

CERTIFICATE

Robi Tomc

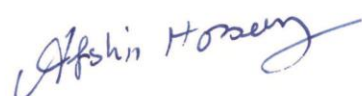
has completed a three day ECA-Course on 7 to 9 May 2025 in Vienna, Austria covering the following subject

ECA - Computerised System Validation: The GAMP 5 Approach

Contents of the course:

- Validation Overview
- Regulatory Framework Overview + Annex 11
- Self Evaluation of CSV Regulatory Compliance
- GAMP®5 Software Categories
- GAMP®5 Second Edition: A Risk-based Approach to Compliant GxP Computerised Systems
- Data Integrity Considerations for CSV
- Validation Planning
- Specifying Requirements
- Functional Specifications – Building the Bridge
- Design Specification
- Requirement Traceability / Design Review – More Than a Milestone: A Process
- Testing of GxP Systems
- Feedback Session: Self Evaluation of CSV Regulatory Compliance
- Test Incident Management
- Change and Configuration Management
- Validation Reporting and Handover to Operation
- Presentation to Inspectors
- CSV – Specific Aspects: Automation
- Workshops:
 - Change Management
 - Validation Planning
 - Specifying Requirements – URS vs FS
 - Managing Test Incidents
 - Software Categorisation according to GAMP®5

Heidelberg, 9 May 2025



European Compliance Academy



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