PMO/Portfolio/Program/Project Mgmt.
Strategic & Operational Planning
Operational Excellence Programs
Process Improvement & Remediation
IT, ERP, SDLC, Manufacturing & Supply Chain
Quality Assurance & Regulatory Compliance

Warren A. Opfer, MBA, CCP, PMP

Life Science Services International (LSSI)
6077 Far Hills Ave #123, Dayton, Ohio 45459
Mobile: 937-272-0063 - Office: 937-433-2220
waopfer@lssi-us.com

- **Yielded $250 million over 5 years in client estimated operational savings** from major process improvements including improved communication and information systems, updated and improved quality system and regulatory compliance, improved operational processes, and enhanced information technology. Project Executive working with the company President and SVP for this highly successful multi-year Operational Excellence Program and SAP ERP upgrade for a Fortune 100 Class III medical device company.

- **Rescued a Top 10 project now exceeding $100 million annually in new revenue.** Led and influenced cross-functional teams as Project Manager for the "project rescue" of this corporate top 10 strategic project. Worked for the SVP R&D on this Oracle-based Laboratory Information Management System (LIMS) international implementation for this Fortune 100 pharmaceutical company.

- **Process Improvements with $60 million in client documented annual savings.** Program Executive and CIO Strategic Advisor for a 2½ year Compliance Improvement Program to improve processes, reduce operating costs, and ensure regulatory compliance. JDE/Oracle ERP design and implementation, improved the SDLC, and managed the Project Management Office (PMO) this Fortune 100 Class III combination product manufacturing company.

- **Plant Renovation generates revenue of over $300 million annually.** Updated and validated manufacturing processes, facilities, equipment, plant utilities, cleaning and sterilization, Supervisory Control and Data Acquisition (SCADA) system, and Digital Control System (DCS). Led cross-functional teams as Project Manager for this Fortune 100 pharmaceutical company.

The accomplishments above are representative of my ability to achieve objectives and meet critical deadlines in fast-paced, regulated environments. I am a high energy and innovative program/project executive synthesizing leadership, teamwork, and technology into exceptional operational excellence, process improvement, information technology, quality, and regulatory compliance initiatives that facilitate business growth and profitability.

I am a trusted advisor to corporate executives at all levels. Effectively leading and influencing diverse, international, cross-functional, high performing teams, I formulate and implement strategic and operational plans supporting business operations, developing new and improved products, ensuring quality and regulatory compliance, improving the customer experience, and achieving financial objectives.

AREAS OF COMPETENCY

- **Operations & Engagement Management**
- **PMO/Portfolio/Program/Project Mgmt.**
- **Information Technology & Systems Dev.**
- **ERP, MRP, Manufacturing & Supply Chain**
- **Strategic & Operational Planning**
- **Quality Assurance & Regulatory Compliance**
- **Operational Excellence/Process Improvement**
- **Agile, CMMi, Lean, Six Sigma, Kaizen**
- **QSIT Audits, CAPAs, and Failure Investigations**
- **Computerized Systems Validation (CSV), IV&V**
- **SDLC, NPD, and PLM Methodologies**
- **Change & Configuration Management**

