

EXPERIENCE

- Over 21 years of hands-on professional experience in the fields of Quality Systems, Worldwide Regulatory Compliance and Submission, Quality Assurance, Engineering, and Operations.
- Expert in use of Statistical Process Control for process optimization, experimental designs, stability, software and process validation.
- Expert in Risk and Reliability Analysis including Fault Tree and FMECA.
- Established QS/Compliance for eight start-up operations worldwide (Brazil, France, Germany, Japan, Malaysia, Puerto Rico, Scotland and United States.)
- Directed quality organizations through start-up, mergers, acquisitions, divestitures, and OEM alliances.
- Established, directed, maintained and audited a highly recognized Best-In-Class Global Quality System with perfect compliance record.
- Responsible for regulatory compliance that meets GMP, GLP, FDA-QSR, ISO9001, ISO14000, EN46001, Medical Device Directive and other International Quality Standards.
- Managed 6-Sigma Blackbelt program.
- Established and maintained highly effective relationship with Federal and local FDA offices.
- Facilitated design, implementation and continual improvement utilizing company Balance Scored Card between process and business results (I.e., Malcolm Baldrige's criteria.)
- Specializes in acquisition due diligence on companies for quality, regulatory compliance and liability.

CREDENTIALS

- American Society for Quality (ASQ) Senior Member and is actively involved with HIMA, AAMI, ISO, and RAPS
- ISO 9000 lead assessor
- Worked jointly with ISO Standard Committee Working Groups, involved in the new standard ISO 9000-year 2000.
- Recognized throughout Johnson & Johnson family of companies franchise as an in-house expert for worldwide compliance (FDA, Notified Body, Government Authority), ISO Certification, CE marking, hardware and software validation, MDR, European Vigilance standards and practices.
- Management responsibility for a staff of 98 worldwide.
- Former Member of a division of J&J's Management Board
- Speaks fluent Japanese and Vietnamese
- MBA - University of Redlands, California
- Master of Engineering - Cal Poly University, Pomona, California (40 units)
- BS in Mechanical Engineering, Japan
- Duke University - World Class Manufacturing
- Johnson & Johnson - Advanced Management Program / Executive Leadership Program
- Harvard Business School - Executive Management Program
- Quality System Regulation (QSR) Trainer (AAMI/ FDA)