JOB TITLE:	Regulatory Affairs Officer Zentiva
REPORTS TO:	Regulatory Manager
BUSINESS AREA:	Regulatory Affairs Zentiva
DATE AMENDED:	February 2018

This role will be based in the Zentiva UK offices in Guildford, Surrey.

Zentiva is a generics pharmaceutical company, operating in 25 countries and reaching a target population of over one billion people. Our mission is to provide patients with reliable access to valuable and affordable high-quality, safe and effective medicines. We are the 3rd biggest generics company in Europe and we have ambitious growth plans.

JOB PURPOSE

To achieve success it is critical that the Regulatory Affairs Officer;

- Contributes to timely communication of safety information to Regulatory Authorities, Healthcare Professionals and patients.
- Provides input into plans for development, commercialisation and discontinuation / transfer at a local and Corporate level.
- Contributes to ensuring an uninterrupted supply of product to the market that is in compliance with the licensed particulars.
- **Contributes to the effective running of project teams (e.g. product, supply chain).**

KEY RESULTS/ACCOUNTABILITIES

1. *Develop and maintain a comprehensive understanding of the regulatory environment**,** including data requirements, relating to marketing authorisations for medicinal products in the UK and Europe and for non-medicinal products e.g. Devices. Cosmetics etc , under their responsibility.*

2. Develop an understanding of the commercial environment in the UK and contribute to the commercial success through product teams, including product defence (e.g. issue management). Provide regulatory advice during development, to support life-cycle management and commercial activities. Inform line management and marketing teams of deviations from regulatory schedules which may affect marketing plans.

3. *Use SOP's where applicable. Highlight issues with SOP compliance.*

4. *Primary submissions (e.g. marketing authorisation applications) - establish and maintain the ability to critically review, prepare or manage the preparation of high quality documentation in appropriate format for submission to UK Regulatory Authorities and other Competent Authorities in accordance with timeframes meeting the needs of the business.*

5. Maintenance of marketing authorisations - establish and maintain the ability to critically review, prepare and submit the necessary documentation to the regulatory authorities, including justifications.

6. *Responses to enquiries/requests for further information relating to regulatory submissions - establish and maintain the ability to critically review and efficiently prepare and submit the necessary documentation.*

KEY RESULTS/ACCOUNTABILITIES
7. *Establish and maintain the ability to review labelling, Patient Information Leaflets and Summary of Product Characteristics etc. to ensure compliance with current legislation, registered particulars, Company standards/policies and Company Core Safety Information and to secure regulatory approval where necessary.*
8. *Establish and maintain effective liaison with the UK Regulatory Agency, Non-medicinal Competent Authorities and other relevant organisations and personnel, including marketing, production, regulatory and research and development personnel, both internally and externally, in order to facilitate activities required to meet the needs of the business.*
9. *As necessary, perform administrative tasks to ensure effective operation of the department and company, including updating of local and Corporate databases and registration files. Handle Controlled Drug activities, as required. Contribute to the writing and maintenance of Standard Operating Procedures as required. Contribute to development of new initiatives within the department and company. Actively contribute to Team and Department Meetings and promote the work of the department within the Sanofi organisation.*
10. *Support activities to ensure regulatory compliance, identifying, highlighting and resolving issues where necessary.*
11. *Work with Supply Chain personnel and Launch Manager to agree regulatory strategy and timings, and manufacturing schedules, to achieve an uninterrupted supply of compliant product to the market.*
12. Pro-actively review critical new legislation and guidance documents and disseminate to relevant parties (both within and outside Sanofi Regulatory) information of importance to the business.
13. *Support other activities of the Scientific Affairs Department, as required.*

KEY WORKING RELATIONSHIPS

INTERNAL

Regular, close contact with:

- Medical, Marketing, Supply Chain, Quality Assurance, commercial, all business customers of Regulatory Affairs.
- Zentiva HQ regulatory affairs functions
- Zentiva EMGx department
- Regulatory site officers, packaging development teams and production personnel at production sites

Occasional contact with:

- Legal, Senior Management, IS.
- Other affiliate sites.

EXTERNAL

Regular, close contact with:

- UK Regulatory Authorities to progress applications, provide data, discuss concerns of the Authority and obtain regulatory guidance.
- Other government healthcare bodies and trade associations.

Occasional contact with:

KEY WORKING RELATIONSHIPS
■ Joint venture, licensee, licensor and co-development companies. ■ Staff at third-party manufacturing sites for generation and maintenance of artwork. ■ PAGB, Staff from external companies.

SKILLS, EXPERIENCE & KNOWLEDGE REQUIREMENTS
■ A degree or professional qualification in science, preferably a life science, and preferably some experience in Regulatory Affairs. Additional experience in the pharmaceutical industry or a related field would be an advantage. ■ Familiar with the pharmaceutical research and development process, and capable of critically reviewing and integrating scientific information from a variety of disciplines. ■ Administratively well-organised, have attention to detail, possess strong written and oral communication skills and be able to manage multiple priorities. ■ Training in regulatory requirements should continue, both externally through courses and meetings, and internally, to maintain an understanding of current regulatory requirements and issues

COMPETENCY REQUIREMENTS	LEVEL
Act for Change Cooperate Transversally Commit to Customers Strive for Results	Leading Oneself

Approved

Date:	
Job holder:	
Manager:	