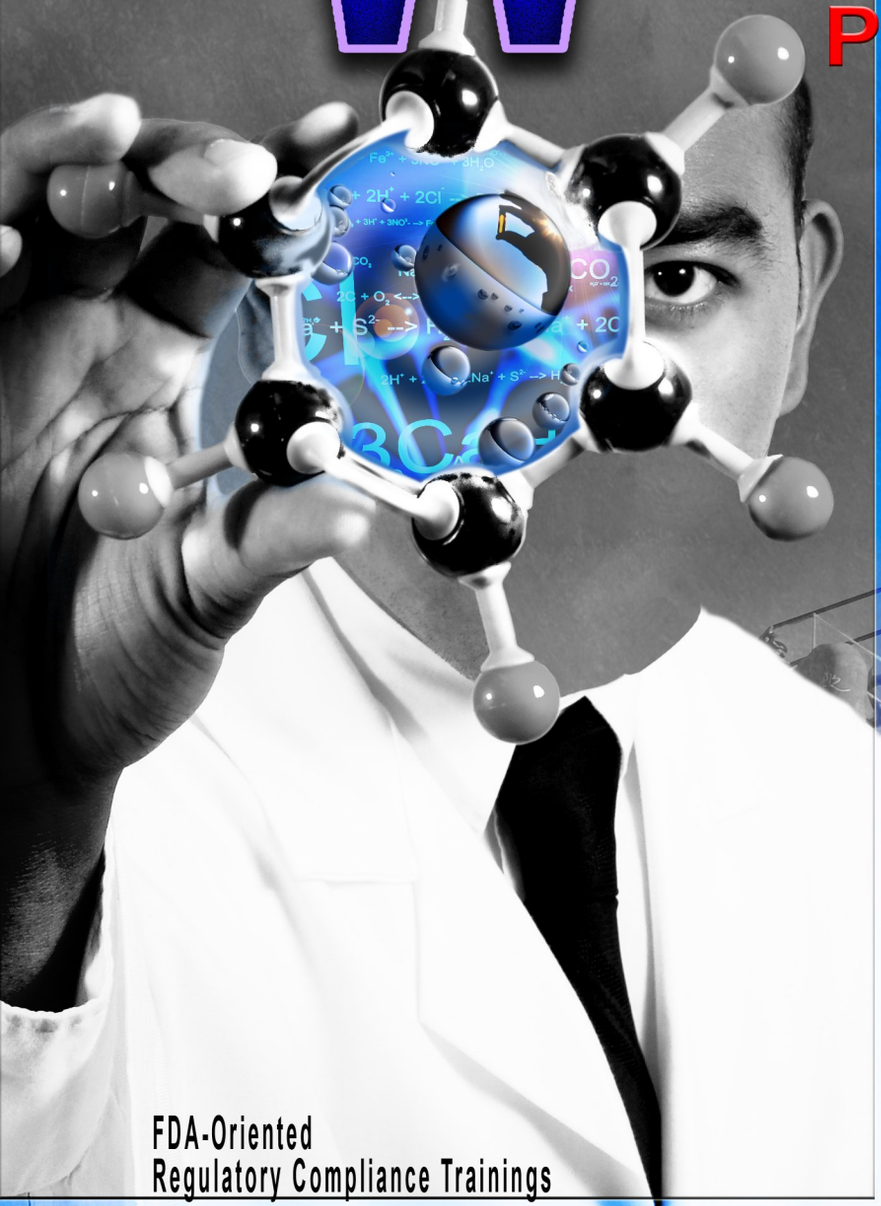
Guerra

consultinggroup,inc.™

"Established Since 1999"

GCGI's WEB TRAINING PROGRAM.™



FDA-Oriented
Regulatory Compliance Trainings

"Learn how to think...

...like the FDA"®

www.guerraconsultinggroup.com

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

Tel. 1-787-283-1518

GCGI's WEB TRAINING PROGRAM™

GCGI's on-site Training Program is available via web. Seminar and courses are presented live including group discussions, exercises and Q&A sessions.

