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Validation ensures computer systems are thoroughly and rigorously planned, tested, and records are in place to prove this process. Kindus analyses systems to identify those needing validation.

What is computer systems validation?

The FDA defines Process **Validation** as "the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product". Process validation involves a series of activities taking place over the lifecycle of the product and process.

Why validate?

Validation is essential for a number of reasons. Most importantly, it is an expectation from pharmaceutical regulatory bodies such as the FDA and the MHRA. Failure to comply with regulations could lead to lawsuits, financial repercussions or even patient deaths. **Validation** also creates positive benefits. For example, it constitutes the 'right-first-time' approach, which reduces application failures and increases production time. **Validation** provides confidence to regulators, assurance to employees, and trust to patients.

When and what to validate?

CSV applies throughout the system's development life cycle from design and planning through development testing, implementation and revision. Regulated areas include Good Management Practice (GMP). Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), all together known as GXP. Validation requirements will consider the software itself, the operating system that it runs on and all associated hardware. This includes servers, control systems and other external hardware inputs (such as sensors) and outputs that the software interacts with. Operating procedures, training schemes and technical manuals will be analysed. Network connectivity, computer and user security are all factors that will impact on the system **validation**.

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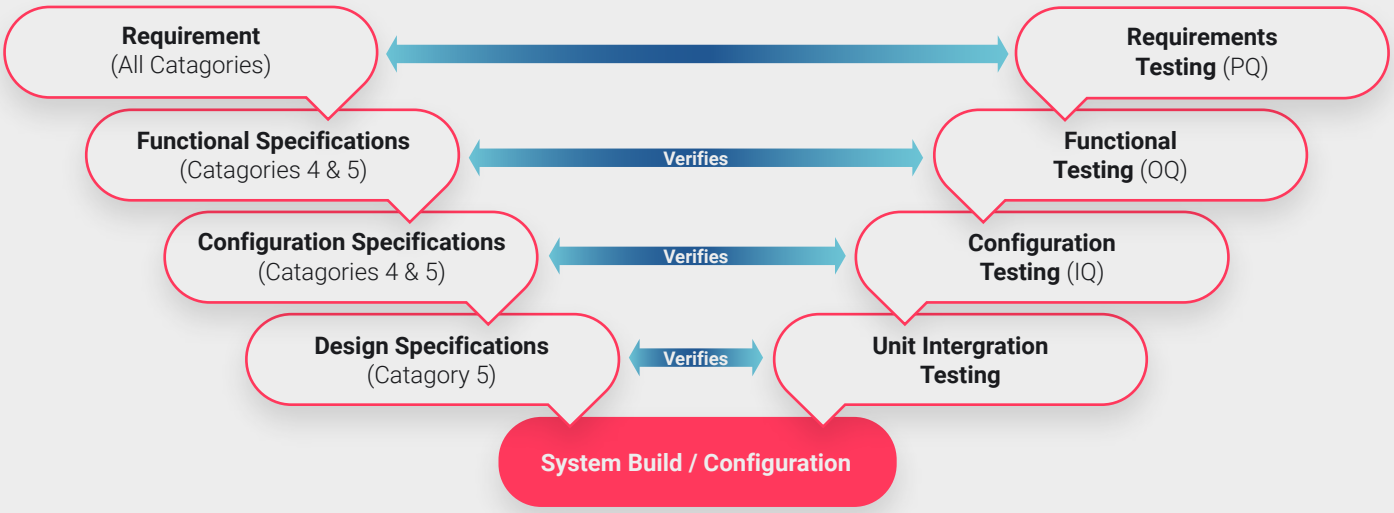
Our approach to validation

Kindus takes the Good Automated Manufacturing Practice (GAMP) approach to validation. This provides a framework where a system is evaluated and assigned to a predefined category based on its intended use and complexity. Categorisation helps guide the writing of system documentation (specifications, test scripts etc.) The GAMP approach is best illustrated by the V-model diagram.



Our expertise

- Implementation of computerised system life cycle with 21 CFR Part 11 compliance and EU Annex 11 compliance
- Computerised system audits
- Implementation of IT policies and SOP
- Change controls and deviation management
- Qualification of equipment
- Spreadsheet validation
- Infrastructure qualification
- Creation of CSV procedures and templates

Glossary of terms

CC	Change Control
DS	Design Specification
FAT	Factory Acceptance Testing
FS	Functional Specification
FRS	Functional Requirement Specification *(See Functional Specification)*
GCP	Good Clinical Practice, *a collection of quality guidelines for clinical operations.*
CFR	Code for Federal Regulations
GLP	Good Laboratory Practice, *a collection of quality guidelines for pharmaceutical laboratory operations.*
GMP	Good Manufacturing Practice, *a collection of quality guidelines for pharmaceutical manufacturing operations.*
GxP	Also called **cGxP**, Current Good Practices *An abbreviation combining **GCP**, **GLP**, and **GMP***
IQ	Installation Qualification
IOPQ	Installation/Operational/Performance Qualification
IQQ	Installation/Operational Qualification
PQ	Performance Qualification
OPQ	Operational/Performance Qualification
OQ	Operational Qualification
RTM	Requirement Traceability Matrix
SAT	Site Acceptance Testing
SDS	Software Design Specification *(See Design Specification)*
SOP	Standard Operating Procedures *(SOP's)*
TM	raceability Matrix
UAT	User Acceptance Testing
URS	User Requirement Specification
VMP	Validation Master Plan
VP	Validation Plan