

## GLOBAL REGULATORY OPERATIONS LEAD

Bermuda Health Council invites applicants for the position of Global Regulatory Operations Lead.

The Global Regulatory Operations Lead will be responsible for developing and implementing progressive global regulatory strategies for Bermuda's health system, in alignment with the Bermuda Health Council's mission, mandate and strategic goals.

Responsible for leading a comprehensive and strategic approach to developing and executing integrated regulatory operational strategies that account for the complex interplay between health system stakeholders in Bermuda and international partners (including US, EU, Canada, UK, Caribbean), the Global Regulatory Operations Lead will represent the Bermuda Health Council with domestic and international stakeholders, regulatory authorities, contractors and corporate partners. The Global Regulatory Operations Lead will also develop and lead the Bermuda Health Council's regulatory strategy, while providing regulatory support for various projects, and internal/external teams/committees.

### Responsibilities:

- Direct regulatory operational strategies for assigned projects and programs, in collaboration with internal regulatory market leads.
- Lead pre-clinical, clinical, and post-clinical regulatory strategies.
- Identify and assess regulatory risks and gaps within the Bermuda Health system and define strategies to mitigate risks.
- Provide regulatory guidance to Bermuda Health Council's team throughout the research, development, and policy implementation processes.
- Contribute to strategic direction and lead the global regulatory operations submission process with the Health Policy & Regulations team
- Support the preparation of clear and effective legislative submissions.
- Prepare and deliver effective presentations for external and internal audiences.
- Monitor and analyse appropriate regional health regulatory activities in areas of interest to the company.
- Assess impact of regulatory activities on local healthcare programs.
- Manage, mentor and guide direct reports with an array of skills and responsibilities.
- Build and maintain excellent relationships with relevant stakeholders, contractors and health system partners.
- Provide leadership on project teams and subcommittees in all areas of regulatory affairs and product development.
- Provide feedback to Executive Management team.
- Maintain a global view as lead of regulatory operations.
- Oversee the development and execution of project plans, ensuring targets are achieved and provide guidance on process improvement.
- Provide accurate and timely reporting of project status throughout its life cycle
- Any other tasks as designated by the CEO or designate.

### Qualifications:

- Post-graduate degree or equivalent in health/medical, legal, health insurance, or social science field
- Minimum of five years' post-qualification experience within health systems.
- Minimum of three years' experience supervising staff
- Minimum of five years' experience in regulatory operations.
- Experience in health system financing/economics or health policy/regulation
- Knowledge of healthcare systems in high-income countries
- Expert knowledge with respect to the respective regulatory landscapes in relevant partner countries.
- Direct experience in interfacing with relevant regulatory authorities (FDA, CQC, EU Regulatory).
- Experience in interpretation of regulations, guidelines, policy statements, etc.
- Experience and knowledge in the preparation of major regulatory submissions and supportive amendments or supplements.

### Key Knowledge, Skills and Abilities Required:

- Technical and analytic capabilities in policy development and the legislative process
- Strong organizational and planning skills
- Excellent communication and interpersonal skills, with the ability to effectively interact with a variety of stakeholders.
- Highly developed writing and presentation skills
- Excellent problem solving skills and ability to prioritise among competing tasks
- Proven ability to influence individuals, and manage people and contractors
- Excellent time management skills and proven ability to meet deadlines
- Foster effective, positive interactions with stakeholders, and health system partners.
- Ability to lead and influence project teams, committees, etc. to attain group goals.
- Demonstrate excellent leadership and communication skills.
- Ability to represent the organization and regulatory department in project teams, committees and external meetings.
- Demonstrate strong organizational skills, including the ability to prioritize personal workload.
- Strong sensitivity for a multicultural/multinational environment. Experience leading multi-disciplinary teams.
- Supervisory/mentoring experience, including ability to guide, train, supervise and prioritize workload of direct reports if applicable.

Interested persons should apply via Bermuda Job Board or submit their resume and cover letter via email to [crfrancis@gov.bm](mailto:crfrancis@gov.bm) no later than **5pm November 10th, 2022**.

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