Richard Smith | Northboro, MA 01532 | (508) 320-4861 / rick@smithqualitysolutions.com

EXPERIENCE

Smith Quality Solutions LLC — Northboro, MA

Owner | Principal Consultant — **1/2018 - present**

- Quality System development & implementation
- Regulatory strategy research
- Quality system improvement or compliance project management
- Supplier & Internal Auditing / Gap Assessments

BionX Medical Technologies, Inc. — Bedford, MA

Sr. Director, Quality & Regulatory — **9/2014 – 3/2018**

Quality Assurance / Regulatory Affairs member of Senior Leadership Team, reporting to the CEO

- Made significant improvements to virtually every aspect of the Quality Management System, including: almost 10x reduction in both open complaints and complaint cycle times, implementation of electronic Document Control system, reduction in external audit findings each year, with zero findings in most recent ISO13485 re-certification.
- Provide guidance to Engineering on Design Assurance topics such as: Design Controls, Risk Management, Software Validation & Compliance Testing
- Performed regulatory assessments for all regions of distribution, including complete re-structuring of the product Technical File for the EU and creation of a 510(k) file for the US.

ConforMIS, Inc. — Bedford, MA

Director, Quality Assurance — **5/2011 – 9/2014**

Responsible for all aspect of Quality, including: QC, Design Assurance, Quality Systems & Document Control

- Direct a quality team of 20+ individuals, including 3 managers
- Led Quality System improvements in Design Controls, Risk Management & Production Controls (Lean methodology)
- Point person for the facility's first FDA Inspection and annual ISO audits

Hologic, Inc (formerly Cytyc Corporation) — Marlborough, MA

Director, Quality Assurance — **11/2007 – 5/2011**

Design Assurance and Quality Systems management for surgical products division

- Management Representative - point person for 2 FDA inspections and annual ISO audits
- Manage Design Assurance and Quality Systems personnel
- Led Quality System overhaul to support Oracle and Agile PLM system implementations

Regulatory Affairs Specialist — **3/2006 to 11/2007**

Regulatory Affairs representative in support of both PMA and 510(k) surgical and in-vitro diagnostic devices.

- Provided regulatory assessments and support for new product develoment teams.
- Prepared and submitted 510(k) and PMA supplements
- Maintained technical files in support of CE marking

Sr. Quality Engineer — **6/2005 to 3/2006**

Quality Engineering representative on core teams for development of medical devices related to the imaging and review of cytological specimens

- Represented Quality Engineering on development core teams
  - Awarded a "Signature Award" for significant contributions to major development project.
- Developed database for tracking and trending manufacturing failures.
- Led process improvement team to improve effectiveness of the corporate Risk Management process.

Analogic Corporation — Peabody, MA

QA Manager – Medical CT Division — 6/2004 to 6/2005

Responsible for all Quality Assurance and Design Assurance activities in an organization that designs and manufactures medical CT scanners, including:

- Establish and maintain quality processes per ISO13485 and FDA's Quality System Regulations (QSR).
- Supervise and direct the efforts of Quality Engineers and Inspectors.
- Provide reports to executive management on the status of divisional quality systems.

Implemented or improved the following quality processes: Customer Complaints, Corrective/Preventive Action (CAPA), Risk Management (ISO14971), and Requirements Management (DOORS).

Quality Engineer – Customer Service — 10/1999 to 6/2004

- Supervised a team of technicians responsible for repair of complex integrated analog/digital electronics.
- Responsible for Quality Assurance activities, including: Internal ISO9001/13485Audits, Material Review Board (MRB), Supplier Corrective Action Reports, Customer Complaints, and Failure Trend Analysis.

US Navy - Nuclear Submarine Officer — 1994 to 1999

Division Officer

- Managed personnel responsible for operation, maintenance and repair of all electrical, auxiliary mechanical and reactor controls equipment on-board a Los Angeles class fast attack submarine.
- Awarded the *Navy and Marine Corps Achievement Medal* for superior operational performance. Received a grade of 'Excellent' during a reactor safety inspection for flawless tracking of potentially radioactive material and crew's radiation exposure.

Ship's Diving Officer

- Responsible for the ship's watertight integrity and calculations used to determine ship's buoyancy prior to submerging.
- Integral member of team responsible for the first year-long overhaul of its kind to be completed on schedule in Navy history. Trained the ship control teams after an extended shipyard overhaul, resulting in flawless handling of the ship at design limits.

EDUCATION

Physics — **BS, Worcester Polytechnic Institute, GPA 3.7** — **1994**

Major Qualifying Project: Used Quasi-Elastic Light Scattering Spectroscopy (QELSS) to determine the size and shape of molecules in solution.

- Physics Department awards for excellence in both scholarship and research.
- Member of Sigma Pi Sigma (physics) and Tau Beta Pi (engineering) honor societies.

Nuclear Power School / Navy Nuclear Prototype — 1994 to 1995

- Intensive graduate-level coursework in Mathematics, Physics, Chemistry, and Engineering.
- Qualified to supervise the operation of a naval nuclear reactor.

Prospective Nuclear Engineer Officer School — 1998

10-week course of study in the detailed theory, design and operating parameters of a Naval nuclear power plant. Successfully completed two-days of extensive oral and written examinations at the Naval Reactors organization in Washington, D.C ; the technical qualifications to become the Engineering department head of a nuclear submarine.