YR = Present year

Scope:

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

Summary

The QC department consists of a microbiological and a physical-chemical laboratory.

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

- Analyze raw materials, semi products and final products;
- Implement, document and maintain analytical assays and procedures;
- Receive, control and store production vials from Big Pharmas central vial laboratory;
- Propagate vials for production;
- Give support to production for production optimization projects;

Receiving of samples for analyses

Samples for routine analysis are normally delivered by the operators to the refrigerator in the entrance hallway to the QC laboratory. The samples must be labelled with product or raw material type, batch identification and date.
Each morning (Mon-Fri) the fridge content is emptied, and the samples are evaluated.
According to the number and type of samples the programming of the QC work is done.

Analytical work

All analyses are to be performed according to standard analytical protocols validated and approved by Big Pharma QA, which specifies which analysis to be done and the accept criterias for each individual analysis.
All analytical protocols, standard operational procedures and forms are stored in the Laboratory Information Management System (LIMS).
Each type of raw material and product has an analytical assay protocol.

It is the responsibility of the laboratory technicians to know and follow the appropriate analytical protocols. The number of repetitions for each analysis are stated in the protocols and are determined by statistical evaluation and validation.

Before analytical work is started for a specific batch, the laboratory technician must check the particular batch in the LIMS system for any possible remarks, blockage or quarantine orders issued by QA.

All notes, remarks and calculations regarding the analytical work must be noted in the laboratory logbooks.

Handling of analytical results and data

When the results from the analytical work are ready, the results are entered into the LIMS system by the person who performed the analysis.

The QC supervisor will verify the analytical results in the LIMS typically at the end of the work day. Approved results according to specifications will be approved which means they are transferred to Quality Assurance for final evaluation.

Quality Control analyzes each production batch according to the product specification for the product. 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.

Receiving and storage of production vials

Pharma A/S receives the vials with the microorganism strains for production from Big Pharmas central vial laboratory in the US. According to the production plan schedule for Pharma A/S, the appropriate types and numbers of production vials are sent in special isolated and sealed containers containing dry ice via air freight to Denmark.

At receival by Pharma A/S QC in Lyngby, the container is opened, and the temperature registration unit is retrieved and connected to a PC. The storage temperature during transport is checked and data are stored in LIMS. In case the temperature has been above the specified

max temperature the whole batch of vials is rejected. In case the temperature is OK, the vials are stored in the special vial freezer room at QC.

Only QC personnel and the Quality Unit manager have access to the freezer room.

Each freezer has a power and temperature alarm system. In case of a power outage or if the temperature in a freezer exceeds a certain temperature limit, a light and an alarm will sound outside the freezer room.

Training and Competencies of QC Personnel

The Quality Control Supervisor must have as a minimum a Bachelors degree in biochemistry, chemistry or similar and have min 2 years experience from a quality control laboratory.

The QC Supervisor must be a laboratory technicians or technicians from the industry with minimum 3 years experience in laboratory work or similar.

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	Specification of receiving of vials	Q Unit Mgr	01.09.(YR-1)