REGULATORY AFFAIRS

Director

EMEA, LATAM AND CANADA

Based in Basel, Switzerland

elemed

THE COMPANY

This is an exciting leadership position to join a global Lifescience company at the forefront of healthcare innovation, whose focus is on advancing scientific discovery and improving lives. With almost 10,000 employees worldwide, the company is not just made up of employees but some of the brightest minds in the industry; scientists, innovators, problem solvers and leaders. If you're looking for a company where growth, progress and discovery are core to the mission, look no further. This company enjoys one of the best employee retention rates in the industry!

THE ROLE

Your role as Director Regulatory Affairs EMEA, LATAM & Canada:

The Regulatory Affairs Director will provide leadership and strategic direction for all commercial regulatory affairs topics in key markets; leading teams in Canada, LATAM and Eastern Europe. This is a multicultural, multilayered role, interfacing heavily with the senior leadership of the Global Commercial Organisation within the company.

If you're looking for a technical regulatory role focussed on creating technical documentation, this role isn't for you. This role is all about regulatory complexity across different regions, leading culturally diverse teams and acting as a key strategic partner to the business to support timely registration, regulatory clearance and regulatory approvals in the regions. Do you have a customer orientated, problem-solving mindset?

THE ACTIVITIES

This is a position with a high level of visibility within the company and reports to the Global VP of Regulatory Affairs. As director of regulatory affairs you will:

- Define regulatory strategies taken from evaluating diverse scientific and regulatory issues and drawing risk-based conclusions regarding the best path for introducing products to market
- Provide leadership to local regulatory teams and develop regulatory strategies to achieve timely regulatory clearance in the company's key commercial markets
- Develop the strategy and budget to achieve and optimize these key objectives
- Build a sound working relationship and partner with the leadership of the Global Commercial Organization to set objectives and priorities in line with business goals
- Proactively partner with the relevant registration bodies in order to negotiate cost effective and timely registration pathways
- Lead an international and cross cultural department, managing managers in multiple countries across EMEA, LATAM & Canada. Develop and manage upcoming leaders to improve overall team performance
- Regulatory Intelligence: provide guidance on regulatory changes and opportunities in the region to legal manufacturer teams and executive management
- Foster strong collaborative relationships with the Commercial organisation to ensure that processes relating to the review and approval of promotional material (print/web, scientific publications etc) is consistent and effective.
- Work with peers in order to establish best practices and harmonization across global registration approaches in a rapidly changing and evolving regulatory environment
- Partner with Global QA teams to support complaint reporting requirements, this includes overseeing regional customer and regulatory authority notifications for adverse events, field safety corrective actions, and other CAPA related activities.
- Support key company wide initiatives and transformation projects; IVDR, company site scale ups, new system deployments etc.

THE REQUIREMENTS

We are looking for a strong regulatory leader with a proven track record managing culturally diverse teams. If you are excited by the prospect of working in a growing company that favours innovation and inclusion, this is the role for you! Strong leadership skills, the ability to delegate as well as innovate in light of changing situations required!

Expectations:

- Degree in Life Sciences or Engineering
- Min. 12+ years working experience in medical devices OR IVDs (in vitro diagnostics)
- Multi-layer management experience (managing managers)
- Fluent English
- Regulatory experience (medical device or IVD) covering countries in one of the following regions: EMEA, LATAM, Canada
- Ability to build relationships with other areas of the organisation and influence

INTERESTED *position?* IN THIS

CONTACT ELENA@ELEMED.EU

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