

Qualification and validation

Qualification and validation of computer-assisted systems

From a sensor in the field via SPS and process control systems through to the management level (MES)

Our service ...

You are working in a GxP-regulated environment (e.g. pharmaceuticals, biologics, medical devices, food and beverages) and need qualified automation equipment and validated computer systems? Either retrospectively or prospectively?

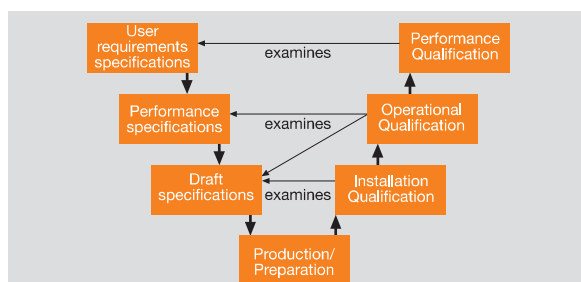
As part of an internationally operating healthcare group we can offer you qualification and validation services which are state of the art and focus on the operator's requirements.

We know from experience – experience we are only too happy to share with you – that with qualification and validation procedures a lot of money can be saved if the requirements are appropriate and the whole concept is right. We can therefore perform the following tasks for you:

- Preparation or review of the required instruction system
 - taking your QM system into account (gap analysis and action plan)
 - on the basis of the life cycle model
- Project management for qualification and validation so that the GxP requirements are integrated into the project process from the start.

Our services related to the execution of qualifications and validations extend from the project idea right up to assistance with product approval. Our range of services includes the following:

- Preparing the validation master plan
- Examining the existing system documentation (gap analysis) in the case of retrospective validation
- Drawing up plans for system qualification under the V model (in accordance with GAMP)



V model for specification and qualification [GAMP]



We also offer the following modules:

- GxP review of requirements and performance specifications
- Preparation/review of risk analysis (FMEA, HACCP)
- GxP review of tender documents
- Execution of supplier audit
- Drawing up/review of qualification test schedules for IQ, OQ and PQ taking FAT and SAT into account
- Design qualification (DQ) and drawing up of the requirement traceability matrix
- Execution and GxP-compatible documentation of IQ, OQ and PQ
- Drawing up of qualification and validation findings
- Assessment and documentation of conformity with 21 CFR Part 11
- Assistance in drawing up system documents for product submission in accordance with CTD

Once the system has been qualified or validated, this status must also be maintained in day-to-day operation. To ensure this we assist you by:

- Establishing procedures for configuration and change management
- Drawing up SOPs for system operation
- Training employees in the GxP-compatible supervision of qualified and validated systems
- Carrying out system reviews and audits

If this is too much for an initial order, the services described can be obtained from us as a complete package or individually in line with your requirements, either on a stand-alone basis or as an integral part of our range of process control engineering and operational management services.



... is your gain.

Based on our operator know-how, you can be confident of meeting the regulatory requirements set by the authorities (e.g. FDA, EU) and of qualifying or validating your automation technology quickly and at low cost. Moreover, you will be laying the foundations for obtaining validated status over the facility's entire service life.

Even if you have had little experience of GxP to date and have heard a great deal only about the high costs involved, you will soon learn to appreciate the structured approach coupled with reasonable costs as a lasting contribution to quality-driven operational excellence. What does this mean? Let's simply hear what one of our customers had to say:

"There is no doubt computer systems compliance contributes to the overall integrity of our products just like accurate lab testing and proper filing of batch production records do."

*Steve Height, Vice President, Corporate Quality Assurance
Bayer HealthCare – Biological Products*

Our methods

Our work is based on the relevant official requirements, as laid down, for example, in the following documents:

- FDA 21 CFR Part 11 "Electronic Records; Electronic Signatures"
- FDA 21 CFR Parts 210, 211 "Current Good Manufacturing Practice for Finished Pharmaceuticals"
- FDA 21 CFR Part 110 "Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food"
- EC Guide to GMP, Annex 11 "Computerized Systems"
- EC Guide to GMP, Annex 15 "Qualification and Validation"
- EC Guide to GMP, Annex 18 "Good Manufacturing Practice for Active Pharmaceutical Ingredients".

Our approach follows the customary international recommendations, including:

- FDA General Principles of Software Validation
- GAMP 4 (GAMP guide to validation of automated systems)

- GAMP Good Practice Guide: Validation of Process Control Systems
- PIC/S Guidance "Good Practices for Computerized Systems in Regulated 'GxP' Environments"

Compliance with these recommendations means, first of all, making a decisive contribution to product quality. Moreover, it means speaking the language used by inspectors and fulfilling their expectations.

Official requirements and recommendations only form the framework, however. The whole thing is laid down in binding form in your instruction system. We are therefore used to working according to the customer's instruction system. And our references show that we are masters of practical application.

References

We have many references for our qualification and validation services. Often these services are performed as an integral part of a project during the planning and implementation of automation solutions for GxP areas. We also provide GxP services alone as an independent third party, however.

How much does it cost? Our contracts range from 5 man-days to 2 man-years – depending on the customer's needs. Here are some examples:

- Bayer HealthCare – Pharma: prospective validation of process control technology and manufacturing execution systems (MES), Electronic Batch Recording System (EBRS)
- Bayer HealthCare – Consumer Care: prospective validation of process control technology and MES, EBRS
- Bayer HealthCare – Biological Products: management of the business unit's Computer Systems Validation and 21 CFR Part 11 Compliance project worldwide
- LanXess: EBRS, drawing up of SOPs
- Customer (Biologics): preparation of risk analysis, review of OQ, PQ test schedules, including drawing up of traceability matrix
- Customer (Food): prospective qualification of process control technology in a newly built plant
- Various customers (Pharma): retrospective validation of process control technology and MES

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