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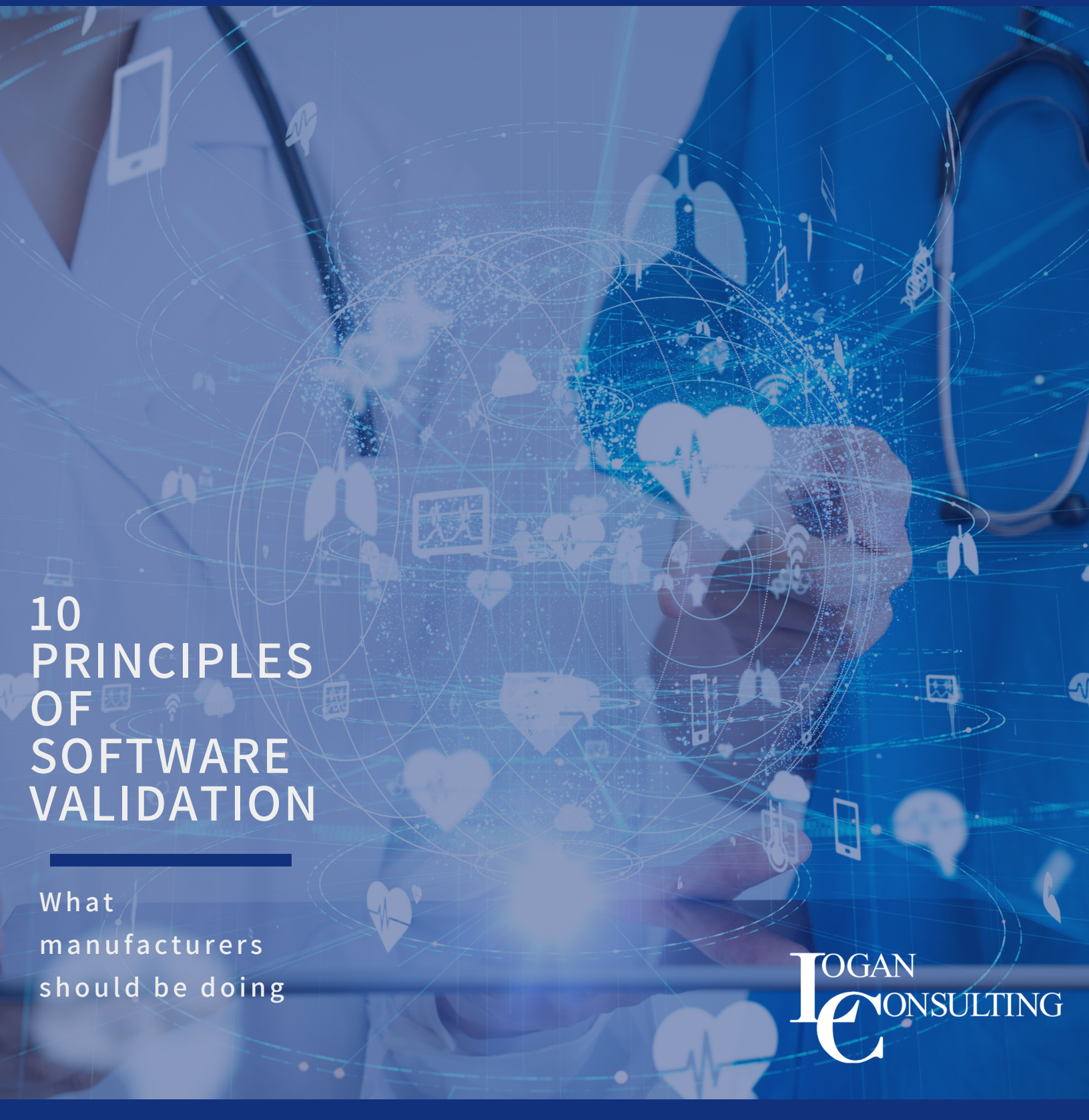
FDA Validation

Software for Medical Device Manufacturers



10 PRINCIPLES OF SOFTWARE VALIDATION

What manufacturers should be doing

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The Goals of the FDA

The Food and Drug Administration is responsible for protecting public health and making sure there is safety, efficacy, and security in all of the life sciences.

Validation:

Process of establishing documentary evidence which demonstrates that a procedure, process, or activity carried out in testing and then in production can maintain a desired level of compliance at all stages.

Some Types of Validation

1. Process Validation
2. Analytical Method Validation
3. Software Validation

FDA Software Validation

Purpose

The FDA outlines general principles that should be applied to the validation of medical device software or the validation of software used to design, develop, or manufacture medical devices.

