Rita M. Wadleigh
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Work Experience:

General Comments

Numerous positions below overlap in their duration. On more than one occasion I have held permanent full or part time positions while continuing to consult for other medical device manufacturers.

During the times covered by this resume I was asked to speak at numerous events for the American Society of Quality (ASQ) and I was proud to participate. These presentations focused on the FDA Quality System Regulations, the ISO 9000 Standard, and Internal Auditing.

Device Compliance Consulting, LLC, Hollis, NH September 2009 – present
Principal/President

The business description provided below applies today.

Integra Luxtec, Inc., West Boylston, MA,
Director, Quality Assurance and Regulatory Affairs June 2007 to September 2009
Quality Assurance and Regulatory Affairs Manager September 2002 to June 2007

Luxtec is the world's leader in illumination devices for surgery – light sources, fiberoptic cables and headlight systems. The majority of Luxtec products are Class II 510k products.
I manage the Luxtec Quality Management System and support regulatory activities such as 510k filings, compliance testing and international product registrations. I am responsible for the CAPA System; Internal Auditing; Complaint Management; the Product Development Process including Risk Management and Post Market Surveillance; developing the facility Master Validation Plan; OEM customer support; Incoming and Final QC; the Document Control function; international product registration support and quality record retention. In addition, I organize the Management Review Meetings and am the Management Representative for FDA, ISO and customer Audits. Luxtec was acquired by Integra LifeSciences in May of 2007. I'm proud to say that the Luxtec Quality Management System serves Luxtec well while satisfying all regulatory and quality system requirements for a medical device manufacturer.

Device Compliance Consulting, LLC, Hollis, NH, October 1996 to 2002.
President

Device Compliance Consulting (DCC) was a consulting firm specializing in the development or enhancement of the quality management systems of smaller medical device manufacturing companies.
DCC consisted primarily of myself although I contracted additional consultants occasionally and often assisted other consultants. DCC worked with over 20 small medical device manufacturers including Physiometrics, Hologic, Maxilon, Matrix Technologies, and Luxtec; the majority of which manufactured FDA Class II devices. DCC provided ISO and FDA quality system training; QMS development; internal auditor training; internal auditing; corrective action management; and 510k/513g regulatory support. The systems/processes I helped develop were designed with the company size in mind and ensured that each organization could support the processes efficiently and collect the quality data needed to continue to improve their quality system and grow their company.

Maxilon Technologies, Amherst, NH October 2001 to January 2004
Maxilon is a medical device developer specializing in dental surgical devices. I worked closely with the President of Maxilon to develop their QMS. At that time Maxilon was a small medical device start-up company in the early stages of organizing production. After about 6 months I was asked to serve as their Manager of QA/RA on a permanent part time basis. I chaired Management Reviews, approved engineering changes, handled customer feedback, tracked corrective actions, and managed internal audits, etc. I also managed regulatory matters as they arose.

Matrix Technologies Corporation, Hudson, NH, June 1999 to March 2001
QA Manager/ Quality Engineer
Matrix Technologies developed and manufactured highly accurate pipetting devices for use in lab testing. I was responsible for Quality System development, implementation, and training. This included the management of document control, customer complaints, calibration, the product calibration lab, and corrective actions. I also worked with the Director of QA/RA to develop the monthly quality reporting to executive management on the status and effectiveness of the quality management system.

SleepNet Corporation, Manchester, NH February 1994 to October 1996
(formerly Innovative Medical Systems)
Regulatory Affairs/ Document Control Coordinator/Internal Auditor.
SleepNet Corporation was a medical device manufacturer specializing in products to alleviate the symptoms of Adult Obstructive Sleep Apnea. My responsibilities involved coordinating all regulatory and document control efforts in support of the introduction of five new products - three electromechanical medical devices and two non-electrical reusable devices, all class II 510k products. My responsibilities also included maintaining regulatory compliance throughout SleepNet and managing Internal Audits.

UroMed Corporation, Needham, MA, July 1991 to June 1992
Sr. Project Engineer
UroMed was a start-up company specializing in medical devices to alleviate the symptoms of urinary incontinence. My responsibilities supported new product research and development.

CR Bard, Inc., August 1984 to July 1991
Staff Engineer-Technical Liaison, Billerica, MA and Galway, Ireland, 9/89 to 7/91.
Section Head, Advanced Engineering and Development, Billerica, MA, 7/ 88 to 9/ 89.
Product Engineer, Advanced Engineering and Development, Billerica, MA, 10/85 to 7/88.
Manufacturing Engineer, Glens Falls, NY, 8/84 to 10/85.
All of my experience at Bard involved the cardiology division, primarily angioplasty catheters.

Education and Certifications:

ASQ Certified Quality Auditor (CQA) since 1998 (Past QS-LA)
BS, Mechanical Engineering, Clarkson University, Potsdam, NY, 1980.
AS, Engineering Science, Monroe Community College, Rochester, NY, 1978.

Professional Organizations:

Past and Current Member of the Executive Board of the Biomedical Division of ASQ.
Past Chairman of the Board for the New England Biomedical Discussion Group (NEBDG-ASQ).
Member of the American Society of Quality (ASQ).