary of what constitutes an FDA’s Form 483 Findings and the sequence of events that triggers its progression into the next stage of FDA’s disciplinary action ***“FDA’s Warning Letter”.***
2. Summary of what constitutes an FDA’s Warning Letter and the sequence of events that triggers its progression into the next stage of FDA’s disciplinary action ***“Issuance of a Consent Decree”.***
3. Understanding what an FDA’s Consent Decree is and what triggers the initiation of a Consent Decree.
   1. **Detailed Understanding of an FDA’s Form 483 Compliance Issue** **Findings**
   2. What triggers an FDA’s Form 483 Compliance Issue Findings?
   3. What Constitutes an Adequate response time to an FDA’s Form 483 Compliance Issue Findings?
   4. What Constitutes an Effective Handling and Response to an FDA’s Form 483 Compliance Issue Findings?
   5. How to Resolve an FDA’s Form 483 Compliance Issue Findings?
   6. What Some Companies are **Doing Well** in Effectively Addressing and Resolving an FDA’s Form 483 Compliance Issue Findings?
   7. What Some Companies **Not Doing So Well** in Effectively Addressing and Resolving an FDA’s Form 483 Compliance Issue Findings?
   8. What Does a Recurring Non-compliance of an FDA Form 483 Compliance Issue Findings mean?
   9. Impact and Next Disciplinary Actions if the Compliance Issue Findings are not effectively resolved by Companies.
   10. How to Effectively Perform a Remediation of an FDA’s Form 483 Compliance Issue Findings?
   11. Remediation Activities Associated with FDA’s Form 483 Compliance Issue Findings?
   12. Preparing for Future FDA Visits and Audits after a Previous FDA’s Warning Letter Compliance Issue Findings.

**11:15 a.m. –11:30 p.m. Break**

**11:30 a.m.- 12: 30 p.m. Session 2**

**Topic: Detailed Understanding of an FDA’s Form 483 Findings-Compliance Issues**

**Knowledge Base:** Attendees will gain an understanding in the following key areas:

1. What triggers an FDA’s Warning Letter?
2. What Constitutes an Adequate response time to an FDA’s Warning Letter
3. What Constitutes an Effective Handling and Response to an FDA’s Warning Letter
4. How to Resolve an FDA’s Warning Letter
5. What Some Companies are **Doing Well** in Effectively Addressing and Resolving an FDA’s Warning Letter?
6. What Some Companies **Not Doing So Well** in Effectively Addressing and Resolving an FDA’s Warning Letter.
7. What Does a Recurring Non-compliance of an FDA Warning Letter Compliance Issues mean?
8. Impact and Next Disciplinary Actions if FDA’s Warning Letter Compliance Issues are not effectively resolved by Companies.
9. How to Effectively Remediate an FDA’s Warning Letter
10. Remediation Activities Associated an FDA’s Warning Letter Compliance Issue?
11. Preparing for Future FDA Visits and Audits after a Resolution of a Previous FDA’s Warning Letter FDA’s Form 483 Compliance Issue?