NOW you can benefit from the highest quality live seminar and courses in the latest FDA regulatory trends.

GCGI's Web courses are provided on demand and can be customized to meet your teams' training and scheduling needs.

Enjoy the full benefits of GCGI's Training Program at considerably reduced rates when compared to on-site presentations.

Cost-Effective Benefits:

- Assortment of live interactive web seminars and courses.
- Webinars are a cost-effective solution because they:
  - ✓ Eliminate travel expenses.
  - ✓ Eliminate personnel unavailability on-site.
  - ✓ Eliminate travel time.

"Fantastic! I greatly appreciate how you are able to fully explain the rationale behind each response. I find that is the most important and challenging aspect of meeting regulations - anyone can read and understand them, but exactly how to implement them in your systems is a much more complicated issue, even simple things like dating and initialing. Thanks again for your time."

"Mr. Guerra, I just wanted to let you know how much I enjoyed your seminar. I have been to many through the years, but yours was very informative in a short of time."

"Mr. Guerra, thanks very much for your presentation yesterday. Our staff enjoyed hearing your tips and suggestions on meeting FDA and 21 CFR 58 requirements, and I think they will help us to improve compliance within our systems."

How does it work?

1

1. Call GCGI and discuss training needs.
2. GCGI will develop a customized Web seminar or Web course training.

2

Web seminar/course log-in information and presentation handouts sent two days prior to the training activity.

3

Participants log-in to WebEx from a conference room, office or mobile device from any location worldwide!

Cisco webex Event Center

4

Participants are connected to GCGI and able to talk directly to the speaker and/or use the Chat Box for interactive discussion!

5

Presentations are delivered in 1-3 hour sessions with 10 min. break interval(s). Interactive discussions are maintained throughout the use of a digital graphic tablet, including a whiteboard for optimized learning. Webinar evaluations and certificates are sent after the completion of training. Additional Q&A is available after the completion of the training session. GCGI will follow-up to ensure training effectiveness.

GCGI's WEB TRAINING PROGRAM™

The following is a partial listing of the companies that have benefited from GCGI's Web Training Program:

Abbott – A Promise for Life
gsk GlaxoSmithKline
Wyeth®
ALLERGAN
Boston Scientific – Defining tomorrow, today.™
MERCK SHARP & DOHME
Baxter
Medtronic
JANSSEN PHARMACEUTICAL LTD
BD
AstraZeneca
sanofi aventis
Lilly
Johnson & Johnson
Pfizer
Bristol-Myers Squibb
AMGEN
NOVARTIS
COVIDIEN – positive results for life™
Schering-Plough

"Thank you Johnny. The training definitely provided a lot of food for thought and this was helpful. It's been an on-going debate as to how long we should keep documents".

"Hi Johnny. It was a very informative webinar and you are quite experienced in your speech topic."

"Hi Johnny. Thank you for putting on an excellent presentation this morning on Human Errors. I was attracted to your seminar because of my project and the difficulty in establishing best practice within the industry. I like your categories better than ours and plan to re-characterize our assessment based on your work. Your points on corporate policy, and "right supervisors" are well taken. Nothing leads to cultural change like the act of measurement. Thanks again for putting on a good show, and for taking the time to reply to my questions."

Training Program:

GCGI's Web Training Program is divided into six categories including a Human Error Program, Quality Events & Failure Investigations Certification Program and a Computer System Validation (CSV) Certification Program.

The following list shows course titles that will help you obtain the required knowledge, skills and expertise to meet the regulatory compliance demands. Customized courses could be developed by combining two or more titles from one or more categories.

CALL NOW at 1-787-283-1518 for customized training sessions suited to your team needs!