PROFESSIONAL OVERVIEW

Life Science Services International (LSSI) – Practice Leader – 1994-Present

- Founding partner in this program/project management, operational excellence, process improvement, and information technology products and consulting services firm. Specialize in information technology, ERP systems, manufacturing, supply chain, quality assurance, and regulatory affairs.
- Highly sought after executive advisor and implementer of operational excellence, process improvements, information technology initiatives, and regulatory compliance programs. I work with C-level and other client executives at all levels to plan strategies and aggressively manage the improvements and programs. Working with diverse, international, cross-functional teams, I ensure all business and operational objectives are achieved on schedule, budget and scope. Dedicated to moving organizations in matrixed environments to operational excellence and a state of continuous improvement. Highly sought to assist in resolving FDA 483's, Warning Letters, and Consent Decrees. Experienced in assisting companies in merger and acquisition integrations.
- Highly experienced in portfolio, program, and project management, PMO establishment and governance, and high performance team building. Expert in regulatory compliance, manufacturing and supply chain operations in regulated environments. Designer and developer of the LO1 Tracker System for manufacturing process control, product traceability, and electronic batch records. Managed teams of over 120 people and budgets over $100MM.
- Strong relationship and team builder based on trust established by doing what I say, leading by example, and positive results. Highly developed coaching, mentoring, training, influencing, motivating, consultation, persuasion, facilitation, and negotiation skills. Excellent customer facing skills. My philosophy of leadership, teamwork, and a proactive management style (not micromanagement) has led to major business improvements and transformations for organizations evolving them to a state of continuous improvement and growth by focusing on the needs of the customer, optimizing processes, ensuring quality and regulatory compliance, empowering employees, building high performing teams, and improving financial performance.
- Typical efforts include regulatory compliance analysis, strategic planning, risk management, audits, gap assessments, process improvements, responding to FDA and international agency inquires and inspection observations, requirements analysis, Business Process Management (BPM), Business Process Reengineering (BPR), change management, workflow mapping, gap analysis, six sigma DMAIC analysis, ERP system (SAP, Oracle/JDE, E1, MS Dynamics) implementations, system architecture and design, Systems Development Life Cycle (SDLC), database and software development, data management, validation including computerized systems validation (CSV), AIDC, RFID, independent verification & validation (IV&V), PLM and SDLC methodology, product development and management, manufacturing and supply chain improvements, calibration & preventive maintenance (Mainsaver), complaint handling & CAPA (Trackwise), batch record analysis, Document Management System (DMS) implementation, SOP and Work Instruction development, Learning Management Systems (LMS) implementations (ComplianceWire), instructional design, custom course development, and instruction (ILT & WBT). Highly proficient with the MS Office Suite, Visio, and MS Project. Expert in U.S., FDA, and international regulations, guidelines, and industry best practices including, but not limited to the GxPs, ICHs, Quality System Regulation (QSR), FDA Quality System Inspection Technique (QSIT), ISO 9000, 13485 & 14971, 21 CFR Part 11, Annex 11, IEC 62304, EMEA, MDD, CMDR, GAMP 5, IEEE, Six Sigma DMAIC, PMI/ANSI PMBOK, HIPAA and SOX regulations.
- Primary company duties include operations management, engagement management, strategic planning, business development, customer relationship management (CRM), PMO, portfolio, product, program and project management, sales and marketing, contracting, full P&L accountability, proposal development, contract negotiation and contract administration, accounting, finance, capital planning and budgeting, portfolio and resource prioritization, human resources, information technology, new product development (NPD), and product management.

Major Accomplishments:

