



## **Darla Williams**

*Regulatory Consultant*

Darla Williams has over six years of regulatory experience during which she worked with a wide variety of medical devices and gained experience with the EU, US, and Asia Pacific markets. She has worked extensively with electro-medical devices, wound care, and, most recently, in vitro diagnostics. She has excellent knowledge of the Chinese regulatory system (SFDA) and has had many successful submissions. Previously, Darla was with Siemens Healthcare Diagnostics, ArjoHuntleigh, and Fresenius Medical Care, where she was responsible for regulatory submissions, regulatory compliance, and project management for a variety of product lines.

### **EXPERIENCE:**

#### **Regulatory Consultant, Emergo Group – 2011 to Present**

Responsible for: classification of devices and identification of requirements in global markets, providing both on-site and off-site support for international registration dossiers (particularly within the APAC region).

#### **Regulatory Affairs Manager, Siemens Healthcare Diagnostics Products, Ltd – 2009 to 2011**

Responsible for: updating and creating regulatory standard operating procedures. Reviewed change controls for regulatory impact. Lead the Llanberis team in preparing dossiers for the Chinese registration of 400 products. Solved manufacturing issues directly affecting Chinese registration in order to meet registration deadlines. Participated in the IVDD audit and identified gaps within the technical files and quality system. Lead the 510(k) review across two sites to identify and fill gaps. Streamlined the process involved in preparing legalized documentation for registrations. Participated in the Middle Manager's Monthly Meeting. Participated in the 60% people 40% task initiative for better site management. Participate in company-wide Taiwanese registration by collating and reviewing product line documents for regulatory accuracy. Lead Llanberis team in Indian registration. Organize component testing for Japanese registration. Lead CAPA team resolving USA shipping issues. Participated in the preparation of the ANVISA audit. Participated in the preparation of the FDA audit. Participated in the preparation of the Japanese audit.

#### **Regulatory Submission Manager, ArjoHuntleigh – 2008 to 2009**

Responsible for: global regulatory submissions for four companies (Arjo, BHM, Huntleigh Healthcare Diagnostics, ArjoHuntleigh) under the parent company, Getinge. Registered products in the following categories: diagnostics, pressure area care, topical negative pressure, intermittent pneumatic compression, electric hospital beds, sterile wound dressings, treatment couches, patient lifters, burn treatment baths, and trolleys. Used the Medical Device Directive and various international standards to ensure the regulatory compliance of the various products sold by the company. Regulatory lead for Project Alpha, an ongoing project in which all company documentation and registrations must be updated to reflect the new company ownership. Participated in new product design by providing



regulatory input, guidance, and strategy. Responsible for: sourcing and organizing a centralized registration database for the five companies. Main steer in regulatory strategy and compliance for entering the new markets of Brazil, Japan, and Korea. Main steer for global regulatory strategy in the existing markets. Lead a team responsible for finding a resolution to a historic FDA issue involving US subsidiary, legal counsel, and product management. Liaised with global competent authorities to resolve issues and complete registrations. Advised on regulatory portions of ISO 13485. Assisted in preparing manufacturing locations in Suzhou, China, and Poland for UL audits and Japanese specific audits. Recruited new staff. Managed and trained a staff of two regulatory employees.

### **Regulatory Affairs Manager, Fresenius Medical Care North America – 2006 to 2007**

Worked with Legal counsel and the Vice President of Regulatory Affairs to solve regulatory issues at the Federal Government level. Conducted research regarding applicable regulations concerning the licensing and education required by each state for Primary Care Technicians. Worked with Area Managers, Clinical Managers, and Regional Vice Presidents to prepare regulatory filings for dialysis clinics. These filings helped obtain the Medicare number, which allows the clinics to operate and bill for services. Prepared and submit state license applications for dialysis clinics. Prepared and submitted the regulatory filings needed in order to obtain National Provider Numbers for each of our 1600 dialysis clinics. Completed regulatory research pertaining to Fresenius's acquisition of Renal Care Group, Inc. Responsible for the Lockbox Project, a massive filing of regulatory paperwork updating the Federal Government on the regulatory status of each of our clinics. Solely responsible for all regulatory work pertaining to 1600 clinics for the first 7 months in the position while other Regulatory Affairs Manager was out on maternity leave. Worked with Business Unit Presidents, Regional Vice Presidents, and Legal staff to solve regulatory issues pertaining to clinics, staff, or billing. Worked closely with the Compliance Department to solve Regulatory/Compliance related issues within our clinics. Conducted research and participated in the creation of a Pandemic Action Plan for the company. Conducted research and prepared regulatory filings for acquisitions and divestitures of clinics. Assisted in the registration of hemodialysis and peritoneal dialysis machines in the US market.

### **Compliance Project Manager, Fresenius Medical Care North America – 2004 to 2006**

Participated in and coordinated the HIPAA Security Gap Analysis Project for the Products and Hospital Group. Evaluated the use of social security numbers and protected health information within the Products and Hospital Group in order to determine if current procedures were compliant with HIPAA regulations. Responsible for the Q1, Q2, and Q3 Training and Screening Audits for the Products and Hospital Group and US Vascular Access. Responsible for the Q2 Corporate Training and Screening Audit. Assisted the Business Unit Compliance Officer with research pertaining to various health care regulations and their impact on the company (particularly the PhRMA code). Participated in a preliminary HIPAA evaluation of a Peritoneal Dialysis patient database and clinical evaluation application currently under development by the Products and Hospital Group. Responsible for the monitoring of compliance training for the Products and Hospital Group and US Vascular Access. Responsible for the coordination and completion of the 2005 Annual Corporate Compliance Training. Assisted the Business Unit Compliance Officer in the creation and implementation of the Annual Sales and Marketing Compliance Training. Coordinated the Products and Hospital Group Donations Committee. Participated in the Divisional Privacy and Security Officer Strategy Sessions. Participated in the HIPAA Security Task Force. Member of the Products and Hospital Group Compliance Committee. Member of the US



Vascular Access Compliance Committee. Received a promotion to Regulatory Affairs Manager.

**Executive Assistant to CEO, Advanced Care, LLC – 2003 to 2004**

Conducted research pertaining to CMS regulations as well as state, federal, and international health care regulations. Conducted research pertaining to Egyptian Health care regulations and American export laws. Worked closely with legal staff in order to successfully enter the Egyptian market and adhere to federal and state healthcare provider regulations. Worked closely with legal staff to begin the drafting of company compliance and regulatory procedures. Completed and filed all paperwork necessary to operate in the Egyptian market. Completed and filed Medicare 855 forms. Assisted in the procurement of Medicare and Texas Medicaid provider numbers. Responsible for research pertaining to compliance, safety, and regulatory issues. Conducted market research for the both the American and Egyptian market. Created and implemented business plans in both the American and Egyptian markets. Coordinated conferences and presentations. Fielded customer service calls from clients and patients. Dispatched qualified technicians for service calls. Managed the day-to-day workings of the office.

**EDUCATION:**

- BA (Hons) from University of Massachusetts at Amherst, MA