John Cuspilich, Sr. Auditor
The Auditing Group

John is the CEO and Senior Auditor for The Auditing Group, Inc. 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
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Course Agenda

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

- What is cGMP and the GMP Lifestyle?
- The Agency History and Objectives
- Roles and Responsibilities
- The 10 Principals of GMP
  - Writing Procedures
  - Following Procedures
  - Good Documentation Practices (GDocP)
  - Validation and Verification
  - Facilities Design/Layout
  - Facilities Equipment, Maintenance and Metrology
  - Training Programs and CV Management
  - Sanitation and Cleanliness
  - Control for Quality, Materials and Process Control
  - Audit for Compliance
- The History of GMP, the Agency Inspections and 483s
- 483s and Warning Letter Reviews

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21 CFR Part 11 Electronic Records

- 21 CFR Part 11 Basic Overview
  • Definitions, System Types and Classifications
  • 21 CFR Part 11 Electronic Records; Electronic Signatures – 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
  • Steering Committee and Part 11 Initiatives

Good Auditing Practice and QMS Prerequisites

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

The QMS Basics

- Corrective and Preventive Actions (CAPA)
- Non-Conformance (Materials, Process and Products)
- Change Control – Facilities, Process and Documents
- Deviations – Documents, Process and Procedures
- Out of Specifications / Out of Trend – Process, Analytical and Materials
- Complaint Management
- Product Traceability and Recalls
- Audit - Internal, Agency, Customers, External Audit
- Quality Review – Management Review
- Vendors, Suppliers, Contractors and Consultants