Siegfried

Position Description

Title: Quality Analyst
Department: QA/QC
Supervisor: Sr. Quality Manager
Date Last Reviewed or Revised: 03/14/2016

Direct Reports:
None

Scope and Purpose of Position
This position supports the Quality Management System and QA Product Release Group.

Responsibilities

1. Release or reject incoming materials and finished goods for all product lines.
2. Support the implementation and maintenance of an efficient system for reviewing and releasing finished product.
3. Provide support for the QA Complaint system for all product lines. Duties include the receipt and Investigation of complaints, correspondence with internal/external customers and with RA/QC.
4. Investigate specific customer complaints or operational problems to identify root causes and effective corrective and preventive actions.
5. Perform and coordinate QA documentation system. Assist in the review and modification of different manufacturing procedures and documents as part of continuing process improvements. Also provide support in the preparation of QA documentation for the introduction of new product lines.
6. Provide in-process support in the manufacturing of all Alliance Medical Products saleable products.
7. Receive, sample and analyze appropriate samples for the release testing of raw materials and in-process materials. Perform the QA testing on all applicable AMP, FDA, USP, NF, CFR and other standards.
8. Maintain protocols and final report files, reserve samples, product complaints and batch records.
9. Perform internal and suppliers' audits to identify deficient systems or operations to ensure timely delivery of consistent components or smooth efficient internal process and in compliant with GLP, GMP and ISO standards.
10. Perform validation testing to support the release of raw materials, in-process materials and finished product. Prepare and execute protocols/reports to support the validation of new equipment and process/products.
11. Review all notebooks and summary reports for accuracy, completeness and compliance to relevant procedures and standards.
12. Communicate with laboratory personnel/manager to correct and improve deficiencies in data collection, analysis and reporting.
13. Investigate laboratory deviation or systemic problems to identify root cause and effective corrective and preventive actions.

Required Knowledge, Skills and Abilities

- Working knowledge of QA/QC principles
- Knowledge and training in GMP/GLP/ISO guidelines.
- Good computer skills
- Strong attention to detail
- Good oral and written communication skills

Required Education and Experience

- BS degree in Biochemistry, Chemistry, Engineering, Biology or closely related discipline required
- 4 - 6 years' experience in Quality Assurance / Manufacturing environment or equivalent demonstration of completing Quality Analyst duties.