Decus Biomedical, LLC

Tav T. Rotondale, B.S.E.

Summary of Qualifications

• 24 years engineering experience including 19 years in new product development, 11 years in medical devices
• Strong risk management experience
• Demonstrated ability to lead a team to complete complex projects
• Experienced in management of quality assurance and regulatory affairs including writing of the 510(k)
• Successful verbal and written communication skills in cross-functional environments

Summary of Professional Experience

2008 - Present	Quality Assurance Specialist, Decus Biomedical, Berkeley, CA
2007 - 2008	Contract Quality Assurance Manager, iScience Interventional, Menlo Park, CA
2005 - 2007	Compliance & Regulatory Affairs Manager, Optiscan Biomedical, Hayward, CA
2004 - 2004	Contract Project Manager – Medical Devices, Lathrop Engineering, San Jose, CA
1997 - 2003	Engineering and Project Lead, ADAC / Philips Medical Systems, Nuclear Med., Milpitas, CA
1994 - 1997	Engineering Consultant, Page Automated Telecommunications Systems (overlapping)
1995 - 1997	Project Engineer, Therma-Wave, Fremont, CA
1993 - 1994	Project Engineer, S-TRON, Mountain View, CA
1990 - 1993	Opto-Mechanical Engineer, Xinix / Luxtron, Santa Clara, CA
1988 - 1990	Design Engineer, United Technologies, San Jose, CA
1986 - 1988	Contracted Mechanical Engineer for NASA Ames Research Center, Moffett Field, CA
1984 - 1986	University Co-Op Engineer, NASA Ames Research Center, Moffett Field, CA

- Decus Biomedical is a spin-off company from ISM, Inc., a medical device consulting firm. We provide services in the following areas:
  - Regulatory (strategy, submissions, compliance)
  - Clinical (design, execution and analysis of studies)
  - Quality (quality system establishment, audits and gap analysis)
  - Software development processes and validation
  - Technical services (basic research, verification, product documentation, risk management)

- iScience Interventional is a venture-backed startup company that develops and manufactures micro-catheter and imaging technologies for ophthalmology therapies. I was contracted to provide quality assurance management services, oversaw and developed the complaint handling and CAPA processes representing these in FDA and ISO 13485 audits, wrote a part for an IND, and conducted internal audits

- OptiScan Biomedical is a venture-backed startup company that develops an automated ICU point-of-care continuous blood glucose & lactate monitor using spectroscopic analysis of blood plasma. My responsibility was to develop and rapidly implement a quality assurance system for GMP / GLP / GCP, train employees, participate in design reviews and lead risk management activities, develop regulatory strategies, and author the 510(k) for the company.

- Lathrop Engineering is a privately-owned engineering firm providing services to a variety of clients. My responsibility was to facilitate their transition into working with more medical device companies. Client projects included a portable flow cytometer, an ultrasonic imaging catheter, a micro-fluidics biosensor, a portable cholesterol tester, and an atomic absorption mercury tester for seafood.

- ADAC / Philips Medical Systems develops nuclear gamma cameras and Computed Tomography systems. My responsibilities encompassed full life-cycle engineering, project management, leading risk management, assisting in re-vamping the quality system in response to an FDA warning letter, serving as the liaison between engineering and QA and manufacturing, conducting internal QA audits, writing a part of the 510(k), reviewing all cross-disciplinary test protocols and reports, attending pilot testing at a

radiological clinic, and serving as the engineering signatory to the change control board. Received top-level patent for new type of robotic gamma camera system.

- Page Automated Telecommunications Systems was developing fiber-optic systems for aircraft and other applications. I served as the mechanical engineering consultant and gave client presentations.

- Therma-Wave developed and manufactured wafer thin film metrology equipment for OEM's. I served as a design and project engineer of high-precision mechanisms.

- S-TRON developed and manufactured equipment for the defense industry. I provided engineering design and testing services and helped write a proposal for a major government contract (21st Century Land Warrior).

- Xinix / Luxtron developed end-point detection systems for wafer fabricators and fiber optic temperature measurement systems for a variety of applications. I served as an R&D engineer in the development and test of these products, one of which was coupled as part of an invasive medical device to reduce an enlarged male prostate gland. Received patent for infrared endpoint detection sensor system.

- At United Technologies, Chemical Systems Division, I served as a design and test engineer of rocket and missile components such as for the Titan, Tomahawk, and Trident II systems.

- I started at NASA Ames research center as a university cooperative engineer and continued after graduation as a contract engineer. Projects were varied and included developing systems for flight simulators, space shuttle, and wind tunnels.

Summary of Academic Experience

- 1980 - 1986 B.S. Engineering, (Mechanical Engineering – Stress and Fluid Mechanics emphases)
  San Francisco State University, San Francisco, CA
- 1988 – 1991 Electronics / Programming technical course work
  Mission College, Santa Clara, CA

Certifications

- ISO 14971 Standard, 2/ 2002
- Internal Assessor, ISO 9000 & Medical Regulation, 5/2002
- Internal Assessor, ISO 14001 Environmental Management System: 7/2002
- Risk Management Certificate, Virginia Polytechnic Institute & State Univ.: 7/2002