Program
Managing GMP audits

Length :14 hours (2 days)

Training: In-house or inter-site / Face-to-face or remotely

Target audience : Responsible Pharmacist, Quality Assurance Managers and Teams, Production Managers and Operators, Managers and support services teams (Utilities, Industrial Transfer, Qualification/Validation...), Quality Control Managers and Technicians within the pharmaceutical, biotechnological industries whether in human or animal health

Pre-requisites : no pre-requisite

Training accessible to people with disabilities

Teaching goals

- Identify the general content of GMPs
- Understand the principle of Quality Risk Management
- Identify the modalities of a Quality Audit (preparation, audit plan, process, report and audit follow-up)
- Understand the right behaviors to adopt and the mistakes to avoid

Training content

- Describe the general content of GMPs (Parts I to IV and annexes)
- Explain the principle of Quality Risk Management (QRM) according to ICH Q9 in Part III of the BPF
- Describe the requirements of Chapter 1 of Part I: Pharmaceutical Quality System
- Describe the requirements of Part I, Chapter 2: Personnel
- Cite audit deviations to describe the contents of Part I, Chapters 3 and 5: Premises and Equipment; Production
- Define the necessary quality documentation and understand its management in accordance with Chapter 4 of Part I: Documentation
- Identify the specific points specific to control laboratories by benefiting from feedback from the trainer in accordance with Chapter 6 of Part I
- Group Chapters 7, 8 and 9 of Part I to introduce the principle of Quality Audit
- Identify the key points defined in Annexes 15 and 16 of GMP: Qualification and Validation; Certification by a Responsible Pharmacist and Batch Release
- Describe an audit process with the steps of preparation, audit plan, conduct, report and audit follow-up and the good behaviors to adopt and the errors to avoid
- Analysis of a concrete audit example
- Open-ended questions BPF

How the course is organised

Speakers : Pierre CHAZELLE or Pierre DEVAUX or Laurent MERLI

Teaching and technical tools

- Training materials.
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Question and answer sessions

Tool for monitoring the implementation of the training results assessment

- Attendance sheets.
- Assessment tests of the acquisition of knowledge
- Certificate of training.