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Experience

January 2021 – Present **Vice President of Enterprise Regulatory Compliance**
Johnson and Johnson (New Brunswick, New Jersey)

- Responsible for Enterprise Compliance dashboard and reporting preparation for the Johnson & Johnson Compliance Committee, Executive Committee, Board of Directors.
- Provide expert consulting in compliance crisis management; inspection readiness and management, directed audits, special investigations, health authority responses and mitigation of systemic compliance risks.
- Provide strategic direction for quality systems based on current and emerging regulatory trends, ensure readiness for regulatory inspections, and collaborate across the Enterprise to lead cGMP compliance initiatives
- Assure implementation of both proactive and outcome measures of compliance/compliance profiles at all operating units of all types (R&D, Supply Chain, Distribution, Marketing Company).
- Assure Standards are contemporaneous with the external regulatory view and provide the appropriate level of information to assure compliance and reduce the overall risk profile to the Company

March 2014 – January 2021 **Vice President of Quality, Regulatory, Legal, Compliance, and Global Supply Chain Management**
Acumed LLC (Hillsboro, Oregon)

- Official correspondent with the FDA, Health Canada, ANVISA, CFDA, Notified Bodies, and competent authorities. Led the achievement of MDSAP certification in 2018
- Led reduction of backorders from over $1.5M to under $75,000 in less than a year through a systematic process of root cause identification, supplier development, and production planning
- Quality System strategist responsible for the advancement of the QMS and continuous improvement of overall product quality. Created and conducted company-wide certification training for Quality Systems.
- Architected and executed design assurance changes through improved Risk Management techniques, better Voice of Customer collection, and product testing strategies.
- Work done to reinvigorate Quality, Regulatory, and Compliance teams resulted in assignment as head of Project Management Office, leading the incorporation of better design assurance techniques and schedule discipline through project leadership.
- Developed strategies and execution plan for company remediation projects to ensure regulatory compliance

June 2011 – March 2014 **Global Director of Quality and Regulatory**
TE Connectivity Medical Products (Wilsonville, Oregon)

- Directed a multi-site, international team of quality inspectors, engineers, quality system and supplier specialists in the production and design of custom medical device connection solutions (Mexico, China, and United States)
- Responsible for the redevelopment of the business Quality System to include production controls, process validation, design assurance measures, and corrective action reporting procedures and processes.
- Created a CAPA program and cadence that ensures the timely completion of CAPA tasks and assures accountability through cross-functional leadership and oversight
- Spearheaded coordination of design requirements and risk management in product realization process.
- Led the reduction of product complaints by over 40% in a two year period through corrective and preventative actions driven through a system of cross functional meetings focused on responding to Quality Metrics
- Official correspondent for all FDA and Notified Body administration, communication, and audit activity.

July 2003 – June 2011 **Various Positions**
Medtronic Neurologic Technologies (Goleta, California / Fort Worth, Texas)

- **Director of Quality (July 2007 – June 2011)**
  - Directed a team of quality inspectors, engineers, quality system administrators, and supplier specialists in the realization of neurosurgical devices used in the treatment of hydrocephalus and cranial trauma injuries.
  - As Project Leader, spearheaded the introduction a new External Drainage System ahead of schedule
  - Ensured products are manufactured in a manner that is consistent with FDA and ISO standards
  - Directed site through Class I Field Corrective Action, served as point of contact for affected accounts

- Coordinated all FDA and Notified Body communication, audits, MDR's, vigilance reports

- **Director, Project Management (October 2005 – July 2007)**
  - Tasked with the responsibility to meet Powered Surgical revenue plan for twice market growth revenue as the site's product development leader for spinal and neurological products
  - As a site change leadership agent and quality specialist, created initiatives and executed tactical plans to ensure compliance to federal regulations to initiate the "turn around" of a troubled business. *Subsequent FDA audit had no findings and zero 483's*
  - *Awarded Medtronic Star of Excellence Award for leadership role in turn-around efforts at business.*

- **Manager, Quality Engineering (July 2003 – October 2005)**
  - Led development for medical industry's first purity specification for polylactic acid to ensure the launch of Medtronic's first resorbable implant suitable for use in pediatric craniomaxillofacial cases
  - Managed team of Quality Engineers and Complaint Specialists through a series of remediation projects. Complaint closures reduced by 33%, Validations Plans created and executed for 100% of all processes.

January 2001 – July 2003 **Quality Engineer**
Stryker Endoscopy (San Jose, California)

- Responsible for the production and design for video processing and documentation systems
- Initiated testing and 510k submission for first Bluetooth device authorized for use by FDA (SIDNE)
- Developed innovative design control measures and validations to ensure products conformed with strict FDA requirements while facilitating completion aggressive time-to-market requirements

July 2000 – January 2001 **Program Manager**
Cadence Design Systems (Santa Barbara, California)

- Served as account leader for strategic relationship with key partners; instituted cost saving measures and schedule controls that regularly provided firm with project margins at least 10% above budget
- Initiated agreements that allowed Cadence to realize 20% in additional revenue streams in a declining market

August 1998 – July 2000 **Systems Project Engineer/Program Manager**
Honeywell Engines and Systems (Torrance, California)

- Tasked with the development of environmental control systems in both military and commercial aircraft
- Performed dual roles as both proposal manager and integrated process team leader for power thermal management system solution on Joint Strike Fighter. Incorporated savings initiatives to reduce customer costs by 25% in a contract totaling over $10M in non-recurring engineering efforts
- Managed initial Joint Strike Fighter program contract for group and provided technical evaluation of thermodynamic solutions model by the team.

September 1994 – August 1998 **Captain**
Civil Engineering
United States Air Force (Lompoc, California / Cocoa Beach, Florida)

- Managed architects and construction teams in the realization of various Air Force infrastructure projects
- Served as Base Engineer and Officer in Charge of 67 troops stationed at Al Dhafra Air Base, United Arab Emirates. Awarded the *4413th Air Refueling Squadron Company Grade Officer of the Month* – December 1996
- Recognized as 30th Engineering Squadron's *"Military Manager of the Year",* 1997*;* and the 30th Support Group's *"Company Grade Officer of the Quarter"* (Q3 1996)

Education

July 2008 **The University of Texas at Austin, McCombs School of Business** **Austin, TX**
Master of Business Administration

May 1994 **Rensselaer Polytechnic Institute** **Troy, NY**
Bachelor of Science in Mechanical Engineering