CATEGORY I:

HUMAN ERROR, QUALITY EVENTS & PROCESS/ BUSINESS EXCELLENCE

A. A GMP Approach to the Detection, Correction & Prevention of Human Errors.
B. ICH Q8, Q9 & Q10 as a Preventive Quality Tool in the Pharma Industry.
C. An FDA Regulatory Perspective to Training Effectiveness.
D. An FDA Regulatory Approach to Six Sigma for Business Excellence.
E. Documentation of Failure Investigations and Quality Events.
F. A Regulatory and Business Perspective to CAPA Effectiveness.
G. FDA Approach to Process Validation.
H. Investigating Out-Of_Specification (OOS) Test Results for Pharmaceutical Production.

CATEGORY II:

MEETING FDA & GMP REQUIREMENTS

A. Annual GMP Training for Medical Device and Pharma Industries.
B. Vendor Audits and Manufacturing Supplier Certification Program.
C. How to be prepared for an FDA Audit: Laboratory & Manufacturing.
D. Regulatory Aspects of Quality by Design (QbD) and Process Analytical Technology (PAT).
E. Good Documentation Practices for Engineering, Facilities and Utilities.
F. How to Prevent and/or Address FDA-483 and/or WL observations.
G. FDA Perspective to Batch Record Review.
H. An FDA Auditing Approach to Pre-Approval Inspections (7 modules).

CATEGORY III:

ANALYTICAL LABORATORY

A. How to Audit for GLP, 21 CFR Part 58 Compliance.
B. An FDA and ICH Approach to Analytical Method Validation.
C. CGMP Compliance and Auditing in the Quality Control Laboratory.
D. CGMP Quality Indicators in FDA Regulated Laboratory Systems.
E. USP/NF Methodology: Understanding the Reference.
F. CGMP Compliance in HPLC Systems.
G. Good Laboratory & Documentation Practices.
H. Laboratory Auditing Techniques Workshop.
I. Analyst Certification Program.
J.Data Integrity in Laboratory Operations.

CATEGORY IV:

EQUIPMENT QUALIFICATIONS

A. An FDA Regulatory Perspective to Laboratory & Manufacturing Equipment Validations.
B. DQ, IQ, OQ, PQ and PV in Laboratory & Manufacturing Areas.
C. ISO 17025 Approach to Instrument Qualification and Certification.
D. A cGMP and ISO Approach to Calibration.
E. Preventing FDA-483s in Laboratory and Manufacturing qualification data.
F. Auditing laboratory and manufacturing equipment companies.
G. Documenting failures during equipment calibration and qualifications

CATEGORY V:

COMPUTER SYSTEM VALIDATION (CSV)

A. Computer and Software System Validation for Manufacturing and Laboratory Systems.
B. A GAMP Approach to CSV.
C. Development of DQ: Validation Plan, URS, FRS, Vendor Audit and SDS.
D. Development of Functional Testing Requirements.
E. A cGMP Approach to CSV Vendor Audit.
F. Proper Documentation of CSV Quality Events and CAPAs.
G. Documenting Field Acceptance Testing (FAT) to meet FDA and cGMP requirements.

CATEGORY VI:

ELECTRONIC RECORDS; ELECTRONIC SIGNATURES (21 CFR Part 11)

A. A Software Approach to Part 11.
B. A Management Perspective to ER/ES.
C. Part 11 *"Scope and Application"* - FDA Requirements.
D. Vendor Audit Requirements under Part 11.
E. CSV Auditing Techniques within Part 11.
F. Application of Part 11 in Process Analytical Technology (PAT).
G. An FDA Approach to Inspection Readiness for Part 11.
H. An FDA Regulatory Perspective to Data Integrity and Part 11.

GCGI's WEB TRAINING PROGRAM™

Find Us on LinkedIn

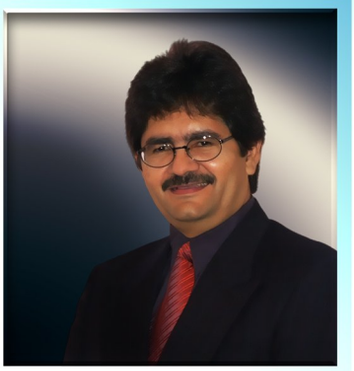
Meet the Instructor:

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 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 was later certified in Electronics Engineering in Minicomputers and Microprocessor Technology by the Capitol Radio Engineering Institute (CREI), Washington, D.C.

