"A three-tiered approach to the detection, correction and prevention of Manufacturing and Laboratory Quality Events."

THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS™

GUERRA CONSULTING GROUP, INC.

Presented By Johnny Guerra, Industry Consultant and Former FDA Official

THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS ™

GCGI's THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS & QUALITY EVENTS ™

Effectively combines auditing, workshop training and consulting follow-up coaching activities (either web based or on-site visits) to make participant's learning experience a complete success!

GCGI'S THREE-TIER PROGRAM is designed to improve your personnel's Critical Thinking and Regulatory Technical Writing skills essential for conducting and documenting robust investigations of Quality Events in Manufacturing, Packaging, Labeling, Chemistry and Microbiology Laboratory Operations. GCGI will train your employees on how to effectively implement a Quality Event and Failure Investigations system from an FDA regulatory and technical perspective in order to prevent FDA-483 observations, Untitled Letters, Warning Letters or higher level enforcement regulatory actions such as Injunction and Seizures. The program provides in-depth consulting, coaching and training activities in **FDA REGULATORY TECHNICAL THINKING (RTT)**, with emphasis in CAPA development and monitoring from an FDA Regulatory Perspective.

Program Overview

Failure Investigations and Quality Events are the first documents that the FDA Investigator takes into consideration when directing its auditing strategy to manufacturing and laboratory areas.

GCGI's THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS ™ is geared toward the correction and prevention of events that may have a direct or potential impact to product quality that otherwise could end as a regulatory sanction impacting negatively all cGMP activities. The program provides process excellence mechanisms to direct toward the organization's goal of improving competitive advantage, securing the best employees, delivering superior customer value and earning a premium return for its investors.

TIER: 1

GCGI's TIER-ONE module is an auditing activity related to firm's Manufacturing and Laboratory Quality Event system. The objective is to determine the degree of regulatory compliance the company might have when compared to FDA expectations and guidance documents in handling, documenting, correcting and preventing deviations and quality events.

Since regulatory deviations (usually ending as FDA-483 objectionable observations) are normally due to incomplete and/or incorrect policy statements, recommendations are then provided to correct SOPs prior to the execution of GCGI's TIER-TWO and TIER-THREE portions of the program. The evaluation also includes the detection, correction and prevention of human errors in manufacturing and laboratory operations.

TIER: 2

GCGI's TIER-TWO module is the training session. Twelve (12) or eighteen (18) hours of workshop training sessions are available. The course titled ***"FAILURE INVESTIGATIONS: A WORKSHOP ACTIVITY"*** is geared toward the chemistry/ microbiology laboratories and manufacturing operations. The training is presented from an FDA Auditor's perspective as it relates to current GMP regulations, laboratory and manufacturing events, non-conformances and out-of-specifications. The course allows each participant to understand the essential elements of the process, particularly ***"How To Think Like The FDA"*** ® while auditing firm's investigations, including the regulatory rationale behind the investigative process as well. The training is directed toward management and technical personnel involved in QA, Training, Manufacturing, Validation, Laboratory and Engineering departments. Employees maintaining professional licenses will be able to submit the course to their respective Board of Examiners for the evaluation and approval of Continuing Education Units (CEUs).

TIER: 3

GCGI's TIER-THREE module is the last activity of the program allowing firm's personnel to grasp and ***"FINE-TUNE"*** the knowledge acquired from the first two-tiered activities. Firm's personnel will receive a **ONE-TO-ONE** coaching and consulting service enabling the application of ***"FDA-THINKING"*** when documenting quality events. Furthermore, this knowledge will allow the detection, correction and prevention of issues in areas that might be prone to quality deviations as well.