- *Sigma International General Medical Apparatus, LLC. 2012* - Project Manager and Software Quality Assurance SME for the infusion pump Master Drug Library and infusion statistics Gateway software validation. Working directly with the software development contractor and Sigma team.
- *Philips Healthcare 2011* – Project Manager for Global Q&R Operations for the review and remediation of the Quality System for global software tools including SAP, Trackwise, and MetricStream. Engagement to provide project management and quality system and regulatory affairs subject matter expertise for the remediation of the Quality System with a team of client staff and consultants. Computer System Validation (CSV), Risk Management, Complaint Handling, Document Control, CAPAs, and resolution and remediation for internal audit observations and FDA 483's and Warning Letters.
- *Life Technologies 2010-2011* – Program Manager for the review and remediation of the Quality System for the Invitrogen IVD business unit following the FDA QSIT model. Long term engagement to provide project management and quality system and regulatory affairs subject matter expertise for the complete update of the Quality System with a team of 93 staff and consultants. Oracle E1 ERP, SAP, Agile eDMS, SDLC, and PLM environment. NPD Design Control, DMR, DHF, Validation (Process, Test Methods, & CSV), Calibration & Preventive Maintenance, Labeling & Packaging, Regulatory Affairs, Complaint Handling, Acceptance Activities, Facilities & Environmental Controls, Risk Management, Purchasing & Supplier Controls, Handling, Storage & Distribution, Management Controls & CAPA, and Training are the project teams. Implemented ComplianceWire, Trackwise and Mainsaver. Efforts included resolution for internal audit and regional audit agency observations, FDA 483's, and a complete quality system remediation.
- *Abbott Medical Optics 2009-2010* – Project Manager and SME for this major west coast Class III medical device (combination implantable product) operating company of a Fortune 100 corporation. Planning, project management, SME consulting, and risk management for this SAP ECC 6.0 upgrade project. SAP ERP upgrade to Unicode and from v4.7 to ECC 6.0 including full requirements analysis, functional and design specifications and validation/user acceptance testing of all modules. SDLC gap assessment and remediation following FDA guidance and IEC 62304. Assessment of regulatory compliance for systems utilized by the company. Worked with a large international multi-disciplinary team. Utilized Agile Project Management techniques to assist integrating this acquired company. Efforts included FDA 483 resolution and remediation.
- *Sandoz-Novartis 2008-2009* – Project Manager and SME for this major international pharmaceutical company providing manufacturing, packaging and labeling systems remediation, validation, and Standard Operating Procedure (SOP) remediation. SAP ERP environment. Preparation for a FDA audit. SAP ERP updates and enhancements. Efforts included FDA 483 resolution and remediation.
- *BioCryst Pharmaceuticals 2008* – Engagement Manager and Senior SME Consultant for an enterprise-wide regulatory compliance gap assessment. Provided assistance in strategy formulation, Part-11 analysis, retrospective evaluation, remediation, training, teambuilding, SOP development and updating. Performed laboratory and manufacturing systems remediation and validation (Quality Manual, VMP, CSV & Part-11 methodology, FMEA and Batch Record review). Preparation for a FDA audit.
- *Cardinal Health Alaris/Pyxis 2007-2008* – Project Executive for this highly successful multi-year Operational Excellence Program for this infusion pump medical device manufacturing operating company. Major process improvements, improved communication and information, updated and improved quality system and regulatory compliance, and improved operational processes and information systems. Worked with the President, the Senior Vice President QA/RA, and an expert team to improve the Customer Relationship Management (CRM) system, Complaint Handling including Trend Analysis and Complaint/MDR gap assessment and remediation, Post-Market Surveillance, Corrective and Preventive Action (CAPA) including a gap assessment and remediation, Issues/Defect Resolution System, Design Control, Risk Management, Document Control, and the Document Management System. Completely revised and improved the Oracle-based SAP ERP system, CAPA System, and the CRM system. Performed strategic planning, project management, CAPA resolutions, complaint handling, MDR's, corrections & removals, CRM, issue defect tracking, non-conforming material and products, failure investigations, risk management

under ISO 14971, validation, DHF and FMEA reviews, and enterprise BPR efforts. Consent Decree resolution project and process transformation. New regulatory compliant quality system design and implementation. Worked with a large multi-disciplinary team. Operational Excellence program with Six Sigma and Kaizen projects. Provided Instructional Design, Course Development, Instructor Led Training (ILT), and Web-Based Training (WBT). Client estimated $250 million in operational savings. Acquisition integration for Alaris and Pyxis into Cardinal Health. Efforts included FDA 483, Warning Letter, and Consent Decree resolution and remediation.

