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

*FREE 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 and The Agency's Inspections
- The QMS Components and General Requirements
- Part 11 Electronic Records; Electronic Signatures

The Webinar is FREE, however, there is a $29.95 Registration Fee* Includes:
- - Course Materials – 300+ Slide e-Workbook
- - Certificate of Attendance (Completion)**
* The Webinar is Free; however, the cost is for the e-Workbook and Certificate, and to eliminate 'No-Show' attendees.
** Must complete course by Analytics.

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 Predicate Rules
- The FDA Agency, Inspections, Warning letters and 483s
- Quality Terminology

The QMS Basics

- CAPA - The basics about Corrective and Preventive Actions;
- Non-Conformance - Materials Supply, to End of Use Complaints;
- Change Control - Documentation, Engineering, Production and Distribution;
- Deviations - Deviation management essentials;
- Out of Specifications / Out of Trend - Management of OOS and OOT;
- Complaints - Receipt, Qualifications, Risk Assessments and Remediation/Resolution;
- Recalls - The process, and indications of failures;
- Product Traceability;

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- Audit - Internal, Agency, Customers and External Audit;
- Vendors, Suppliers and Contractors - Quality Agreements;
- The Meetings - Management and Quality Meetings;

- The 11 General Orders / Principals of GMP

1. Writing Procedures (with template examples);
2. Following Procedures (and the failures that occur);
3. Documentation (Requirements, and the Regulations);
4. Validation (Concepts, and basic process requirements);
5. Design/Build Facilities and Equipment (In-depth look into a GMP facility requirement);
6. Maintain Facilities and Equipment (Maintenance, Calibration, Use and Cleaning of Facilities/Equipment);
7. Competency (The Training Requirements);
8. Sanitation and Good Housekeeping Practices (General requirements for all facilities);
9. Control for Quality (from Materials Receipt, Production, Packaging and Distribution);
10. Audit Requirements
11. Prepare for Battle! The Traceability Process;

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)
    - *a) Validation*
    - *b) Copies of records*
    - *c) Protection of records*
    - *d) Limiting system access*
    - *e) Audit trails*
    - *f) Operational system checks*
    - *g) Authority checks*
    - *h) Device checks*
    - *i) Education, Training, Experience*
    - *j) Policies and Procedures*
    - *k) Systems documentation*
  - Microsoft Excel

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 ISO Correlations ISO 13485 and 14971

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- 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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