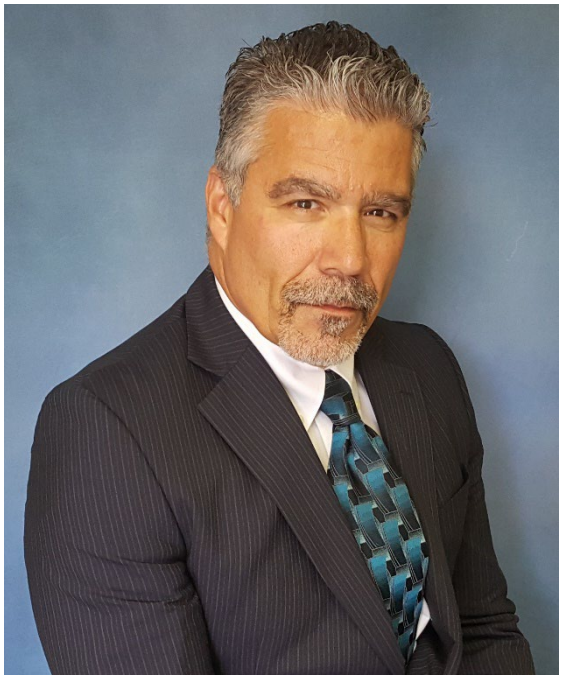
# John F. Cuspilich

## Sr. Compliance Auditor, Instructor & Remediation Consultant



**Introduction: (***Standard Excerpt***)**
*"... More than 2400 GxP audits, training and remediation projects with over 35 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, Clinical and Drug Development, 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 (DEA), CBER, CDRH, CVM, CFSAN), cGMP, GLP, ICH, OECD, GAMP, ISO, SFDA (China), OECD, OSHA, HACCP, HIPPA, EPA and GCP regulations and thorough knowledge in the process of implementation of these standards. 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/GLP/GCP Auditing and Training – Quality Management Systems, GMP Process, Equipment, Facilities, Systems, Software, & Validation:***

- ***Good Manufacturing Practice requirements supporting Bio-Pharmaceutical – API / Excipients***
- **Medical Device SME – QMS Remediation SME**
- *GMPs for the Cosmetic Industry.*
- *Good Laboratory Practice requirements supporting laboratory and testing services. Including GCLP.*
- *Good Clinical Practice requirements supporting clinical activities. Supporting GCLP.*
- *'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;*
- *Auditing of 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:***
*35 years of extensive Process, Equipment, Systems, Device, Computer systems, and Software Validation and GXP Audit experience for the Regulated Industry. 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 / Boot Camp Instructor – Regulated Industry Compliance Audits**
  - **QMS – cGMP SME** – Pharmaceutical, Medical Device, Cosmetics and Dietary Supplements;
  - Vendor, Supplier, Contractor, Consultant, GXP Audits. Systems in support of GXP Activities,
  - Corporate Acquisitions, Risk Assessments and Gap Analysis
  - Pharmaceutical Drug, Medical Device, Clinical, Combination Products, Blood and Tissue, Laboratory and Biologics, Controlled Substance, Cosmetics, Food and Dietary Supplements
  - 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
    - Clinical Parts 312, 314, 320 and CTM Operations.
    - 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, PAI, WHO, EMeA Audits and Pre-Audit Inspection Preparations**
  - GMP – PAI – GLP – GCP – ISO – ICH – OECD – Ethical – OTC – Manufacturing – R&D
  - 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 US/EU requirements, Investigator, Site Monitoring, Pharmacovigilance, IND, AND, ANDA, BLA, PMA & 510k. ICH E6 – ICH Audits (E2A/B). Good Data Management Practice and database audits.
- **Gap Analysis and Remediation Consultant – Audit remediation and project management**
  - Project Management – Gantt Management –
  - Quality Management Systems Implementation
  - CAPA Management – Remediation Project Management
  - Site Compliance Remediation and Readiness Initiatives
  - Post Audit Remediation – Resolutions – Deviations
  - FDA warnings 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 and Off-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 and Quality Management Systems (QMS)
  - Software / Systems Development Compliance Requirements under 21 CFR Part 11
  - Engineering and Validation Services, Validation and Qualification – GAMP
  - Food, Cosmetics and Dietary Supplement GMPs
  - Laboratories (GLP Compliance under 21 CFR Part 58 – 42 CFR Part 493)
  - Manufacturing (Pilot and Full Scale) Packaging and Warehousing

**1998 to Present:**

- **The Auditing Group and GXP Services**
- **GMP Publications (GMP Publications**
- **GMP Boot Camps and GxP Conferences**
- **GxPNews and FDA.COM**

**Current Work History:**

- **The Auditing Group, Inc. and GXP Services – 2001 to Present**
- GMP Boot Camps and GXP Conferences - January 2011 - Present
- GMP Publications, Inc. – May 1999 to Present (Parent Company)
- GXPNews e-Newsletters – and FDA.COM 2003 – Present – Senior Editor

