

# Company Description

**SENIOR REGULATORY AFFAIRS SPECIALIST**

**DEXTER, MI**

MC3 Cardiopulmonary is dedicated to developing and manufacturing innovative and effective new extracorporeal life support (ECLS) technologies that will be used to treat severe heart and lung failure. We have experienced high growth over the past few years and have a state-of-the-art production facility and have launched several successful products. This growth is expected to continue as we seek to become the ECLS market leader.

**Position Description:** The Senior Regulatory Affairs Specialist is responsible for regulatory affairs activities in the product development phase of products that are being prepared for clinical evaluations and/or market introduction as well as compliance and reporting activities in the post-market phase. The position is also responsible for developing regulatory approaches for devices under development, planning for clinical evaluations, and preparing pre-market regulatory submissions as well as post approval reports, annual reports, export certificates and establishment registrations and device listings and GUDID updates. Responsible for the preparation of medical device and vigilance reports in accordance with the regulations.

**Job Responsibilities:**

* Prepare and support US and non-US product submissions such as 510(k), PMA, IDE, CE technical file and dossiers. Ensures compliance of submissions with all applicable regulations, guidance, and SOPs for regulatory submissions.
	+ Write and update SOPs, policies and work practices.
	+ Ensure Medical Device Technical Files are accurate and updated in compliance to requirements.
	+ Works closely with product development team to assure timeliness of product clearance and approvals.
	+ Assures that the product technical files are maintained with respect to state-of-the-art information including international standards.
	+ Support the implementation of clinical investigations and post-market activities.
* Review, approve and provide guidance for labeling and advertising of device products.
* Participate in the risk management process and assure the Risk Management file is accurately maintained.
* Provide guidance on regulatory compliance issues related to US and International Quality Management Systems.
* Interact with US and non-US government officials on product approval and compliance issues.
* Responsible for assuring proper response to 3rd party audits and inspection findings.
* Leads Internal Audit Program.
* Maintain up-to-date knowledge of US and international regulations and guidelines (including risk management). Monitor external publication sources for issues applicable.
* Responsible for engineering change evaluation from regulatory perspective in order to determine when notifications and updates to the regulatory authorities are required.
* Implement required activities of post market reporting processes.
* Performs a broad variety of tasks in support of compliance as assigned by the department head.

**Required Qualifications:**

* Bachelor’s Degree or higher in applicable science or engineering discipline or equivalent combination of education and relevant experience.
	+ 4 years professional experience, minimum two year in either RA or QA in medical device industry.
	+ Working knowledge of US Quality System Regulations, EU Medical Device Regulations and ISO standards for medical devices required. Knowledge of worldwide regulations, guidelines and standard industry practices preferred.
	+ Exceptional analytical, problem solving & root-cause analysis skills.
	+ Strong regulatory aptitude ( i. e. able to read & comprehend regulations and technical documentation & execute procedures),
	+ Excellent communication skills (written and oral) and very strong organizational skills. Team player with demonstrated collaboration, negotiation & conflict resolution skills.
	+ Ability to multi-task & handle tasks with competing priorities effectively.
	+ Working knowledge and solid understanding of statistics.
	+ Demonstrated experience and proficiency with MS Office word processing, spreadsheet, presentation, and database applications.

**Desired Qualifications:**

* Additional professional training desirable such as RAPs or ASQ certification or other scientific/technical training.

**Travel Required:**

* + Valid US driver’s license
	+ Travel expected both domestic and international – up to 10%

**Job Specifications:**

* Prolonged periods sitting at a desk and working on a computer.

Send cover letters and resumes to kranella@mc3corp.com with “Senior Regulatory Affairs Specialist” in the subject line.