CERTIFIED

CERTIFICATION TESTS

Quality Event Solutions Expert ™

- *"LEARN–BY–DOING"* Educational Approach
- Step–By–Step Strategy Guides
- Master the Investigation Process

Avoid FDA - 483's using these methods

Guerra consultinggroup,inc.

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Learn how to THINK like the FDA®

★★★★ Endorsed By Industry Professionals

QE 242 SE ™

Certification Approach

The **Three-month (72 hours) Certification Program in Quality Events** focuses in a ***"LEARN-BY-DOING"*** educational approach. The program emphasizes on extensive exercises, individual and/or group discussions, homework, certifications exams and continuous interactive learning experience geared toward the correction and prevention of quality events and ultimately; ***"How to Think and Emulate the FDA Investigator".***

Certified individuals become **Quality Event Solutions Expert (QESE)** enabling them to be in the forefront of Process Excellence (PE) initiatives evaluating processes and systems in terms of how effectively and efficiently they create value to the company.

The training methodology involves presentations, discussion and exercises of manufacturing and laboratory quality event investigations as well as the evaluation and discussion of exam results. The program is delivered either on-site, via web or a combination of both.

Program Details

MODULE 1:

FIRST MONTH

6 HOURS/WEEK
TOTAL HOURS: 24

Regulatory Issues and Quality Events

- Types of Quality Events.
- What triggers a Quality Event and Failure Investigation?
- The FDA-483 and EIR as a diagnostic tool.
- Trending firm's FDA regulatory history.
- Identification of quality systems requiring improvement.
- The documented investigation.
- Root-Cause-Analysis (RCA) and Problem-Solving Techniques (PST).
- CAPA effectiveness and monitoring.
- Understanding FDA Guidance Documents: HOMEWORK & DISCUSSION #1:
  - Quality Systems.
  - Out-Of-Specifications (OOS).
  - Auditing Manufacturing and Laboratory Operations.
- Understanding the FDA thinking.
- How to complete the QA loop for product disposition.
- How to determine when an event becomes an FDA-483 objectionable observation.
- How to determine when an event could escalate to an FDA Warning Letter.
- In search of FDA-483 items: How to audit previous and on-going investigation reports.
- CERTIFICATION EXAM #1: REGULATORY ISSUES & QUALITY EVENTS

Cont. Program Details

SECOND MONTH

6 HOURS/WEEK
TOTAL HOURS: 24

MODULE 2:

Documenting Quality Events: The Investigation Report

- What triggers the documentation process?
- Elements of the investigation process.
- How to conduct the investigation.
- Technical and regulatory writing and wording:
  - Documenting the main event.
  - Documenting side events.
  - Quality impact of documentation.
- Resources required to complete the investigation.
- Regulatory aspects of the Investigation Template Report: HOMEWORK & DISCUSSION #2.
- The Validated State:
  - Quality by Design (QbD), Process Development and Process Validation.
  - Analytical Method validation, method transfer and method verification.
  - Qualification and validation of instruments, equipment and computers.
- Evaluation and elimination of reoccurrence:
  - Human errors.
  - Data Integrity.
  - Manufacturing and Laboratory Quality Events.
- Auditing the investigation report.
- Workshop activities – Evaluation of Investigation Reports: HOMEWORK & DISCUSSION #3.
  - EXERCISE #1: Manufacturing Investigation Report.
  - EXERCISE #2: Chemistry Laboratory Investigation Report.
- CERTIFICATION EXAM #2: DOCUMENTING QUALITY EVENTS – THE INVESTIGATION REPORT

Cont. Program Details

THIRD MONTH

6 HOURS/WEEK
TOTAL HOURS: 24

MODULE 3:

Evaluation of Investigation Reports

- Workshop activities – Evaluation of Investigation Reports: **HOMEWORK & DISCUSSION #4.**
  - **EXERCISE #3:** Microbiology Laboratory Investigation Report.
  - **EXERCISE #4:** Data Integrity Investigation Report.
  - **EXERCISE #5:** Manufacturing Investigation Report.
  - **EXERCISE #6:** Chemistry Laboratory Investigation Report.
  - **EXERCISE #7:** Microbiology Laboratory Investigation Report.
  - **EXERCISE #8:** Manufacturing Investigation Report.
  - **EXERCISE #9:** Manufacturing Investigation Report.
  - **EXERCISE #10:** Chemistry Laboratory Investigation Report
- Integration of Quality Events methodology with Process Excellence projects including Total Quality Management (TQM), Lean Six Sigma, Lean Manufacturing, Kaizen, Business Process Engineering and Variation Reduction, among others.
- **CERTIFICATION EXAM #3: EVALUATION OF INVESTIGATION REPORT**
  - Each participant receives and investigation report for evaluation as the final certification exam.

Each participant receives a printed certificate with unique "*QESE*" certificate number.

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What's Included

The certification program includes all course presentations, workshop case studies, certification exams and reference materials for a complete learning experience. Reference materials improve knowledge acquisition during course presentations, discussions and exercise sessions.

