John F. Cuspilich

Sr. Compliance Auditor & Remediation Consultant

Introduction: (*Standard Excerpt***)**
"... More than 1000 GxP audits, and remediation projects with over 30 years, hands-on technical and management level audit and remediation experience within the Pharmaceutical, Biotechnology, Medical Device, Petrochemical, Validation, and regulated industries worldwide.

Serving within various business units within Quality Assurance / Regulatory Affairs, Training and Development, Manufacturing, Research, Engineering, Technical Mechanical Departments, etc.., John has assisted many companies in meeting and exceeding regulatory compliance, pertaining to 'for-cause' or 'due-diligence' initiatives. Assisting 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.

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 and thorough knowledge in the process of implementation of these standards. John also enjoys speaking and engaging with and at many of the Industry professional associations, seminars, and trade shows worldwide, conducted both on-site and off-site training seminars, and speaking engagements."

GMP Audits - Process, Equipment, Facilities, Systems & Software, and Validation:
John has conducted over 1000 on-site and desk GMP Audits and Remediation consulting projects in support of, but not limited to:
- *Good Manufacturing Practice requirements supporting Bio-Pharmaceutical Industry.*
- *Good Laboratory Practice requirements supporting laboratory and testing services.*
- *Good Clinical Practice requirements supporting clinical activities.*
- *'For-Cause' and 'Due-Diligence' audits*
- *Quality Management Systems Audits - Medical Device Industry (FDA / EMeA / ISO)*
- *Electronic Systems and Software Audits (21 CFR Part 11 / EU Annex 11)*
- *Validation and Qualification Audits*

Assists firms to meet compliance requirements by implementation of standards through;
- *Audit existing systems, software and attendant documentation*
- *Development of Remediation and Resolution Plans*
- *Development of Validation Protocols for Software and Systems*
- *Development of validation, programming and quality audit procedures and standards*

Process, Equipment, Facilities, Systems & Software Qualification, Validation Expertise:

30 years of extensive Process, Equipment, Systems, Device, Computer systems, and Software Validation and GXP Audit experience.
Work experience includes Project Management, field validation and qualification of equipment, process and software/systems for companies world-wide in support of Good Validation Practice Standards, and Compliance requirements. And as a member of the GXP Conference organization, John also conducts numerous conferences and seminars on Quality Systems Management, Computer Systems Validation and 21 CFR Part 11 Compliance requirements

Areas of Expertise:

- **Compliance Auditor / Instructor – Regulated Industry Compliance Audits**
  - Vendor, Supplier, Contractor, Consultant, GXP Audits. Systems in support of GXP Activities,
  - **Corporate Acquisitions, Risk Assessments and Gap Analysis**
  - Drug, Medical Device, Combination Products, Blood and Tissue, Laboratory and Biologics, Controlled Substance, Food and Dietary Supplements, Nutraceuticals, and Regulatory
  - Title 21 Code of Federal Regulations Auditing and Remediation Services
    - Parts 11 Electronic Records, Electronic Signatures; EMeA Annex 11;
    - Parts 58 Good Laboratory Practice; OECD General Principles
    - Parts 110 and 111 Food and Dietary Supplement GMPs
    - Parts 210/211 Drug GMPs/API Manufacturing
    - Part 820 Quality Systems Regulations – Medical Device
    - **Cosmetic GMP Audits – 21 CFR Part 700 and 701**
  - 'Due-Diligence', 'For-Cause' & 483 Site Audits and Follow-up Remediation Services
  - **Mock FDA, WHO, EMeA Audits and Pre-Audit Inspection Preparations**
  - GMP – PAI – GLP – GCP – ISO – ICH – OECD – Ethical – OTC – Manufacturing – R&D
  - GCP Pharmacovigilance auditing in accordance with 9a EU ICH requirements
  - Computer Systems, 21 CFR Part 11 ERES, IT, MIS Services, EDC, Clinical Systems and Data Capture (ASPs, ISPs and internal management systems, Site Remediation, 'For-Cause', (E2B), ISO 13485/14971, IEEE Standards. EU Annex 11 – 15.
  - Quality Management Systems / Quality Assurance, Part 820 QSR, QSIT, ISO 13485, ISO 14971, ISO 14644 Clean Rooms.
  - GMP Good Manufacturing Practice Audits (21 CFR Part 210/211, ICH Q7A) CAPA Management Programs and Methodology.
  - GLP Good Laboratory Practice Audits, 21 CFR Part 58, CLIA, OECD, Engineering, Facility & Validation, ISO 17025, Canadian 1510e Standard.
  - GCP Good Clinical Practice Audits (Clinical Process & Systems in accordance with 21 CFR Parts 50, 54, 56, 312, & 314, & 511) Investigator, Site Monitoring, Pharmacovigilance, IND, AND, ANDA, BLA, PMA & 510k. ICH E6 – ICH Audits (E2A/B). Good Data Management Practice. Database auditing and programming standard audits.
  - CE Mark Preparation Audits support of WHO / EMeA Audits
- **Remediation Consultant – Audit remediation and project management**
  - CAPA Management – Remediation Project Management
  - Site Compliance Remediation and Readiness Initiatives
  - Post Audit Remediation – Resolutions – Deviations
  - FDA EIR 483 Remediation
- Computer System Validation, Engineering, Development & Protocol Execution Audits
- 21 CFR Part 11 Site(s) Remediation Initiative Project Management. Global Standardization
- Project Engineering – Pharmaceutical Facilities, Manufacturing / R&D
- Facility Project, Maintenance, Engineering & Quality Management & Procedural Development
- On-Site Training and Development – Customized training packages and presentations:
  - 21 CFR Parts 210/211 Drug GMPs - Pharmaceuticals – Finished and APIs
  - 21 CFR Parts 11 – Electronic Records; Electronic Signatures
  - 21 CFR Parts 820 – Quality Systems Regulations
  - 21 CFR Part 58 – Good Laboratory Practice – Toxicology & Non-Toxicology
  - Software / Systems Development Compliance Requirements under 21 CFR Part 11
  - Engineering and Validation Services
  - Food and Dietary Supplement GMPs
  - Laboratories (GLP Compliance under 21 CFR Part 58 – 42 CFR Part 493)
  - Manufacturing (Pilot and Full Scale)
  - Validation and Qualification – GAMP
  - Packaging and Warehousing