- *Takeda Pharmaceuticals 2007* – Engagement Manager for this contract providing project management consulting for drug new product development projects for this major Japanese pharmaceutical company leading to three successful NDA submissions.
- *Advanced Computer Systems (ACS) 2007* – Senior Consultant and SME for this major west coast Clinical Trial software vendor and creator of the Study Manager system. Regulatory compliance review and technical design consulting. Assessed the Clinical Trial Management System (CTMS), Electronic Data Capture (EDC), and Software-as-a-Service (SaaS) software, processes, and secured data center. Regulatory compliance review and technical design consulting. Focus on process review, quality assurance, compliance, Agile and SCRUM technique implementation, design consulting, software validation, SQA, electronic data acquisition, and training.
- *InterVascular-Datascope 2006-2007* – LO1 Tracker System designer, developer and implementer. Launched LO1 Tracker System on time and on budget. Project Executive and system architect on this 18 month contract to improve and lean production operations for this French Class III combination product manufacturer significantly improving throughput, reducing inventory levels, and reducing operating cost over $10MM annually. Worked with the company President and Executive Committee to plan and implement this AIDC based process control system integrated with the Oracle/JDE ERP to ensure traceability from raw materials to finished goods, facilitate QA/QC, and improve process control. System provides product traceability from raw material to finished goods, improved manufacturing throughput, reduced inventory levels, quicker time-to-market, and reduced operating cost. Utilized Agile and SCRUM techniques for design and development. LSSI retained the intellectual property rights for LO1 Tracker.
- *Gambro Renal Products 2006-2007* – Senior Consultant for this Italian device manufacturer regarding FDA/EMEA/ISO regulatory requirements and best practices and the development of Quality System policies and procedures. Efforts included FDA 483 resolution and remediation.
- *Seno Medical 2006* – Senior Consultant for this new medical device startup regarding FDA/ISO regulatory requirements, best practices, and the development of a Quality System Manual (QSM) and Validation Master Plan (VMP).
- *MedImmune–AstraZeneca 2006* – Project Manager for this new facility Process Analytical Technology (PAT) implementation. Provide SME consulting and project team facilitation.
- *BioHorizons 2005-2006* - Senior Consultant and Project Manager for this Class III medical device/biotech company (implantable devices and tissue products) to develop a Validation Master Plan (VMP) and provide implementation support and computer system validation (CSV) and Part 11 (security) verification for the MS Dynamics GP ERP system. Complete implementation and validation of the ERP system with documentation and certification. PM for several another projects including Lab System validation, VMP, Validation Strategy, and SOP development. Developed a Validation Master Plan (VMP). Efforts included FDA 483 resolution and remediation.
- *Johnson & Johnson (Cordis, DePuy & Ethicon) 2003-2006* - Program Manager and CIO Strategic Advisor for a 2½ year Compliance Improvement Program to improve processes, reduce operating costs, and ensure regulatory compliance. Oracle/JDE ERP design, validation, and implementation for business, laboratory and manufacturing systems. Requirements analysis, functional and design specification. Improved the SDLC methodology. Managed the Project Management Office. Assisted in resolving two Warning Letters and numerous 483's from previous FDA inspections. Reviewed and evaluated over 900 applications and revalidated over 500 to ensure operational and regulatory compliance. Participated in due diligence for a major merger effort. Reviewed and contributed to several 510k submissions. Reviewed and resolved CAPA's and internal and external inspection observations. Conducted a mock audit of labs and manufacturing. Contributed to Control Room efforts for FDA inspection preparing documents for submission to auditor and briefing staff prior to and debriefing after interviews. Performed audit of Complaint Handling

System and assisted in remediation and upgrade of the system. Provided training on Inspection Do's & Don'ts. Completed successful internal and FDA inspections with minimal observations. $60 million in client documented annual savings for this Fortune 50 Class III combination product operating company. Also an additional 6 month engagement as Project Manager for consulting and training on project management techniques, computer system validation (CSV), Part-11 verification, and medical device company regulatory compliance. Review and contributions to a 510k submission. Efforts included FDA 483 and Warning Letter resolution and remediation.

