Sharon L. Timberlake, MSHS, RAC, CCRA

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SUMMARY

Clinical, regulatory and quality professional with over 20 years of experience with Class II & III medical devices, targeting female health, infectious disease, urology, vascular, ophthalmology, dermatology, aesthetics, and general surgery. Proven track record of successful FDA collaborations to obtain 510(k) multiple Premarket Notification clearances and PMA approval, including obtaining the first ever FDA clearance of an over-the-counter Class IV laser device. Industry Representative for the FDA General and Plastic Surgery Devices Advisory Panel. Strong industry ties maintained by active participation with FDA, MassMEDIC, ACRP and RAPS, including multiple presentations at annual professional conferences.

PROFESSIONAL EXPERIENCE

Sharon Timberlake Consulting, Bedford, MA 11/15-current
Provide clients with expert medical device consulting services focusing on U.S. and international regulatory and clinical matters from strategy through commercialization. Perform regulatory, quality and clinical due diligence for medical device company acquisitions.

United States Food & Drug Administration, Silver Spring, MD 09/11- 08/15
Nominated and appointed for a 4-year term as the Industry Representative on the United States Food & Drug Administration General and Plastic Surgery Devices Advisory Panel. Actively participate in the PMA review process and device reclassifications for various devices from the perspective of the medical device industry concentrating in regulatory, quality and clinical matters. Also supported multiple circulatory panel meetings related to device reclassifications and PMA reviews.

- PMA review to expand the indication for use for the Radiesse Injectable Implant (Radiesse) device for hand augmentation.
- PMA review for the Juvéderm Voluma XC sponsored by Allergan.
- TissuGlu Surgical Adhesive indicated for the approximation of tissue layers where subcutaneous dead space exists between the tissue planes in large flap surgical procedures such as abdominoplasty.
- Discussion and recommendations regarding the possible reclassification of blood lancet devices.
- PMA review to expand the indications supported by the BLOCK HF trial to apply to all market-approved Medtronic Cardiac Resynchronization Therapy-Pacemaker (CRT-P) and Cardiac Resynchronization Therapy-Defibrillator (CRT-D) devices.
- PMA review of the CardioMEMS HF System device that is a permanently implantable pressure measurement system designed to provide daily pulmonary arterial pressure measurements including systolic, diastolic, and mean pulmonary arterial (PA) pressure.
- PMA review of the MarginProbe System by Dune Medical, that utilizes electromagnetic waves to characterize human tissue in real time and provides intraoperative information on the malignancy of the surface of the ex vivo lumpectomy specimen.
- Discussion and recommendations regarding classification of external pacemaker pulse generators (EPPGs).
- Discussion and recommendations for the regulatory classification of the Membrane lung for long-term pulmonary support systems (ECMO).

T2 Biosystems, Inc. Lexington, MA
Early stage in-vitro diagnostic company focused on developing innovative diagnostic devices which utilize magnetic resonance technology to diagnosis sepsis, hemostasis properties, and lyme disease.

Vice President, Regulatory & Clinical Affairs 07/14-10/15

- Responsible for successful multiple pre-submission meeting activities related to new device and/or indications for use
- Provide regulatory guidance to leadership team during the course of strategy formulation
- Design clinical protocols for R&D and marketing purposes
- Responsible for overseeing multiple clinical trials related to sepsis, lyme disease, and coagulopathy devices
- Primary contact for FDA filings and facility registrations
- Develop complaint handling process and lead weekly complaint handling meetings

OmniGuide, Inc., Cambridge, MA
Small sized privately held medical device manufacturer specializing in CO_2 surgical laser devices focusing on gynecology, otolaryngology, neurology, and general surgical specialties.

