JOB DESCRIPTION

Position Title: Associate Director, Regulatory Affairs

Location: Charlestown, Massachusetts

Reporting to: General Manager, US

Classification: Full-Time, Exempt

Updated: March 2018

About Theragnostics:

Theragnostics Ltd was founded in August 2015 to develop and commercialize diagnostic and therapeutic agents. Theragnostics Inc was established in November 2016 to provide a US presence through our office in Boston, MA. Our aim is to provide a complete portfolio of products to transform patient care, from initial diagnosis to therapy, including treatment planning and monitoring. Our most advanced product is THG-001, aka Ga-68 THP-PSMA, which is currently under clinical development.

Summary:

The Associate Director, Regulatory Affairs is responsible for assisting with the implementation of international and domestic regulatory strategies to advance Theragnostics' portfolio of radiopharmaceutical products in the US and Canada. This individual will, among other relevant duties: (1) assist with the preparation, coordination, and compiling of applications to foreign and domestic regulatory agencies; (2) respond to common inquiries from customers, members of the business community, and regulatory agencies; and (3) participate in customer complaint reviews to ensure global regulatory compliance.

Essential Duties and Responsibilities: (Other duties may be assigned).

- Compile and maintain regulatory documentation databases or systems.
- Coordinate, prepare, or review regulatory submissions for domestic or international projects.
- Communicate with regulatory agencies regarding pre-submission strategies, potential regulatory pathways, compliance test requirements, or clarification and follow-up of submissions under review.
- Interpret regulatory rules or rule changes and ensure that they are communicated through corporate policies and procedures.
- Provide technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
- Advise project teams on subjects such as premarket regulatory requirements, export and labeling requirements, or clinical study compliance issues.
- Identify relevant guidance documents, international standards, or consensus standards and provide interpretive assistance.
- Maintain current knowledge base of existing and emerging regulations, standards, or guidance documents and distribute updated information regarding domestic or international laws, guidelines, or standards.
- Participate in internal or external audits.
- Prepare or maintain technical files as necessary to obtain and sustain product approval.
- Direct the collection and preparation of laboratory samples as requested by regulatory agencies.

Certificates, Licenses and Registrations: RAC certification is a plus.

Education and/or Experience:

- Bachelor's degree in scientific development or a related field. At least 4 years of regulatory experience in the pharmaceutical industry. Experience in the radiopharmaceutical industry, is a plus.
- Solid working knowledge of drug development process and of FDA regulatory requirements for pharmaceutical products in the U.S. required; knowledge of Canadian regulatory requirements for radiopharmaceutical products is a strong plus.

- Must have successfully submitted INDs, ANDAs, and NDAs to FDA, EMA and other regulatory applications.

Computer skills:

- Proficient with Regulatory Affairs, FDA required software (*e.g.*, Common Technical Document, (CTD), Electronic Common Technical Document, (ECTD) and QMS) and MS Office Suite