JOB TITLE:	Head of Scientific Affairs Zentiva
REPORTS TO:	General Manager, Zentiva
BUSINESS AREA:	Scientific Affairs
DATE AMENDED:	October 2019

JOB PURPOSE

The Head of Scientific Affairs Zentiva is accountable for leading the scientific affairs function within Zentiva. This will include:

- Leading and managing Zentiva Regulatory Affairs, Medical, Pharmacovigilance and Quality
- Contributing to management of any issue concerning public health related to Zentiva
- Is responsible/supervises the interactions with UK health authorities in all areas of responsibility
- Ensuring that Zentiva works in full compliance to drug regulatory requirements and GxP rules
- Secure active participation in relevant working groups of UK Gx associations and active search for competitive intelligence information
- Leading ethical compliance working collaboratively with compliance, transparency and other divisions to ensure a common approach to all customer facing code requirements, including KOL (Key opinion leaders) interactions.
- To provide strategic input and medical advice on commercial plans from the Scientific affairs perspective.
- To provide key support to the General Manager as member of the management committee in all related matters as needed
- Collaborate with Patient Advocacy Group for patient association interactions and act as point of contact in a cross-functional way representing the Zentiva.
- Ensure transversal support of business development and launching initiatives in areas of responsibility securing in-time launch
- Develop business excellence in all areas of responsibility in line with Zentiva rules
- Secure proper documentation archiving and relevant databases management
- Manage actively portfolio prioritization and optimization
- Is responsible for local subcontractor's management and quality oversight

KEY RESULTS/ACCOUNTABILITIES

1. REGULATORY AFFAIRS:

- Ensure agility in daily interaction with authorities and competitive intelligence
- Cooperate closely with Central RA in regulatory strategies, submission planning and implementation of business excellence measures and business reporting
- Secure and timely complete new regulatory approvals in national and (if relevant) European approval processes
- Accountable for orderly and timely completion of all regulatory requirements to retain the registered product portfolio, its variation and, if decided, termination of approvals.
- Accountable for orderly and timely creation and maintenance of compliant regulatory documentation and labelling documents in line with agreed Ways of Working

KEY RESULTS/ACCOUNTABILITIES

2. MEDICAL:

- To be in contact with external Key opinion leaders
- Leading the Ethical Compliance (transparency reporting)
- Is responsible for Medical compliance - approval of educational, promotional and non-promotional materials and events, adherence to Industry Codes of Practice
- Oversight and management of Medical Information function

3. PHARMACOVIGILANCE:

- Support Periodic Reports (planning, local submissions)
- Ensure local support to Market Research
- Maintain routing of relevant web-links locally presented as a web of Side effects alerts
- Ensure active communication with Sanofi, based on TSA agreement (to forward all case reports and get informed about the local literature & signals)

4. QUALITY:

- Is responsible for implementation and management of all local Quality systems and further lifecycle management according to local legislation and company standards.
- To effectively manage local Quality Service provider to ensure compliance with all relevant Quality / GXP requirements, including;
  - local GMP/GDP licence lifecycle management, GMP training of the local team, and Annual Quality Review execution and management
  - product importation, MBR control, testing and GMP / GDP release if applicable
  - internal / external inspection management, and qualification and further management of vendors and customers within distribution chain
  - regular PQRs review by MAH, and deviation, complaint and CAPA execution and management
  - risk and product alert management, execution and management of product recalls, and Quality assessment of product relating variations if applicable.

KEY WORKING RELATIONSHIPS

INTERNAL

Regular, close contact with:

- General Manager
- Commercial team
- Zentiva HQ regulatory, pharmacovigilance, quality, medical and compliance teams
- Legal (often related to medical compliance)

Occasional contact with:

- Financial Controller
- Business Support Functions

EXTERNAL

KEY WORKING RELATIONSHIPS

Primary point of contact for:

- Respective vendors for PV, medical information and quality services.
- Key Opinion Leaders (KOL), Healthcare professionals (HCPs) and Healthcare organisations (HCOs)
- Health Authorities
- Patient organisations
- Pharmaceuticals trade association
- Research establishments and organisations
- Professional and Learned societies

SKILLS, EXPERIENCE & KNOWLEDGE REQUIREMENTS

- 10 years plus Pharmaceutical Industry experience covering the leadership of transversal functions
- Experience of setting, balancing and managing a budget to target
- Ability and track record of leading, managing and developing teams.
- Detailed knowledge of Regulatory guidelines, Medicines Act and the Human Medicines Regulations, Industry Codes of Practice and standard operating procedures, and experience of their implementation within the business environment
- Knowledge of the structure and management of the relevant national health system

Approved

Date:	
Job holder:	
Manager:	