AlfaNordic Academy

1-day | GMP - basic

Purpose

The course provides the participants with a basic insight to the principles of quality understanding and patient safety, based on current Good Manufacturing Practices, legislations and standards within the pharmaceutical industry.

Target group

The course is targeted academics and technicians, who aim to achieve a basic knowledge within GMP regulated production environments in the pharmaceutical industry, and not yet having an in-depth knowledge or broad experience within the area.
The course is relevant for newly educated as well as experienced, whom consider applying for or have recently been hired for a job in the pharmaceutical industry.

Content

Course content is covering the mandatory training requirements for employees to perform processes in a GMP regulated production environment. The following topics are discussed on the course:

- GMP-background – Why do we have GMP, how did GMP occur?
- Legislation, regulations and standards – How to transform regulations into practice
- Quality Management System
- Change Request, deviations and CAPA (Corrective Actions and Preventive Actions)
- Introduction to qualification/validation/risk management
- Introduction to data integrity
- Inspections/audits, findings, examples where GMP has been circumvented, warning letters
- Good documentation practices, RFT – Right First Time, batch records, logbook
- Behavior in a GMP regulated production environments (room classification/airlocks, hygiene, gowning)
- Good distribution practices

Teacher

The course is conducted by Susanne Drasbæk Bertram, Senior Consultant, AlfaNordic A/S. Susanne is educated Pharmaconomist and has a broad experience within:

- Regulatory requirements
- QA
- Pharmaceutical production
- Teaching/ training

The course is organized as a combination of lectures and practical activities, to combine theoretical knowledge and practical understanding, with every day examples from GMP regulated production environments.

Learning objectives

The course provides the participants with a knowledge of:

- International guidelines and their intended use through the companies QMS
- Quality understanding and the underlying operational principles and their significance
- Challenges and limitations of working in a highly regulated world

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Date

The course is held the 28th of November, from 9 AM to 4 PM

Course fee:

DKr. 3650,00 excl. local VAT

Venue:

IDA Conference, Kalvebod Brygge 31-33, 1780 København V

Register before the 20th of November to

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