



**John Cuspilich, Sr. Auditor
The Auditing Group**

John is the CEO and Senior Auditor for The Auditing Group, Inc and GMP Boot Camps. In addition, John also serves as the Senior Editor at **GMP Publications, Inc.** and the CEO of **The Validation Group.**

John has conducted more than 1200 GxP audits, Gap Analysis and remediation projects world-wide, with over 35 years, hands-on technical and management level experience within the Food, Supplements, Pharmaceutical, Biotechnology, Medical Device, Cosmetics, Petrochemical, Electronic Systems, Validation, and regulated industries.

John has conducted hundreds of speaking engagements, seminars and bootcamp style training seminars world-wide.

Published, co-sponsored and conducted audit reviews of thousands of technical and professional papers, journals and books for hundreds of Companies in the regulated industry.

John has assisted hundreds of companies in meeting and exceeding regulatory compliance, pertaining to 'for-cause' or 'due-diligence' initiatives. Assisting companies to achieve, resolve, remediation and exceed regulated industry requirements, mandates, 'for-cause' and 'due-diligence' priorities with the technique of promoting GxP standards and practices through interactive hands-on training.

John has extensive knowledge in industry standards; FDA (CDER, CBER, CDRH, CVM, CFSAN), cGMP, GLP, ICH, OECD, GAMP, ISO, OECD, OSHA, HACCP, HIPPA, EPA and GCP regulations with thorough knowledge in implementation of these standards.

GMP / QMS WEBINAR TRAINING *'From the Auditor's Perspective'*

This intense 8-hour cGMP Boot Camp 101 focuses on;

- The cGMP Basics 101
- The Auditor's Basics
- The QMS Requirements
- Part 11 Electronic Records; Electronic Signatures

*Includes (*for paid Customers Only):

- - Course Materials
- - Certificate of Attendance (Completion)
- - Handbook (21 CFR Parts 11, 210/211, 820 & ICH Q7 APIs)

**Taught by Auditing SMEs with the focus on;
*'From the Auditor's Perspective'***

**Get your annual cGMP Training at home, at your
convenience. Sign up today to secure your seat!**

**Conducted Monthly – Check dates at
www.gmpbootcamps.com. Starts 10:00am EST – 6:30pm EST**

Course Agenda

GMP QMS 101 The Basics - The required GMP Training for all employees who work in regulated industry.

- GMP and the GMP Focus and the GMP Lifestyle?
- The History of GMP, the FDA Agency, Agency Inspections, Warning letters and 483s
- Warning Letter Reviews (Review of actual violations)
- The 11 General Orders / Principals of GMP
 - Writing Procedures (with template examples);
 - Following Procedures (and the failures that occur);
 - Documentation (Requirements, and the Regulations);
 - Validation (Concepts, and basic process requirements);
 - Design/Build Facilities and Equipment (In-depth look into a GMP facility requirement);
 - Maintain Facilities and Equipment (Maintenance, Calibration, Use and Cleaning of Facilities/Equipment);
 - Competency (The Training Requirements);
 - Sanitation and Good Housekeeping Practices (General requirements for all facilities);
 - Control for Quality (from Materials Receipt, Production, Packaging and Distribution);
 - Prepare for Battle! The Traceability Process;
- Quality Terminology



856-596-2333

info@gmpbootcamps.com

The QMS Basics

- CAPA - Everything you wanted to know about CAPA,
- Non-Conformance - From Materials Supply to Production to End of Use Complaints,
- Deviations - Deviation management is essential for every company,
- Change Control - Documentation, Engineering, Production and Distribution,
- Out of Specifications / Out of Trend - Correct Management of OOS and OOT for regulated industry,
- Complaints - Receipt, Qualifications, Risk Assessments and Remediation/Resolution,
- Product Traceability - The most under-rated requirement in the industry today,
- Recalls - The process, rationale for plan for success,
- Quality Review and Management Review - Processes for meeting the requirements for annual reviews,
- Vendors, Suppliers, Contractors and Consultants; The Qualification Process explained. The Quality Agreements,

Good Auditing Practice and QMS Prerequisites

- The Auditor/Auditee's Basics 101
- The 5 Basic Binders
 - The Quality Manual
 - IT Strategy Plan
 - Standard Operating Procedures
 - Validation Documentation
 - Drug/Device Documentation

21 CFR Part 11 Electronic Records

- 21 CFR Part 11 Basic Overview
- Definitions, System Types and Classifications
- 21 CFR Part 11 – Predicate Rule
 - Part 11.10 Sections a) - k)- - *Validation*
 - *Copies of records*
 - *Protection of records*
 - *Limiting system access*
 - *Audit trails*
 - *Operational system checks*
 - *Authority checks (h) Device checks*
 - *Education, Training, Experience*
 - *Policies and Procedures*
 - *Systems documentation*
 - Scope and Application Risk Analysis - Determine Which Systems Need to be Validated
 - The Part 11 Initiatives

Questions and Answers

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Additional Training Courses Available at GMP Boot Camps and The Auditing Group, Inc:

- 1 Day, 2 Day and 3 Day Master GMP Training – Medical Device with Correlation to ISO 13485 & ISO 14971
- 1 Day, 2 Day and 3 Day Master GMP Training – Pharmaceutical with ICH Q7 GMPs for APIs
- 1 Day – 2 Day GMP Training – Dietary Supplements
- 1 Day GMP Training – Cosmetics
- 1 Day GMP Training – Good Laboratory Practice (GLP)
- 1 Day and 2 Day Good Clinical Practice (GCP) Training
- 1 Day and 2 Day Compounding Facilities 503b
- 1 Day – DEA GMP Training
- 1 Day – Good Engineering Practice Training – Design/Build Requirements for Drug Manufacturing
- 1 Day Good Validation Practice – Process
- 1 Day and 2 Day – Good Validation Practice – Software and Systems – 21 CFR Part 11
- 1 Day and 2 Day – Good Validation Practice – Equipment (Process and Utilities)

**1, 2 and 3-Day Pre-Training Audits
Available to support Training Sessions!**

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