JOB TITLE:	Head of Regulatory Affairs Zentiva
REPORTS TO:	Head of Scientific Affairs
BUSINESS AREA:	Zentiva Pharma UK Ltd

JOB PURPOSE

- Lead and manage Zentiva UK Regulatory Affairs department.
- Responsible for provision of an efficient and proactive Regulatory service to meet the business objectives and deadlines for Zentiva in the UK and EU.
- Is responsible for interactions with UK governmental agencies in all areas of responsibility, including MHRA, Department of Health and Home Office.
- Oversee 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.
- Develop and implement local UK 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.
- Direct and oversee management of workload and personal development of staff.
- Supervise and train other regulatory staff within department as required by the Head of Scientific Affairs.
- Actively manage relationships with Zentiva corporate regulatory affairs functions to ensure global and local processes and priorities are fully aligned
- Mange third party service providers
- Be responsible for and manage UK Regulatory Affairs budgets
- Actively Engage with external stakeholders and regulators to gain competitive intelligence and to contribute to UK regulatory strategy development.
- Participate in relevant working group of UK Gx association

KEY RESULTS/ACCOUNTABILITIES

Job Description

- Utilise 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

KEY RESULTS/ACCOUNTABILITIES

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.

- Provide regulatory advice and expertise to commercial teams, business development, R&D, alliance partners and other activities related to innovating, developing and enhancing the value of the pipeline.

- Works proactively to build contacts with UK and EU Regulatory Authorities and participates in industry trade groups and regulatory affairs professional societies in order to facilitate activities required to meet the needs of the business.

- Oversee 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.

- 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.

- 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

Management of Resources

- Responsible for setting and management of Zentiva UK Regulatory Affairs budget.
- Adheres to company-defined processes for the selection of and agreement of commercial terms with vendors

People Leadership

- Performance manages the UK Regulatory Affairs team through setting and reviewing

KEY RESULTS/ACCOUNTABILITIES

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

Ethical Leadership

- Takes personal accountability to use personal experience and knowledge, as well as the training and tools provided by Zentiva, to maintain a good knowledge and understanding of all ethics and governance relevant to the role (including the Industry Code of Practice, Zentiva Policies and Procedures and any relevant legal requirements); and demonstrate personal leadership in applying these to all work undertaken.
- Escalates any decisions, or seek the support of colleagues or management if personal knowledge and understanding is not at the level required to carry out any part of the role.

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
- Trade Associations (BGMA)
- Third party service providers

Occasional contact with:

- Department of Health
- 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 managing and supervising staff.
- A record of proven success in achieving regulatory approvals in the UK.
- 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.

COMPETENCY REQUIREMENTS	LEVEL
Act for Change * Cooperate Transversally * Commit to Customers * Strive for Result * Think Strategically * Develop People Makes Decisions * Lead Teams *= applies to all roles in the organisation	*Leading others through People / Project Management*