

Start2Pharma: cGMP for professionals new to the industry

1. Goal of the training

This course will provide to professionals new in the industry, a good overview of Regulatory context of working in a Pharmaceutical environment. The participants will become aware of the importance of working with GMPs and will learn how to find the GMPs they need. They will also learn the role of authorities, legislation & inspections in safeguarding pharmaceutical quality. This training can be an addition to the internal GMP training, where this program gives helicopter view and more background.

2. Regulations considered

FDA 21 CFR 211-210-820, FDA guidance, EU V4, SFDA, PMDA, ICH, PICS,

3. Added value

This training will give you a broad background on GMP & Quality in drug manufacturing. It enables you to understand the bigger scope besides what you learn in GMP introductions in companies. The training is given by experts in the field.

Learning Objectives

At the end of the course participants will be able to

- Know & understand the Regulatory context of working in a Pharmaceutical environment
- Identify where these regulations come from & know which regulatory agencies are important
- Learn the differences between law & guidance's
- Find the GMPs on different topics
- Know & understand the basic GMPs important to his/her area

Scope

- Awareness & practice
- Introduction in GMPs where principles are learned
- API & drug manufacturing
- Interpretation of some general GMPs
- Academic level

Foreseen in other modules:

- Good Documentation
- Contamination Control
- Interpretation on specific GMPs
- GMPs for technicians and operators
- Quality In Product Life Cycle

Program

1. GMPs for drug products
2. Why GMP?
3. GMP regulations & GMP Guidelines
4. Different Markets + Differences between US/EU
5. Typical expectations of FDA and European inspectors
6. Other important standards: ICH, PICS, GAMP...
7. Exercises on general & specific GMPs

Methodology

1. Theoretical knowledge
2. Exercise through workshops

Audience

Academic professionals new to the industry

Practical

Language: English

Location: Plasma Industries, Neder-Over-Heembeek

Data: 0.5 day

Trainer: An De Boelpaep / Mik Staes / Bas Vandamme