**The Auditing Group, Inc. & GXP Services – Compliance Auditor and Remediation Consultant:**

- GMP, GLP, GCP, QMS, ICH, ISO, & WHO Audit and Remediation Consulting (1200+ compliance audits, training and remediation projects) Supporting Drug, Biologics, Medical Device and Combination Devices. Pharmaceuticals for Commercialization, Feasibility and Clinical Trials. 3rd Party Contract Forensics Compliance Officer – Supporting 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, Radiopharmaceuticals, Nutraceuticals, Bulk API
    - Supporting – US FDA, EU EMA, SFDA (NMPA), TGA, and WHO Audits
    - Manufacturing, API, CMO, CPO, CAO, Warehouse and Distribution Audits
    - Laboratories in support of GMP and / or GCP Activities
- Validation Audits and Gap Analysis (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 / Annex 11 Electronic Systems Auditing, Remediation and Computer Systems Validation
- Quality Management Systems (QMS) Audit, Gap Analysis, and Remediation – Supporting US and ISO Requirements
- Process, Manufacturing, and Analytical Equipment, LIMs, EDC, Clinical Data Management, SAE, AER, PLC, SCADA, etc.
- Engineering (Design / Build Facility Audits), Maintenance and Technical Compliance Audits
- 'For-Cause' and Due-Diligence Audits
- Vendor and Supplier Qualification Audits
- FDA Assisted Audits, PAI, Pre-FDA Inspection Audits and Clinical Trial Audits
- Employee HR / Investigator Audits and Investigations (CV Audits)

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

- Technical review and 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.

**GMP Boot Camp Training and GXP Conferences, Inc. – Senior Instructor**

- Conducted over 420 instructional webinars
- Conduct hundreds of on-site GMP, QMS, QSR, ISO, 21 CFR Part 11 Electronic Systems, GLP and GCP Training Seminars
- Training and Development – Customized training packages and presentations:
    - 21 CFR Parts 210/211 Drug GMPs - The Basics 101 / The Basics 102, Pharmaceuticals – Finished and APIs – ICH Q7 GMPs for Active Pharmaceutical Ingredients
    - 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 - OECD GLP, GCLP and Laboratory Controls supporting manufacturing processes.
    - Cosmetic GMPs
    - Dietary Supplements under 21 CFR Part 111 and Predicate Rules
    - Software and Systems Development Compliance Requirements under 21 CFR Part 11
    - Validation and Qualification - The Basics 101
    - Validation and Qualification - The Basics 102
    - Risk Management
    - Combination Devices
    - Quality Management Systems Gap Analysis Auditing Training
    - ISO 9001 – Quality Management Systems and Quality Process
    - ISO 13485 Quality Management
    - ISO 14971 Risk Management
    - EU GMPs 1-9 – EU GMPs Annex 1-20
    - Chinese Decrees 79 (and 64), US GMPs 21 CFR Parts 210/211 and EU GMPs Chapters 1-9
- Hosted hundreds of Domestic GMP Conferences
    - Pharmaceutical cGMPs (US, EU and ICH Q7)
    - Medical Device GMPs and the QMS (US and ISO 13485)
    - Combination Devices (Drug and Device)
    - Validation and Qualification

**1999 to February 2004: SCIREX Clinical Research Organization (CRO)**

**Title:** Associate Director Quality Assurance and Senior Quality Auditor

Roles and Responsibilities – Sponsor, Vendor, Supplier, Site, DMS, Statistics, SME and Auditor, Associate Director Quality Assurance / Regulatory Affairs – Good Clinical Practices in accordance with US and EU Regulatory Requirement's. Supporting IP and Clinical processes, GMP, GLP, Part 11 Electronic Records; Electronic Signatures, Drug Development cGMP for Phase 1 and Medical Devices for Clinical.

**Duties:** Conducted over **600** GCP, GCLP and GMP Audits supporting Global Clinical Trials in all aspects of clinical activities, IND, NDA/ANDA/Orphan, BLA, PMA/510k. 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.…
- Conducted Government Sponsored Clinical Training for the Institute for Clinical Research India (ICRI)
- Senior Auditing Responsibilities – Development Audit Standards for;
    - Sponsor and CRO Audits
    - Auditing of Investigator Sites, Investigators, Financial Disclosure and State Board Certifications
    - IRB Audits
    - Informed Consent form reviews
    - Monitors and Clinical Supervisory Personnel
    - Auditing Sponsor's Vendors and Suppliers
    - Database Audits (Database Management Systems)
    - Biostatistical Audits
    - SAE/AE/AR Filing Audits
    - MedWatch and Product Safety Audits
    - 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

- Training Curriculums - Good Clinical Practice (GCP) / Good Clinical Laboratory Practice (GCLP)
- 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. – Sentry Auditing Services (Pharmaceuticals)**

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

- Sentry 2000 Quality Management Software and Auditing System
- 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:

- Developed and Managed the Sterling 2000 Quality Management Software System
- 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
    - Propulsion Engineering,
    - 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**

- Over 6300+ hours cGXP Training supporting Bio-Pharmaceutical, Medical Device, Cosmetics, Combination Devices, 503B, FDA, DEA, CDC, ISO, EMA, and Dietary Supplements.
- 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.

**Partial List of Clients available upon request**

<end>