1998 to Present:

- **The Auditing Group and FDA.COM)**
- **GMP Publications (GMP Publications**
- **GxP Conferences**
- **GxPNews**
- **FDA.COM**

Work History:

- The Auditing Group, Inc. & Validations.com – October 2001 to Present
- FDA.COM – May 2001 - Present – Site Moderator (Division of GMP Publications, Inc.)
- GXP Conferences - January 2011 - Present
- GMP Publications, Inc. – May 1999 to Present (Parent Company)
- GXPNews e-Newsletters – January 2003 - Senior Editor

The Auditing Group, Inc. & Validations.com – Compliance Auditor and Remediation Consultant:

- GMP, GLP, ICH, ISO, WHO & GCP Auditing and Remediation Consulting (800+ compliance audits)
  3rd Party Contract Forensics Compliance Officer – FDA CDER, CBER and CDRH Divisions.
  - Manufacturing, Research & Development, Clinical, Medical Device, Laboratories
  - Vendors & Suppliers, Consultants & Contract Manufacturer Audits
  - Audits for Bio-Pharma OTC, Ethical, Nutraceuticals, Chemical, Bulk API
- GMP Compliance Auditor – US FDA, EU EMA, SFDA, TGA, and WHO Audits
  - Manufacturing, API, CMO, Warehouse and Distribution Audits
  - Laboratories in support of GMP and / or GCP Activities
- Validation (Process, Facility & Equipment) Auditing Services
  - Process Equipment, Manufacturing, Utilities, Engineering
  - EDC, MRP, MMCS, LIMS, SCADA, PLC, DCS, Custom and COTS applications
- Auditing and development of validation master plans for Computer Systems and Software including but not limited to:
  - SDLC, VMP, VPD development, user requirements and functional requirements
  - Design qualifications, including schemas, flow diagrams and data modeling
  - Installation qualifications, gap analysis, and component inventories
  - Operational qualifications, test script development, training and executions
  - Performance qualifications
- 21 CFR Part 11 Auditing, Remediation & Computer Systems Validation
- Auditor - Process, Manufacturing, and Analytical Equipment, LIMs, EDC, Clinical Data Management, SAE, AER, PLC, SCADA, etc.
- Engineering (Design / Build Facility Audits), Software Programming and Code Management Audits, Maintenance and Technical Compliance Audits
- 'For-Cause' and Due-Diligence Audits
- Vendor and Supplier Qualification Audits
- FDA Assisted Audits, Pre-FDA Inspection Audits and Clinical Trial Audits
- Employee / Investigator Audits and Investigations (CV Audits)
- Conduct GMP, QSR, Part 11 Electronic Systems, GLP and GCP Training Seminars

