Job Title: Regulatory Affairs Specialist

Job Summary: Regulatory Affairs Specialist will focus on ensuring Dynex Technologies is meeting all applicable regulations, such as those established by the Food and Drug Administration, Health Canada, Chinese FDA, and the European Medicines Agency, for products and services relating to medical devices. This individual is responsible for completing and filing marketing applications and post-marketing reports with the appropriate local, state, federal agencies and European Notified Bodies for the company's products.

Essential Functions: Represent regulatory affairs on project teams and provide guidance on how to interpret regulatory requirements for related projects.

- Critically review data and reports from product development teams to assure scientific rigor, accuracy and clarity for inclusion into regulatory submissions.
- Coordinate team efforts associated with the preparation of regulatory submissions for the company's products.
- Compile and maintain regulatory documentation databases or systems to track product registration and submissions globally.
- Perform post market surveillance and post market clinical follow up on marketed products and recommend changes necessary to meet regulatory requirements and customer expectations.
- Develop and conduct periodic employee training on regulatory requirements.
- Participate in regulatory audits, serve as a regulatory content expert during government and third party audits, and lead efforts to address any audit findings.
- Regularly monitor, interpret, and communicate global regulatory changes to management and update corporate policies and procedures, as applicable.
- Review product promotional materials, labeling, batch records, specification sheets, or test methods for compliance with applicable regulations and policies.
- Identify and interpret relevant guidance documents, international standards, or consensus standards to assure the company meets appropriate regulatory requirements.
- Maintain current knowledge base of existing and emerging regulations, standards, or guidance documents.
- Participate in internal or external audits.
- Prepare or direct the preparation of additional information or responses as requested by regulatory agencies.
- Prepare or maintain technical files as necessary to obtain and sustain product approval.
- Prepare responses to customer requests for information, such as product data, written regulatory affairs statements, surveys, or questionnaires.
- Review clinical protocols to ensure adequate collection of data needed for regulatory submissions.
- Write or update standard operating procedures, work instructions, or policies.
- Coordinate recall or market withdrawal activities as necessary.
- Other duties as assigned.

Supervisory Responsibilities: Currently one Regulatory Associate, and manage assigned projects.

Success Factors:

- Knowledge of regulatory requirements related to product development from pre-clinical, clinical commercialization, and post-marketing.
- Proven experience in collaborating in matrix teams in a technical environment.
- Strong program management and project management skills and adept at working collaboratively with cross functional teams.
- Strong interpersonal and communication skills.

Minimum Qualifications / Education:

- BS in science or engineering, plus a minimum 4 years of experience with Medical Devices required. A Master of Science degree is highly desirable.
- Prior working knowledge of regulatory submissions such as 510 (k), IVDD Technical files, etc. Related experience will be considered.
- Prior experience working in a medical device, biotechnology or pharmaceutical company.
- Working knowledge of regulatory requirements for software development is desirable.
- Knowledge of FDA design control (21 CFR 820), electronic signatures (21 CFR 11), Medical Device regulations; EU IVDR, and medical device regulations in other countries.
- RAC certification is highly desirable. A postgraduate certification in regulatory affairs will be considered in lieu of RAC certification.

Travel: Ability to travel in and out of country is required approximately 10% of the time.

Computer Skills: Proficient in Microsoft Windows, Word, Excel, PowerPoint and Visio.

Work Environment: Office.

Physical Requirements: Must be able to meet National Institute for Occupational Safety & Health (NIOSH) Standards.

DYNEX Technologies, Inc. is an Equal Opportunity/Affirmative Action Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, including sexual orientation and gender identity, national origin, disability, protected Veteran status, or any other characteristic protected by applicable federal, state, or local law. DYNEX Technologies provides medical, dental, life and disability insurance, Section 125, 401(k), flexible schedules, educational assistance and a great work environment!

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https://recruiting.paylocity.com/recruiting/jobs/All/c7607535-18ba-4fab-b961-c2f9d9661fef/Dynex-Technologies

If a disability prevents you from applying via the URL provided above, please email your resume and cover letter to hr@dynex.com.
Visit our website www.dynextechnologies.com.