

# Program

## The GMPs and the Audit approach

**Length :**14 hours (2 days)

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

**Target audience :** Head Pharmacist, Quality control managers and technicians in the pharmaceutical, biotechnology, human and animal healthcare industries.

**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 methods used during a Quality Audit (preparation, audit plan, process, report and audit follow-up of the audit)
- Understand the right behaviours 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) pursuant to ICH Q9 in Part III of GMP
- Describe the requirements of chapter 1 of part I: pharmaceutical quality system
- Describe the requirements of Chapter 2 of Part I: personnel
- List any audit discrepancies to describe the content of chapters 3 and 5 of part I: premises and equipment; Production
- Define the necessary quality documentation and understand its management in accordance with chapter 4 of part I: documentation
- Identify the main points specific to control laboratories by using trainer feedback pursuant to chapter 6 of part I
- Combine chapters 7, 8 and 9 of part I to introduce the principle of quality auditing
- Identify the key points defined in Annexes 15 and 16 of the GMPs: Qualification and Validation; Certification by a Head Pharmacist and Batch Release.
- Describe an audit process with the stages of preparation, audit plan, conduct, reporting and follow-up of the audit and the right behaviours to adopt and mistakes to avoid.
- Analysis of a concrete audit example
- Open questions GMP

## How the course is organised

### Speakers :

Pierre CHAZELLE

### Teaching and technical tools

- Training materials.
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Question and answer sessions
- Self-assessment using a grid

### Tool for monitoring the implementation of the training results assessment

- Attendance sheets.
- Knowledge acquisition assessment test
- Certificate of training.