

**MARIE MARLOW**  
President & CEO



**Professional Experience:**

M SQUARED ASSOCIATES, INC. - Washington, DC  
**Founder, President & CEO**, April 2001 to present.

HEALTHTRONICS, INC. - Marietta, Georgia

**Vice President, Clinical and Regulatory Affairs**, September 1996 to April 2000: HealthTronics is a service provider and distributor of medical devices based on extracorporeal shock wave (ESW) technology. Accomplishments: FDA approval of 2 original PMA's, one for an established technology in 65 days and one for a first of a kind new technology in 9.4 months. Successfully guided the overseas manufacturing facility through 3 major FDA Quality Systems inspections without any significant 483 observations.

BIOMETRIC RESEARCH INSTITUTE (BRI), (now Quintiles Transnational) - Rockville, Maryland

**Senior Technical Advisor**, May 1995 to August 1996: BRI was a leading FDA regulatory consultant and clinical research organization (CRO). Accomplishments: Project manager for Class III orthopedic and cardiovascular implantable devices.

CAMBRIDGE HEART, INC. - Bedford, Massachusetts

**Director of Regulatory and Clinical Affairs**, February 1994 to May 1995: Cambridge Heart is a developer and manufacturer of noninvasive diagnostic cardiac devices based on measurement of T-wave alternans. Accomplishments: Member of start-up management team. Clearance for a first-of-a-kind cardiology diagnostic technology via the 510(k) process.

BARD ELECTROPHYSIOLOGY - Haverhill, Massachusetts

**Director of Regulatory Affairs**, September 1993 to February 1994: Bard EP is a division of C.R. Bard, Inc., that manufactures steerable intracardiac catheters and computerized monitoring systems. Accomplishments: successfully completed 2 intensive FDA GMP inspections without significant 483 observations; PMA Supplement approval for a new software product.

INTRA-SONIX, INC. - Burlington, Massachusetts

**Director of Clinical and Regulatory Affairs**, June 1989 to August 1993: Intra-Sonix was a medical start-up company and developer of an integrated ultrasound and laser device for minimally invasive surgery. Highlights: Managed multisite U.S. clinical trials; obtained European Ministry of Health approvals for a Class III minimally invasive surgical system.

HOWMEDICA DIVISION OF PFIZER, INC. (now Stryker Orthopaedics) - New York, New York

**Clinical Programs Manager**, June 1988 to June 1989: Howmedica / Stryker Orthopaedics is a worldwide leader in the development and manufacture of orthopedic implants and trauma systems. Accomplishments: Managed clinical studies for implantable spinal fixator devices.

ADVANCED BIOSEARCH ASSOCIATES - Danville, California

**Regulatory / Clinical Consultant**, June 1987 to June 1988: ABA was an FDA regulatory consulting firm specializing in medical devices. Highlights: Primary clinical consultant for a bone growth stimulator clinical trial.

XENOTECH LABORATORIES, INC. - Irvine, California

**Manager, Clinical Affairs**, September 1985 to June 1987: Xenotech was a medical start-up company and developer of tissue heart valve and prosthetic ligament devices. Highlights: Managed multisite clinical trial with U.S. and international investigational sites.

UCSF MT. ZION MEDICAL CENTER - San Francisco, CA;  
UCLA MEDICAL CENTER - Los Angeles, CA;  
CEDARS / SINAI MEDICAL CENTER - Los Angeles, CA;  
LA COUNTY / USC MEDICAL CENTER - Los Angeles, CA

**Registered nurse** June 1975 to September 1985: Areas of specialization included operating room, orthopedic surgery, cardiovascular surgery, and emergency services.

**Education:**

Registered Nurse: California Hospital School of Nursing / University of Southern California (USC) School of Nursing.

Additional undergraduate studies: California State University Long Beach; St. Joseph's College of Maine.

**Publications / Presentations:**

Ogden, J.A.; Alvarez, R.; Levitt, R.; Cross, G.L.; Marlow, M. Shock wave therapy for chronic proximal plantar fasciitis. Clin Orthop (2001 Jun) (387):47-59 (Comment in: Clin Orthop. 2002 May; (398): 267-8; discussion 268-9)

Ogden, J.A.; Alvarez, R.G.; Levitt, R.; Marlow, M. Shock wave therapy (Orthotripsy) in musculo-skeletal disorders. Clin Orthop (2001 Jun) (387):22-40

Ogden, J.A.; Alvarez, R.G.; Marlow, M. Shockwave therapy for chronic proximal plantar fasciitis: a meta-analysis. Foot Ankle Int (2002 Apr) 23(4):301-8

Marlow, M. Medical Device Compliance. in Fundamentals of Regulatory Affairs, 2003 Update. Rockville, Regulatory Affairs Professional Society.

Marlow, M. Moderator, "Update on Third Party Review and the Accredited Persons Program." Regulatory Affairs Professional Society, Annual Conference, Baltimore, October 19-22, 2003.

Marlow, M. Presentation, "U.S. Overview: Regulatory and Reimbursement Considerations." Marcus Evans Global Orthobiologics Conference, London, November 20-21, 2003.

Marlow, M. Moderator, Medical Device Panel Session, "Clinical Development". Tri-State SBIR Forum, Roanoke, VA, March 21-23, 2006.