- *Boehringer Ingelheim - Roxanne Labs 2003-2004* – Project Manager for facilities design, development, and relocation of the BI Roxanne data center. A major facility commissioning and qualification project. Working with CTG a large Tier 2 international consulting firm developed $2.5 million in new business with BI. Subject Matter Expert (SME) consulting in GxP, QSR, ICH, ISO, and GAMP. Provided program/project management, business development, proposal development, sales and marketing support, client presentations, training, and mentoring and coaching for the staff.
- *Digene Corporation 2003* – Senior Consultant and SME for gap assessment for FDA, ISO, and SOX regulatory requirements. Developed detailed gap analysis and remediation recommendations.
- *Abbott Laboratories 2000-2003* – Leader of cross-functional teams as Project Manager to accomplish a mandatory regulatory sNDA submission on schedule and with the pre-approval inspection and final FDA plant inspection yielding no observations. The updated plant generated over $300 million in annual revenue. Updated and validated manufacturing processes, facilities, equipment, plant utilities, cleaning and sterilization, Supervisory Control and Data Acquisition (SCADA) system, and Digital Control System (DCS). Project Manager and Senior Validation Consultant for the eSubmissions program for a major pharmaceutical company. Worked with a large cross-functional team to define requirements, develop specifications, verify and validate implementation, provide training, and deploy the system. Project Manager and Senior SME Consultant for a Part 11 compliance program. Provided assistance in strategy formulation, Part 11 applicability, legacy system retrospective evaluation, remediation, training, and teambuilding. Remediation of Standard Operating Procedures for the consolidation of global pharmaceutical R&D. Developed and revised compliance program plans, managed remediation plans and efforts, worked with cross-functional teams, developed policy recommendations, and performed regulatory compliance auditing. Established and managed the project management office for the company. Project Manager leading and influencing cross-functional teams for the "project rescue" of this corporate top 10 strategic project. Worked for the SVP R&D on this Discovery Laboratory Information Management System (LIMS) international implementation. The success of this project is leading to new collaborative products. The first of these yielded over $100MM annually. Project Manager and validation SME for a GxP and 21 CFR Part 11 gap analysis and developing regulatory interpretation and policy recommendations. Revised standard operating procedures (SOPs) on security, system decommissioning, software inventory, regulatory compliance assessment, and remediation processes. This was a major remediation effort as the result of major reorganizations and changes in responsibilities. The project was considered a major initiative for the division and the corporation. Led this and other operational initiatives over a 3½ year engagement. Efforts included FDA 483 and Warning Letter resolution and remediation.
- *Project Management Institute (PMI) 1999-2000* – Project Manager for a research grant contract for this Project Management Institute (PMI) sponsored project. Performed in conjunction with Xavier University, Cincinnati, Ohio. This research was present in Paris at the 2000 PMI Research Conference and was published in the PMI Research Conference Proceedings, the PMI Project Management Journal, and in two PMI books on project management. The research definition developed for this study has been adopted as the standard for PMI.
- *Lion Apparel 1997-1999* – Project Executive for the design, development and implementation of an Intranet-based Manufacturing Specifications System. This was a major improvement in product version control and communication of specifications between the design group and the manufacturing plants. The time for distribution of new product specifications to the manufacturing plants was shortened from days to few minutes. This system also created a common product specification repository accessible 24/7/365 to all of the manufacturing plants. Integrated with the Oracle/JDE ERP.