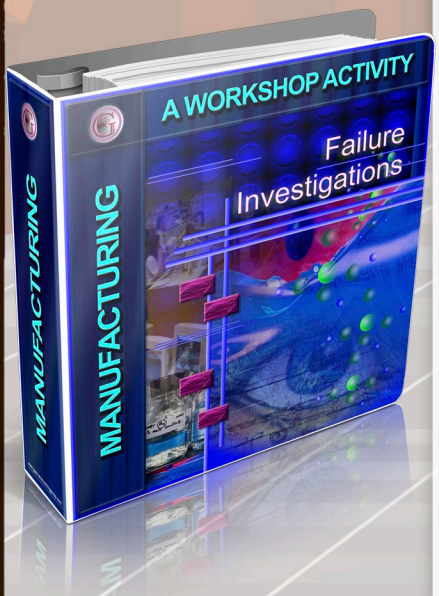
Program Details

TIER: 1

AUDITING ACTIVITY - QUALITY EVENTS

- Evaluation of firm's regulatory compliance on notification of events (NOE), non-conformances and failure investigations in the manufacturing and laboratory areas.
- Planning stage for investigations including Quality Risk Management Assessment.
- Evaluation of procedures used in the development of Investigation Reports.
- Assessment of documents and compliance checklists.
- Advise on alternatives for NOEs and deviations.
- Evaluation and consulting on FDA audit reports including FDA-483 items.
- Evaluation and consulting on investigations related to Consumer Complaints, Field Alert Reports, Annual Product Reviews, Product Recalls and others.
- Evaluation and consulting on Corrective and Preventive Action Plan (CAPA) documents.
- Verification of other procedures as required by the firm including action plans.
- Written report on above activities.

TIER: 2



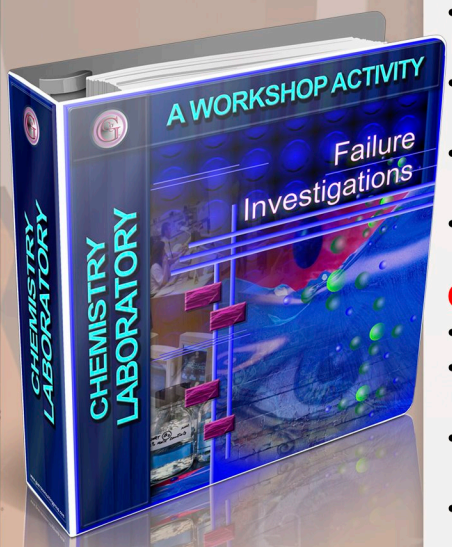
TRAINING ACTIVITY

Training course titled ***"FAILURE INVESTIGATIONS: A WORKSHOP ACTIVITY"*** geared toward manufacturing operations and chemistry/microbiology laboratories.

COURSE ABSTRACT

Not quite frequently, unexpected laboratory test results as well as manufacturing events or non-conformance conditions are obtained even when following procedures on validated systems. Investigation reports are then generated whenever unplanned, atypical or failure events take place leading to a possible impact on the safety, strength, quality and purity of a drug product. Such investigations are mainly derived from observations and expressed as a written justification of a situation leading to the identification of its root cause. A corresponding corrective action plan is finally generated to prevent the reoccurrence of such non-conformance. This course allows the participant to understand the basic elements of the process, how the FDA thinks while auditing firm's investigations and the regulatory rationale behind the investigation process as well.

Emphasis is given to procedures used for writing investigations taking into consideration the accuracy, integrity and security of data within a pharmaceutical operation. The course also focuses on regulatory aspects of Root-Cause-Analysis (RCA) when documenting non-conformances in manufacturing and laboratory operations. Included is a workshop section where exercises with Problem-Solving Tools (PST) are discussed such as Brainstorming/Affinity Diagrams, Lean Sigma 5-Why's, Fishbone Diagrams, Kepner–Tregoe®, Input-Process-Output(IPO), Pareto Charts and Failure Mode & Effect Analysis (FMEA). Furthermore, the workshop extends to real-life situations where firm's investigations are studied within an educational context for the proper understanding and application of the subject material.