Vice President, Regulatory Affairs & Quality Assurance 01/13-07/14

- Responsible for the Quality System Requirements that applies to ISO/EN ISO, FDA, CMDCAS, TGA and other country requirements
- Responsible for US and international product regulatory approvals and/or registrations
- Responsible for preclinical & clinical trial management that supports marketing claims and product approvals
- Design and review clinical protocols to support research and marketing applications
- Develop worldwide regulatory strategies for innovative laser technology
- Responsible for adverse event/MDR complaint handling process

Palomar Medical Technologies Incorporated, Burlington, MA
Small sized medical device manufacturer specializing in cosmetic, dermatology, aesthetic and general surgical light and laser devices.

Vice President, Global Regulatory Affairs & Quality Affairs 07/03-01/13
(Initial position held was Director of Clinical & Regulatory Affairs)

- Oversee the quality function of the company
- Senior staff team member for overseeing ISO, FDA and other country quality & clinical audits
- Work closely with R&D to develop new product technology
- Participate in management bi-yearly review meetings
- Responsible for communicating all quality and regulatory operations to senior staff and partner companies
- Official FDA correspondent for all Investigational Device Exemptions
- Design and review clinical protocols to support research and marketing applications
- Develop FDA regulatory strategies for innovative technology
- Led several successful FDA pre-IDE meetings
- Obtained first of its kind FDA clearance for over-the-counter laser device
- Obtained over 20 FDA 510(k) clearances
- Oversee Canadian, EU, Asia, South America, Australia and U.S. product registrations and applications
- Responsible for obtaining CE Marking

- Responsible for cleaning and sterility planning and routine device validation methods
- Responsible for managing package integrity testing
- Responsible for adverse event/MDR complaint handling process
- Regulatory input and sign-off for marketing and sales material and product labeling
- Develop all product regulatory strategies
- Participate in corrective and preventive action routine meetings
- Responsible for clinical & regulatory initiatives for joint ventures (Gillette Company/P&G; J&J)

Biosphere Medical Incorporated, Rockland, MA
Small cap company that developed a Class III device used for embolization of hypervascular tumors, uterine fibroids, and arteriovenous malformations.

Manager, Clinical, Regulatory, and Quality Affairs 04/01-7/03

- Oversee daily activities of clinical research organization (CRO) for 11 site clinical trial involving 150 patients including site management, statistics, and data management functions
- Increased patient enrollment schedule by 30% to meet clinical and company timelines
- Managing priorities, budget ($1,200,000) and resources for Clinical and Regulatory department
- Communicating clinical operations to senior staff, CRO, and clinical sites on a weekly basis
- Negotiated with FDA to file 510(k) 3 months ahead of schedule
- No 483 issued by FDA from clinical site inspections
- Managed and participated in successful filing of 510(k) applications for several devices
- Obtained 510(k) clearance for Uterine Fibroid Embolization using Embosphere Microspheres
- Managing complaint process and Medical Device Reporting
- Performing internal quarterly audit of Quality System (QS)
- Performed QS audits of manufacturing facility in Paris, France
- Oversee Corrective and Preventive Actions Program
- Created culture committee (The Big Fish Committee)

Assurance Medical, Incorporated, Hopkinton, MA
Small start-up company involved in Class III Non-Significant Risk medical devices for women's healthcare products.

Clinical Research Project Manager 01/99-4/01

- Evaluated, and selected CRO to oversee a 12 site clinical trial and negotiated a $750,000 contract.
- Project managed CRO to support clinical goals and timelines.
- Developed and presented proposed clinical protocol, regulatory strategy, and trial results at FDA meetings.
- Designed and executed product development clinical protocols for multiple devices.
- Communicated clinical feedback to marketing and R&D to further refine product technology.
- Developed and managed device training programs for clinical sites.
- Selected, initiated, and trained multi-center sites on clinical protocols and procedures for clinical trial start-up activities.
- Negotiated individual clinical site contracts and study budgets.
- Developed educational incentive programs to accelerate patient enrollment.
- Designed, communicated, and implemented clinical trial project timelines in support of PMA.