GMP Publications, Inc. – CEO - Senior Editor, Director Quality Assurance – Technical Writing

- Technical development of the Code of Federal Regulations publications for The Government Printing Office, Washington, DC.
- Quality Assurance Duties – Change Control, SOP development, Content Validation, Custom publication development
- Support the Government Printing Office (GPO). Conduct annual review, proofing of new regulations pertaining to 21 Code of Federal Regulations. Conduct Quality Assurance assistance in ensuring that new regulations are free of text defects, and that content meets conformity and clarity. Title 21 Code of Federal Regulations Parts 1 - End.
- In charge of the distribution of over 5mm+ copies of the Code of Federal Regulations / ICH Mini-Regulation handbooks to over 8,100 companies worldwide.

GXP Conferences, Inc. – Senior Instructor

- Conducted over 120 instructional webinars
- Training and Development – Customized training packages and presentations:
  - 21 CFR Parts 210/211 Drug GMPs - The Basics 101 / The Basics 102
  - 21 CFR Parts 11 – Electronic Records; Electronic Signatures
  - 21 CFR Parts 820 – Quality Systems Regulations
  - 21 CFR Part 58 – Good Laboratory Practice – Toxicology & Non-Toxicology
  - Pharmaceuticals – Finished and APIs
  - Software and Systems Development Compliance Requirements under 21 CFR Part 11
  - Validation and Qualification - The Basics 101
  - Validation and Qualification - The Basics 102

1999 to February 2003: SCIREX Clinical Research Organization (CRO)

Title: Senior Instructor, Auditor, Associate Director Quality Assurance / Regulatory Affairs – GMP, GLP, Part 11 Electronic Records; Electronic Signatures, 820 Quality Systems Regulations and Clinical Training
Duties: Global 21 CFR Part 11 Initiative Developments and Remediation. Developed, Implemented and Directed the SCIREX Global 21 CFR Part 11 Remediation Initiative for 9 US sites and 7 EU sites on a global scale. Included but not limited to:

- Develop, Implement, Manage and Conducted SCIREX Internal, Sponsor, Supplier and Vendor audits pertaining to IT, Validation, GMP, GLP, ICH, 21 CFR Part 11 and Facility Compliance. Conducted internal personnel, Sponsors, and Vendor training in Good Auditing Practices, 21 CFR Part 11, Good Validation Practice and Techniques, Quality Systems Regulations (Part 820), Good Programming Standards and Practices, etc…
- Senior Auditing Responsibilities – Development Audit Standards for;
  - Auditing Sponsors
  - Auditing Sponsor's Vendors and Suppliers
  - FDA Assisted Audits, Do-Diligence, For-Cause, and Clinical Trial Approval Audits
  - Acting as 3rd. party auditors for Sponsor Contracts
  - Acting as 3rd. party auditors for FDA Assisted Audits
- Development, training and execution of the Corporate Validation Standards and Policies
- Development, training and management of the Corporate Validation Steering Committee
- Implementation of the Corporate Computer Systems Validation Guidelines for multiple sites
- Developed the Steering Committee 21 CFR Part 11 Charter, Validation Master and Project Plans
- Coordinated the Validation efforts utilizing in-house technicians and Contractors
- Developed the Global Computer Systems and Application Inventories
- Published SOPs outlining Validation activities, SDLC process and individual tasks
- Based on the verified inventory, implemented the Gap Analysis process which determined the components of the inventory items and requirements.
- Based on the verified inventory, implemented the risk analysis and assessment process, which determined the level of validation, qualification or verification required.
- Developed the project timelines (based on risk assessments and needs), using various validated or qualified tools such as MS Project Gantts, databases and 3rd. party software, i.e. Trackwise, Software Magic, Track-it and others.
- Developed individual Software Systems and Application validation protocols (see http://www.validations.com for additional validation effort details)
- Implemented IT, development and service support SOPs
- Developed Maintenance, IT Support and Systems or Application retirement plans
- GMP, GLP, ICH & GCP Auditing

1994 – 1999 Sentry Technologies, Inc.

