GCGI's WEB TRAINING PROGRAM™

FAILURE INVESTIGATIONS & QUALITY EVENTS: LABORATORY OPERATIONS

www.guerraconsultinggroup.com

P.O. Box 193271 San Juan, P.R. 00919-3271

FAILURE INVESTIGATIONS & QUALITY EVENTS:
LABORATORY OPERATIONS

ABSTRACT

Not quite frequent, unexpected laboratory test results as well as manufacturing event conditions are obtained even when following procedures on validated systems. Investigation reports are then generated whenever non-planned, 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 upon 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 **nine (9) hours, three (3) modules** training course concentrates on current and legal issues related to non-conformances discussing the essence of quality events, failure investigations and Root-Cause-Analysis (RCA) in Laboratory Operations.

The course includes an interactive workshop activity where participants would be able to apply problem-solving techniques to their current investigations in light of the new information acquired during training sessions.

COURSE AGENDA

A. MODULE 1: INTRODUCTION TO QUALITY EVENTS (3 HOURS)

- The Documented Investigation.
- International GMP Requirements.
- Laboratory Investigation:
  - Human Error and Human Error Precursors.
  - Flowchart of the Investigation Process.
- The Validated Condition: Manufacturing and Laboratory Operations.
- Where to Start?
  - Laboratory Operations.
  - Discussion of Checklist for Investigation Reports.
- Exercise Session: Identifying Areas for Improvement.

B. MODULE 2: LABORATORY OOS (3 HOURS)

- Discussion of FDA Guidance for Industry: "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production".

C. MODULE 3: WORKSHOP EXERCISE (3 HOURS)

- Discussion of firm's laboratory investigations applying concepts learned from Modules 1 & 2.
- Referring to Investigation Reports, participants will address the rationale of the investigation report indicating impact to:
  - The validated state condition,
  - Impact to product quality, and
  - Impact to consumer health.
- Discussion of CAPA effectiveness.
- Evaluation if an addendum to the investigation report would be required based on previous learnings.

WHO SHOULD ATTEND? WHO CAN BENEFIT FROM THE TRAINING SESSION?

Any pharmaceutical, API, 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

SPEAKER

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 37 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

Presenting...

GCGI's WEB TRAINING PROGRAM™

and

GCGI's ON-SITE TRAINING PROGRAM™

CALL NOW at 787-283-1518 or e-mail us:

gcgi@guerraconsultinggroup.com

and request a quote for training courses.

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

...and that is why GCGI...

"Is Your Trainer of Choice!"

Online Quote Request

Web and On-Site Trainings:

- ✓ The training session includes a PDF handout and Certificate of Participation.
- ✓ Optional course manuals available by request.
- ✓ Web-based and On-Site trainings are all-inclusive. Your company invests once for the corresponding group of individuals.
- ✓ Web presentations delivered in 1-3 hour sessions.