QA-RA Compliance Officer

Number of Positions: 1

Contract Type: Indefinite

Job description

Assists the Quality Assurance Manager in the day-to-day operation and management of the quality system according to EU GMP and GDP.

- Updates QA documentation maintain quality logs and document registers.
- Participates in the self-inspection program to audit operational practices and staff for compliance with established documentation, policies and procedures.
- Perform training sessions on GMP/ Quality topics for company personnel.
- Compilation/ review of periodical Product Quality Reviews.
- Report all findings related to quality deviations in a report and if required, in a way that all relevant parameters are traceable and easily understood.
- Assist in quality deviations and support the execution of corrective and preventative actions and related documents to ensure compliance is achieved and maintained.
- Liaise and support department managers in the implementation of CAPA identified from the findings related to deviation investigation.
- Assist the immediate superior in problem solving exercises and other exercises aimed at improving quality and efficiency.
- Receipt, reporting of customer complaints and follow-up investigations with the manufacturer and the customer.
- Analytical test methods and specifications regulatory compliance review.
- Review and distribution of the Product Approval Package (PAP).
- Review and approval of Printed Packaging Materials Artwork.
- Review and maintenance of (Item) Master Data in Oracle.
- 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 in Oracle.
- Upkeep and maintenance of Quality Technical Agreements and Service Agreements.
- Oversees the manufacturers' change control program in relation to regulatory updates.
- Review CAPAs to ensure all actions are implemented and adhered to for quality compliance. Oversees the CAPA Program to monitor the effectiveness of CAPA, as a means of continuous improvement.
- Reviews and process internal change requests. Participates in Change Control assessments, as required, and project meetings to ensure the compliant status of affected equipment/ systems/ processes is not compromised.
- To liaise effectively with other departments to ensure assigned validation exercises are conducted in a timely manner and in compliance with GMP.

- Ensures all new and existing equipment is assessed appropriately and validated for its intended use. Coordinates procedure/ process testing and provides reviews of audit trails.
- Ensures all software used for the generation of Good Manufacturing Practices (GMP) activities meets the standards required for data integrity compliance.
- Review of protocols and reports from other departments/ companies.
- Performs risk assessments to determine high risk equipment and determines appropriate corrective action.
- Upkeep and maintenance of local product Marketing Authorisations (pertaining to MAH: Aurobindo Pharma Malta).
- Participate in quality audits of Aurobindo and third-party API and finished dosage form manufacturing sites.
- Assists the Quality Assurance Manager during regulatory and customer audits.
- Carry out other duties as may reasonably be required.

Requirements
- English language skills
- Diploma/Degree in Sciences

Training provided
Induction Training
On the job training

Any assistance with accommodation/relocation
One time re allocation bonus to anyone reallocating from outside of Malta

Any other benefits
- Health Insurance
- Gym Benefits
- Mobile and home plan internet benefits

Salary
24,000 – 26,000 EUR per year

How will the interviews be held
Online

To apply
CVs and a covering email are to be sent by email to **eures.recruitment.jobsplus@gov.mt** and should be written in English. Please quote the vacancy name and number in your email.