GCGI's WEB TRAINING PROGRAM.

AN FDA REGULATORY PERSPECTIVE TO: BATCH RECORD REVIEW

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ABSTRACT

Batch records provide step-by-step instructions for production-related tasks and activities, besides including areas on the batch record itself for documenting such tasks.

The batch record review is an essential tool for assuring the quality of a pharmaceutical process and to determine product's approval or rejection as a sole responsibility of the Quality Unit under 21 CFR 211.22(a) requirements.

The review process focuses on key pieces of information contained in a batch record taking into consideration the identification of batch related discrepancies.

Adequate procedures should be in place that would differentiate incidents that can be addressed with an explanation in the batch record from those requiring the filing of a deviation followed by the execution of an investigation.

This **six (6) hours** course explains all relevant aspects to conduct and to improve the system of the batch record review from an FDA auditing and regulatory perspective.

Participants will learn how to prepare for a technical review of batch records, as well as how to measure the effectiveness of the review process.

COURSE AGENDA

A. Batch Records and Regulations:

- Regulatory Requirements.
- Impact to Product Quality and Validated State.

B. Documentation Requirements for Batch Records:

- Documentation activities.
- Training Requirements for the Batch Record Reviewer.
- Data Integrity.
- Documenting Electronic Batch Records.

C. Conducting an Effective Batch Record Review:

- Quality Review Process.
- Responding to Batch Record Deviations.
- Batch Record Review SOPs.

D. Quality Events and Failure Investigations:

- When to investigate?
- The Investigative Process.
- Corrective and Preventive Action Plan (CAPA).
- Follow-up to Quality Events, Investigations and CAPAs.

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).

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