



Computerized System Validation

WE DRIVE YOU TO GXP COMPLIANCE

Our end-to-end solution is tailored to your requirements and is the path to GxP compliance – whilst being efficient and pragmatic.

COMPUTERIZED SYSTEM VALIDATION

We carry out validation in accordance with the following guidelines and laws

The validated state must be maintained for the entirety of the system lifecycle within the GxP-regulated environment. We have developed a process that enables effective, cost-efficient validation whilst also observing the following guidelines and legislation:

- ▶ EU Directives and the quality management standard ISO 13485
- ▶ Pharmaceutical legislation
- ▶ U.S. Food and Drug Administration (FDA) requirements
- ▶ Regulations from 21 CFR Part 820, 21 CFR Part 11 and EU GMP Annex 11

Validation of systems usually takes place in accordance with GAMP®5 industrial standards.

Axians Computerized System Validation (CSV) Services

Streamlined, smart processes and a risk-based approach are the key to cost-effective CSV. With our end-to-end solution, we can support our customers to consistently and reproducibly ensure that computer-aided systems are GxP compliant. In this case, **our service is available as an ongoing service, on a project basis, or as a consulting contract.**

1

Consulting

Validation, training and advice all tailored to your needs.

2

Validation as a Service

A turnkey approach and offers based on defined project services.

3

Greenfield

We support you in the creation, implementation and maintenance of your own framework.

Consulting:

Do you already have basic knowledge about validation of your computer-aided systems and thus only require support in specific areas? Are you lacking resources in certain areas or would you like to train your staff? We would be delighted to provide our expertise precisely where you require it.

Validation as a Service:

Do you not have the necessary resources for partial or complete performance of system validation? If so, then our managed service is just right for you. We handle validation on your behalf, so you can concentrate on your core business.



Greenfield

Would you like to validate in accordance with your own CSV Framework so that you are ready for further validations? But you don't have the foundations in place and the required expertise for cost-efficient, reproducible implementation?

We adapt the Axians CSV Framework to your requirements and help you implement your own CSV Framework. Our Axians CSV Framework is characterized by the following features:

- ▶ Simple to understand and apply.
- ▶ Minimal training outlay with your organization as a multiplier.
- ▶ Repeatable: after implementation, it can be applied repeatedly.
- ▶ Reproducible: The standard leads you to the result.
- ▶ Focused: Risk mitigation is key, not the volume.
- ▶ Our CSV Framework ensures GxP compliance and audit readiness

Our Process:



Our Core Services:

Our philosophy is to provide you with a turnkey approach built on project-based services. The following services are at the heart of the project:

- ▶ **Validation and revalidation**
- ▶ **CSV Training**
 - On-site training
 - Coaching your internal resources
- ▶ **CSV Framework**
 - Design and implementation of your CSV Framework based on the Axian framework
 - Landscaping and evaluation of the current situation
- ▶ **Troubleshooting**
 - Planning and design
 - Monitoring legacy issues
 - Mock audit

Your benefits:

- ▶ **Full service** for validation of your computer-aided systems.
- ▶ Preparation of a **customized framework based on your requirements** as well as our **Axians CSV Framework**.
- ▶ **Access to resources with comprehensive experience** in the regulated industry.
- ▶ **Validation based on services** with rigorous **cost control**.
- ▶ Our service is available as an **ongoing service, on a project basis, or as a consulting contract**.

Do you need a partner that provides support in line with your requirements?