TRAINING ACTIVITY - COURSE OUTLINE

Chapter 1: Handling Investigations

- FDA's position within the Investigation Process, FDA-483 Trends and Warning Letters.
- Chemistry, Microbiology and Manufacturing Failure Investigations/Quality Events.
- Discussion of cGMP requirements and ***"FDA's Thinking"*** related to Quality Events.
- Systems Assessment, Regulatory questions and concerns for Laboratory and Manufacturing Operations.
- Detection, Correction and Prevention of Human Errors in cGMP Operations.

Chapter 2: Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST)

- Systematic approach for determining possible causes of deviations.
- Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST) applicable to Investigation Reports.
- FDA Regulatory Investigation's Life Cycle approach within Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST).
- Problem-Solving Tools (PST) within an FDA-Investigator's frame-of-thought: Brainstorming/Affinity Diagrams, Lean Sigma 5-Why's, Kepner-Tregoe® (KT), Input-Process-Output (IPO), Cause-and-effect (Fishbone) Diagrams, Pareto Charts and Failure Mode and Effect Analysis (FMEA).
- **QUALITY EVENT EXERCISE SESSION:** The application of Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST) on firm's Quality Events.

Chapter 3: Writing Investigation Reports

- Methodology of the Investigation.
- FDA and cGMP Regulatory considerations.
- Technical-Writing (TW): Issues to be considered when writing the Investigation Report, i.e., Active vs. Passive Sentences, critical thinking, etc.
- Discussion of an Investigation Report Template for Laboratory and Manufacturing Operations that meets FDA regulatory requirements.
- Discussion of a Failure Investigation's Checklist used during the documentation and auditing of failure investigations and quality events.
- Relationship to RCA, PST, Impact to Product Quality, Accuracy, Integrity and Security of data.

Chapter 4: Investigations Report Workshop Exercise

- The workshop activity takes a snapshot of FDA's point of view during the interpretation of RCA and PST on Investigation Reports.
- The study and evaluation of firm's Quality Events in an educational forum.
- Learn the difference between a well-written investigation report from another that would end as an FDA-483 objectionable observation.
- Learn how to document a well-balanced, FDA-compliant investigation report that could be understood on its own.
- Participants will re-write an approved investigation report applying Root-Cause-Analysis (RCA), Problem-Solving Tools (PST) and learnings from previous Chapters with an FDA regulatory perspective.

TIER: 3

CONSULTING & COACHING ACTIVITY - QUALITY EVENTS

Following the training session, participants will be able to apply learnings using recommended failure investigation templates, checklists and visual aids. The **TIER-THREE** module consists of coaching activities in regulatory and technical writing with emphasis in CAPA development and trending. Throughout the evaluation of in-process and/or completed manufacturing and laboratory failure investigations & quality events, the firm will be able to measure participants' improvement when documenting investigation reports. As an internal audit activity, GCGI's evaluation will classify investigation reports as: (1) acceptable with no comments,(2) acceptable with minor comments or (3) for further evaluation and action plans. Regular meetings (either web-based or on-site) will be scheduled to discuss evaluation reports. The meeting will rehearse a typical FDA inspection scenario alerting participants of critical investigative elements. As an outcome of the meeting, Addendums to investigation reports will be recommended to correct and prevent similar quality events.

The **THREE-TIER** module has been designed as a continuous consulting, coaching and training activity in Failure Investigations. The firm can select **3, 6, or 9-month options** depending on the level of knowledge and experience in quality events. Once this module is completed, participants will be able to apply the ***"FDA-THINKING"*** during the documentation of failure investigations and quality events in manufacturing and laboratory operations. The invaluable knowledge obtained during this module translates into practical skills allowing for the detection, correction and prevention of quality issues that otherwise could end up being written as FDA-483s, FDA Warning Letters or acknowledged on higher regulatory sanctions.

As an additional benefit, experience has shown that the FDA Investigator will acknowledge firm's commitment to product quality and adequate cGMPs based on the quality of investigation reports. This translates to a faster completion of the FDA inspection with less interruptions to the business side, and all within a high degree of regulatory control level.

ACTIVE LEARNING!

WEEKLY EXERCISE SESSIONS!

