JOB TITLE:	Quality Assurance Manager Zentiva UK
REPORTS TO:	Head of Scientific Affairs
BUSINESS AREA:	Zentiva UK
DATE AMENDED:	March 2020

JOB PURPOSE

Job Details:
Location: Guildford
Hours: Full time
Benefits: 10% company pension contributions, private medical and dental insurance
Contract: Permanent

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.

We are looking for an experienced Quality Manager to join our team to provide an efficient and proactive Quality service to meet the business objectives and deadlines for Zentiva in the UK, as well as being the Responsible Person on the Zentiva WDA(A).

This role would suit somebody with a degree in science with record of proven success in developing and maintaining a compliant QMS to support both a WDA(H) and MIA in the UK, as well as experience in the Pharmaceutical industry. A qualified auditor with a proven track record of auditing third parties (API, Finished Product – all dosage forms, Warehousing and Laboratories) in line with GMP and GDP.

KEY RESULTS/ACCOUNTABILITIES

Job Description

- Create and maintain an effective Pharmaceutical Quality Management System (QMS) to support MIA 17780 and WDA 17780 and ensure compliance with the requirements of EU GMP and GDP and, Corporate Quality Guidelines.

- Provide strategic input into the business development and new product introduction processes to support the 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 whilst maintaining compliance with the relevant legislation and Corporate Quality Guidelines. Identify issues which may impact on project timeframes and compliance.

- Manage the workload and personal development of staff. Supervise and train other quality staff within department as required by the Head of Scientific Affairs.

- Develop and maintain a comprehensive understanding of EU GMP and GDP regulatory requirements to ensure that MIA 17780 and WDA 17780, and the QMS that supports them, are in line with current regulatory requirements. Pro-actively review critical new legislation

KEY RESULTS/ACCOUNTABILITIES

and guidance documents and disseminate to relevant parties information of importance to the business.

- Develop, implement and maintain an effective QMS to support MIA 17780, WDA 17780 and the requirements of the Zentiva UK business.
- Manage the Zentiva UK GMP and GDP Training Programme.
- Manage the Zentiva UK Product Quality Complaints process.
- Manage the Zentiva UK Internal Audit Programme and conduct Internal Audits in line with the agreed plan.
- Support the Third Party Audit Programme managed by the Corporate QA Department. Ensure that all required audits are planned and conducted to support the UK business function and act as a qualified auditor to support Corporate QA and other Zentiva affiliates.
- Maintain the Quality Department tracking spreadsheets for Documentation System, Product Release, Technical Agreements, Audits and PQRs to ensure that all required documents are in place and are updated when required.
- Manage the PQR review process.
- Manage the monthly Quality Review Meeting process to ensure that KPIs, trends and key issues are reviewed, documented and circulated to the QP, Zentiva UK Senior Management and Corporate Quality.
- Act as the main contact with the MHRA and DMRC in the event of any Recalls or Product Quality Alerts.
- Host and manage any Regulatory Inspections of MIA 17780 or WDA 17780 at Zentiva UK's offices.
- Participate in the evaluation of potential in-licence/third party projects, collaborating with other relevant departments for compliance with quality and development requirements. Advise sales and marketing functions of implications to the business and to put forward proposals for further action.
- Schedule, prioritise and supervise the workload of team members to ensure that targets are achieved and resources are used effectively. Support the work of other team members in their absence.
- Communicate with supply chain to ensure quality 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

KEY RESULTS/ACCOUNTABILITIES

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 QMS, the quality department and Zentiva UK, including updating of the Corporate Track Wise database, monitor and implement department KPIs

- Deputise for the Head of Scientific Affairs as required

Management of Resources

- Adheres to company-defined processes for the selection of and agreement of commercial terms with vendors
- Understands and uses internal procedures and tools to ensure the compliant and efficient operation of the "Purchase to Pay" process.

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

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.

Environmental and Safety Leadership

- To care for his/her own safety and wellbeing and the safety of others, and to co-operate with the company to ensure a safe place of work. Employees are therefore expected to: -
    - Support and conform to Company safety rules and procedures to ensure a safe and healthy working environment
    - Report any accident, incident or near miss, whether it be of personal injury or property damage.
    - Assist in the investigation of accidents with the objective of introducing measures to prevent recurrence.

KEY RESULTS/ACCOUNTABILITIES

  - Thoroughly read all safety documentation issued by the Company and comply with its requirements. Escalate any doubts or uncertainties to their supervisor and/or manager.
- To ensure the overview and management of arrangements for the health, safety and wellbeing of their team, maintaining compliance with legislative requirements and with the Company's policies.
- Ensure that all new employees undertake HSE Induction Training
- Ensure that employees receive sufficient information, instruction and training to carry out work safely
- Where an employee is required to drive a motor vehicle for their role, ensure that the appropriate professional driving skills training is completed and reviewed.
- Regularly include health, safety and wellbeing matters on the agenda of departmental meetings
- Investigate, report and record, with the assistance of the HSE Manager, all accidents and near misses, however slight.

KEY WORKING RELATIONSHIPS

INTERNAL

Regular, close contact with:

- Zentiva Commercial team
- Global Zentiva Quality
- Supply Chain
- Medical Affairs
- Pharmacovigilance
- Regulatory Affairs
- Manufacturing sites
- Third Party Warehouses

Occasional contact with:

- Legal, IS, Facilities

EXTERNAL

Regular, close contact with:

- MHRA
- Trade Associations (BGMA)
- Contract Manufacturing Organisations

Occasional contact with:

Other Government healthcare bodies

SKILLS, EXPERIENCE & KNOWLEDGE REQUIREMENTS

- A degree in science (preferably a life science), with record of proven success in developing and maintaining a compliant QMS to support both a WDA(H) and MIA in the UK.
- Eligible to act as Qualified Person or experience in acting as a Responsible Person (preferred but not required)
- Additional experience in the pharmaceutical industry in a related field is a requirement, in particular a good in depth knowledge of the EU Guidelines on GMP and GDP and experience of managing a QMS.
- Qualified Auditor with a proven track record of auditing third parties (API, Finished Product – all dosage forms, Warehousing and Laboratories) in line with GMP and GDP.
- Experience of managing regulatory inspections 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.

SKILLS, EXPERIENCE & KNOWLEDGE REQUIREMENTS
• 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:	