

Pharma A/S

Training Program for Operators

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YR = Present year

Scope:

This procedure defines the general training program to all new operators starting at the Pharma A/S production plant in Lyngby, Denmark.

It contemplates process operators, utility operators and logistics operators.

It does not include other functions or operators at other sites of Big Pharma.

Summary of training program

The training program for all new operators contains 5 phases:

1. Introduction to Pharma A/S. Normally during the first month after hire. General knowledge about the company, policies, GMP and safety. Common program for all operators.
2. Introductory training program. 2 to 4 weeks duration on day shift. The new operator is introduced to all the different operator job functions in own department.
3. Intermediate cross training. During the first 3 months after hire. One week introduction to quality control, quality assurance, GMP, and other not own operator functions (production, utilities or logistics) Dayshift.
4. On the job training. The operator starts on the operator team and in the assigned shift work schedule. This training period will have to prepare the operator for certification in a specific job function.
5. Certification in specific job function.

For already certified operators who will prepare for a new certification in another operator job function, the person will do steps 4 and 5.

The training plan template attached as Attachment 1, is started to be registered right after hire.

Operator job functions

There exist four different operator functions:

Production fermentation operator

Production downstream operator (Centrifugation, Ultrafiltration, Evaporation and Spray drying)

Maintenance utility operator

Logistics operator

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Detailed training program

Production:

The Intermediate training program (step 2) for all production operators in training, consist of 4 weeks of observation and training in Production on dayshift including:

- 1 week fermentation
- 2 weeks downstream
- 1 week control room

The Intermediate cross training week (step 3) consist of one week on dayshift to understand the basics of the following functions and how they interact with Production:

- Utilities
- Logistics
- Quality Control and Quality Assurance

On the job training on shiftwork (step 4)

Training in assigned job function together with an experienced operator to prepare for the later certification.

The certification test should normally be done for a maximum of 6 months after the start of the on the job training.

Maintenance:

The Intermediate training program (step 2) for a utility operator consist of 2 weeks of observation and training in all utilities (Steam, Cooling water, Process water, Process air, Compressed air) with an experienced operator:

The Intermediate cross training week (step 3) consist of one week on dayshift to understand the basics of the following functions and how they interact with Utilities and maintenance:

- Production
- Logistics
- Quality Control and Quality Assurance

On the job training on shiftwork (step 4)

Training to prepare for the later certification.

The certification test for the utility operator should normally be done for a maximum of 6 months after the start of the on the job training.

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Logistics:

The Intermediate training program (step 2) for a logistics operator consist of 2 weeks of observation and training in all logistics functions:

Handling and storage of raw materials

Handling and storage of finished product

Shipping of finished product

The Intermediate cross training week (step 3) consist of one week on dayshift to understand the basics of the following functions and how they interact with logistics:

Production

Maintenance

Quality Control

On the job training (step 4)

Training to prepare for the later certification.

The certification test should normally be done for a maximum of 4 months after the start of the on the job training.

Certification

Certification is done in the presence of the trainer and a supervisor.

A special certification test program is provided.

After certification the operator may train other operators in the certified function.

Responsibilities:

This document: Production Manager

The introduction week: HR

Operator training plan, job training and certification:

Production: Production Supervisor

Utilities: Maintenance Supervisor

Logistics: Logistics Manager

Change Log

| Version | Description | Initials | Date |
|---------|---------------|----------|--------------|
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Attachment 1

Training plan template Pharma A/S operator

Operator Training Plan Pharma A/S, Lyngby Site

Full Name:

Hire Date:

To be trained in operator function:

Production Fermentation ☐

Maintenance Utility ☐

Production Downstream ☐

Logistics ☐

Introduction to Pharma A/S

Dates: _____ to _____

Initials/ Date; Operator: _____ HR: _____

Intermediate cross training:

Dates: _____ to _____

Responsible: Initials / Date:

Function:

☐ QC and QA

☐ GMP

☐ Production

☐ Maintenance Utilities

☐ Logistics

On the Job Training (OJT):

Start date: _____

Initials / Date Operator: _____ Trainer: _____

Certification obtained:

Date: _____

Name and initials:

Operator:

Trainer:

Supervisor:

Manager: