Training for Life sciences &
Pharmaceutical industry

Start2Pharma: QMS for professionals with 0 – 2 years' experience in the industry

1. Goal of the training

This course will provide to professionals with little experience in the industry, an overview of the importance of Quality systems in a Pharmaceutical environment & the relations between the different systems. This training is an addition to the internal QMS training, which focuses on the "how". This training focusses more on the frameworks & background of QMS and high-level overview on how Quality is built in a drug product. In this specific session we will also teach more details on how to handle non-conformities.

2. Regulations considered

FDA 21 CRF 211-210-820, FDA guidance, EU V4, ICH

3. Added value

This training will give you a broad background in Quality Management Systems expected in API & drug manufacturing. It will enable you to understand the bigger scope. The training is given by experts in the field.

Learning Objectives

At the end of the course participants will be able to

- Know the basic requirements of a Quality Management system and how this helps to safeguard Quality of your product.
- Discuss ICH Q10 : Manual on QMS
- Identify the different quality systems & their underlying relations.
- Understand the basic principles of how Quality is built in a drug product: RA, validation, change control, process controls ….
- Know the basics of deviation control
- Handle non-conformities, write root causes & rationale
- Understand where human errors come from.
- Write a CAPA & understand the basic principles.

Scope

- Awareness, giving helicopter view on the importance of Quality systems.
- API & drug manufacturing
- Practice deviation handling
- More detailed training is foreseen in the training modules below

Foreseen in other modules:

- GDP & Technical writing skills
- Quality In Life Cycle of drug product
- 6Sigma: DMAIC in root cause analyses
- Human error
- Validation & change control training
- Structure on Documentation

Program

1. QMS overview
2. ICH Q10
3. QMS relations
4. Quality in product life cycle:
   - RA
   - Change control
   - Validation
   - Stability
5. Handling non-conformities
   - Root cause analyses
   - Handling deviations
   - Human error
   - CAPA

Methodology

1. Theoretical knowledge
2. Exercise through workshops

Audience

Academic professionals new to the industry

Practical

Language: English

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