chanelle

Qualified Person / Compliance Officer

BASIC SUMMARY:

To ensure that all products are released in accordance with GMP guidelines and the relevant marketing authorisations.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

1. Responsibility for batch release as per EU guidelines by ensuring the following requirements have been met:
   a. the batch and its manufacture comply with the provisions of the marketing authorisation (including the requirements for importation where relevant);
   b. manufacture has been carried out in accordance with GMP (in the case of an imported batch that it has been manufactured to standards equivalent to EC GMP);
   c. the principal manufacturing and testing processes have been validated (account has been taken of the production conditions by review of the relevant documentation);
   d. any deviations or planned changes have been duly authorised. Any changes requiring variation to the marketing authorisation have been notified and authorised by the relevant authority.
   e. all the necessary checks and tests have been performed;
   f. all necessary production and Quality Control documentation has been completed and endorsed by the appropriate staff;
   g. Forward any incoming reports (whether it is through post, e-mail, fax or in Person) regarding Pharmacovigilance / Adverse Action Reports to the relevant QPPV in a timely manner.
   h. all audits have been carried out as required by the QA system;
   i. take into consideration any other relevant factor that may affect the quality of the batch.
2. Forward any incoming reports regarding Pharmacovigilance/Adverse Action Reports to the relevant QPPV in a timely manner.
3. Partake in Pharmacovigilance audits as required.
4. Conduct Routine Quality Audits of the facility to ensure compliance with current EU GMP, be proactive in resolving issues which may arise.
5. Ensure the Internal Audit schedule compliance as per schedule.
6. Ensure the preparation and compliance of the annual GMP site training programme.
7. Conduct External audits, compile reports and manage associated responses as required.
8. Management and assistance with the site change control system.
9. Management of the customer complaints system and associated CAPA's.
10. Quality review and approval of validation protocols and reports.
11. Participate in regulatory/customer audits of the site as appropriate and when required
12. Quality approval of rejection notices as appropriate and when required.
13. Signing GMP declaration forms for API suppliers as appropriate and when required.
14. Investigate and approve QC and stability out of specifications.
15. Provide technical support for Product Launch and existing Products, ensuring compliance with the registered dossier

16. Review /lead Process investigations and ensure any such investigations are documented appropriately with relevant corrective actions, if necessary.
17. Ensure Process transfer is documented and conducted in accordance with Regulatory Standards.
18. Quality review and approval of manufacturing documentation for Chanelle & third party contract manufacturing.
19. Provision / Updating of existing Quality Procedures in order to ensure compliance with EU GMP
20. Contributing to the overall improvement of the company from a Quality/GMP perspective with an emphasis on continuous improvement of the quality system.
21. Preparation of Key Performance Indicators for the Quality Assurance department and also assisting in the maintenance of records for the company KPIs as per Quality Management review requirements.
22. Ensure timely feedback on customer/production queries as appropriate.
23. Preparing product quality review schedule and reports for Chanelle and third party contract manufacture products & ensuring compliance.
24. Assist in product investigations and ensuring risk assessment approach is applied
25. Management of the deviation & CAPA's system.
26. Collating weekly & monthly trends and assisting Visual Management & the Quality Material Review Board meetings.

PERSON SPECIFICATION:

- Degree in Science discipline or equivalent.
- Minimum of 5 years' Quality Assurance experience within the pharmaceutical industry; B.Sc. degree as a minimum requirement
- Qualified person named on licence, preferably in solid dose facility
- Strong organisational skills / ability to prioritise work
- Proven track record as a team player
- Excellent communication and presentation skills with a hands-on approach

Chanelle is an equal opportunities employer
(ALL ENQUIRIES AND APPLICATIONS WILL BE TREATED IN THE STRICTEST CONFIDENCE)