www.johncuspilich.com

John Cuspilich,
Sr. Auditor & CEO for:
The Auditing Group & GMP Publications
www.gmppublications.com

- - The Auditing Group; auditing.com
- - GMP Boot Camps; gmpbootcamps.com
- - CAPA Management; capamanager.com
- - The Validation Group; validations.com

With over 35 years in the regulated industry, John has conducted and lead the teams for more than 2400 GxP Audits, Gap Analysis and remediation projects world-wide, educated with real-world, hands-on technical and management level experience within the Drug, Medical Device, Clinical, Dietary Supplements, Biotechnology, Cosmetics, Bulk chemical, Electronic Systems and Part 11, Validation, and regulated industries.

As a speaker, 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 and guided companies in meeting and exceeding regulatory compliance, supporting 'for-cause' or 'due-diligence' initiatives. Assist companies to achieve, resolve, remediate 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 and guidance.

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

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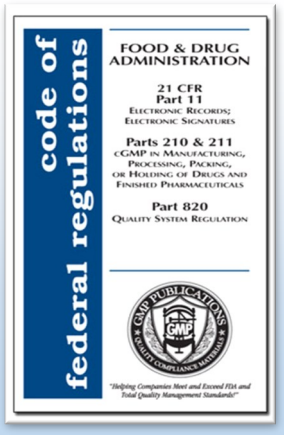

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Course Agenda

GMP QMS 101 The Basics - The required GMP Training for all employees.

- GMP and the GMP Focus and the GMP Lifestyle
- The Predicate Rules
- The FDA Agency, Inspections, Warning letters and 483s

Quality Terminology

The QMS

- The Quality Management System (QMS) Basics
- CAPA - The basics about Corrective and Preventive Actions;
- Non-Conformance - Materials Supply, Specifications and Quality;
- 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, Risks and Remediation/Resolution;
- Recalls - The process, and indications of failures;
- Product Traceability;
- 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 Compliance

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 at GMP facility requirement);
6. Maintain Facilities and Equipment (Maintenance, Calibration, Use and Cleaning of Facilities/Equipment);
7. Competency (The Training Requirements);
8. Sanitation and Housekeeping Practices (General requirements for all facilities);
9. Control for Quality (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)
- ALCOA++ - Data Integrity
- Microsoft Excel

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- 1 Day – 2 Day GMP Training – Dietary Supplements
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- 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)

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