

CHERITA JAMES
Regulatory Consultant I



Professional Experience:

M SQUARED ASSOCIATES, INC. - Washington, DC
Regulatory Consultant I, April 2004 to present.

HIGH MEDICAL TECHNOLOGIES-USA - Atlanta, GA

Senior Clinical Specialist, Feb. 2002 to April 2003. HMT-USA is the US distributor of the VersaTron, extracorporeal shock wave devices designed for treatment of musculoskeletal disorder in veterinary medicine. As Senior Clinical Specialist, duties included: Protocol development, study initiation and site management of ESWT clinical trials; Communication with US and European clinical investigators to stay abreast of protocol information and provide this information to device users in the US; Development and implementation of clinical applications programs for veterinarians and distributor representatives; Conduct onsite training throughout the US and Canada regarding device use and appropriate indications for treatment; Providing customer support for clinical and technical concerns; Representing HMT-USA as an exhibitor at regional, national, and international symposiums; and Assist in ongoing sales and marketing strategies.

HEALTHTRONICS SURGICAL SERVICES, INC. - Atlanta, Georgia

Manager, Applications and Training, July 2000 to Jan. 2002. HealthTronics is the US distributor for HMT-AG of the OssaTron ESWT device for treatment of human musculoskeletal disorders.

As Applications Manager, the responsibilities included: Development of physician training program for ESWT treatment of plantar fasciitis; Coordination of nationwide physician training program; Training and supervision of 2 training assistants and 22 technologist providing OssaTron services throughout the US; Monitoring marketing materials, labeling, device use and maintenance in regards to FDA regulations and product liability; Providing customer support to orthopedic surgeons, podiatrist, and surgical staff for clinical and technical concerns; and Assist in ongoing marketing and reimbursement strategies.

Clinical Applications Specialist, May 1998 to July 2000. As clinical applications specialist with HealthTronics, the duties were: Performing device operations and protocol compliance of 3 multi-center, class III FDA clinical trials; Training and monitoring of investigators/staff at clinical sites to insure compliance with FDA protocol; On site study monitoring of multiple sites, and assisting research department with data management, adverse event reporting and GMP inspections; Communication of device failures/complications with the regulatory department and manufacturer; Observing treatments abroad and designing protocols for future indications; and Representing HealthTronics as an exhibitor at regional, national, and international orthopedic and podiatric symposiums.

Nuclear Medicine Technologist for 15 years in both hospital and mobile settings.

Education:

AS, Allied Health Sciences, Radiologic Technology
Certificate Nuclear Medicine Technology
Certificate Basic Magnetic Resonance Imaging

Professional Licensure:

American Registry of Radiologic Technology- RT,N
Nuclear Medicine Technology Board Certified-CNMT