CESPE ACADEMY

GAMP TRAINING

Good Automated Manufacturing Practice

Course Programme

Schedule Day 1

Introduction to GAMP
- o Lifecycle phases
- o GAMP categories
- o Key principles

Detailed Lifecycle
- o Planning specification configuration and/or coding

Regulations
- o 21 Cfr part 11
- o Annex 11

Extended Exercises on
- o Validation
- o User requirements specifications
- o Functional specifications
- o Risk assessment
- o Test scripts

Schedule Day 2

Detailed Lifecycle
- o Verification reporting

Operational Phase

Extended Exercises on
- o Test execution
- o Test report
- o Validation reporting
- o Requirements traceability matrix

Test

Information

Time and Date: 9:00 - 17:00 **10th -11th March 2026**

Place: Leslokaal 0.2 'Gertrude Elion'
Faculty of Pharmaceutical Sciences
Ottergemsesteenweg 460, Ghent, Belgium

Contact: Mark.Gontsarik@UGent.be

Course Description

This course focuses on automation of validation processes in pharmaceutical manufacturing setting. **QbD Group experts** provide a two-day training course in which they build knowledge on Good Automated Manufacturing Practice (GAMP), Computerized System Validation, regulations and more.

Production systems for the pharmaceutical and food industries have to comply with ever-stricter legislation. This training not only offers you theoretical knowledge of the basic aspects of GAMP – with a focus on the detailed life cycle – but also offers multiple practical exercises. Additionally, a test will be provided so that you can check if you can apply your gained knowledge.

The course begins with at introduction to GAMP principles and gradually builds to more complex examples and exercises.

Target Audience

The target audience are professionals or students in chemical, pharmaceutical & healthcare sciences and engineering.

- No prior knowledge needed
- Practical learning approach
- Ideal for more in-depth practitioners, who want to get more examples and use cases included as part of the training

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