Clinical Research Associate 04/97-06/99

- Trained R&D engineers on clinical procedures for R&D clinical trials.
- Responsibilities included site initiation, monitoring and close-out of multiple clinical sites.
- Designed case report forms, clinical protocols, and regulatory materials for various studies.
- Created clinical standard operating procedures for start-up manufacturer.
- Managed clinical data collected from investigational centers.

Summit Technology, Incorporated, Waltham, MA
First excimer laser company to receive FDA PMA approval to market device for laser vision correction.

Clinical Research Monitor 07/95-04/97

- Managed 15 clinical centers nationwide to assure compliance with protocol, IRB, and regulatory requirements for class III significant risk medical device studies.
- Trained physicians and their staff nationwide to comply with Summit protocol requirements with Summit and FDA guidelines and regulations.
- Conducted annual audits of 10 clinical centers and investigational device studies.
- Trained clinical research monitors on in-house and on-site procedures.
- Developed clinical procedures and policies for Clinical/Regulatory department.
- Primary contact for clinical sites to troubleshoot and implement resolution of protocol issues.
- Performed data analysis and compiled technical information required for successful filing of a PMA for a class III ophthalmic excimer laser medical device.
- Responsible for organization and archival of patient data records.

EDUCATION

George Washington University School of Medicine and Health Sciences 01/05-5/08

- MS in Health Sciences, Clinical Leadership, with a concentration in Clinical Research Administration
- 3.96 GPA

Fitchburg State University, Fitchburg, MA 09/87-05/91

- BS Business Administration, with a concentration in Marketing.

Boston University School of Medicine, Boston, MA 05/98-05/99

- Clinical Science Research Certificate Program

Northeastern University, Boston, MA 10/00

- University College Certificate in Principles and Practices of Regulatory Affairs

Worchester Polytechnic Institute (WPI), Worchester, MA 12/04

- Medical Device Management Certificate Program

PROFESSIONAL DEVELOPMENT

- Member, Association of Clinical Research Professionals (ACRP) 98-Present
- Local chapter member, Association of Clinical Research Professionals 99-Present
- Member, Regulatory Affairs Professionals Society (RAPS) 99-Present
- Dale Carnegie 12 Week Course 08/02
- Dale Carnegie Team Leader 05/03

- Babson College Leadership and Mentor Program 03/01

CERTIFICATIONS

- Certified Clinical Research Associate (CCRA), Association of Clinical Research Professionals, national certification examination (1999)
- Regulatory Affairs Certified (RAC), Regulatory Affairs Professionals Society, national certification examination (2000)

PRESENTATIONS

- Lead Faculty for Medical Device Submissions and Compliance Strategies for U.S. Market for Regulatory Affairs Professional Society 2 Day Workshop, presented on multiple topics in Rockville, MD. April 2009, April 2010, June 2011, March 2012, March 2013, and March 2014.
- Presentation accepted by the Association of Clinical Research Professionals (ACRP) for the 2008 Annual Conference and Exhibition. Session entitled, "Inspection in Device Clinical Trials: Taking Steps to Ensure Your Trial Succeeds".
- "Adverse Events: A Medical Device Perspective", presented at the 2007 Association of Clinical Research Professionals (ACRP) in Seattle, WA.
- Presentation accepted by the Association of Clinical Research Professionals (ACRP) for the 2005 Annual Conference and Exhibition. Session entitled, "Should We Hire a Contract Research Organization? A Dilemma Facing Small Medical Device Companies".
- "Strategies for Preparing and Facilitating a Successful Pre-IDE Meeting", presented at the Regulatory Affairs Professionals Society (RAPS) Annual Conference and Exhibition, October 12, 2004, Washington, DC.
- "Small Company Perspective: Planning a Clinical Study", presented at the MassMEDIC session on FDA 101-A Primer for the Medical Device Community, March 26, 2004, Waltham, MA. Presentation focused on challenges and considerations when running a clinical study and surviving a bioresearch monitoring audit.
- "How to Hire and Manage a Contract Research Organization", presented at American Society for Quality (ASQ) Biomedical Division seminar for clinical trials for medical devices, November 18, 2003, Needham, MA.