GCGI's WEB TRAINING PROGRAM™

FDA's PRE-APPROVAL INSPECTION (PAI) TRAINING.

Objectionable Observations:
1. Lack of a quality system designed to achieve sufficient control over manufacturing operations.
2. Inadequate evaluation of manufacturing and laboratory changes related to the development of a new drug substance.
3. Inadequate sampling, testing and evaluation of components, in-process materials and finished products.
4. Inadequate supplier qualification program.
5. Lack of equipment controls to prevent contamination of the API.
6. Inadequate instructions, processing parameters and process controls for the proposed commercial process.

Is your organization ready with a good understanding on the requirements set forth by the FDA on its Pre-Approval Inspection (PAI) program?

Is your firm ready to pay the price corresponding to million of dollars in licensing and commercial manufacturing delays due to lack of FDA's PAI approval?

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"FDA expectations culminating in compliance issues continue to be problematic, costing pharmaceutical manufacturers million of dollars every year."

- Lack of suitable and practical knowledge on preparing for pre-approval inspections decreases the chances of regulatory success.

GCGI's Web Training Program in Pre-Approval inspections will teach participants FDA's inspection techniques and PAI requirements from the start of the drug development process through the required readiness for commercial manufacturing and distribution of drug products.

GCGI's web seminar approach to FDA's Pre-Approval inspections is based on **7 modules**, **2 1/2 hours** each. For training effectiveness, GCGI suggest the learning of all modules, although participants could alternate with the selection of individual modules as well.

Includes
DATA INTEGRITY!

Learn the latest FDA's PAI auditing techniques that will result in a rapid regulatory approval for the timely delivery of your drug products!

1 MODULE 1: FDA/PAI REGULATORY REQUIREMENTS

- FDA expectations of the PAI Program - Compliance Program (CP) 7346.832.
- PAI aspects in formulation development.
- Linking the application with FDA's inspection process.
- FDA's System-Based Inspection.
- cGMP Risk Assessment and PAI Management Strategy.
- PAI Inspection Readiness.
- Steps to avoid failing a PAI.

2 MODULE 2: PAI AND THE QUALITY SYSTEM

- A Quality by Design (QbD) approach to Drug Development, procedures and specifications.
- Validation protocols, reports and Change Control.
- Quality events, failure investigations and product defect evaluations.
- Personnel qualifications and trainings.
- Contract laboratory and manufacturing.
- Supplier Quality Management.

3 MODULE 3: PAI AND THE FACILITY/ EQUIPMENT SYSTEM

- Regulatory compliance on facilities, structures and maintenance.
- Equipment qualifications, calibrations and preventative maintenance.
- Cleaning validation.
- Process performance qualification.
- HVAC, compressed gases and water systems.

4 MODULE 4: PAI AND THE MATERIALS SYSTEM

- Raw materials and vendor evaluation programs.
- Regulatory aspects of water or gases incorporated into the product.
- Containers and closures.
- Evaluation of computerized inventory control processes.
- Drug storage, records and distribution controls.

5 MODULE 5: PAI AND THE PRODUCTION SYSTEM

- The Master Batch Record.
- Executing Batch Records.
- In-process sampling and testing.
- Process Validation.
- Computer System Validation (CSV) and Part 11.
- CGMP aspects of Cloud Computing.
- FDA/CSV requirements of Manufacturing Execution Systems (MES).

6 MODULE 6: PAI AND THE PACKAGING/ LABELING SYSTEM

- Regulatory aspects of label examination, usage, storage and issuance.
- Validation of packaging and labeling operations.
- Computer System Validation (CSV) and Part 11 in packaging line operations.

7 MODULE 7: PAI AND THE LABORATORY CONTROL SYSTEM

- CGMP requirements of laboratory procedures.
- FDA's perspective to sample integrity.
- Documentation of reagents, standards and test solutions.
- Validation and verification of analytical test methods.
- Computer System Validation (CSV) and Part 11 requirements for laboratory instruments.
- The stability program.
- Environmental testing and microbiological controls.

WHO SHOULD ATTEND? WHO CAN BENEFIT FROM THE PROGRAM?

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

PROGRAM DIRECTOR, SPEAKER & COACH

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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Presenting...

GCGI's WEB TRAINING PROGRAM™

and

GCGI's ON-SITE TRAINING PROGRAM™

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...and that is why GCGI...

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