JOB DESCRIPTION

Associate Director Quality Assurance
Location: Charlestown, MA

Prepared Date: May 2018

Reporting to: Director Quality Assurance

About Theragnostics:
Theragnostics, Ltd. is a UK-based clinical stage company developing a portfolio of innovative radiopharmaceutical products for both the management and treatment of cancer patients, from initial diagnosis through response to therapy. In 2017, Theragnostics, Ltd. entered into a mutual distribution and manufacturing agreement with ROTOP Pharmaka GmbH. Under the agreement, Theragnostics will distribute select ROTOP products in the U.S., Canada, Australia and New Zealand. To support FDA approval and commercialization in the United States, Theragnostics, Ltd., established Theragnostics, Inc., a wholly-owned subsidiary company based in Charlestown, Massachusetts.

Summary:
The Associate Director Quality Assurance is responsible for providing operational quality support to commercial and clinical teams responsible for the manufacturing and distribution of Therapeutics products. This individual ensures effective communication and constructive working relationships to all functional company groups as well as with external collaborators and regulatory authorities.

Essential Duties and Responsibilities
Additional duties may be assigned.

- Develop and maintain GXP required Standard Operating Procedures (SOPs) and other required documents. Author and/or approve required SOPs ensuring control of GXP operations and activities.
- Provide assistance in the implementation and validation of a Quality Management System (QMS) to be utilized for the control of all quality managed programs and documents.
- Document, resolve or provide assistance to other groups with Corrective Actions, Deviations, Customer Complaints, and Change Controls. Approve actions as necessary and monitor for effectiveness and timeliness of completion.
- Assist in, or perform, periodic reviews of all prescribed programs including Vendor Management, Quality Agreements, Annual Quality Management Reviews, and in the performance of internal audits of quality controlled activities as executed by other departments.
- Assist in the oversight of third party manufacturers (TPMs) and authorized product distributors, including, but not limited to, performance of quality audits as directed by senior management.
- Provide assistance to Quality management during audits performed by external groups and regulatory agencies. Develop action plans to resolve documented observations and ensure adequate resolutions are achieved.
- Review Batch Production Records as received from TPMs.
- Compile data and information required for Annual Product Quality Reviews (APQR).

- Support Regulatory Affairs in the compilation and review of data required for Annual Product Reviews.
- Monitor the development of new ICH/Quality requirements or guidance documents and advise product teams of the impact on the business or development programs.

Supervisory Responsibilities:

May lead and coach other direct reports and other company staff in any quality driven aspect of the company's obligations and responsibilities for providing safe and effective drug products.

Certificates, Licenses and Registrations: None required

Education and/or Experience:

- Bachelor's degree in a science discipline. Master's Degree preferred.
- At least 10 years of experience in the pharmaceutical industry with at least eight years of increasingly responsible experience in Quality Assurance.
- Quality Assurance experience in the radiopharmaceutical industry is a plus.

Abilities and skills Required:

- Strong oral and written communication skills, and negotiation skills
- Willing to set and drive aggressive project timelines
- Capable of strategic thinking and proposing innovative solutions to quality problems
- Comfortable in a results-driven, highly accountable environment where you can make a clear impact
- A team player, who listens effectively and invites response and discussion

Computer skills:

- Experience with MS Office Suite, QMS.

Physical Demands: *The physical demands here are representative of those that must be met by an employee to successfully perform the essential functions of this job.*

- This position requires minimal travel; average travel for this position is ≤25% with some variation based upon the demands of the business imperatives.