Job Description

Regulatory Affairs Specialist/ Senior Regulatory Affairs Manager

July 2017

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The company

Company:	EQL Pharma
Role:	Regulatory Affairs Specialist / Senior Regulatory Affairs Manager
Reporting to:	Chief Executive Officer
Place of residence:	Lund/Malmö vicinity

”EQL Pharma is looking for a key co-worker to join the most market-driven niche generics company in the Nordics”

EQL Pharma (EQL) is an entrepreneurial pharmaceutical company focusing on simplicity and efficiency at all levels of the value chain to be able to deliver a large portfolio of niche pharmaceuticals to pharmacies and hospitals, with direct sales in the Nordic and by out-licensing for the rest of Europe. EQL is based in Lund, Sweden and employs around 10 people.

EQL is specialised in developing and selling niche generics, i.e. drugs that are medically equivalent to niche original medicines. EQL conducts extensive development in cooperation with leading contract manufacturers and major pharmaceutical companies in Europe and Asia.

Our strategy is to build a large portfolio of generic medicines in areas where the competition is limited, so-called niche generics. We do not focus on specific therapeutic areas, but rather on the opportunities we can identify in primarily the Nordic market for prescription medicines sold in pharmacies or used in hospitals.

EQL has a signed pipe-line of 32 products and an extensive funnel of in-licensing and developmental product candidates.

For more information about EQL, see EQL homepage, www.eqlpharma.com

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The role as Regulatory Affairs Specialist

The Regulatory Affairs Specialist is responsible for ensuring that regulatory strategies and regulatory activities are effectively executed to meet the business objectives and legal requirements. The Regulatory Affairs Specialist reports to the CEO.

Responsibilities and main tasks:

- Manage the activities of Regulatory Affairs within the field of responsibility ensuring the implementation of appropriate and effective regulatory strategies
- Manage and oversee all relevant maintenance activities potentially including Life Cycle Management strategy
- Provide expert regulatory input to strategic decision making; including portfolio review, prioritization, and external communications
- Provide expert regulatory input to in-licensing evaluations and due diligence activities
- Provide advice about regulations to manufacturers/scientists
- Coordinate successful submissions and approval of all applications
- Ensure that quality standards are met and that the deliverables meet strict deadlines and fulfil European regulatory and quality standards
- Plan, undertake and oversee product trials and regulatory inspections
- Keep up-to-date with changes in regulatory legislation and guidelines
- Write comprehensible, user-friendly, clear product information leaflets and labels
- Liaise and negotiate with regulatory authorities
- Develop and establish policies and standards that convey the best practices in the company
- Review and report overall quality status to the management team
- Project management of development of new generic products
- Use a variety of specialist computer applications

Requirements:

- MSc / PhD in a scientific discipline
- Deep experience from pharmaceutical industry from a regulatory affairs perspective
- Knowledge of European pharmaceutical legislation, relevant guidelines, procedures and requirements
- Fluent in oral and written Swedish and English
- IT skills

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Desired Skills/Experience:

- Thorough understanding and demonstrated ability to apply regulatory guidelines/regulations to successful dossier preparation, submission and maintenance
- Ability to develop innovative strategies and creative solutions within the regulatory context within the scope of global requirements and available resources
- Strong initiation and organizational skills
- Outstanding written and oral communication skills, with ability to influence others and negotiate successful outcomes
- Strong analytical skill and technical/ scientific competence
- Attention to details and ability to appropriately assess risks and formulate risk-management strategies, including taking "the big picture" view on various options
- Team-player, able to positively influence team members at all levels with an entrepreneurial "can do" attitude
- Proactive, quick learner and independent worker able to effectively multi-task in a high pressure environment and follow issues through to conclusion
- Experience from working with generics is an advantage
- Experience in pharmacovigilance is an advantage

Opportunities with the role

This is an opportunity to work in a key role with a broad spectrum of responsibilities in a small listed pharmaceutical company and to contribute to the growth of the company. The vision is to build the largest niche generics portfolio in the Nordic countries, where the regulatory function plays a crucial role in this development.

The work is with international focus and performed in close cooperation with several international development partners and licensing partners. Since the company focuses on "first-in-class generic" products, responsibilities include different therapy areas, compilation of full registration files, and direct contact with authorities, primarily in the Nordic countries. The position also includes project management and international travelling.

Contact

For inquires and more information about the position, please contact:
Catharina Herbertsson or Eva Runnerström, Recruitment consultants at PeakSearch.

catharina.herbertsson@peaksearch.se, +46 (0)706 152 772
eva.runnerstrom@peaksearch.se, +46 (0)701 725 379
www.peaksearch.se

Application: Apply for the position at PeakSearch homepage www.peaksearch.se or send your CV directly to either Catharina or Eva, see above.

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