YR = Present year

Scope:

This procedure defines the responsibilities and the competencies and training required for the personnel in the Quality Assurance department of Pharma A/S Lyngby, Denmark.

Summary

The QA department has the main responsibilities to (in no order of priority):

- Implement and control raw materials and product specifications;
- Release, quarantine and rejection of raw materials and final products;
- Facilitate Management Reviews;
- Management and coordination of internal and external audits and training of internal auditors;
- Manage and facilitate the Correction and Preventive Actions system (CAPA);

Release of raw materials

Raw materials are received by the logistics department. Certificate of Analysis (CoA) for received raw material batches are delivered to QA who approve, quarantine or reject the batches according to BIG Pharmas raw material specifications. Results are entered into the Pharma A/S LIMS system.

Release of final products

Quality Control analyze each production batch according to the product specification for the product. Results are verified by the QC Supervisor before being entered into the LIMS system. QA approves, quarantines or rejects the final product batches according to the analytical results and the final product specifications.
Approved batches are automatically transferred to the Sales departments IT system where batch CoAs can be retrieved which contains an electronic signature of the QA person authorizing the release.
For non-approved or returned batches a CAPA register must be done.

Management Reviews

To enhance the managements leadership and commitment to customer satisfaction, product quality and employee development, QA will compile relevant information to issue the status of the key performance indicators for a quarterly Management Review.
QA will facilitate that the action plans defined in the Management Review meetings are being assigned responsible functions and due dates.

Audits

QA manages the internal audit plan and train the internal auditors, see procedure: Internal Audit Program, Doc: PAS-QA-012.EN.

QA will facilitate external audits and together with the external partner or authority, define an appropriate audit program including to convoke the Pharma A/S personnel to participate in the audit.
QA will facilitate the audit practicalities during the audit.
QA will receive the audit report after the audit and facilitate the deviations are transferred to the Pharma A/S CAPA system and responsible functions and due dates are assigned.
QA will compile all relevant audit deviation responses and send to the relevant lead auditor.
QA will file the final audits reports.

QA will audit critical Pharma A/S suppliers according to the criterias defined by BIG Pharma QA guidelines. Based on the audit results suppliers are approved, quarantined or rejected.

Corrective and Preventive Actions

All deviations or aspects with potential negative impact on product quality, e.g. within batch records, production, maintenance, logistics, audits, etc., must be registered in the CAPA system. It is the responsibility of the owner of the information to perform the registration.

The CAPA system should also be used by the organization to register improvement ideas and preventive actions from employees.

QA facilitates that each CAPA register has a responsible function or person and a due date for resolution is being defined.

QA maintains a register of all CAPA records and provide relevant statistics for the Management Reviews.

Training and Competencies of QA Personnel

The Quality Unit Manager must be competent to be approved as Pharma A/S´s Qualified Person according to the Danish Medicines Agency (Lægemiddelstyrelsens) criterias.

The QA engineer must as a minimum have a Master degree in Chemical or Biochemical Engineering or similar relevant education.
The QA technical assistant must have a technical degree like laboratory technician, technician from the pharmaceutical or food industry, or similar relevant education with minimum 3 years experience.

Responsibilities:

This document: Quality Unit Manager

References

Internal Audit Program, Doc: PAS-QA-012.EN.

Change Log

Version	Description	Initials	Date
1	This is first version	Q Unit Mgr	01.05.(YR-1)
2	Implementation of quarterly Management Reviews	Q Unit Mgr	15.06.(YR-1)