# Mastering Challenges of Data Integrity and Computer System Validation

## Overview

Data Integrity is currently a hot topic in the pharmaceutical industry and in the focus of health authority inspections.

A properly validated computer system allows to establish and maintain over time the data integrity: once the regulatory requirements are met through a consistent and rigorous validation process, this implies that the required controls are in place.

This 2-day training course provides practical guidance to understand the basics of data integrity and computer system validation and offers real world learning examples of integrated approaches. A mixture of lectures and interactive sessions provides a maximum of learning success.

On the first day the focus is on regulatory foundation of data integrity, ALCOA(+) principle, data governance, modelling of data/process flows, and hybrid systems. The second day consists of workshops around risk evaluation and presentation/discussions about general principles of computer system validation and audit trail reviews.

### Who Should Attend

- Managers responsible for IT systems in pharma and supplier companies
- Validation Managers
- Laboratory Supervisors
- Production Supervisors
- QA Managers
- Everybody, who is involved in the topics of Data Integrity and Computer System Validation

### Learning Objectives

- Acquire basics about Data Integrity and Computer System Validation
- Apply concepts of data integrity on computer system validation
- Gain experience through real world examples
- Obtain knowledge to deal with the audit trail review challenge
- Understand the ideas behind ALCOA
- Perform computer system validation by your own

### Faculty

**Roberto Bertini,** *Operations Director, PQE*
A +18 years long career in Computerized Systems Validation and Data Integrity assurance. Degree in Physics at the University of "La Sapienza" in Rome, he joined PQE in 2000. He is currently Operations Director at PQE for Spain, DACH and CIS Regions, where he is leading the service delivery related to the Business Lines for Data Integrity Assurance. He has managed the validation process of most common Computerized Systems used in the Life Science environment (e.g. ERP, MES, LIMS, WMS, Lab Systems, PCS, Serialization domain) and he has supported the implementation of Quality Management Systems for the IT governance. He is currently supporting a number of pharmaceutical companies in the establishment of Data Integrity Governance and in the resulting Data Integrity Assessment and Remediation.

**Stefan Godersky,** *Consultant, SGMP*
Stefan Godersky has been active in the pharmaceutical industry since 1995 in various positions of development and production departments of Global Players for production sites in Europe and Asia. Now running his own company - he has been a consulting engineer for the medical device and pharmaceutical industry since 2010, with a focus on risk management and validation of computerised systems. Since his degree in process engineering, he has been involved in topics and projects at the interface of software development, pharmaceutical manufacturing processes and quality assurance.

**Stefan Wurzer,** *Global Data Integrity Lead, Roche*
Stefan Wurzer is Global Data Integrity Lead in Pharma Technical Operations at Roche in Basel. He is responsible for the global Data Integrity project, development and sustainment of data integrity standards and trainings, and leads a global network of Data Integrity stewards. He is working in the field of computer system validation since more than 12 years. Prior he worked for Novartis as global eCompliance Manager and as part of this role he was involved in the validation of a globally used SAP system. He holds a bachelor degree in Business Information Systems and is a frequent speaker at conferences.

| Wednesday, 17 October 2018 | 9:00 – 17:15 |
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| 9:00 | **Welcome and Introduction** |
| 9:15 | **Regulatory Update**<br>• **Essential Requirements / Update Guideline Changes**<br>• **Inspection Findings / e.g. Warning Letters** |
| 10:15 | **Coffee Break** |
| 10:45 | **"ALCOA +"**<br>• **General requirements and principals**<br>• **Interactive session** |
| 12:15 | **Lunch Break** |
| 13:15 | **Code of Conduct/Data Governance** |
| 13:45 | **Data Lifecycle / Data Integrity – Part 1**<br>• **Presentation of a sample process** |
| 14:15 | **Managing Hybrid Systems**<br>• **pH-meter, autoclave , HPLC** |
| 14:45 | **Coffee Break** |
| 15:15 | **Data Lifecycle / Data Integrity – Part 2**<br>• **Interactive Session: Modelling the Process** |
| 17:15 | **End of Day 1** |

| Thursday, 18 October 2018 | 9:00 – 16:30 |
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| 9:00 | **Recap Day 1** |
| 9:15 | **Data Lifecycle / Data Integrity – Part 3**<br>• **Interactive session: Risk evaluation, risk mitigation measures** |
| 10:45 | **Coffee Break** |
| 11:15 | **Validation and Data Integrity**<br>• **Principles of Computer Systems Validation**<br>– Software Categories<br>– Validation Approaches<br>• **System Validation lifecycle**<br>– Simple vs. complex systems<br>• **Validation responsibilities and role of suppliers** |
| 13:00 | **Lunch Break** |
| 14:00 | **Validation of commercial software**<br>• **Data Migration projects**<br>• **Part 11, Annex 11** |
| 14:30 | **Interactive Session**<br>• **Risk evaluation of simple vs. complex types** |
| 15:15 | **Coffee Break** |
| 15:30 | **Audit Trail and its Review**<br>• **Requirements for Audit-Trail**<br>• **Risk-based approach to the review of Audit Trail** |
| 16:00 | **Wrap-up, Q&A** |
| 16:30 | **End of Course** |