Medina House,
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BAP Pharma
promise delivered

Regulatory Affairs Manager – Medicines Access

Location: Marlow, Buckinghamshire, UK
Salary: Competitive base salary + performance-based bonus
Ref: BAPRAMUK
Hours: Full Time
Contract Type: Permanent
Experience Level: Experienced (non-manager)

Our Company

BAP Pharma are the fastest-growing, independently owned clinical trial supply organisation, with specialist divisions in comparator sourcing, secondary packaging & labelling and medicines access. Our story is one of incredible growth and success, with steady expansion in operations and global presence.

We are a global leader in the clinical trial supply industry, through our expertise, innovation and dedication to providing exceptional value and unrivalled customer service.

We are a team of dedicated professionals, with an open, honest and respectful culture and passion for delivering on our promises to each other and our customers.

We are now looking for individuals who are devoted to providing high quality customer service and helping the business continue its growth. Our people are our greatest asset – our future is exciting, come join us!

Job Description

The Regulatory Affairs Manager will conduct all associated regulatory activities for all markets globally. The role will also contribute to the implementation, leading of projects and building of expertise within the Unlicensed Medicines space.

Responsibilities

- Contribute to Cross-functional Teams and Build Regulatory Expertise and provide regular updates
- Utilise regulatory expertise to develop and deliver optimal regulatory strategies and plans to support the achievement of country business goals for unlicensed supply globally of products on behalf of clients
- Attend relevant team and client meetings with cross-divisional colleagues to provide technical guidance and support for teams as necessary
- Ensure teams understand the potential opportunities and constraints that the latest legislation/upcoming changes to legislation might create for their commercial activities
- Provide regulatory input to commercial strategic and operating planning process
- Use knowledge of EU/national legislation, guidelines, regulatory environment to provide insightful responses to enquiries from cross-divisional colleagues and direct or indirect interactions with external customers
- Advise on matters of compliance, regulatory requirements and regulatory policy
- Partner with above-country operational hubs to prepare and collate information needed for contribution to departmental and ad hoc reports

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- Seek authority advice/clarification if regulatory position is unclear and answers are not available through internal network
- Respond to requests from authorities promptly and accurately
- Proactively take opportunities to develop or enhance working relationships with Regulatory Authorities and trade associations
- Develop and enact appropriate strategies in order to negotiate optimal outcomes for the business and patient on product issues
- Utilise local knowledge of Regulatory authority's expectations, ways of working etc to appropriately direct company strategy. Share updates with colleagues.
- Work with authorities if company position differs from authority position in order to obtain a better outcome for the business/patients as appropriate
- Populate and Maintain Regulatory Databases. Responsible for database entry and the document management of regulatory transactions undertaken at local level
- Participate in ad hoc and routine QC checking of regulatory data bases
- Authority Approvals for Supply of Unlicensed Medicines (Named Patient/Compassionate Use)
- Obtain Following a request from a prescriber and corporate approval, obtain necessary approvals to import and supply unlicensed medicines to address unmet patient needs
- Product Discontinuations: Liaise with internal and external client team/commercial/medical functions and advise on regulatory action required for discontinuation of a product in the country marketplace
- Ensure implementation of Good Regulatory Practice (appropriate for all tasks)
- Adhere to relevant procedures and practices to ensure GRP is maintained

Requirements

- Life sciences or chemistry graduate to honours level or equivalent
- Master's degree, Post Graduate Diploma or PhD preferred
- Relevant Professional Qualifications desirable, (e.g. MSc in Regulatory Affairs)
- Previous experience in Regulatory Affairs (Guidance note 14 Medicines The supply of unlicensed medicinal Products)
- Member of The Organisation for Professionals in Regulatory Affairs (TOPRA) preferred
- Knowledge of the global unlicensed medicines market and or the Pharmaceutical industry is preferred

Competencies

- Excellent communication skills with internal and external partners
- Analytical thinking
- Ability to prioritise effectively
- Results focused with attention to detail
- Ability to multitask
- Excellent written and verbal communication skills
- Able to work on own and make decisions independently, where needed

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Conditions

This role reports to the Global Director Medicines Access. Additional hours may be required from time to time to meet project deadlines. You must have the ability to work under own initiative and as part of a team. Some travel may be required for the purpose of meeting with clients to the USA, Europe and within UK. BAP Pharma are proud to state we have a diverse range of employees, from different cultures and backgrounds and are committed to diversity and inclusion.

You can apply to this role through the BAP Careers Portal here.