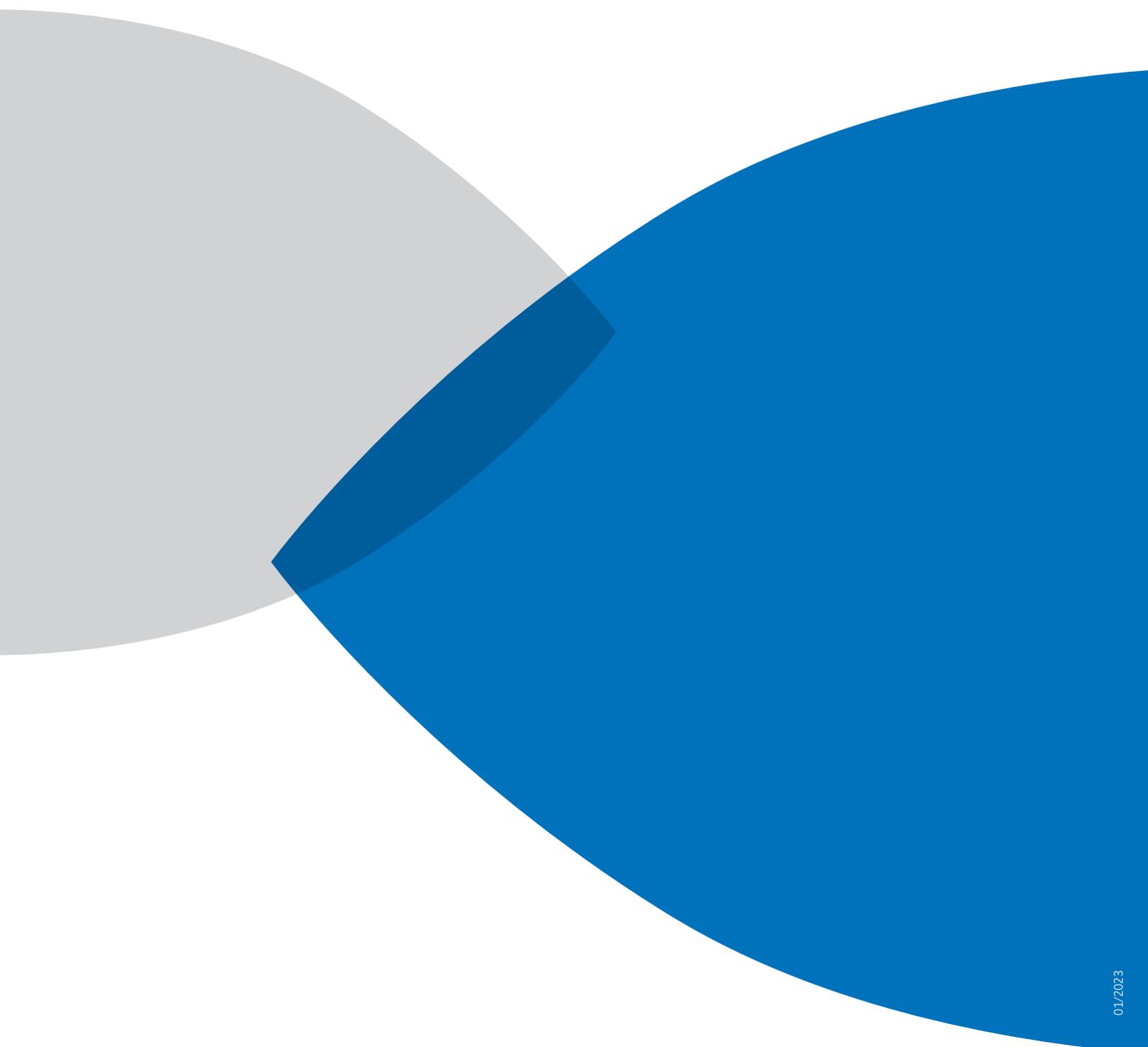
Get in touch with us today to receive more information and let us help you by preparing an offer that is completely tailored to your requirements.



YOUR POINT OF CONTACT

Cornelius Blumer
(CSV & Quality Manager)

E-Mail: cornelius.blumer@axians.com



01/2023

axians

Axians IT Services AG · Arlesheim · Rotkreuz · Zürich

Tel.: +41 61 716 70 70

E-Mail: info-ch.ibs@axians.com · www.axians.ch