Title: CEO Senior Auditor / Developer / Senior Consultant (GMP – GCP – GLP – Systems) –

- Sentry 2000 Pharmaceutical Compliance Software System
- Sentry 2000 Calibration Management System
- Sentry 2000 Work Order Management System
- OEM 2000 Equipment Management Software for Vendors and Suppliers
- Bio-Pharm 2000 Software for Inventory Management - CMOs

Management of over 600 installations world-wide.
Technical Services Auditor / Engineer – Asset Auditor, Validation, Engineering, Application & Development Contract Engineering Services – Development, Systems Implementation and Validation Projects. Technical services and support consultant - **Merck**, **Novartis**, **SKB**, **Bayer**, **Sterling Pharmaceuticals**, GMP Institute, Johnson & Johnson, McNeil Consumer, The Validation Group, Judge, Integrated Project Services, etc…

- Development, implement and validation of Maintenance, Material Management, SCADA, DCS, PLC, Compliance and Engineering software applications and systems
    - Validation Master Plan Development
    - Project Plan Development - User requirements - Functional requirements
    - Design qualifications (DQ)
    - Installation qualifications (IQ)
    - Operational qualifications (OQ)
    - Performance qualifications (PQ)
- Auditing Services for Asset and Compliance Management
- Development and Validation of Inventory Systems for Asset Control Systems
- Engineering, Design/Build, Maintenance and Technical CAD Services
- Turn-key Process, Equipment and Software Validation Services
- Laboratory Design / Build Project Management
- Laboratory Equipment Validation:
    - HVAC, Fume Hoods, Bio-Cabinets, Glove boxes, Class 100 – 100k, etc..
    - Process, Manufacturing and Laboratory Equipment
    - HPLCs, GCs, AA, Spectrophotometers, etc.
    - Software – System Gold, Pinnacle Millennium, Agilent/HPChemStation, etc...
    - Gases, Mobile Phase Pumping, AutoSamplers/AutoEnjectors,
    - Detectors, FTIR, UV Vis, Diode Array, Gas Flame, Mass Spec, NMR, etc.
    - Asset Inventories and Gap Analysis

1989 – 1995: Sterling Pharmaceuticals - Bayer Pharmaceuticals – Integrated Project Services (IPS)

Title: Manager of Engineering, Auditing and Technical Services contracted to Sterling Pharmaceuticals
Duties: Direct, Audit, Maintained and Design/build responsibilities for Sterling Pharmaceuticals NJ R&D, & PA Manufacturing Facility. Managed in-house and contract technical staff. Developed SOPs, Validation Protocols and Project Plans. Maintained Process, Utilities and Facility Equipment. Development of Equipment specifications, Purchasing, and Validation of all Facility, Utility & Process Equipment and Systems:

- Computer Systems, SCADA, DCS and PLC, validation protocols including VMP, IQ, and OQ
- Network and Desktop Validation Protocols including VMP, IQ, and OQ
- Analytical Equipment, Spectrophotometers, Samplers/Injectors, Pumps, Assay Equipment, etc.
- Fluid Bed, Tray and Static Dryers, Mixers, Blenders & Sifters/Screeners
- Steam Systems, Process & Utility, Water Systems, Process & Utility Washers, Sterilizers, Autoclaves
- Electrical Systems and Power Generating Equipment
- Tablet Manufacturing Equipment – Presses, Coaters, Sorters, Counters, Fillers & Gel Equipment
- Environmental Equipment – HVAC, Environmental Chambers, Stability Chambers and Freezers
- Packaging Equipment, Lab Equipment, Manufacturing Equipment
- Development of Corporate Validation Standards for Process, Packaging, and Facility Equipment, Systems and Applications.
- Clean-in-Place, Sterilize-In-Place, and Clean Room Process Cleaning validation.
- Developed Corporate standards (Eastman Kodak, Sanofi and Sterling Pharmaceuticals) for OSHA 1910.143, EPA Response, HAZMAT First Responder, Inventory Controls, and Engineering

1985 – 1989: Purolite

Title: Maintenance and Engineering Director / Manager US
Technical Consultant – UK
Duties: Chief Engineer – **Senior ISO Auditor** - Construction and Maintenance.
Development of ISO preparation documentation, services and procedures.
Development of Quality Assurance initiatives in support of ISO Certifications.

