SynCardia
A Picard Medical Company

SAVING LIVES,
ONE HEART AT A TIME

Job Description

International Regulatory Affairs Manager, Salaried

v. 5.16.24 4:39 PM

Position:
International Regulatory Affairs Manager, Salaried

Reports to:
Director of Regulatory Affairs

Reports to:
Tucson, AZ

Company description:

SynCardia Systems, LLC, a Picard Medical Company, is headquartered in Tucson, AZ. We manufacture and sell the world's first and only US Food and Drug Administration (FDA) and Health Canada approved total artificial heart as bridge to transplant for patients suffering from biventricular heart failure The SynCardia Total Artificial Heart™ is available in two sizes to accommodate patients' diverse physiologies. The Freedom Portable Driver™ allows clinically stable patients to be discharged from the hospital to enjoy life at home while they wait for a heart transplant. The SynCardia Total Artificial Heart™ has been successfully used in over 2,000 patients and is the most widely used and extensively studied total artificial heart in the world. For additional information and label information, visit us at www.syncardia.com.

Position description:

SynCardia is looking for an energetic International Regulatory Affairs Manager. The successful candidate will be responsible for managing SynCardia's international product registrations in Canada, Europe, and in the rest of the world. Specific tasks will include planning, preparing, managing, monitoring, and budgeting the Company's international regulatory affairs projects: coordinating and working with regulatory consultants; and managing and preparing submissions to authorities in SynCardia's international markets. To this end, the International Regulatory Affairs Manager will be working together with Regulatory Affairs, Quality, R&D, and Clinical Affairs professionals at the Company's Tucson site. Moderate travel is required.

Principal responsibilities:

- Assist in the preparation of regulatory submissions and filings, such as applications, amendments, supplements, annual reports, deficiency letter responses, Form 483 responses, warning letter responses, adverse experience reports, recall communications, license renewals, registrations, reports, correspondence, and telecommunications.
- Gather, assemble, and prepare appropriate documents for submission supporting the EU and other international markets.
- Independently research regulatory issues and/or information as directed.
- Independently track and follow-up on Regulatory commitments to assure commitments are completed and maintained.
- Prepare documents, as directed, for internal use or submission to regulatory authorities.
- Support regulatory filing processes in collaboration with a multi-disciplinary professional support staff.
- Independently monitor and improve tracking/control systems for regulatory documents.
- Participate in Design Control meetings with Product Development to provide regulatory input.
- Initiate action to prevent the occurrence of nonconformities relating to the product, process, and Quality System.
- Identify and record potential problems relating to the product, processes, and Quality System.

Job Description

International Regulatory Affairs Manager, Salaried

- Initiate, recommend or provide solutions through designated channels.
- Other duties as assigned.
  Provide regular updates to the Director of Regulatory Affairs and Company management on clinical International Regulatory Affairs statuses, plans, budgets, timetables, and bottlenecks.

Requirements:

- Minimum of 5 years of International Regulatory Affairs experience gained in a similar position with at least 3 years in the cardiovascular device arena
- University degree from a top-tier academic institution in a relevant field
- Extensive knowledge of relevant government regulations, standards and guidelines
- Strong analytical and problem-solving skills & excellent interpersonal and communication skills & team player.
- Proven track record of working in a dynamic, international environment
- Excellent written and spoken English.

Qualifications:

- Proven experience of successfully directing the efforts of diverse teams located across multiple locations/time zones is required.
- Effective team builder and problem solver, exhibiting a collaborative management style and the ability to bring out the best in people through example.
- Strong regulatory and business mind; he/she should be able to visualize future strategy while also outlining and driving tactics to complete the milestones to successfully execute that strategy.
- Comfortable leading the execution of all aspects of International Regulatory Affairs including prioritization of projects
- Advanced experience and knowledge of ISO 13485, MDR, MDSAP & 21 CFR 820.
- Excellent communicator who radiates compassion, integrity, and loyalty to SynCardia and its customers, partners, shareholders, and employee..

Application process:

If you are a team player with excellent interpersonal, communication and leadership skills, have as strong sense of ownership and a proven track record of professional and / or academic accomplishments, you should submit your CV with a cover letter indicating the position you are applying for, and highlighting your motivation, skills, background, and salary expectation to peopleculture@syncardia.com. Only applications in English will be evaluated.

About SynCardia Systems, LLC
SynCardia Systems, LLC, a Picard Medical Company, is headquartered in Tucson, AZ. We manufacture and distribute the world's first and only US Food and Drug Administration (FDA) and Health Canada approved total artificial heart. The SynCardia Total Artificial Heart is the most widely used and extensively studied artificial heart in the world.

The SynCardia Total Artificial Heart (STAH)
The STAH has been successfully implanted in over 2,000 patients suffering from advanced stage heart failure. The implant is available in two sizes to accommodate patients' diverse physiologies. The STAH is approved for sale in the US and in Canada where it is indicated for use in cardiac transplant-eligible patients at risk of imminent death from biventricular failure. EU and international approvals are pending. For additional information and label information, visit us at www.syncardia.com.

About Heart Failure*
Heart failure (HF) is a growing burden for the United States and other developed countries due to the aging of their populations. Approximately 6.7 million individuals had HF in 2023 and the prevalence of advanced stage HF has been estimated to be as high as 25% of the total HF populations. Approximately 300,000 (5%) of advanced stage HF are refractory to guideline directed therapy.

Medical Advice Disclaimer
The information, including but not limited to, text, graphics, images, and other components contained in this material are for informational purposes only. No information in this material is intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or a qualified health care provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of information you have read in this material.

** Bozkurt B, et al., J Card Fail. 2023 Oct;29(10):1412-1451; (2) Abouezzeddine et al., Congest Heart Fail. 2011 Jul-Aug;17(4):160-8.*

SynCardia Systems, LLC
1992 E. Silverlake Rd. Tucson, AZ 85713 | US
+1 520-545-1234 | info@syncardia.com
www.SynCardia.com

#SynCardia