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.

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).

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 CERTIFICATION 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 Certification Program is perfectly suited to:

- Deviation Investigation Writers
- CAPA Investigators
- Pharmaceutical Technical Writers
- Specialist/Technical Writer-Documentation
- Technical Writer - Investigations Specialist
- Process Excellence Specialist
- Lean Six Sigma Leaders
- Consultants

The Certification Program is also of interest to:

- Contract Laboratories
- Contract Manufacturers
- Contract Engineering
- Contract Personnel

Certification Instructor

PROGRAM DIRECTOR, CERTIFICATION INSTRUCTOR

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

Program Benefits

- Understand FDA's thinking and rationale when documenting Quality Events.
- Learn how to prevent FDA-483s objectionable observations.
- Learn how to emulate the FDA auditing approach when documenting a deviation or quality event.
- Detect system failure and deviations that could end as FDA-483s, FDA Untitled and Warning Letters.
- Develop and master REGULATORY TECHNICAL WRITING (RTW) skills.
- Prevent documentation inconsistencies.
- Decrease amount of time required to document a deviation.
- Learn how to detect, correct and prevent voluntary and careless-work type of human errors.
- Integrate Quality Event methodology with Process Excellence initiatives, i.e., Lean Six-Sigma, TQM, Kaizen and others.
- Learn how to document a deviation in terms of impact to product quality.
- Learn how to document a deviation related to Consumer Complaints.
- Learn how to maintain scientific, robust and compliant procedures in place at the Corporate, Region and Local levels.
- Learn how to apply Root-Cause-Analysis (RCA) and Problem-Solving Techniques (PST) in any cGMP area.
- Be able to detect, correct, prevent and predict failures/deviations and quality events in any cGMP area.
- Predict and prevent deviations to the validated state in pharmaceutical systems.
- Learn how to document and monitor effective CORRECTIVE AND PREVENTIVE ACTION PLANS (CAPAs).
- Make wise Quality Risk Management decisions avoiding firm's regulatory penalties.

Certification via Web

The complete program is available via web.

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

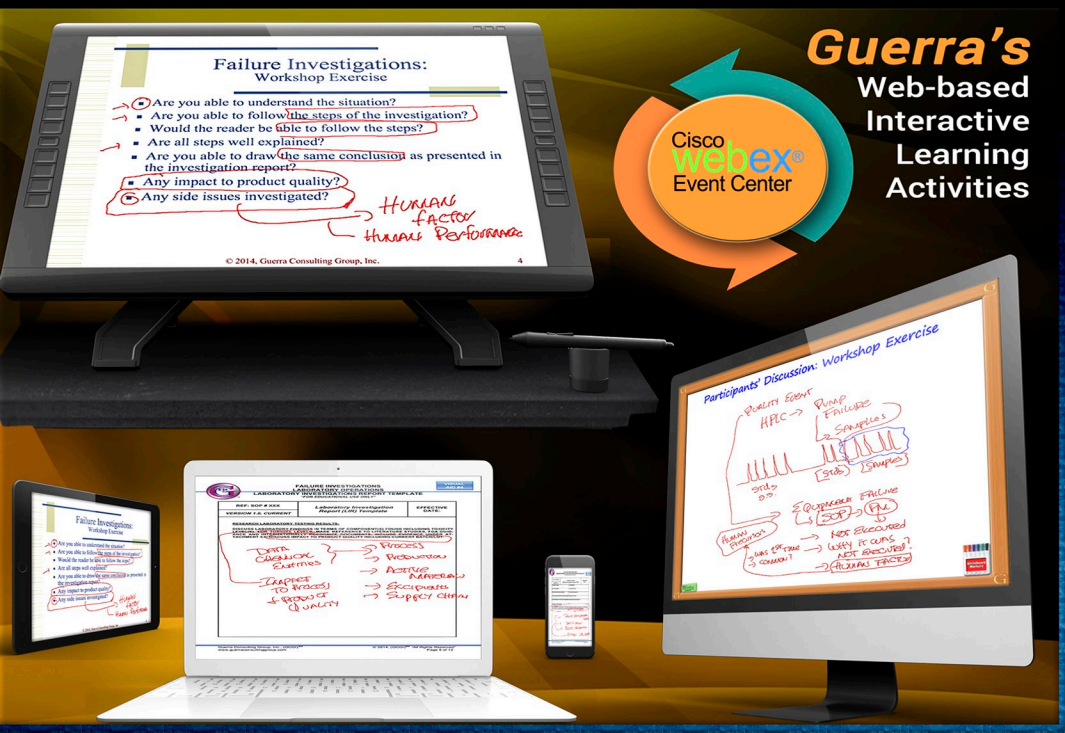
Cisco webex Event Center

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

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.

Are you ready to become a leader as a Compliance Investigator Professional?

Get Certified Now as a Quality Event Solutions Expert (QESE).

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Request a quote

Online Quote Request

or e-mail Us at:

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