- *Catholic Health Initiative 1997-1999* – Project Manager for design and development of a custom inventory system for use in CHI hospitals. Utilized barcode readers and handheld computers to facilitate inventory control and physical inventories. The system also performed specialized inventory analysis focused on improving control and turnover of expiring pharmaceuticals and medical expendables in hospitals.
- *State of Montana 1997-1998* – Project Manager and SME performing a needs analysis and specifications development for real property valuation and taxation systems for the State of Montana. This was part of a complete replacement of the revenue systems and included both a document management system and a CRM implementation.
- *Microtek 1996-1997* – Designer and developer for a custom Just-in-Time (JIT) system for product configuration and order processing for this Class II/III medical device manufacturing and distribution company. Oracle-based implementation integrated with the JDE ERP system. Client estimated over $12 million in new annual revenue from the system implementation due to the 50% reduction in time-to-market. Web-based interface allowed customers to configure products, determine delivery time, place orders, and check order status online in real-time.
- *Abacus Technologies 1996-1997* – Defense Enterprise Information Service (DEIS) sub-contract (EDS/LORAL/ABACUS Team) supporting the Defense Finance and Accounting Service (DFAS) evaluating migration and legacy accounting information systems in the DOD transportation business area. Project Manager and SME for the transformation and migration of legacy systems to an Oracle DBMS environment.
- *GS1 previously Uniform Code Council (UCC) 1995-1999* – Developed a hypertext version of a 450 page international bar coding standards specifications document for the Uniform Code Council (UCC) including the development of over 300 technical figures and tables. Developed the first website for the UCC. Joint Application Design (JAD) and requirements analysis for new systems for the UCC. Developed a hyperlinked CD-ROM "The Art of Producing Bar Codes Tool Kit". This product included UPN and health system related Application Identifiers (AIs). Performed various other activities and projects.
- *St Jude Medical 1995-1996* – Senior Consultant in this operational, computer system, packaging, labeling and barcoding upgrade project. Analysis of operations and business practices for this medical device manufacturer for the purposes of implementing and integrating Universal Product Numbering (UPN) and barcoding in compliance with government and commercial requirements. UPN was a critical issue for the company that was under a government deadline for implementation. The project was successful and preserved orders that represented 45% of its business.
- *The Dayton Group, Inc. 1994-2010* – Program/Project Manager and subject matter expert consulting in portfolio/program/project management, IT project management, leadership, teambuilding, risk management, earned value, critical chain method, PMO establishment and governance, Portfolio/Program/Product Life Cycle Management (PLM), and Systems Development Life Cycle (SDLC). Develop project charters, OMB Business Cases, Federal Enterprise Architecture models, and benchmark Key Performance Indicators (KPI), CMMI and continuous process improvement, and OPM3 for both government and commercial clients. Thorough working knowledge regarding federal contracting, FAR's, contract administration, business case development (OMB 300), system engineering, and the Federal Enterprise Architecture. Proposal preparation and reviews. Administer FAA, GSA MOBIS, and GWAC IDIQ contracts. Key U. S. government agency customers include DFAS, DOD, DOT, FAA, GSA, and NOAA working with executives, program and project managers, engineers, research scientists, and information technology professionals. Products personally developed include the Leadership Assessment Tool (LAT), the Project Auditing Tool (PAT), Instructor Led Training (ILT) and Web-Based Training (WBT) courses. Project Management Institute (PMI) Charter Registered Education Provider (R.E.P.). Developed portfolio, program, and project management career development matrix with core competencies and proficiencies for career development and progression for the Federal Aviation Administration (FAA). This career matrix approach was subsequently adopted by the U.S. CIO Council for use in executive branch agencies. Developed the GSA mid to senior level government executive portfolio/program/project education program under the GSA Star Program. Highly successful program lauded for its effectiveness. Participants have consistently given the course the highest rating for excellence.

- *Thomas Endocrinology Associates 1994-1995* – IT systems and insurance claims processing software support for a doctor's practice.

Sabre Systems and Services – Senior Vice President – 1991-1994

- SVP and Business Unit Head for a $25MM information technology products and services division of an operating company of Fortune 500 Moore Corporation Limited (now merged with RR Donnelley).
- Reorganized a large, troubled division to restore balance, revenue growth, and profitability. Accountabilities included full P&L, operations and engagement management, business development, customer relationship management (CRM), portfolio, program, and project management, product management, information technology, R&D, new product development (NPD), data center management, help desk management, quality, contracting, purchasing, facilities, sales, marketing, and fulfillment.
- Managed a portfolio of up to 117 projects with project budgets up to $1.5MM. Sold the largest IT contract in the company's history and personally grew company revenue over $5 million. Led technical staff of 75 and four sales and marketing personnel. State and local government contracting. Managed development, large IBM/DEC/HP data center, and IT infrastructure.
- Made presentations to the Board of Directors. Member of the M&A team. Assisted in selling the division.

