Computer System Validation

For Automated and Computerized Systems

Exyte – your plant design and construction partner

Exyte is a leading international engineering company specializing in the design and construction of plants and systems for the life sciences sector. Our experienced specialists develop state-of-the-art solutions for you – offering the full scope of services from consultation, concept development and design, to the delivery of qualified and validated turnkey plants and systems.

Computer system validation – systems in question, legal regulations and approaches

Modern production methods in the life sciences industry largely rely on computerized systems, making computer system validation (CSV) an extremely important topic in this sector.

- But at what point is a system computerized and what are the regulatory requirements for CSV?
- Do all computerized systems have to be validated to the same degree?
- What documents have to be prepared as part of the CSV process and what is the protocol after a system goes live?

Life sciences companies have to answer these and a host of other questions around data integrity, the deployment of modern storage concepts such as cloud-based solutions and their validation.

Reference Clients

Abbott | Boehringer Ingelheim | B. Braun | Bracco/BIPSO | Catalent | CSL Behring | Dong-A | Kantonsapotheke Zürich | Merz Pharma MSD | Novartis | Ohly | OncoGenerix | Roche | Takeda |

Close to you

We help you get your computer systems validated, and make sure that they retain this status. We also provide support with all other issues related to CSV. Our experts can inform you about legal regulations, guidelines and standards such as Good Automated Manufacturing Practice (GAMP 5), Annex 11 and 21 CFR Part 11 (FDA). They can also help you implement and adapt your company's internal policies and practices to ensure they align with the risk-based approach set out in the ISPE GAMP 5 lifecycle model.

Our CSV Strategy

Services, Regulations and Standards

Our services

Consulting and concept development

- CSV and IT compliance for computerized and automated systems, laboratory systems, ERP, MES, PLS, LIMS, SCADA, SPS, IT infrastructures and interfaces
- Data integrity and audit trail reviews
- Cybersecurity (see our flyer on "Cybersecurity for automated and computerized systems")
- Development of CSV strategies and validation master plans (VMPs)
- Assessment of validation status, including system inventories, CSV assessments, 21 CFR Part 11 evaluations, GAP analyses and the creation of action plans
- Support in defining user requirement specifications (URS) and selecting suppliers (including supplier audits)
- Drafting of all requisite validation documents from the validation plan (VP) to the final report, including risk analyses (SIA, FMEA, FTA) and test plans (DQ, IQ, OQ, PQ)
- Test management and test automation
- Measures to retain validated status (periodic reviews, re-evaluations)
- Creation of CSV SOPs and operational IT SOPs; electronic SOP systemse
- Project and quality management, including deviation, fault, change and CAPA management
- Preparation and management of audits and inspections (EU, FDA)
- Training sessions and seminars
- Workshops

Regulations, guidelines and standards

EU GMP guideline, Annex 11 "Computerized Systems", and Chapter 4 "Documentation"

Annex 11 outlines the requirements governing electronic records, and must be interpreted in conjunction with Chapter 4 "Documentation" of the EU GMP guideline. Like FDA 21 CFR Part 11, Annex 11 focuses on electronic records and electronic signatures. Unlike the FDA guideline, however, Annex 11 also outlines general requirements for computer validation.

FDA 21 CFR Part 11 "Electronic records, electronic signatures"

Part 11 outlines detailed requirements specifically for electronic documents and electronic signatures that are binding for the US market. The FDA guidelines on computer validation are important for interpreting this regulation, in particular, the "Guidance for Industry: Part 11; Electronic Records; Electronic Signatures – Scope and Application", which emphasizes the importance of a risk-based approach.

The PIC/S guidance PI 011 on "Good Practices for Computerized Systems in Regulated GxP Environments"

Detailed guide for inspectors engaged in reviewing computerized systems.

ISPE GAMP 5 Guide

Industry standard covering all aspects of CSV. It drills down through a range of good-practice guides for the individual chapters. These consistently outline a risk-based approach and propose a wide range of scalable validation approaches.

ZLG Aide-Mémoire 07121202
"Überwachung computergestützter Systeme"
(Monitoring computerized systems)

Designed to help interpret Annex 11, this document provides further insight into inspectors' expectations (only available in German).

MHRA GMP Data Integrity Definitions and Guidance for Industry

This guideline is published by the UK's Medicines & Healthcare Products Regulatory Agency and includes an extensive glossary of definitions and terms.

Learn more about Biopharma & Life Sciences
Contact us at **info.bls@exyte.net**
or visit **exyte.net/biopharmalifesciences**