

Keith Franklin

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HIGH LITES

Experienced Project Manager

ASQ Certified
Quality Engineer
(CQE)

ASQ Certified
Quality Auditor
(CQA)

Expertise in
flowcharting, Pareto
analysis

EDUCATION

Master in Business
Administration
(MBA), City
University
Bellevue, WA (1992)

Bachelors of Science
in Vocational
Education,
Specialization in
Curriculum
development,
Technical Writing,
and Training
Southern Illinois
University
Carbondale, IL 1988

EXPERIENCE

Systems Inc.

Director of Operations, 2000 - Present

- Responsible for ISO 9001. Currently, managing five professionals in the areas of Continuous Improvement, FMEA, QS9000, validation, PPAP, AQP, and Six Sigma. Performed over 100 compliance audits, and been audited over 40 times by various government and independent agencies for ISO, Six Sigma, and IT Security, and HIPPA. Experience in machining, welding, fabrication, and large assembly processes.

SIMS Portex

Manager Medical Devices, 1996 - 2000

- Responsible for FDA, OSHA 18001, and EPA requirements, training, and all aspect of quality and manufacturing including increasing efficiencies, reducing scrap, and customer complaints. Prepared and managed an annual budget in excess of 5 million dollars and a staff of 100 individuals over 4 shifts. Concerned with FDA Regulatory Compliance, 21 CFR Part 803 (Medical Device Reporting, and New Device Submissions).

Warner Lambert (acquired by Pfizer)

Senior Quality Engineer Pharmaceuticals, 1990 - 1996

- Implemented, for OTC and prescription drugs, cGMP vendor certification program, root-cause analysis and CCB boards, Continuous Improvement, DOE, FMEA, and raw material inspections.

Codman and Shurtleff (a Johnson & Johnson company)

Quality Engineer Medical Devices, 1988 - 1990

- Responsible for internal and external GMP process and products audits\validations for Class 1, 2, and 3 medical devices and 510k submission assistance, Vendor Certification Program, software validation, and Statistical Process Control (SPC). Supervised two Packaging Engineers in critical materials packaging, testing, and sterilization.

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Technical Experience	Credentials
Hardware	IBM-compatible PCs, Android
Operating Systems	Server 2000\2003, NT, XP, Windows 3.X-2003, Novell Netware
Programming Languages	Visual Basic .Net, and .ASP, JAVA
Statistical Software	Stat-Graphics, Stat-Ease, limited SAS, Excel
Databases/File Structures	SQL Server, FoxPro, dBase
Other	Visio, Adobe InDesign, PowerPoint, Word, Excel, Access, PowerPoint, MS Project, ACL
Certifications	<p>(ISC) ² Certified Information Sys. Security Professional (CISSP #candidate) ISACA Certified in Risk and Information Sys. Control (CRISC #1000097) ISACA Certified Information Systems Manager (CISM # 1013082) ISACA Certified Information Systems Auditor (CISA # 0977514) ASQ Certified Quality Engineer (CQE certification #20696) ASQ Certified Quality Auditor (CQA certification #1665) RAB Certified QMS-ISO Auditor (Certification # Q09217) Metrology (science of measurement) US Navy</p> <p>ASQ CSSBB Six Sigma Black Belt Certification (6Sigma Dec 2011) IAIDQ Information Quality Certified Professional (IQCP Aug 2011)</p>
Instructor	<p>US Navy 1983 to 1986 (Curriculum Development, Delivery & Instruction) Edison Community College, Fort Myers, FL. 00 to 03 (Info. Technology) American Society for Quality, Little Rock, Ar. 10 to Present (Auditing)</p>