Cole-Layer-Trumble (CLT), Universal Technology Corporation (UTC), Systems Research Laboratories (SRL), and NCR Corporation – Sr. Analyst to Sr. VP – Prior to 1991

- Increasing leadership and management responsibilities leading from Senior Analyst to Senior Vice President and full P&L accountability. Functional areas include operations, engagement management, customer relationship management (CRM), information technology, portfolio, program and project management, product management, R&D, new product development (NPD), quality, data center management, help desk management, quality, human resources, contracting, facilities, purchasing, manufacturing, supply chain, facilities, distribution, sales, marketing and fulfillment.
- Operating budgets up to $17MM and program/project budgets up to $100MM. Federal, state, and local government contracting. Managed the delivery of the two largest contracts in the company's history for CLT. Moved company to a new facility and developed a new data center and SCIF for UTC. Supported major DOD contracts for SRL and UTC. Designed and developed an inventory management system, migrated finance and accounting applications to a new computer hardware environment, implemented project management and MRP systems, managed large IBM/DEC/HP data center and infrastructure for SRL. Sr. Financial Analyst and Project Manager for NCR.
- Member of the Executive Committee, Member of the Mergers and Acquisitions Team, and made presentations to the Board of Directors.

EDUCATION & PROFESSIONAL CERTIFICATIONS

- Post Graduate Studies, University of Strathclyde, Glasgow, Scotland; Leadership & Project Mgmt.
- M.B.A. Wright State University, Industrial/Production Management and Economics
- B.S. Wright State University, Business Management/Computer Science
- Cost/Schedule Control Systems Criteria Course (Earned Value), Air Force Institute of Technology
- Certified Computing Professional (CCP), Inst. for Certification of Computer Professionals
- Project Mgmt Professional (PMP) Certification, Project Management Institute (PMI)
- Sandler Sales System Training, Sandler Sales Institute

PROFESSIONAL ASSOCIATIONS

- American Society for Quality (ASQ)
- American Society for Testing and Materials (ASTM International)
- International Society for Pharmaceutical Engineering (ISPE)
- Project Management Institute (PMI)

REPRESENTATIVE PUBLICATIONS, PRESENTATIONS, AND COURSES TAUGHT

- Contributing author for the textbook *Contemporary Project Management*, by Timothy Kloppenborg published by South-Western 2009 and v2.0 2011. Topics include Lean Project Management, Agile Software Development and SCRUM technique.
- Presented a series of Product Monitoring courses including Complaint Handling, AERs/MDRs, and post market surveillance 2008.
- Developed and presented Failure Investigation “hands-on” case-based workshops, Corrective and Preventive Action (CAPA) course, and Quality Assurance Awareness training courses 2007-2008.
- Developed and presented a series of Change Management courses for a Fortune 100 pharmaceutical company 2006.
- Updated the “Leadership Assessment Tool (LAT)” to v2.0 in 2006. Initially published in the book *Project Leadership*, Timothy Kloppenborg, et al, published by Management Concepts, 2003.
- Developed and instructed courses on Computer System Validation (CSV) Methodology and Change Control, Document Control, and on Inspection and Audit Handling Dos and Don’ts, 2003-2006.
- Chapter author on “Building a High Performance Project Team” for the book *Field Guide to Project Management*, 2nd edition, David Cleland, et al, published in 2004.
- Contributing author for the book *Project Leadership*, Timothy Kloppenborg, et al, Management Concepts, 2003.