Mr. Guerra has over **36 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 & 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.

Mr. Guerra was the Chairperson of FDA's Automated Data Processing (ADP) Advisory Committee and the FDA Local Area Network (LAN) Committee. The outcome of such work is now reflected in FDA's nationwide automated frame of operation and the creation of LAN management centers.

In addition, Mr. Guerra has published several articles in Pharmaceutical Technology on Method Validation, Quality Assurance, GMPs in the Chemistry Laboratory, Laboratory Computer Validation, Instrument Design, Power Failure Detector and others, and 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). Throughout his 20 years of FDA career, Mr. Guerra has earned hundreds of awards including Cash Awards for instrument design, Cash Awards for computer systems auditing and development, Commendation Letters for speeches and training, seminar development, publications, project management, managerial abilities and the **FDA Commendable Service Award** for outstanding performance in the development of the automation process for FDA's nationwide field offices and San Juan District laboratory automation.



The **WEB Training Program** is offered directly by Johnny Guerra, a **FORMER FDA OFFICIAL** counting with 20 Years of Agency experience and additional 16 years of International Consulting, Auditing, Training and Validation experience. This former FDA official has refined training skills conducted on hundreds of courses and seminars during **36 years** of Industry, Agency and Consulting service by training more than 75,000 individuals worldwide since 1979. This reputation for excellence in training is worldwide renowned and that is why...

"GCGI is Your Trainer of Choice!"

As an International Consultant, Mr. Guerra has also excelled in World-Wide Consulting, Auditing and Training activities by providing the Pharmaceutical, Biotechnology, R&D and Medical Device industry with FDA-Related Regulatory Expertise in the design and implementation of Laboratory/Manufacturing Failure Investigations, Quality Events, Human Factor/Human Error Precursors and Data Integrity Programs. Such programs place emphasis on deviations related to Human Errors, Data Integrity, Consumer Complaints, Line Clearance, Mix- Ups, Mix-Labels and Short-Fill situations. He has also assisted management in responding to FDA-483s, Untitled/ Warning Letters and executed Part 11 (Electronic Records; Electronic Signatures) & Data Integrity Risk Assessment/GAP Analysis, Computer System Validation (CSV), Software Vendor Audits and Laboratory/CSV Certification Programs.

In the Validation area, Mr. Guerra has conducted Computer and Software Validation (including Data Integrity and Part 11) studies of Chromatography Data Acquisition Systems (Waters' Millennium32 and Empower) in several Pharmaceutical Companies.

Mr. Guerra is very active as an educator and has provided courses for the last **36 years** to FDA Investigators and Chemists, Service & Scientific Instrument and Calibration Companies and the Pharmaceutical, Biotechnology, R&D and Medical Device industry through the American Chemical Society (ACS), Pharmaceutical Manufacturing Association (PMA), Parenteral Drug Association (PDA), Institute for International Research (IIR), Pharmaceutical Training Institute (PTI), Institute of Validation Technology (IVT), Barnett International, International Quality and Productivity Center (IQPC), Lunden-Ellow a/b (Euro-GMPs), Puerto Rico Pharmaceutical Quality Assurance (PRPQA), Pharmaceutical Industry Association (PIA), Puerto Rico Chemists Association (PRCA), Puerto Rico Institute of Chemical Engineers, School of Pharmacy/University of Puerto Rico and other Scientific and Professional Organizations.

Presenting...

GCGI's WEB TRAINING PROGRAM™

and

GCGI's ON-SITE TRAINING PROGRAM™

CLICK HERE TO Request a Quote

CALL NOW at 787-283-1518 or e-mail us:
gcgi@guerraconsultinggroup.com
and request a quote for training courses.

