GCGI's WEB TRAINING PROGRAM™

CGMP REQUIREMENTS FOR: INCOMING & SUPPLY CHAIN OPERATIONS

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ABSTRACT

As an initiative to modernize 21 CFR 211 requirements, the FDA expects industry, including manufacturers, distributors and users of excipients, APIs and components, to improve their quality efforts based on current regulatory issues prompted from tragic incidents of contamination of pharmaceutical excipients and food chemicals.

These quality efforts encompasses a thorough knowledge of the supply chain at the manufacturing site and subsequent handlers, supplier audits testing of each container in a shipment, requiring tamper-evident packaging and security features, non-conformities investigated and addressed, notification to the FDA of any contaminated shipments or lots, and that pharmaceutical product manufacturers only use components recognized as safe for their intended use or included in an approved application.

This **six (6) hours** course about the incoming goods control of APIs, excipients and supply chain will provide participants with a comprehensive overview of the specific tasks and regulatory requirements expected by FDA during pharmaceutical manufacturing and distribution of drug products.

COURSE AGENDA

- Meeting FDA and cGMP Requirements for Incoming and Supply Chain Operations.
- Validated state of Raw Materials.
- Retention samples.
- ANSI sampling and areas to consider when out of the validated state.
- Vendor Audits and Manufacturing Supplier Certification Program.
- Contract Agreements: Discussion of FDA Draft Guidance document "***Contract Manufacturing Arrangements for Drugs: Quality Agreements, May 2013.***"
- Supplier Certification levels.
- Quality Events related to inadequate supplier certification programs.
- Regulatory approach to reduced testing.
- Data Integrity.
- Investigation of Non-conformances: Manufacturing and Laboratory operations (firm's and supplier levels).
- Non-conformances and Human Error Investigations.
- Maintaining Incoming and Supply Chain Operations within FDA-regulatory Compliance.
  - o Field Alert Report (FAR).
  - o Consumer Complaints.
  - o Annual Product Review (APR).
  - o Adverse Events.
  - o Monitoring quality events and CAPA effectiveness.
  - o Re-evaluation of the validated state.

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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and

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