Resume of
DEBORAH IAMPIETRO

OVERVIEW:
Over 30 years of experience in the areas of Quality Assurance, Quality Control, Regulatory Affairs and Clinical Affairs. Significant experience with the implementation and maintenance of quality systems in accordance with US FDA QSR and ISO regulations. Extensive background in regulatory submissions (510k, IDE, PMA, technical files, design dossiers) in both domestic and international areas.

EXPERIENCE:

2004 **Regis College – Wellesley, MA – Faculty**
Medical Device Regulatory Affairs - Regis College - Master of Science - Health Product Regulation Program

2003 – Present **ISO 13485 Lead Medical Device Auditor for SGS Registrar and Notified Body**
Audits for ISO 13485, MDD, CMDR, Sterilization, Technical files

1998 - Present **QRC Consulting Associates - President**
Owner/operator of quality, regulatory and clinical consulting business. Providing consulting to the medical device industry in the area of quality systems and ISO 9000 implementation and compliance, regulatory submissions both domestic (510k, IDE, PMA) and international, product testing and protocol development, sterilization and packaging validation, biocompatibility assessments and assistance with software QA and validations.

1998 **Galileo Corporation - Sturbridge, MA**
Manufacturer of Medical Devices and Scientific Detector Products
Corporate Director of Quality and Regulatory -
Responsible for all aspects of the Quality Assurance and Regulatory Affairs functions for 3 business divisions, including all activities related to supplier qualification programs, complaint handling, quality engineering, process validations, incoming inspection, internal audits and corrective actions. Responsibilities also include both domestic and international submissions and approvals, including ISO 9001 registration and CE Marking of devices.

1996 - 1998 **Assurance Medical - Hopkinton, MA**
Start up Manufacturer of Class III Medical Device
Director of Clinical and Regulatory Affairs -
Responsible for the development of all aspects of the clinical trials and regulatory programs for a start up manufacturing facility. Write clinical protocols, obtain IRB approvals, implement protocols, monitor, and initiate and close out sites. Work directly with FDA to develop acceptable clinical protocol. Set up all Clinical, Regulatory and Quality systems programs.

1994 - 1996 **St. Jude Medical/Cardiac Assist Division - Chelmsford, MA**
Manufacturer of Cardiac Assist Devices
Director of Quality Assurance and Regulatory Affairs
Responsible for all aspects of the Quality Assurance and Regulatory Affairs functions: daily QA activities, quality engineering (disposable and electrical) including assuring compliance with international medical device directives and electrical safety standards, complaint and MDR systems, 510K, IDE and clinical programs, labeling and literature reviews, field corrective actions. Responsibilities include both domestic and international submissions and approvals. Also responsible for field service activities.

1993 - 1994 Vision Sciences Inc. - Natick, MA
Manufacturer of Endoscopic Products
Director of Quality Assurance and Regulatory Affairs

Responsible for all aspects of the Quality Assurance department including vendor programs, complaint reviews, quality engineering, new product design reviews, process validations, document control, incoming and inprocess inspection. Also responsible for all aspects of the Regulatory Affairs function including MDR reporting, 510K submissions, FDA escorts and regulatory compliance, and compliance with UL and electrical safety standards.

1988 - 1993 Boston Scientific Corp.- Watertown
Manufacturer of Disposable Medical Products - Cardiovascular and implant products
Quality Assurance Director/ Regulatory Compliance Manager

Directing a staff of three managers (Biological, QE, and QC) responsible for the implementation of a total quality system and just in time manufacturing, including, quality cost and vendor programs, process and product validation. Involved with all phases of new product development, including preparation for IDE, PMA, and 510k submissions. Involved with the assessment and implementation of ISO 9000. Responsible for the complaint and MDR systems. Written 510(k) and PMA supplements.

1984 - 1988 Haemonetics Corporation, Braintree, MA
Manufacturer of Disposable Medical Products
Manager of Disposables QA

Responsibilities include managing the incoming inspection function, injection molding and disposable products inspection, metrology and quality engineering. Also, interfaced with R&D to ensure successful introduction of new products, vendor and product qualifications, and product transfers to off shore facilities. Additional responsibilities include management of Document Control, CAD programs, customer complaint/failure analysis, technical support and various regulatory submissions and MDR reporting.

1982 - 1984 Delmed Inc, Canton, MA
Manufacturer of Sterile Pharmaceuticals
Quality Control Manager

Responsible for all aspects of the QC function at two facilities; incoming, in-process and final product - physical, chemical and biological testing.

Production Supervisor

Responsible for qualifying and operating entire RF welding, aseptic filling, sterilization and packaging operations with responsibility for approximately 50 direct, indirect and supervisory personnel.

1980 - 1982 U.S.C.I. - Div C.R. Bard, Glens Falls, New York
Manufacturer of Disposable Medical Products
Quality Assurance Lab Supervisor

Responsible for physical and chemical test labs, writing specifications, test methods and standard operating procedures, statistical program development, and vendor liaison.

1976 - 1980 Astra Pharmaceutical, Worcester, MA
Manufacturer of Sterile Pharmaceuticals
Development Chemist, QA Analytical Chemist

EDUCATION:

1996	Obtained Lead Assessor Certificate for ISO Auditing
1985	MBA - Bentley College, Waltham, MA
1976	Fitchburg State College, Fitchburg, MA Bachelor of Science in Chemistry

PUBLICATIONS:

Medical Device Reporting: A Global Perspective for the 21st Century, W. Cady and D. Iampietro, Medical Device and Diagnostic Industry Magazine, May 1996.

ISO 1345:2003 Maintaining Control of Outsourced Processes, Medical Device and Diagnostic Industry Magazine – Guide to Outsourcing, August 2006.

PROFESSIONAL AFFILIATIONS:

Board member for the New England Biomedical Discussion Group
of the American Society for Quality (ASQ)
Member of ASQ
Member of RAPS
Board Member to Regis College Master of Science in Public Health Policy Degree Program
IRCA Registered Lead Quality System Auditor

Professional Presentations:
Post Market Compliance – ASQ New England Biomedical Conference
Complaint Handling and MDR Reporting – ASQ Monthly Meeting and BOSCON (ASQ Annual Conference)
Overview of the FDA Regulations - Course within the Biomedical Engineering Program at Worcester Polytechnical Institute
Instructor – Medical Device Regulatory Affairs - Regis College - Master of Science - Health Product Regulation Program