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:

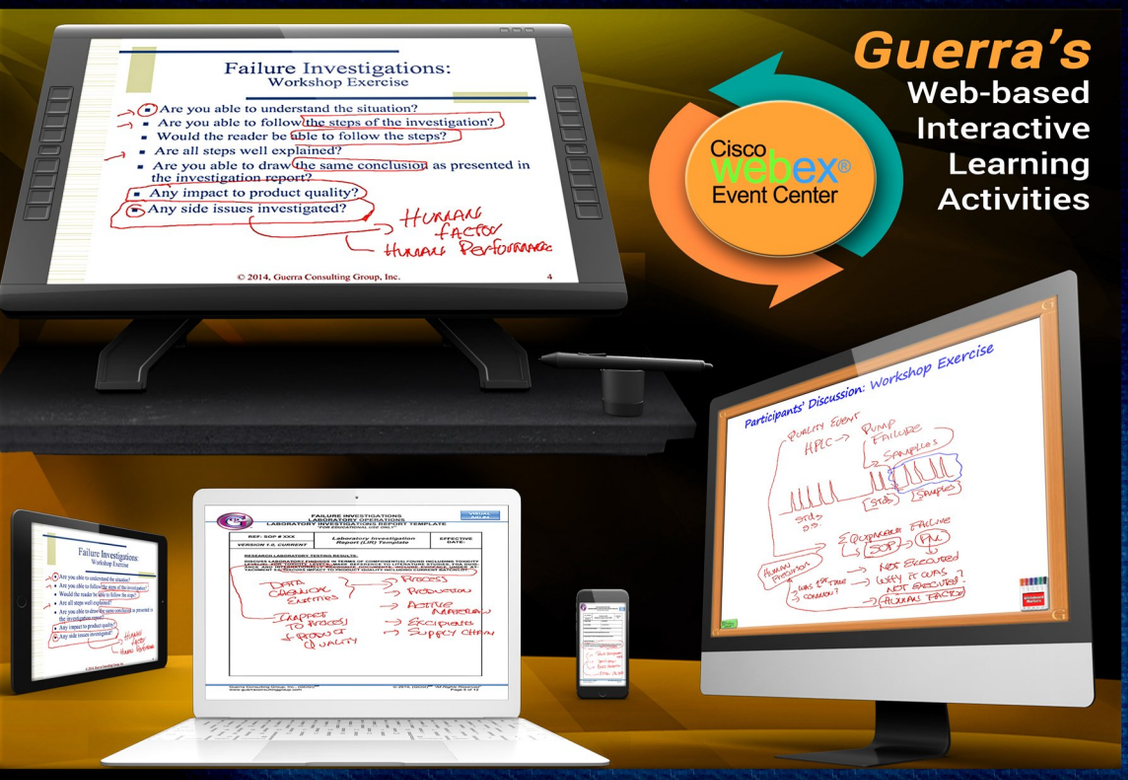
- ✓ The training session includes a PDF handout and Certificate of Participation.
- ✓ Optional course manuals available by request.
- ✓ Web-based and On-Site trainings are all-inclusive. Your company invests once for the corresponding group of individuals.
- ✓ Web presentations delivered in 1-3 hour sessions.

GCGI's WEB TRAINING PROGRAM™

Interactive Virtual Classroom Training;

...the way to learn!

Active employee participation is key to a successful virtual classroom training experience.



Guerra's training activities engage employees and prompt them to think about how the subject matter relates to their own work. Workshop exercises trigger participants' engagement throughout the duration of the virtual training. Typical problems are addressed and solutions furthermore provided.

For group settings, a ***"Test Run"*** is included prior to the training session. This activity ensures that audio/video connections are adequate and that there aren't any glitches that can hinder the overall success of the scheduled training session.

Ready to maximize your training efforts?

Online Quote Request

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