GCGI's WEB TRAINING PROGRAM™

AUDITING THE LABORATORY for DATA INTEGRITY ISSUES

www.guerraconsultinggroup.com

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

AUDITING THE LABORATORY for DATA INTEGRITY ISSUES

ABSTRACT

Laboratory data integrity issues have been repeatedly found during FDA audits. The uncertainty of the origin and creation of data is often the result of inadequate controlled processes, lack of a continuous validated state condition and management oversight.

This **four (4) hours** training course on data integrity discusses the detection, correction and prevention of data manipulation that undermine the truthfulness of data. The course incorporates human performance, human error reduction and the resolution of human error precursors that often trigger data integrity issues.

The evaluation of the validated state condition, SOPs as an outcome of validation activities, instruments, equipment, system administrator, software error logs and vendor's software design limitations is also included in order to prevent any quality impact to GMP laboratory operations.

COURSE AGENDA

A. MODULE 1: LEARN FDA's DATA INTEGRITY EXPECTATIONS ON HUMAN FACTORS (1 HOUR)

- What is Data Integrity?
- Specific examples of data integrity in the laboratory:
  - Group exercise and discussion.
  - Quality issues to act on.
- Difference between analytical careless work error from intentional manipulation of laboratory data.
- Human Factors and Data Integrity:
  - Management.
  - Employees.
  - Product branding consequences.
- Human error reduction.
- Resolution of human error precursors.

B. MODULE 2: LEARN FDA's DATA INTEGRITY EXPECTATIONS ON LABORATORY DOCUMENTATION (1 1/2 HOURS)

- Input/Output process of a typical laboratory operation.
- Product sampling, sample accountability and traceability to manufacturing processes.
- Analytical & electronic notebooks, controlled forms and data entry.
- Evaluation of SOPs from a data integrity perspective:
  - Analytical and Microbiological Method Validations.
  - Laboratory supplies, reagents, standards, media and sample preparations.
- Requirements for analytical test execution, documentation and second person review:
  - Who did what, and when did they do it?
  - Traceability of raw data: Methods, instruments and equipment.
  - Identifying agreement between and within documents.
  - Learn how to detect data integrity flaws when conducting audit trail reviews.
- Documenting laboratory quality events when data discrepancies are observed.
- Preventing Data Integrity issues.

C. MODULE 3: LEARN FDA's DATA INTEGRITY EXPECTATIONS ON INSTRUMENT QUALIFICATIONS AND COMPUTER VALIDATION (1 1/2 HOURS)

- Laboratory equipment and instruments:
  - Instrument qualifications.
  - System Suitability Tests: FDA regulatory aspects of ***"Trial, Test or Preparation"*** chromatographic runs.
  - GMP issues related to vendor's validation and qualification activities.
  - GMP issues involving the System Administrator.
  - Data Integrity issues related to Computer System Validation (CSV) and 21 CFR Part 11 (ER/ES).
  - Raw data, electronic calculators, laboratory spreadsheets and database controls.
- Managing data integrity issues from contract laboratory services.

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.

Online Quote Request

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!"

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.