GCGI's WEB TRAINING PROGRAM™

How to be prepared for an FDA Audit

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How to be prepared for an FDA Audit:
Laboratory and Manufacturing Operations, Pharmaceutical Industry

ABSTRACT

The Food and Drug Administration (FDA) carry out comprehensive audits of regulated facilities to determine firms' compliance to the Code of Federal Regulations (CFR), one among many ways the Agency protects the public health.

What happens during the inspection is always a concern to firms' management particularly when addressing and responding to FDA findings, including any regulatory action. Nevertheless, many of the problems uncovered during inspections are common and recurring problems within the pharmaceutical industry.

How can a firm be prepared as it relates to enforcement policies? The answer relies on a careful planning and preparation, successful management of many issues during the inspection itself, and thorough follow-up after the inspection.

This **six (6) hours** course addresses such planning and preparation, acknowledging typical documents studied by FDA investigators in preparation to the inspection. Within this context, the course emphasizes on pharmaceutical systems that are vulnerable to objectionable observations that would eventually lead to FDA Warning Letters (WLs); the first step in legal action if problems are not properly corrected.

COURSE AGENDA

A. UNDERSTANDING THE TOOLS OF THE TRADE:

- FDA Guidelines, FDA Inspection Guides, FDA Compliance Programs, FDA Policy Statements, IOM and others.
- Understanding GMPs – 21 CFR 210, 21 CFR 211 and others.
- Issuing the FDA-482 & FDA-483.
- Completing the report, EIR and classification of inspection: NAI, VAI, OAI
- Next steps: Warning Letter, legal sanctions and Consent decree.

B. UNDERSTANDING PHARMACEUTICAL SYSTEMS FROM AN FDA PERSPECTIVE:

- Quality System.
- Facilities and Equipment System.
- Materials System.
- Production System.
- Packaging and Labeling System.
- Laboratory Control System.

C. HOW DOES A COMPANY GETS READY FOR THE FDA INSPECTION?

- Types of documentation.
- Presenting the documentation to FDA investigators.
- What FDA investigators will ask for during the inspection?
- How to manage the FDA inspection.
- Due diligence: What to do before inspections?
- Do's and Don'ts during the FDA inspection.

D. EXERCISE SECTION - WHAT WOULD YOU DO? ANALYSIS OF OBSERVATIONS TAKEN FROM FDA-483 AND WARNING LETTERS:

- What is the problem?
- How could it have been avoided?
- Discuss risk assessment approach to consumer health and business impact.
- What to do in the event of an FDA-483?
- What to do in the event of a Warning Letter?

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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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