- Managed 18+ Technical Service Personnel, 3 Engineers and 200+ Trades.
- Design / Build & CAD Engineering
- Pipefitting, Millwright, Welding, Electrical/Electronics, Steam and Water Systems, PLC, DCS, SCADA

Education

- Illinois State University Great lakes Institute of Technology – BS Propulsion Engineering 1978 - 1980
- US Navy Propulsion Engineering. Damage control, Firefighting and HAZMAT training. 1978 – 1980
- Drexel University, PA. – Architectural Design - 1985 - 1986
- Burlington County College - Mechanical Engineering – Computer Sciences – AutoCAD release 11/2000 (Non-degreed)
- Burlington County College – Computer Sciences - Computer Programming/Visual Basic programming (Non-degreed)
- US Navy – A Schools
    - Engine Mechanic
    - Welder
    - Hull Technician
    - Boiler Technician
- ISO Registrar Training, Purolite, PA - Woodward Clyde
- Good Manufacturing Practice – Full training package (North East Branch Rep for GMP Institute)
- DIA Good Clinical Practices – GCP
- PDA Auditor – Tri-Auditors
- ASQ – Certified Quality Auditing Course 1998 – 1999 Temple University
- ASQ – Certified Quality Engineering Course 1998 – 1999 Temple University
- Training seminars, GMPs, Part 11, Clinical, Auditing, GLPs, ISO, etc…
- Pipefitters Apprenticeship Program apprenticeship training program. IAM Local 9
- Star Technical Institute Electronics and Robotics – 18 month program.
- Lyons Technical Institute AC&R – 10 month program
- Stationary Engineering NJ Blue Seal, PA Engineers 'A' Licenses
- Welder Training and Testing Institute (WTTI) – 10 month program
- Woodward Clyde Environmental EPA 165 40 hour EPA certified HAZMAT First Responder Course
- Borland Team B Specialist Training

Licenses, Certificates, Publications and Achievements

- Managing Editor – GXPNews
- Managing Editor and Quality Assurance for Government Printing Office – GMP Publications.
    - Proof reading of new regulations pertaining to 21 Code of Federal Regulations
    - Supporting the GPO in corrections and updating of the Code of Federal Regulations pertaining to 21 Code of Federal Regulations
- Authored - Published:
    - Computer Systems Validation Guideline for Industry, published 8/2000
    - The Auditor's Master Handbook 2005 GMP Publications
    - 21 CFR Part 11 Auditor's Check List 2005 GMP Publications
    - 21 CFR Part 210/211 GMP Auditor's Check List 2007 GMP Publications
    - 21 CFR Part 820 / ISO 13485 Quality Systems Auditor's Check List GMP Publications
    - Active Pharmaceutical Ingredients (ICH Q7) Auditor's Check List 2012 GMP Publications
    - 21 CFR Part 111 Companion's Guide, GMP Publications
- Authored the SENTRY 2000 cGMP Facility Management Software
- Web site author of GMP Publications, Inc. http://www.gmppublications.com
- Web site author The Auditing Group, Inc. & Validations.com
- Web site author CAPA Manager (capamanager.com)
- Web site author of FDA.COM and Managing Editor / Discussions Coordinator http://www.fda.com
- Authored the OEM Management System for Windows
- GMP Training – GLP Training
- GMP Train the Trainer – GMP Institute
- GERM, Tri-Auditor Course, LIMS Management
- Conducted numerous training seminars and conferences on GMPs, Mutual Global Harmonization and 21 CFR Part 11 Implementation and Site Remediation
- Member of the GPO Review Board
- ISPE Active Member and Management of the ISPE Delaware Valley Chapter Web site 1998-2000
- DIA Active Member
    - GERM Course Instructor 2005

- PDA Active Member
  - Tri-Auditor's Course 2004/2005/2006
- ASQ Active Member
  - ASQ CQE – Course – Temple University 1998 – 1999
  - ASQ CQA Course – Temple University 1998 – 1999
- RAPs Active Member
- AASP Active Member
- Borland Developers Licensing partnership group – Team B Specialist
- Microsoft Level 2 and Sun Developers Group
- cGMP, FDA and OSHA compliance audit seminars (GMP Institute)
- Written and conducted in-house fire, OSHA safety training and HAZMAT clean-up response training procedures
- NJ EPA Certified 165.15 & 29 CFR 1910.120 Hazardous Waste Operations and Emergency Response
- Written and conducted Confined Space Entry and Safety Tag & Lock out seminars, procedures and SOPs
- Wrote the Eastman Kodak/Sterling Winthrop Safety Lockout Corporate Manual
- Certified Yale fork truck training instructor
- Red Cross First aid training
- NJ State Blue Seal Engineering and Pa. Engineering A license
- NJ State Blue Seal and Pa. Engineering 'A' Steam Boiler operations instructor.

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