

## **Validation of computerized systems**

### **Business Case and Issues**

In regulated environments such as GMP, GCP or GLP, validation is a must. But also in none regulative environments relying on business critical computerized systems, validation can be a key step to reduce the risk of system failures, and consequent business implications.

Validation is a methodology to develop a system and provide documented evidence that it performs according to the predefined requirements. The key is finding the balance between the validation efforts, and the risk a computerized system imposes on a company.

IBR AG focuses on the planning, implementation and application of validation methodologies on a project or company level.

### **Capabilities and Experiences of IBR AG**

IBR AG has been involved in validation since 1992 and leads projects to implement computerized systems complying with validation standards as well as defining and implementing validation standards in pharmaceutical and other regulated industries. We provide validation services based on customers guidelines and SOPs where available, but are also able to develop validation standards, guidelines and templates for customers.

Projects carried out include:

- Definition and implementation of global validation standards and guidelines for a major pharmaceutical company
- Audit of a validation project
- Implementation and validation of an Internet based patient data collection system
- Evaluation of a none validated clinical system to reach compliance status

As a project management company, efficient realization of validation projects is key to us and our customers.

### **Services and Methodology**

Project management / support for the implementation of computerized systems where validation is required. Validation requirements are evaluated and defined at the beginning based on regulatory requirements, risk of the system and additional requirements from the customer's side.

Validation is performed based on customer's standards to minimize customer's training requirements and to facilitate maintenance of the system after deployment. If requested, IBR AG can develop and implement validation standards and templates based on customer's needs and best practices.



You may expect from us:

**Project management** for computerized system in regulated environment or environments with high quality standards

**Development of validation strategies or standards** based on internal and external requirements and best practices

**Evaluation of legacy systems** to bring them to a compliant status

### **Benefits of partnering with IBR AG**

Project management experience in highly controlled industries, such as pharmaceutical, airline services and financial industry.

Our staff at IBR AG brings many years of business experience combined with validation and information technology knowledge. They are able to bridge communication between business, IT and quality groups, to bring projects to a successful conclusion.