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Manager, Regulatory Affairs (Poland)

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Company: Innovaderm

Location: Poland

Category: business-and-financial-operations

Manager, Regulatory Affairs (Poland)

Poland

CRO - Regulatory Affairs

Full-time

The manager, Regulatory Affairs is responsible to ensure the services provided by the regional regulatory affairs department are conducted according to Innovaderm’s standard operating procedures, applicable regulations and good clinical practices and to the Sponsor’s satisfaction. Responsibilities include providing leadership on regulatory activities that lead to global startup of clinical trials, planning and assigning work, overseeing the performance of direct reports and performing annual reviews, addressing employee relation issues, and escalating issues.

We are looking for someone who has:

Experience in managing a team and capable of respecting established timelines

At least years of experience in clinical regulatory affairs in the pharmaceutical, biotechnology and/or CRO industry

Experience with oversight of preparing and submitting part I and/or part II Clinical trial applications following EU CTR

RESPONSABILITIES

More specifically, the Manager, Regulatory Affairs must:

Manages a team of Regulatory Affairs employees. Manages performance, conducts formal performance reviews and participates in talent conversation meeting.

Ensures adequate resources (, headcount, experience, training) to sustain regional activities of regulatory affairs group.

Manages resources selection and onboarding processes for new employees.

Ensures adequate training of regulatory affairs group and oversees regulatory affairs practices to ensure alignment of practices across the team through adoption and use of all process and technology tools.

Ensures the regulatory affairs' activities are delivered on time, within budget, and in compliance to SOPs and regulations. Identifies and reports out of scope activities to project team.

Develops regulatory affairs' practices, improvement initiatives, tools, processes, and training material to support departmental activities.

Provides regulatory submissions strategic advice and may act as point of contact for Sponsors and subcontractors/project teams.

Oversees resource assignments and participates in the preparation, review, submission, maintenance, and tracking of regulatory authority and IRB/IEC submissions.

Ensures adequate review of activities performed outside of the company by subcontractors (, partner CROs, vendors, consultants) to ensure high quality standards before submission. Supports the project teams with oversight of submissions in global regions, such as Asia Pacific.

Prepares and/or reviews master and country-specific Informed Consent form documents.

Assists with the oversight of vendors supporting the department (eg, central IRB, translation).

Oversees regulatory review of essential documents to authorize shipment of investigational product to clinical sites.

Oversees labelling review of clinical trial drug supplies to ensure conformity with regional regulations requirements.

Oversees the activities associated with clinical SAE reporting (tracking and submission to regulatory authorities, IRB/IEC, and Investigators).

Participates in the preparation and review of SOPs and associated tools.

Ensures centralization of start-up global regulatory information and maintenance of the regulatory intelligence database. Participates in regulatory watch activities.

Participates in bid defense meetings, project Kick-off meetings, audits, inspections, and other project related meetings according to the company / client needs

Contributes to the development of project budgets for alignment with the scope of work and to the development of business development proposals to ensure the accuracy of regulatory submission information.

Participates in function and/or corporate initiatives and special project assignments.

Maintains familiarity with relevant current industry practices and regulatory requirements and guidelines. Maintains high level knowledge about regional regulations in the area of company interest.

Employee may be assigned to other responsibilities that do not pertain to their former description, if they have the required experience, are qualified and/or have received adequate training.

REQUIREMENTS

Education

Bachelor’s degree (or equivalent) in life sciences or scientific discipline

Experience

At least years of experience in clinical regulatory affairs in the pharmaceutical, biotechnology and/or CRO industry;

Experience preparing, reviewing, and submitting Clinical Trial Applications and IRB/IEC packages

Knowledge and skills

Excellent knowledge of applicable regional / national country regulatory and IRB/IEC

guidelines and regulations

Experience in team leadership; line management experience an asset.

Excellent knowledge of Microsoft Office suite;

Fluent in English with excellent oral and written communication skills; additional languages represent an asset

Ability to organize departmental work, prioritize different assignments, and work under pressure;

Attention to detail and accuracy in work;

Versatile and comfortable in a multitasking environment;

·Respect established timelines, expectations, priorities, and objectives;

Good knowledge of good clinical practices, and applicable Health Canada and Food and Drug Administration (FDA) regulations/guidelines.

OUR COMPANY

The work environment

At Innovaderm, you will work with brilliant and driven colleagues. Our values
are collaboration, innovation, reliability and responsiveness. We offer a stimulating work environment and attractive advancement opportunities.
In this position, you will be eligible for the following perks:
Flexible work schedule

Permanent full-time position

Vacation, PPK, health allowance

Home-based position with teleworking allowance

Ongoing learning and development

About Innovaderm

Innovaderm is a contract research organization (CRO) specialized in dermatology. Since its beginnings in , our organization has benefited from a solid reputation for the quality of its

research and services exceeding the expectations of its clients. Based in Montreal, Innovaderm continues to grow and expand in North America and Europe.

Innovaderm is committed to providing equitable treatment and equal opportunity to all individuals. As such, Innovaderm will provide accommodations throughout the recruitment and selection process to applicants with disabilities, upon request.

Innovaderm only accepts applicants who can legally work in Poland.

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