



# Program

## Risk Analysis in the Pharmaceutical Industry

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

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

**Target audience:** Staff carrying out risk analyses

**Prerequisites:** no prerequisite

Training is accessible to people with disabilities

### Learning objectives

- Understanding regulatory requirements
- Understand the mechanisms and methods used to analyze risks
- Be able to identify, prioritize and control the sources of risks inherent in the company's activities
- Be familiar with the various tools used to carry out risk analyses
- Know how to deploy risk analyses on your site

### Training content

- Understand the ICH Q9 quality risk management process
- Understand the applicable risk analysis tools
- Know how to apply the right tool at the right time
- Know how to use various tools: FMEA, HACCP, etc. in the risk management process
- Be familiar with the rules for managing a 'risk analysis' working group
- Be familiar with useful monitoring and decision-making tools
- Know how to manage the process over time
- Understand the challenges of risk analysis in the pharmaceutical industry
- Understand the regulatory framework and applicable standards: ICH QP - Q9 - Q10, ISO, GMP
- Understand the expectations and requirements of GMP regarding quality risk management
- Understand the specific vocabulary used in risk analysis
- Know how to identify and analyze risk
- Be able to assess the risks associated with hazards
- Be familiar with risk analysis methodologies and their fields of application (FMEA, HAZOP, HACCP cause tree, ...)
- Apply theoretical knowledge

## How the course is organized

**Speakers:** Kévin ARHEL ou Pierre DEVAUX

### Teaching and technical tools

- Training materials
- Theoretical presentations, examples of concrete cases
- Practical application exercises
- Questions / answers sessions

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

- Attendance sheets.
- Assessment tests of the acquisition of knowledge
- Training certificate.