Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

1 Purpose

This Guideline provides guidance on the qualification requirements to be applied to the Information Technology infrastructure. The establishment and maintenance of a qualified infrastructure for any regulated company is fundamental to meeting current business and regulatory requirements in respect of systems stability, reliability and security.

2 Scope and Applicability

This guideline applies to all business functions and contracted third parties who install, operate, manage or maintain the infrastructure. The requirement for qualification applies to all components of the infrastructure. This is necessary because of the interconnectivity of the network (a fundamental design requirement) and possible (unwanted) interactions that might ensue without conformance to the minimum standards contained in this Guideline.

The following infrastructure elements are covered by this guideline:

- Local and wide area networks (e.g. data transmission cabling, hubs, routers, bridges and switches, etc.).
- Servers and mainframe computers (and their operating systems and supporting software products).
- Clients (and their operating systems).
- Peripheral equipment (e.g. networked printers and storage devices)
- Electrical power supply and heating, ventilating and air conditioning equipment for server rooms and data centers.
- Server rooms and data centers.
- Infrastructure monitoring, management and maintenance systems.
- Middleware or enabling software., e.g. Oracle, SQL etc.)

3 Definitions

3.1 Installation Qualification

Documented verification that all physical aspects of a facility or system, which affect product quality, adhere to the approved specification and are correctly installed.

3.2 Operational Qualification

Documented verification that all functional aspects of a facility or system, which affect product quality, perform as intended throughout all anticipated operating ranges.

regulatory agencies (health, financial, etc.).

5.2 Infrastructure Life cycle

For infrastructure development a life cycle model must be used. To maintain the logical order, the deliverables from each stage of the life cycle must be approved before the next stage is commenced. A stage in the life cycle is usually broken down into several activities (see suggestions below).

- Stage 1 - Planning
  e.g. Change Management or Project

- Stage 2 - Design

  e.g. requirements, functional specifications, technical specifications, service requirements and design specifications including design qualification (DQ)

- Stage 3 – Development
  e.g. construction, configuration, code development

- Stage 4 - Installation
  e.g. testing of installation and verification of specifications (IQ)

- Stage 5 - Acceptance
  e.g. functional tests and verification of specifications (FQ)

- Stage 6 - Operation
  e.g. operational plans, maintenance, change control, ongoing training

- Stage 7 - Retirement

5.3 Infrastructure Qualification

5.3.1 New and Existing Components

In both cases, a risk assessment must be performed to establish the qualification (and any specific documentation) requirements. If, in the case of existing components, the risk assessment confirms that they are reliable then they do not need to be tested.

Simply ensure that information about the components is recorded ‘as is’. The information must be sufficient to allow the components to be replaced and reconfigured to resume operation as soon as possible if necessary.

As a minimum a qualification plan which describes the retrospective qualification exercise for the existing infrastructure, plus technical and configuration specifications for each component or system needs to be in place and the items must be recorded in the asset register.

New infrastructure components must follow an established procurement and

5.3.3.2 Deliverables Description

Figure: Deliverables Description

Table 1 - Qualification Deliverables

Deliverable	Scope of Deliverable
Qualification Plan (QP)	**The Qualification Plan outlines what information; documentation and processes will be produced or updated. This must include the scope of the activity and what elements need to be qualified based on a risk assessment. It is important to define which middleware components, if any, will be included.** For small changes, a separate document is not required and the planning information may be contained in another document. For larger and more complex changes, a separate document will be required. Local procedures should be consulted for specific guidance.
Inventory Records (Asset Register)	**The inventory must identify both hardware and associated software components** (e.g. operating system).
Requirements Specification	**Requirements must be documented so that the component can be properly specified, procured, installed and tested.**
Technical Specifications	**The technical specifications must include information about the functional, technical, and architectural and design aspects of the component.**
Configuration Records	**Each component with configurable items must have its configuration documented sufficiently to allow the component to be installed and operated correctly and to be maintained or replaced as required. Critical relationships, if they exist between different components, should also be documented.**
Installation Qualification (IQ) Protocol	**The IQ protocol confirms that each critical component, or representative sample of a common class of components, has been procured, installed and connected according to the installation instructions.**
Operational Qualification (OQ) Protocol	**The OQ protocol confirms that the correctly installed component operates according to requirements and includes testing of the operating system if this is necessary for the proper functioning of the hardware.**
Traceability Matrix	**The traceability matrix enables tests and test results to be correlated and traced back to their controlling specification.**
Test Report	**The test report is a summary of testing completed and make mention of any deviations, test failures or constraints and corrections. The test report may be combined with the IQ and OQ protocols.**
Qualification Report	**The results of the qualification work must be summarised and reported, either as a separate document, or combined with the change control**