JOB TITLE:	Regulatory Affairs Manager
REPORTS TO:	Head of Scientific Affairs
DATE AMENDED:	November 2019

Location: Guildford, Surrey or Felstead, Essex.
Industry leading benefits package.

Zentiva Pharma UK Ltd is a leading manufacturer of generic pharmaceutical products throughout the UK and Europe. With more than 2,500 people across Europe and 2 production sites in Prague and Bucharest we strive to be the champions of Generics and Over The Counter (OTC) medicines to better support people's daily healthcare needs.

JOB PURPOSE

- Assist in the provision of an efficient and proactive Regulatory service to meet the business objectives and deadlines for Zentiva in the UK and EU.
- Manage the review, preparation, submission and follow-up of regulatory submissions to the UK regulatory authorities, to high standards, to ensure that marketing authorisations are obtained and maintained in line with the company's plans and goals.
- Provide strategic input into development of registration strategies for commercialisation of products, both locally and in conjunction with the Zentiva corporate team.
- Assist the Head of Scientific Affairs in developing strategies to optimise the efficient running of the department and to manage the achievement of appropriate registrations. Identify issues which may impact on project timeframes.
- Manage the workload and personal development of staff. Supervise and train other regulatory staff within department as required by the Head of Scientific Affairs.

KEY RESULTS/ACCOUNTABILITIES

Job Description

- Develop and maintain a comprehensive understanding of EU regulatory requirements for marketing authorisations and their application in the UK and Ireland, to enable regulatory submissions to be compiled in line with current requirements. Pro-actively review critical new legislation and guidance documents and disseminate to relevant parties information of importance to the business.
- Plan and participate in the technical review and preparation of high quality regulatory submissions to the authorities within agreed timeframes.
- Monitor the progress of submissions and organise the efficient preparation and submission of responses to deficiencies noted by regulatory authorities, facilitating the earliest possible approval. Inform the Head of Technical Services of deviations from regulatory schedules which may affect product supply.
- Develop and implement regulatory strategies and be proactively involved in the decision-making process in order to achieve registrations in a timely manner and in line with company goals. Consider potential obstacles to approval of regulatory submissions and actively problem solve.

KEY RESULTS/ACCOUNTABILITIES

- Participate in the evaluation of potential in-licence/third party projects, collaborating with other relevant regulatory and quality departments for compliance with regulatory and development requirements. Advise sales and marketing functions of implications to the business and to put forward proposals for further action.

- Ensure that Marketing Authorisations are updated in line with new safety information in a timely manner. Ensure Company Core Safety Information are implemented according to corporate requirements. Prepare and review pack labelling, pack leaflets and Summary of Product Characteristics to ensure compliance with current legislation and registered particulars and take action to secure regulatory approval where necessary.

- Schedule, prioritise and supervise the workload of team members to ensure that targets are achieved and resources are used effectively.

- Communicate with supply chain to ensure regulatory strategy is implemented within agreed time-frames to achieve an uninterrupted supply of compliant product to the market.

- Highlight compliance issues with all products within the portfolio and make proposals for their resolution. Actively solve issues concerning product compliance.

- Develop and build upon established relationships with the UK Regulatory Authorities and other relevant organisations and personnel, both internally and externally, in order to facilitate activities required to meet the needs of the business.

- As necessary, perform administrative tasks to ensure effective operation of the department and company, including updating of the corporate regulatory database, monitor and implement department KPIs.

- Propose the requirement for, and contribute to, the writing and maintenance of Standard Operating Procedures, as required. Formulate proposals for, and drive the development of new initiatives within the department and company.

- Deputise for the Head of Scientific Affairs as required

People Leadership

- Performance manages the team through setting and reviewing priorities. Provides appropriate and timely feedback about performance and coaches team members to help them achieve their goals
- Supports the professional and career development of the team by identifying the skills and competencies that employees need for their current and prospective roles and provide opportunities to learn and practice new skills
- Leads the building of a motivated and engaged team through the use of formal and informal recognition, regular communications and the encouragement of cooperation between individuals and teams.

KEY WORKING RELATIONSHIPS

INTERNAL

Regular, close contact with:

- Zentiva Commercial team
- Global Zentiva Regulatory Affairs
- Supply Chain
- Medical Affairs
- Pharmacovigilance
- Quality
- Manufacturing sites (regulatory site officers and packaging development teams)

Occasional contact with:

- Legal
- IS
- Facilities.

EXTERNAL

Regular, close contact with:

- MHRA

Occasional contact with:

- Trade Associations (BGMA)
- Other Government healthcare bodies

SKILLS, EXPERIENCE & KNOWLEDGE REQUIREMENTS

- A degree in science (preferably a life science), with record of proven success in achieving regulatory approvals in the UK and /or Ireland
- Additional experience in the pharmaceutical industry in a related field is an advantage, in particular a knowledge of the regulatory issues associated with registration of generics
- **A record of proven success in achieving regulatory approvals in the UK.**
- A record of proven success in managing and supervising staff.
- Ability to manage multi-functional projects, and to assess detailed scientific information from a variety of disciplines.
- Good organisational skills and ability to manage multiple projects/priorities under pressure and to cope with tight deadlines. Ability to foresee and respond to potential problems and opportunities.
- Self-motivated with strong verbal and written communication skills. Able to communicate effectively and efficiently with other functional departments in the business.
- Good knowledge of the development process for generic medicines, and capable of critically reviewing and integrating scientific information from a variety of disciplines.

Approved

Date:	
Job holder:	
Manager:	