Manager, Regulatory Affairs

Haemonetics - Greater Boston Area

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Job description

Manager, Regulatory Affairs

Accountable to drive and complete all regulatory submission and compliance requirements for a specific product line or business unit. Partners effectively with Regulatory team in other regions/ geographies as needed (OUS) and assists with compiling appropriate technical information for various regulatory submissions. Responsibilities include:
• Facilitate accurate and timely approval of submissions by ensuring compliance with FDA and Health Canada regulations and interpretations.
• Interact with regulatory agency personnel in order to expedite approval of applications, and responses to questions.
• Partner with R&D, Marketing and other cross functional groups to compile appropriate technical information for supporting various regulatory submissions.
• Ensure compliance with Federal Drug Administration (FDA) regulations and function as a contact for the FDA as needed for respective product line or business segment.
• Participate in FDA and other regulatory agency inspections.
• Develop and maintain technical files for compliance to Medical Device Directive (MDD) requirements.
• Provide training and regulatory guidance, subject matter expertise to product development teams regarding specific product submission requirements.
• Responsible for the development and submission of documents for FDA and Health Canada including compiling information and handling and developing responses to questions from reviewing agencies.
• Review proposed design and/or labeling changes to ensure regulatory compliance.
• Partner effectively with other Regulatory Affairs staff and cross functional departments to develop regulatory approval strategies for products.
• Work with the Quality organization to determine reportability for product complaints.
• Communicate and direct activities pertaining to FDA recalls and safety advisories.
• As needed, conduct training programs to educate employees on regulatory requirements, Standard Operating Procedures and Policies (SOPPs) and good regulatory practices.
• Maintain library of regulatory and clinical standards and accepted practices applicable to

Haemonetics' areas of business.
• Review and approve relevant document changes (ECOs).
• Lead and participate in projects as assigned by managerment to improve regulatory processes and facilitate best practice approach to drive functional excellence.
• Assist customers in addressing regulatory issues with respect to product licensing as needed.
• Develop and track metrics for department performance.

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Desired Skills and Experience

Education and Experience Required

• Bachelor’s Degree. Master’s degree highly desirable.
• Minimum 5 years regulatory experience; quality experience and prior management or supervisory experience beneficial.
• Demonstrated strength in written and oral communication skills.
• Proven leadership ability.
• Demonstrated interpersonal, influence and organizational skills.

About this company

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Haemonetics is THE Blood Management Company. Our comprehensive portfolio of integrated devices, information management, and consulting services offers blood management solutions for each facet of the blood management continuum. Collectively they help improve patient care, ensure patient safety, and reduce costs for blood and plasma collectors, hospitals, and patients around the world.

Our Mission
We believe that through proper blood management, our products and services can help our commercial plasma and blood center customers optimize their collection processes. We seek to help ensure a continual supply of high-quality plasma for biopharmaceuticals and blood components for therapeutic use at optimal costs, along with better blood management processes. Working with our hospital customers, we seek to prevent a blood transfusion to the patient who

doesn’t need one, or, if a transfusion is necessary, to ensure the transfusion of the right blood product, at the right time, in the right dose to the patient who does.

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