Training for Life sciences &
Pharmaceutical industry

Quality in Life cycle of a drug product

1. Goal of the training

This course will provide an overview of the different phases in the life cycle of a pharmaceutical product. The participants will learn how a pharmaceutical product is developed, how the quality aspects of the product are established & maintained. Also the role of authorities, legislation & inspections in safeguarding pharmaceutical quality will be explained. The training will provide insights in the different aspects of the product lifecycle that work together to build quality into the product and to secure it throughout the product's life span. It will also answer any questions the participants might have on the how and the why of processes & activities supporting the quality assurance during the product life cycle. Most importantly this training will help them understand their role in this process.

2. Added value

This training will give you a broad background on Quality in drug manufacturing and enable you to understand the bigger scope. The training is given by a senior Pharmaceutical manager with an extensive expertise in the life sciences industry. During the training practical cases and questions can be discussed. Extra coaching can be planned to discuss the trainee experiences and challenges in the field after the training.

Learning Objectives

At the end of the course participants will be able to understand

- why the pharmaceutical industry is one of the most regulated industries
- the definition of quality related to drug products
- the timelines & cost associated with pharmaceutical development
- how quality is built and maintained throughout the product life cycle
- recent views on product lifecycle and quality ((e.g., ICH Q8-Q9-Q10 & QBD)
- future trends that might significantly change the industry

Scope

Focus on manufacturing of drug product.
Not in scope: API, medical devices & blood products
This training gives a high-level overview. More details are being taught in the sequel modules (see overview 'Learning Program for Life Science')

Methodology

1. Theoretical knowledge and awareness
2. Exercises through workshops

Practical

Language: English

Program

1. R&D: Def. therapeutic molecule & dosage form
2. Product design: building target quality product profile
   - R&D: discovery & pre-clinical phase, small vs large molecule drugs
   - Clinical trials: purpose, traditional and novel set-ups
   - Establishing critical quality attributes
   - Product stability
3. Process design: building a process to safeguard product quality
   - Link process parameters with critical quality attributes
   - Process validation: historical vs current views on process validation, establishing validation approach and validation documentation
   - Establishing a control strategy
4. Regulatory file: content of the common technical document, submission and review
5. Routine manufacturing:
   - Legislation: GMPs and Pharmacopeia
   - Routine stability
   - Process Monitoring and Review
   - Change Control
   - Technology transfer
   - Distribution
6. Future trends in pharma

Audience

People with 0-5 years' experience in drug manufacturing.
Specifically people involved in
1. Process development, improvement, validation
2. Technology transfer
3. Quality control method validation & quality assurance
4. Equipment qualification engineers

qpeople
validating expertise

T +320)15/794.794 E info@qpeople.be