Training for Life sciences &
Pharmaceutical industry

Junior Validation training

1. Goal of the training

This course is designed to explain why regulatory agencies require Validation, as well as the consequences of failing to validate processes & systems. Attendees will learn where & how validation and change control fits in to the Quality management system & regulatory filing. The course will provide a walk through the different validation steps, the overall validation methodology and its key deliverables. Attendees will discover which systems require validation - and which do not. They will also learn how to safeguard your Quality through change control.

2. Regulations considered

FDA 21 CRF, FDA guidance on process validation, EU V4 Annex15, EU V4 Chapter 4: Documentation

3. Added value

Practical training given by experts with experience in various domains. The participants will gain sufficient background and tools to work with. A come back session is planned to discuss the trainee experiences in the field.

Learning Objectives

At the end of the course participants will be able to

- Understand the concepts of Validation
- Understand why validation is important to the product quality & regulations.
- Understand the whole validation approach from VMP to different types of validation.
- Explain the different steps in V-cycle of Validation & what IQ, OQ and PQ stands for.
- Understand the main roles in a validation project
- Understand hot topics like QRM, ASTM & QBD
- Practise basic change analyses & write rationales
- Practise basic user requirements analyses
- Practise good documentation in validation
- Practise basic validation tasks
- Know what is expected from them on a first junior validation mission

Scope

- Basic validation course containing general concepts
- Pharma & life science

Out of scope

Foreseen in other modules:

- Technical writing skills
- Advanced QRM
- C&Q and ASTM
- Process validation, QDB and In process controls
- QC method / equipment

Program

1. What is validation?
2. Types of validation
3. Quality by Design
4. V-Model
5. ASTM
6. Quality Risk Management
7. Change Control & Validation Life Cycle
8. Roles & Responsibilities
9. Procedures & Protocols
10. Good documentation practices & rationales
11. Documentation set-up
12. Technology Transfer

Methodology

1. Theoretical knowledge
2. Exercise through workshops
3. InterVision day to practice work-related examples

Audience

Pharma professionals who need a background in validation
o experience in validation

Language: English
Data: 1 day + 0.5 day InterVision

validating expertise

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