**12:30 p.m.- 1:30 p.m. Lunch**

**1:30 p.m. -2:30 p.m. Session 3**

**Topic: Effectively Handling, Resolving and Remediating an FDA Issued Consent Decree**

**Knowledge Base:** The Attendees will gain an understanding in the following key areas:

1. What triggers an FDA’s Consent Decree?
2. Steps that leads to the issuance of an FDA’s Consent Decree
3. What Constitutes an Effective Handling and Response to an FDA’s Consent Decree?
4. How to Resolve an FDA’s Consent Decree Compliance issues
5. What Some Companies are **Doing Well** in Effectively Addressing and Resolving an FDA’s Consent Decree Compliance issues.
6. What Some Companies **Not Doing So Well** in Effectively Addressing and Resolving an FDA’s Consent Decree Compliance issues.
7. Impact and Next Disciplinary Actions if FDA’s Consent Decree Compliance issues are not effectively resolved by Companies.
8. How to Effectively Remediate an FDA’s Consent Decree Compliance issues.
   1. Remediation Activities Associated an FDA’s Consent Decree Compliance issues.
   2. FDA Consent Decree and Third Party Consulting Companies
      1. Role of FDA Approved Third Party
      2. Role of the Company’s Executives and Employees
      3. Outside Consultants and Costs
9. Commitments and Timelines Associated with an issued Consent Decree Agreement
   1. What is known as Commitments and understanding the Criticality of Consent Decree Commitments
   2. Timelines Associated with Consent Decree
   3. Fines Associated with Consent Decree Timelines
10. Impact of a Consent Decree on a Business
    1. Costs Associated with a Consent Decree
    2. Impact to Personnel Within the Company
    3. Impact to the Company
    4. Impact to all Manufactured and New Products
    5. Possible Facility Closure
    6. Possible Business Bankruptcy
    7. Possible FDA Injunction
    8. Possible Debarment-Who may be affected?
    9. Product Recall and Investigations
11. Gaining back Reputation after a Consent Decree Compliance Related Issues
12. Preparing for Future FDA Visits and Audits after a Previously Issued Consent Decree.

**2:30 a.m. –2:45 p.m. Break**

**2:45 p.m. - 3:45 p.m. Session 4**

**Topic: Damaging Effects, Associated Impact and Preventative Measures Associated with FDA’s Form 483, Warning Letter and Consent Decree Compliance Issues**

**Knowledge Base:** Attendees will gain an understanding in the following key areas:

1. Impact of a Compliance Issues on a Manufactured Product and Business
   1. Costs Associated with Compliance Issues
   2. Impact on Personnel Within the Company
   3. Impact on the Business or Company’s Bottom Line
   4. Impact to all New and Existing Manufactured Products
   5. Possible Facility Closure
   6. Possible Business Bankruptcy
   7. Possible FDA Injunction
   8. Possible Debarment-Who may be affected?
   9. Product Recall and Investigations
2. **Review of Case Studies on Pharmaceutical Stability Testing - FDA’s Warning Letters to Companies:** Issues Encountered by Drug Product Manufacturers Based on Failure to Address Compliance Issues, Recurring Form 483 Compliance Issues, Warning Letters and Consent Decree:

**Case Study Category #1 (Companies with Recurring FDA’s Form 483 Compliance Issues):**

1. Discussion of several Case Studies relating to companies with a recurring FDA’s Form 483 compliance findings and triggered Warning Letter issuance.
2. What was not done “Right” in addressing the compliance related issues based on the FDA’s Form 483 Findings?
3. Effective ways and approach to resolution that was not applied. Best practices that these companies would have applied that would have prevented the progressive discipline by the FDA into the issuance of an FDA’s Warning Letter.
4. Examples will be discussed and an interactive session on this case study will be applied.

**Case Study Category #2 (Companies with an Issued FDA’s Warning Letter)**

1. Discussion of several Case Studies relating to companies with an FDA’s Warning Letter and what triggered the issuance of the FDA’s Warning Letter.
2. What was not done “Right” in addressing the compliance related issues based on the FDA’s Warning Letter?
3. Effective ways and approach to resolution of the Warning Letter that was not applied.
4. Best practices that these companies would have applied that would have prevented the progressive discipline by the FDA into a Consent Decree.
5. Examples will be discussed and an interactive session on this case study will be applied.

**Case Study Category #3 (Companies with an Issued Consent Decree)**

1. Discussion of several Case Studies relating to companies with FDA’s Consent Decree and triggered issuance of the Consent Decree.
2. What was not done “Right” in addressing the compliance issues based on the FDA’s Findings?
3. Effective ways and approach to resolution that were not applied to prevent a Consent Decree.
4. Best practices that these companies would have applied that would have prevented the progressive discipline by the FDA.
5. Examples will be discussed and an interactive session on this case study will be applied.

**3:45 p.m. – 4:00 p.m. Closing Comments and Adjournment**

**Tuition and Registration**

**TUITION\*– Single Rate:** U.S. **$1,295.00 per person Group Rate:** U.S.**$1,245.00 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

**Course Director**



**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 her Masters in Biotechnology (Biodefense Concentration) at the Johns Hopkins University Advanced Academic Program.