GCGI's Failure Investigation's Resource Toolkit ™

For a complete learning experience and to improve the knowledge gathered during presentations, discussions, Workshop training sessions and coaching activities, GCGI's Failure Investigation's and Quality Events Resource Toolkit ™ has proven to enhance participants' investigative techniques and FDA-type documentation skills. The resource toolkit is divided into: (1) Visual Aids, (2) Templates, and (3) Checklists.

1

VISUAL AIDS:

- The Validated State: Manufacturing and Laboratory Operations.
- The cGMP Manager, Supervisor and Employee.
- Failure Investigations & Quality Events Flowchart.
- Quality Events: A Compliance Culture Action Plan.
- Human Error & Human Error Precursors.
- A QA Compliance Investigation Unit (CIU) Flowchart.
- A cGMP Approach to CAPAs.
- QA in Record Keeping: A Data Integrity Perspective.

2

TEMPLATES:

- Manufacturing Investigation Report Template.
- Laboratory Investigation Report Templates: Chemistry and Microbiology Laboratories.
- Incorporating a QA ***"Addendum"*** procedure to approved Manufacturing and Laboratory Quality Events.
- Preventing & Responding to FDA-483s.
- A Position Paper in the Detection, Correction, and Prevention of Human Errors in Manufacturing and Laboratory Operations.
- Procedures to develop a QA Compliance Investigation Unit (CIU).

3

CHECKLISTS:

- Microbial Identification during Quality Events.
- Failure Investigations and Quality Events Checklist - Manufacturing and Laboratory Operations.
- Preventing Quality Events: Regulatory Inspection Checklist.

WHO SHOULD ATTEND? WHO CAN BENEFIT FROM THE PROGRAM?

Any pharmaceutical, medical device, biotechnology, biologics, GLP and R/D professional who performs or oversees the following functions:

- Corporate Management
- QA/QC Directors, Managers and Supervisors
- Internal Auditors, Regulatory Affairs
- Education/Training Managers and Personnel
- GMP Compliance
- Stability Directors, Managers and Supervisors
- Laboratory Directors, Managers, Supervisors and Scientists
- Validation Scientists
- IT/IM Managers and Personnel
- Project Management
- Technical Operations and Development
- Technical and Analytical Services
- Metrology Groups
- Engineering
- Production/Manufacturing
- Materials Management

The program is also of interest to:

- Contract Laboratories
- Contract Manufacturers
- Contract Engineering
- Contract Personnel
- Consultants
- Formulators
- Consumer Safety
- Laboratory Equipment Vendors and Manufacturers

PROGRAM DIRECTOR, SPEAKER & COACH

Johnny Guerra, Industry Consultant

"Former FDA Instrument and Computer Specialist"
"Former FDA Supervisory Chemist"

Johnny Guerra is an Industry Consultant, Regulatory Compliance, and the President of Guerra Consulting Group, Inc. He worked for 20 years at the Food and Drug Administration (FDA), San Juan District Office and held positions such as Acting Science Branch Director, Supervisory Chemist, the District Instrument and Computer Specialist and as a Senior Food and Drug Chemist.

He received his degree in Chemistry certified by the American Chemical Society (ACS) from the University of Puerto Rico, Río Piedras campus and later was certified in Electronics Engineering in Minicomputers and Microprocessor Technology by the Capitol Radio Engineering Institute (CREI), Washington, D.C.

Guerra has over 36 years of experience in areas such as electronic instrument design, microcomputers, laboratory automation, Local Area Networks (LANs), Quality Assurance, Quality Control and auditing laboratory/ manufacturing computerized processes and manufacturing/laboratory operations at Pharmaceutical, Biotechnology, R/D and Medical Device firms.

He was also member of the FDA Foreign Inspection Cadre where he traveled overseas performing audits in manufacturing processes, quality assurance, manufacturing/laboratory computer validation and analytical methods validation as well.

Guerra has published several articles in Pharmaceutical Technology, has authored many technical papers, reports and course manuals including a chapter titled *"FDA Approach to Laboratory Inspections"*; A Laboratory Quality Handbook of Best Practices, ASQ Quality Press, and others published in FDA's internal scientific journal *"Laboratory Information Bulletin"* (LIB).