Scope

The FDA outlines acceptable elements of software validation. However, these recommendations are not the extent of proper compliance. There are many other activities and tasks that must be completed in order to be compliant. It is each manufacturer's responsibility to be aware of these.

The FDA's guidelines integrate software life cycle management and risk management activities. The FDA does not recommend specific life cycle models, techniques, or methods. Instead, emphasis is placed on software validation and verification activities that are conducted throughout the entire software life cycle.

Off-the-shelf software developers may not be directly responsible for ensuring FDA compliance. Therefore, it is the responsibility of the manufacturer to verify that the software is validated for intended use.

Regulatory Requirement for Software Validation

According to the FDA, the majority (79%) of software related recalls of medical devices were caused by defects within the software. These defects arose when changes were made to the software after initial production and distribution.

Software validation is a requirement of the Quality System Regulation that was passed by the Federal Register. The FDA mandates that “validation requirements apply to software used as components in medical devices, to software that is itself a medical device, and to software used in production of the device or in implementation of the device manufacturer's quality system.”

Title 21 of the Code of Federal Regulations

Any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, complaint handling, or to automate any other aspect of the quality system must be validated according to Title 21 CFR §820.70(i).

With this, computer systems used to create, modify, and maintain electronic records and to manage electronic signatures are also subject to validation, according to Title 21 CFR §11.10(a). This is done to ensure accuracy and reliability, as well as to discern invalid or altered records. It is suggested that manufacturers develop a risk management plan (sometimes referred to Failure Mode Event Analysis) that states possible events of risk or fault and outlines how the business will respond to ensure electronic records aren't lost or incorrectly documented.

10 Principles of Software Validation

Requirements

Documented software requirements provide a baseline for validation and verification. Requirements are the basis of validation and cannot be completed without them. All production and/or quality system software (off-the-shelf, in-house, or under-contact) should have documented requirements that fully define its intended use.

Defect Prevention

Software quality assurance needs to be designed into the software itself, not simply tested after the code is written. While quality testing is crucial and necessary, testing alone cannot ensure quality.

Time and Effort

Preparation for software validation should begin during software design and development. Software validation should be based on evidence collected from planned efforts throughout the software life cycle.

Software Life Cycle

Software validation takes place within an established software life cycle; the software life cycle consists of tasks and documentation that are necessary for validation support.

Validation Plans

A significant quality system tool, software validation plans define “what” is to be accomplished through the software validation effort. Plans specify scope, approach, resources, schedules, activities, tasks, and work items.

Procedures

Procedures establish a record of “how” the validation effort should be conducted. They specify actions that must be taken to complete the activities, tasks, and work items on the validation plan.

Software Validation after a Change

Whenever software is changed, validation analysis should be conducted on the validation of the individual change as well as the on the impact the change has on the validation of the entire system.

Validation Coverage

Validation coverage should be based on the software’s complexity and safety risk— not firm size or resource constraints. For lower risk devices or software, only baseline validation activities may be conducted. As risk increases, additional validation activities should be added.

Independence of Review

Self-evaluation is extremely difficult. Independent evaluation is always favored, especially for higher risk applications. Companies with higher-risk or complex software implementations should contact third-party consultants. In small-scale or low-risk scenarios, organizations can assign internal staff members (with sufficient knowledge), that are not involved in the design or implementation, to conduct validation and verification activities internally.

Flexibility and Responsibility

According to the FDA, “specific implementation of these software validation principles may be quite different from one application to another. The device manufacturer has flexibility in choosing how to apply these validation principles but retains ultimate responsibility for demonstrating that the software has been validated.” Producing a final validation report is highly regarded by the FDA.

Read more on FDA Software Validation

Validation of Off-the-Shelf Software and Automated Equipment

The majority of automated equipment and systems used by device manufacturers are off-the-shelf (OTS) software that is purchased through third-party vendors. **Yet, it is the device manufacturer who is responsible for ensuring that the development methodologies used by the OTS software developer fit their organization's intended use of the software.** Manufacturers may not be given access to the OTS software vendor's validation documentation. If software vendors can provide this information, manufacturers can use it to aid their own validation process. However, this information is frequently unavailable to device manufacturers.

Where possible, manufacturers should consider auditing the vendor's design and development methodologies used to construct the OTS software. They should also assess the development and validation documentation created for the OTS software. These audits can be done by the manufacturer or a designated third-party consultant.

One should note that some vendors are not accustomed to operating in a regulated environment and some vendors may not permit an audit. If the necessary information cannot be accessed, the manufacturer must perform "black-box" testing to ensure the software meets intended use and user needs. Black-box testing alone may not be sufficient, and depending on the risk of the device produced, OTS software may or may not be appropriate.

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