Anthony Raymond

VICE PRESIDENT OF QA/RA, OPERATIONS & CHIEF COMPLIANCE OFFICER - GAMMA MEDICA

North Andover, MA - Email me on Indeed: indeed.com/r/Anthony-Raymond/500475c6c9df827c

Authorized to work in the US for any employer

WORK EXPERIENCE

VICE PRESIDENT OF QA/RA, OPERATIONS & CHIEF COMPLIANCE OFFICER

GAMMA MEDICA - Salem, NH - May 2014 to Present

Salem, NH May 2014 - Present
Gamma Medica, Inc. is dedicated to the development of advanced digital imaging technologies that address the growing importance of overcoming the critical shortcomings of mammography and other screening modalities in the early detection of breast cancer.

VICE PRESIDENT OF QA/RA, OPERATIONS & CHIEF COMPLIANCE OFFICER
Quality Assurance
• Created the Quality Management System and successfully achieved ISO 13485 certification and subsequent re-certification including the CMDCAS (Canada) endorsement
• Provided senior leadership for the oversite and continuous improvement of the QMS by driving Management reviews and day to day activities such as CAPA, Complaints, MRB to ensure a dynamic compliance environment
• Established and maintained strong relationships with Notified bodies, Authorized Representatives, Government agencies and Industry organizations, e.g. Medical Device Manufacturers Association (MDMA) and Advanced Medical Technology Association (ADVAMED)
• Oversaw Medical device hardware and software development activities to ensure that the appropriate design controls were in place and utilized for product realization
• Restructured the Risk Management Procedure and updated the Risk Management files to meet the requirements of the current regulations and standards. i.e. ISO 14971 & IEC 60601-1 3rd ed.

Regulatory Affairs & Corporate Compliance
• Created and deployed of regulatory policies and procedures across the corporation
• Lead the effort to attain CE mark, Canada MDL and Saudi Arabia MDMA for the existing 510k cleared product
• Implemented the corporate compliance office including generation of policies and procedures. Provided continuous monitoring, review and enforcement as required.
• Ensured that the company maintained compliance with the CMS Open Payments program including dispute resolution.
• Drove a corporate wide HIPAA compliance training program for all employees.
• Established Post Market Surveillance Procedures

Supply Chain
• Redesigned, negotiated and maintained company Master Services Agreements (MSA) with Key Suppliers and Distributors ensuring business and quality requirements were met and business risk was acceptable
• Drove Corrective Action to resolve all quality and performance issues through the NCMR and CAPA

processes
• Established supplier and procurement processes and continuous improvement initiatives as the company grew. Implemented regular supplier reviews and metrics to ensure control and manage
business risk

Customer Service
• Established Policies and Procedures for System Installation, Service, and Preventive Maintenance
• Lead the day to day Service Delivery effort for the company including scheduling and deployment of Field Engineers
• Drove weekly Complaint review meetings to maintain timely action plans and closure
• Engaged as executive partner with the Sales organization for resolution of customer escalations as required

DIRECTOR OF QUALITY

SUNRISE LABS - Bedford, NH - May 2011 to May 2014

Bedford NH May 2011 - May 2014
Sunrise Labs is a full service product development consulting firm for medical devices and life sciences instrumentation.

DIRECTOR OF QUALITY
• Instituted Quality Management System and drove continuous improvement activities.
• Demonstrated Executive leadership through multiple successful ISO 13485 and ISO 9001 Certification and Recertification audits. No findings for two consecutive years.
• Provided project leadership and client interface to all Quality and Regulatory related consulting engagements.
Engagements included:
Development of a complete QMS and prepared the organization for their successful ISO 13485 certification audit for a Pulmonary Function Test device design and manufacturing
ISO 606601 3rd edition GAP analysis and documentation remediation for a cardiac device controller for a Left Ventricular Assist Device
Reverse engineered, documented and conducted Verification and Validation of the system hardware and software of a Fully Automated In-Vitro Diagnostic product
Hardware and Software Verification and Validation of a Convective Patient Warming system
Developed Design Control Standard Operating Procedures (SOP's)and Lead the development team through the creation of the required Design Input and Output documentation for an Electronic
Controlled Chest Drain
Generated Design Control SOP's for an early stage software company developing Breast Density assessment products for digital mammography

PRINCIPAL/FOUNDER

NEW HARBOR SQA - North Andover, MA - January 2001 to May 2011

North Andover MA Jan 2001- May 2011
New Harbor was a management consulting firm dedicated to assisting medical devices companies developing and testing software. Providing the leadership and guidance to ensure the Quality and Regulatory requirements were met while achieving the client business objectives.

PRINCIPAL/FOUNDER
• Built a highly successful management-consulting firm from the ground up, providing strategic and operational solutions that supported clients' performance objectives.

• Led engagement planning and execution of a wide variety of endeavors for clients that ranged from a start-up medical device company through large multinational firms.

Engagements included:
Quality lead for a widely distributed product development team delivering a Cardiac Implantable Therapeutic Device.
Conducted Quality and Regulatory GAP analysis for multiple clients leading to efficient and actionable plans to be implemented by the client or through staff augmentation.
Developed Computer System Validation GAP analysis, requirements generation and test protocols for a Medical Implantable Textile Manufacturer in support of their plant wide process validation effort
Conducted a QMS GAP analysis and created a remediation plan for an Enterprise Level Clinical Trials Management Software client
Quality lead including contract negotiation of a $2.5M outsourced product development and testing effort of an enterprise storage virtualization product. The project was delivered on time and on budget and met all specifications.

SENIOR STAFF CONSULTANT-SOFTWARE TESTING

INTEGRATED QUALITY SERVICES - Marlboro, MA - June 2000 to December 2000

Marlboro MA June 2000 - Dec 2000
IQS was an independent product testing and consulting organization utilized by client companies to support their
product development efforts

SENIOR STAFF CONSULTANT-SOFTWARE TESTING
• Drove business development and leadership of software testing group providing outsourced testing to a full range of commercial product companies

Earlier Work History Available on request

EDUCATION

Bachelor of Science in Electrical Engineering in Electrical Engineering

WORCESTER POLYTECHNIC INSTITUTE - Worcester, MA

Executive Leadership Program

BABSON COLLEGE - Wellesley, MA

Certificate in Medical Device Regulatory Affairs

WORCESTER POLYTECHNIC INSTITUTE - Worcester, MA

Certificate in Medical Device Management

Worcester Polytechnic Institute, Bioengineering Institute

Certificate in Software Quality Assurance

Northeastern University

SKILLS

Quality Assurance (10+ years), Regulatory Compliance (10+ years), OPERATIONS (10+ years), Customer Service (10+ years), Corporate Governance and Compliance (10+ years)

AWARDS

Boston Society Award from American Society for Quality, Boston
For Demonstrated Meritorious and Most Distinguished Achievement on Promoting the Quality Principles and in exemplifying the ideals of the Quality Profession.

ADDITIONAL INFORMATION

Core competencies include:

• Global Regulatory • Quality Management • Corp Governance &
Affairs Systems Compliance
• Business Operations • Customer Service • Supply Chain
• Due Diligence & Integration • Strategic Planning • Process Re-engineering
• Risk Management • Product Life-cycle • GAP analysis & Remediation
• Balanced Scorecard • Complex Project leadership