Senior Specialist – Software Product Regulatory Affairs
Job Location – Lexington, MA

Position Summary:

As we expand our portfolio and increase our current advanced technology field, we are looking for a regulatory professional with experience involving electromechanical (including software) devices (knowledge of digital health experience is a plus). The role will provide regulatory advice and support to project teams developing new digital health technologies (such as standalone software, mobile applications, and wearable devices). The successful applicant will collaborate with clinical affairs, product development and a dedicated team of software developers to provide guidance and direct input to multiple programs.

Duties and Responsibilities:

- Be the regulatory expert in development of regulatory strategies, submissions, and processes for this growing segment of the Convatec business.
- Provide input to development teams on applicable regulatory requirements for the device lifecycle (from concept to post marketing surveillance).
- Promote regulatory awareness within project teams and monitor the regulatory environment.
- Ability to discern and explain regulatory pathways for key global markets.
- You will play an integral part of the new product development of our products as well as the maintenance of current accreditations.

Qualifications:

- Submission history for electromechanical devices in the US and Europe.
- Dealing with development teams and providing ongoing and evolving regulatory pathways and strategies.
- Knowledge of design control processes.
- A minimum of a bachelor's degree in Science, Engineering, Medical Technology required. An advanced degree and/or Regulatory Affairs Certification (RAC) is preferred.

- Minimum of at least 5 years of experience in medical device Regulatory Affairs is required.
- Understanding of the regulatory framework for medical devices (hardware and software), as well as cybersecurity.
- Understanding of the Quality System Regulations ISO 13485:2016, recalls and correction and labeling requirements required. International experience with recalls and corrections and labeling requirements is desirable.
- Experience with Class I, II, sterile medical devices.
- Familiarity with Class III, products desirable.

Desired, but not required experience:

- Advanced Degree.
- RAC certification(s).
- In-depth knowledge of preclinical and clinical study rules/regulations.
- Thorough knowledge of other regulations pertaining to the commercialization of medical devices.
- Thorough/Working knowledge of MDSAP (Medical Device Single Audit Program) and EU. Specifically, US Quality System Regulation, Canadian Medical Device Regulation, EU Medical Device Directive or Regulation (EU) 2017/745, and ISO 13485:2016.
- Experience with AI (Artificial Intelligence) and Machine Learning.
- Regulatory Compliance competency (Inspections, Audits, Field Actions).
- International Regulatory submissions experience.
- Clinical Trial experience, including IDE (Investigational Device Exemption) submissions.

Travel Expectations:

- You will be working remotely with potential travel expectations of up to 25%