

JENNIFER M. MARRONE, M.B.A.

Jennifer Marrone is a Founder of RCRI, Inc. and a Principal consultant in worldwide regulatory and clinical affairs. She has 25 years experience in the medical device industry, including preparing regulatory submissions (PMAs, IDEs, HUDs/HDEs, 510(k)s, dossiers, technical files, etc.) as well as in negotiating with governmental authorities, interacting with clinicians, as well as successfully organizing and managing professional staff in regulatory, clinical and quality system/compliance departments for several medical device manufacturers (of varying employee size). Her experience in executive management, staff development and management, along with her hands-on expertise in regulatory, quality and clinical affairs, both US and internationally, enable her to provide innovative service to the medical device industry.

Jennifer holds a Master's Degree in Business Administration. She is actively networked throughout the medical product industry and welcomes opportunities to present on regulatory affairs, clinical study and quality/compliance topics at industry and trade association meetings.

EDUCATION

M.B.A. 1991 University of St. Thomas, St. Paul, MN
B.G.S. 1982 University of Minnesota, Minneapolis, MN

PROFESSIONAL ACTIVITIES, HONORS AND DISTINCTIONS

Co Chair: Medical Alley Regulatory Affairs Special Interest Groups, April 2001-present
IACUC Chairperson: Charles River Laboratory/River Valley Farms Research Laboratory, 1999-present
Member: Medical Alley, 1990-present
Member: Regulatory Affairs Professional Society, 1990-present
Committee Member: Medical Alley Cost Effectiveness Task Force, 1994-1995
Medtronic Technical Achievement Award, Canine Tumorogenesis, 1993
Medtronic Star of Excellence, Epicardial Defibrillator System PMA, 1992
Medtronic Tachyarrhythmia Customer Focused Quality Award for PMA, 1992
Abstract: Benditt D.G., Stokes K.B., Marrone J.M. Long Term Canine Performance of a Porous Steroid Electrode. The University of Minnesota and Medtronic, Inc., Minneapolis, MN. American Heart Association 57th Session, November 1984.

LECTURES

"General vs. Specific Indications for your Medical Device Label", October 2003, RAPS Annual Meeting.
"Overview of U.S. Regulatory Requirements for Devices", RAPS Essentials of U.S. Regulatory Affairs, Web cast Series, June 2003
"Meetings with CDRH", Biomedical Focus, April 15, 2003, Minneapolis, MN.
"Regulatory Strategies and Techniques", RAPS Principles & Practices, September 9, 2002, Minneapolis, MN.
"Technical Requirements from a Regulatory Perspective; Design Principles, Manufacturing & Controls", RAPS Principles & Practices, September 9, 2002, Minneapolis, MN.
"FDA Today and Tomorrow: A Perspective on Agency Change", December 8, 1999, Medical Alley, 11th Annual Device Seminar, Minneapolis, MN.
"FDA Auditing of Corporate Clinical Files/Departmental Procedures", January 20, 1999, Medical Alley Clinical Special Interest Group, Minneapolis, MN.

"Demonstrating the Value of Healthcare Technology: Cost Effective Guidelines for the Industry", July 1995, Biomedical Focus, Minneapolis, MN.

"How to Prepare for an FDA Advisory Panel Meeting", 1995, Medical Alley Regulatory Affairs Special Interest Group, Minneapolis, MN.

"ISO 9000 Registration Planning: Perspective of a Small Company", November 1993, Minnesota Department of Trade, St. Paul, MN.

VOLUNTEER ACTIVITIES:

University of St. Thomas, Mentoring Program, 1999-present
Cottonwood Foundation, Board of Directors, 1991-1995
Women Achieving New Directions, 1991-1993
Connect US/USSR Program, Soviet Business Women's Visit, 1991