Find Us on LinkedIn

THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS ™

GCGI's THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS ™ has been a complete success in pharmaceutical production and laboratory sites.

Since its development in **2005**, participants have been able to fully understand and grasp FDA-type regulatory technical requirements and apply superior technical/ regulatory writing skills when documenting manufacturing and laboratory failure investigations and quality events. The program is kept updated with the latest regulatory requirements and technical trends.

Success!

AstraZeneca

P&G Procter&Gamble

Wyeth®

McNeil Consumer Healthcare

P&G Pharmaceuticals

Warner Chilcott

Comments from satisfied Pharmaceutical Companies...

"In our recent FDA audit, the FDA inspector commented on the quality and thoroughness of our manufacturing and laboratory investigations. He added, ...the best investigations I have seen in my 18+ years as an investigator with the FDA."

"GCGI's THREE-TIER PROGRAM has been responsible for a 70%-85% reduction in our Human Errors!"

"We just recently concluded the FDA inspection. The FDA investigator acknowledged the fact that all issues he can think of were properly addressed during the investigation including CAPAs."

"He even said, ...Congratulations!"

Join the hundreds of employees who have benefited from the program.
Please, contact us at 1-787-283-1518
or e-mail us at **gcgi@guerraconsultinggroup.com**

to request a quote for the program or individual modules. Let GCGI help your company boost productivity under an FDA regulated environment.

THREE-TIER PROGRAM IN FAILURE INVESTIGATIONS ™

GCGI's THREE-TIER PROGRAM is available through online webinars. Seminars and courses are presented live including group discussions, workshop exercises and Q&A sessions.

You can benefit from the highest quality live seminars and courses in the latest FDA regulatory trends. GCGI Web Seminars are provided on demand and can be customized to meet your teams' training and scheduling needs.

Enjoy the full benefits of GCGI's Training Program at considerably reduced rates when compared to on-site presentations.

Cost-Effective Benefits:

- Assortment of live interactive web seminars and courses.
- Webinars are a cost-effective solution because they:
  - ✓ Eliminate travel expenses.
  - ✓ Eliminate personnel unavailability on-site.
  - ✓ Eliminate travel time.

Participants log-in to WebEx from a conference room, office or mobile device from any location worldwide!

Cisco webex Event Center

Participants are connected to GCGI and able to talk directly to the speaker and/or use the Chat Box for interactive discussion!

The complete program is available via web.

PROGRAM BENEFITS

TIER-ONE

- Obtain a complete Assessment of Failure Investigations and Quality Event procedures for any ***"Regulatory Vulnerability".***
- Avoid FDA-483s objectionable observations based on inadequate procedures.
- Avoid documentation inconsistencies.
- Detect, correct and prevent voluntary and careless-work type of human errors.
- Maintain scientific, robust and compliant procedures in place at the Corporate, Region and Local levels.

TIER-TWO

- Understand FDA's thinking and rationale when documenting Quality Events.
- Learn how to emulate FDA's Investigator thinking and auditing approach when documenting a deviation or quality event.
- Learn how to document a deviation in terms of impact to product quality.
- Learn how to document a deviation related to Consumer Complaints.
- Learn Root-Cause-Analysis (RCA) and apply Problem-Solving Techniques (PST) in any area.
- Be able to detect, correct, prevent and predict failures/deviations and quality events.
- Learn to develop effective **CORRECTIVE AND PREVENTIVE ACTION PLANS (CAPAs).**

TIER-THREE

- Obtain a ONE-TO-ONE consulting service and apply the ***"FDA-Thinking"*** when documenting Quality Events.
- Develop **REGULATORY TECHNICAL WRITING (RTW)** skills.
- Correct and prevent situations in areas that might be prone to quality events.
- Correlate deviations with equipments' validated state to maintain qualification status.
- Monitor status of validated pharmaceutical systems.
- Monitor CAPAs efficiently.
- Detect and correct voluntary and careless-work human errors.
- Decrease amount of time required to document a deviation.
- Make wise ***"Quality Risk Management"*** decisions and avoid regulatory penalties!
- Be able to detect and prevent mix-ups, mix-labels and short-fills.
- Improve Line Clearance procedures.
- Detect system failure and deviations that could end as FDA-483s, Untitled and Warning Letters.

