EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Maria Formosa Cassar

WORK EXPERIENCE

April 2019- Present

Medicines Inspector

Malta Medicines Authority (Malta)

Encourage and ensure the effectiveness and efficiency of the QMS, including development and update of quality documents.

Inspection of premises and systems used in to determine GxP status and their follow-up.

Evaluation of administrative and quality/technical data submitted in support of applications for variations and renewals of GxP authorisations, in line with established procedures, current legislation & standards.

Assessing CAPAs following inspections, drawing up and signing inspection reports and pre- and post-inspection letters.

Keeping an up-to-date record of all work done including hard and soft copy records on electronic system used by the Authority.

Managing systems that ensure effective and efficient batch recall procedures and quality defects procedures.

Evaluations, reporting and forming conclusions on batch recall incidents and quality defect monitoring.

Monitoring the quality and safety of authorised medicinal products through a post-marketing surveillance programme.

Technical liaison with, and advice to applicants and professional colleagues in order to facilitate the assessment process.

Continuously engage in updating and ensuring knowledge of new technologies and updated standards and guidelines through ongoing professional education and review of the published literature, including training whilst also identifying annual training requirements and training sources.

Enforcement of regulations governing medicinal products and their follow up in line with MMAs policy, including judicial proceedings.

Participation in operating units of the MMA and execution of professional duties in such a manner to contribute to the efficiency and effectiveness of the MMA.

Representing MMA at meetings, seminars, conferences and other fora, both locally and abroad.

April 2017-April 2019

Qualified Person

APL Swift Services (Malta) Ltd (Malta)

Release of batches in accordance with the Marketing Authorisation, the Manufacturing Authorisation, GMP and legal requirements.

Assist in the investigation of quality related deviations and customer complaints, and support execution of corrective and preventative actions and related documents to ensure compliance is achieved and maintained.

Review and approval of manufacturers change requests.

Co-ordination of return/s and recall/s along with Manager, Quality Unit.

Quality audits of API and finished dosage form manufacturing sites as per the vendor compliance program.

Signing GMP declaration forms for API suppliers as appropriate and when required.

Quality audits (self-inspection).

Review and approval of periodical Product Quality Review.

Assist in the generation, review or approval of Standard Operating Procedures, Corporate Policy Statements and other defined critical documentation.

Assist and participate in internal GMP training sessions and training requirements within the Quality Unit.

Contribute to the continuous development and improvement of Quality systems, processes and

procedures.

Review and approval of validation documents.

April 2016-April 2017

Regulatory Affairs & Pharmacovigilance Team Leader

APL Swift Services (Malta) Ltd (Malta)

Assists the Quality Assurance Manager in the management of the Quality System according to the EU GMP.

Assists the Quality Assurance Manager in the upkeep of the Regulatory and Pharmacovigilance System.

Management of RA-PV Team in day to day activities including:

Receipt, reporting of customer complaints and follow-up investigations with the manufacturer and the customer.

Receipt, reporting and follow-up of ICSR (Individual Case Safety Reports) to Global.

Pharmacovigilance Department (GPVD).

Receipt and reporting of any general or medical enquiries to Global Pharmacovigilance Department (GPVD).

Upkeep and maintenance of local product Marketing Authorisations and PV documentation.

Analytical test methods and specifications regulatory compliance review.

Review and distribution of the Product Approval Package (PAP).

Review and evaluation of Manufacturer's change requests.

Review and approval of Printed Packaging Materials Artwork.

Review and maintenance of (Item) Master Data.

Maintenance of Supplier audits and qualification system.

Verification and maintenance of suppliers/ customers certifications and licensing status.

Review and maintenance of Business Partners Master Data.

Upkeep and maintenance of GMP technical agreements.

Maintenance of system for management of Controlled Drugs in line with current legislation.

Assists the Quality Assurance Manager in quality investigations.

Assists the Quality Assurance Manager during regulatory and customer audits.

Compilation/ review of periodical Product Quality Reviews.

Participates within the vendor compliance program by performing audits.

April 2013-April 2017

Responsible Person (RP)

APL Swift Services (Malta) Ltd (Malta)

Implementation and maintenance of a quality system for the distribution of medicinal products.

Developing and revision of Standard Operating Procedures (SOPs) for carrying out tasks related to GDP.

Organizes training sessions on GDP.

Review and approval of change requests and deviations related to GDP.

Quality audits (self-inspection) as per internal audit schedule.

Investigates customer complaints.

Initiating and co-ordinating batch/ product recalls.

Keeping appropriate records of any delegated duties.

Monitoring handling of medicinal products including transportation.

Ensuring that adequate storage conditions are maintained at all times.

Ensuring that adequate records are maintained and are readily available for audit purposes.

Ensuring that suppliers and customers are approved.

Approval of subcontracted activities which may impact on GDP.

Final disposition of returned, rejected, recalled and falsified products.

Approval of returns to resalable stock

December 2012-April 2017

QA Officer

APL Swift Services (Malta) Ltd (Malta)

Receipt, reporting of customer complaints and follow-up investigations with the manufacturer and the customer.

Assists the Quality Assurance Manager in quality investigations.

Receipt, reporting and follow-up of ICSR (Individual Case Safety Reports) to Pharmacovigilance Department (PVD).

Receipt and reporting of any general or medical enquiries to Pharmacovigilance Department (PVD).

Upkeep and maintenance of local product Marketing Authorisations (pertaining to MAH: Aurobindo Pharma Malta) and PV documentation.

Analytical test methods and specifications regulatory compliance review.

Packaging Component Artwork Compliance.

Review and distribution of the Product Approval Package (PAP).

Review and approval of Printed Packaging Materials Artwork.

Review and maintenance of (Item) Master Data.

Quality audits (self-inspection) as per internal audit schedule.

Upkeep and maintenance of GMP technical agreements.

December 2012- Present

Locum Pharmacist

VJ Salomone Pharma Limited, Various (Malta) (Malta)

Dispensing of POMs and OTC Medicines to patients.

Assisting patients/clients with any queries on their medication.

Up keeping of daily register/controlled drugs/temperature register.

Ensuring that good stock levels are maintained in the pharmacy.

November 2012-December 2012

Pharmacist

Chemimart Group, Hamrun (Malta) (Malta)

Ordering of Medicinal products from approved suppliers.

Assisting and advising patients with queries about their medication.

Dispensing of prescription only medication and over the counter medication

EDUCATION AND TRAINING

October 2008-October 2012

Master of Pharmacy

University of Malta, Msida (Malta) (Malta)

Skills required to be able to approach development of skills required in pharmacy within the local and the EU legal framework governing the production, supply and use of medicines.

Skills for the application of principles of chemistry and biological sciences to development, formulation and use of drugs.

Principles, skills and knowledge of good quality in the development and distribution of medicines.

Able to safeguard patient safety.

Skills in scientific report writing and to develop research skills.

Capacity for lifelong learning.

Demonstrate critical understanding of care frameworks and a comprehensive understanding of evidence-based therapeutic interventions.

Interpret and evaluate patient data in relation to prescription of medicines and the patients overall needs while liaising with other healthcare professionals.

Promote health, wellness and disease prevention.

Manage medication distribution and inventory control in the light of pharmaceutical processes including risk management strategies.

Critically analyse evidence and literature.- Analyse and interpret data, dissemination of results and research report writing.

- ### Certificate of Attendance for Inspire Leadership Training Programme & One to One Coaching

Think Talent (Malta) (Malta)

ADDITIONAL INFORMATION

Expertise

GMP

GDP