Senior Manager, Regulatory Affairs

Astellas Pharma Canada is currently searching for a Senior Manager, Regulatory Affairs reporting to the Director, Regulatory Affairs and Quality. This is a full-time position located at the office of Astellas Pharma Canada., Inc. in Markham, Ontario.

Description:

Responsible for independently providing overall regulatory oversight and direction for assigned therapeutic areas including writing, preparing and/or directing preparation of New Drug Submission (NDS), Supplements, Clinical Trial Applications (CTAs) and Notifiable Changes; interacting and negotiating with Health Canada (HC) on submission related issues; influencing and negotiating regulatory requirements with different local and global groups within Astellas and Health Canada and providing coaching / mentoring of one or more regulatory staff.

Essential Job Duties:

- Develops and implements the overall regulatory strategies for submissions in specific therapeutic areas.

- Independently manages and directs preparation of all components for HC submissions: CTAs, NDSs, Supplements and Notifiable Changes involving the preclinical/clinical/CMC aspects based on the requirements of HC policies and guidelines.

- Independently determines the best ways to present information within regulatory submissions to optimize positive review outcome. Ensures that the compilation and transmittal of submissions are within defined time schedules and meet both HC and Astellas Canada established standards/SOPs.

- Provides direction and prepares responses to HC review questions (Clarifaxes) in consultation with local and global project teams within HC specified timelines. Develop most effective strategy to respond to review issues.

- Influences and negotiates regulatory requirements with HC and Astellas for assigned projects.

- Participates as a member of assigned project teams/task forces (including those coordinated through global development at Astellas US in Northbrook) requiring the interpretation of HC regulations/guidelines on areas pertaining to submissions.

- Actively seeks out knowledge of overall corporate strategy and other general factors that affect the regulatory positions taken within the company and with HC and utilizes this knowledge in the performance of the job.

- Works closely with other individuals/groups in regulatory affairs (both inside Astellas and external) to achieve departmental consistency.

- Interacts with international regulatory staff to exchange information and ensure that information submitted to Canada is consistent with that submitted in other countries.

- Coaches and develops RA staff as required. Participates in the supervision, interviewing, hires of new employees, performance appraisals, objective negotiation, directs the training and development of staff.

Required Qualifications

Master of Science degree in life sciences preferred. Scientific knowledge in specific biological/physical science and ability to apply that knowledge to regulatory issues.

Regulatory affairs experience for 5 or more years; excellent understanding of HC regulations and guidelines. Exposure to health science research and/or pharmaceutical industry manufacturing/development gained through 5 or more years of industry experience.

Excellent writing skills with the ability to meet regulatory requirements and standards. Excellent communication, presentation, negotiation and interpersonal skills are required. Ability to communicate and negotiate effectively and maintain effective relationships.

Proficient in Microsoft Office. Excellent computer skills compatible with current electronic submission requirements and ability to implement future requirements.

Preferred Qualifications

People management experience.

Experience within the Oncology Therapeutic Area

If your skills and experience match our needs, please email your resume to:

employment@astellas.com.

Astellas Pharma Canada welcomes and encourages applications from people with disabilities. Accommodations are available on request for candidates taking part in all aspects of the hiring process.

No telephone inquiries, in-person applications, or agencies please. While we appreciate all applications, only candidates under consideration will be contacted.