GCGI's WEB TRAINING PROGRAM™ and GCGI's ON-SITE TRAINING PROGRAM™

"Learn How to Think... Like the FDA" ®

Whether in a group setting or a private class, GCGI's Training Program is available via multiple methods to best fit your business needs.

CALL NOW at 787-283-1518 for Registration.

Join the hundreds of satisfied participants who are currently applying the acquired regulatory and FDA compliance Knowledge!

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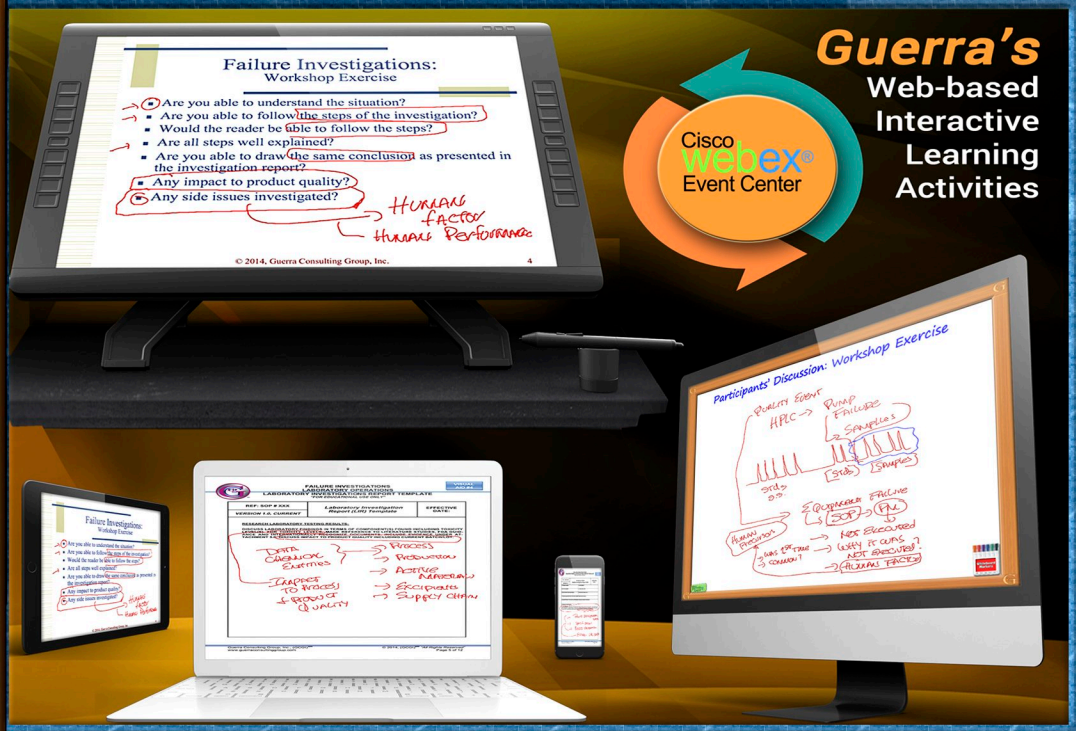
Interactive Virtual Classroom Training;

...the way to learn!

Active employee participation is key to a successful virtual classroom training experience.



Guerra's training activities engage employees and prompt them to think about how the subject matter relates to their own work. Workshop exercises trigger participants' engagement throughout the duration of the virtual training. Typical problems are addressed and solutions furthermore provided.

For group settings, a ***"Test Run"*** is included prior to the training session. This activity ensures that audio/video connections are adequate and that there aren't any glitches that can hinder the overall success of the scheduled training session.

Ready to improve the quality of Investigation Reports?

Online Quote Request