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Document Detail

Type: GLBL-SOP

Document No.: GLBL-SOP-00060[6]

Title: Global IT Infrastructure Qualification SOP

Status: CURRENT

Effective Date: 30-Nov-2024

Legacy No.: N/A

Related

Requirement Number	Title
GIT-GEN-00013	CRL Windows Server Standard
GLBL-FRM-00048	INFRASTRUCTURE QUALIFICATION PROTOCOL
GLBL-FRM-00049	Global IT Infrastructure Qualification Protocol Summary Report - Form
GLBL-SOP-00045	Configuration Management
PABio-SOP-00376	OPERATION AND MAINTENANCE OF THE GENESYS 10S UV-VIS SPECTROPHOTOMETER
GLBL-SOP-00084	Basic Server Installation, Maintenance and Decommissioning Procedure

Document Detail

Document Approval

System Role	Signatory	Sign-off Date	Sign-off By	Approval Decision
GLBL DOCUMENT REVIEWER	Gilles Ducros	20-Nov-2024 9:36 am	GDUCROS	Approve
GLBL DOCUMENT AUTHOR	Srivats Bharadwaj	19-Nov-2024 5:11 pm	CR246830	Approve
GLBL DOCUMENT APPROVER	Birgit Girshick	20-Nov-2024 6:23 pm	BGIRSHICK	Approve
GLBL QA DOCUMENT APPROVER	Marc Altres	20-Nov-2024 7:11 pm	M_ALTRES	Approve
GLBL QA DOCUMENT APPROVER	Jason J O'Hare	22-Nov-2024 7:40 pm	JJO37064	Approve
GLBL QA DOCUMENT APPROVER	Prova Barman	20-Nov-2024 7:09 pm	CR222722	Approve

1.0 PURPOSE

To outline consistent methodologies for infrastructure qualification, requalification, and review, to ensure the CRL infrastructure functions per intended design at all Sites. These qualification methodologies will be observed for the installation and ongoing operation of information technology infrastructure.

2.0 SCOPE

This document applies to the CRL infrastructure at all Sites. Information Technology (IT) will be engaged in implementing changes and maintaining changes to all applicable infrastructure, as outlined within this SOP. This document applies to infrastructure qualification documentation activities that support both projects and Break-Fix (Operations) engagements. (For Windows Server IQ, please refer to GLBL-SOP- 00084 – Basic Server Installation, Maintenance and Decommissioning Procedure.

2.1 Infrastructure components considered to be in scope would include:

2.1.1 Network Devices: Network devices (switches, routers, access points, firewalls, and associated network software).

2.1.2 Storage Devices: Hardware, associated software, and cloud storage solutions services.

2.2 Platforms: A combination of hardware or software that act as a set of objects used to build higher level functional applications and/or services, including, but not limited to virtualization technologies and/or cloud-based services.

2.3 Supporting Components: Including, but not limited to; smart rack systems and uninterrupted power supplies.

2.3.1 Security Appliances and Endpoint Agents.

2.3.2 Infrastructure management and monitoring software.

2.4 Global IT systems used in support of GxP-controlled systems (Citrix and Lansweeper).

2.5 Software applications and their interactions with each other are excluded from the scope of this SOP.

3.0 RESPONSIBILITIES

Vendors and vendor supplied technology must be approved prior to use in accordance with the Global Vendor Program. Additional roles/responsibilities are identified below and may be detailed in the corresponding IQP. Infrastructure changes will be made by authorized Information Technology personnel or authorized and approved vendors who specialize in a specific type of infrastructure technology.

ROLE	RESPONSIBILITY
IT SME / Qualification Engineer	Approve, by dated signature, the TDD, IQP, As Built Document, Test Scripts, Baseline Configuration Documents and IQR.
System Owner	Responsible for providing the overall functionality of the qualified system to the organization and ensuring Annual Reviews are executed completely. Approve, by dated signature, the IQP, and IQR.
System Administrator	Responsible for overall management of the qualified system, ensuring compliance with the appropriate SOPs and/or additional tasks delegated by the System Owner. Responsible for the administration of decommissioning of the qualified systems or components.
GCVQA	Review and approve, by dated signature, both the IQP and IQR as GMP QA (for GxP systems).

4.0 DEFINITIONS / ABBREVIATIONS

TERM / ABBREVIATION	DEFINITION
As Built Document	The As Built document details the final configuration of the infrastructure component(s) under scope for qualification.
Baseline Configuration Document	Baseline Configuration documents detail the configuration of an infrastructure component (if necessary) before any test scripts are executed.
CAB	Change Advisory Board. The change advisory board (CAB) is a body that exists to support the authorization of changes and to assist change management in the assessment and prioritization of changes.
CMDB	Configuration Management Database (Library)
GT	Global Technology
GCVQA	Global Computer Validation Quality Assurance
GxP	General abbreviation for “Good Practices” regulations and guidelines applicable to bio/pharmaceutical and medical device industries (e.g., Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP)).
IQP	Infrastructure Qualification Protocol. Represents a process that captures the steps to be taken and documentation required to qualify infrastructure component(s).
IQR	Infrastructure Qualification Report: Summary Report of activities and results of activities conducted during the execution of the IQP.
MSP	Managed Service Provider. Authorized vendors who specialize and manage specific infrastructure components.
CSP	Cloud Service Provider. Authorized vendors who offer services to create and manage infrastructure components on cloud.

TERM / ABBREVIATION	DEFINITION
RFC	Request for Change. A service desk ticket completed by the change technician to record/track the upcoming installation qualification.
SME	Subject Matter Expert
Sites	Public cloud or private cloud data centers and locations hosting Charles River Laboratories infrastructure and systems
Standard Change	A standard change is one that is frequently implemented, has repeatable implementation steps, and has a proven history of success. As standard changes are pre-approved, they follow a streamlined process in which group level or peer approval and CAB authorization steps are not required.
TDD	Technical Design Document is an internal IT document used to define the project for engineers to follow. It is not part of the qualification package, though may be referenced in qualification deliverables.
Temporary Device	A device intended to be used for a short period of time, e.g., for a Proof of Concept. For example, a device that does not collect or transmit any GxP data.

5.0 MATERIALS

N/A

6.0 PROCEDURE

6.1 General

6.1.1 This procedure describes the qualification process. The use of Kneat as a paperless qualification tool is preferred. The GIT Qualification discipline within Kneat contains approved and versioned documents which comply with the requirements set in this procedure.

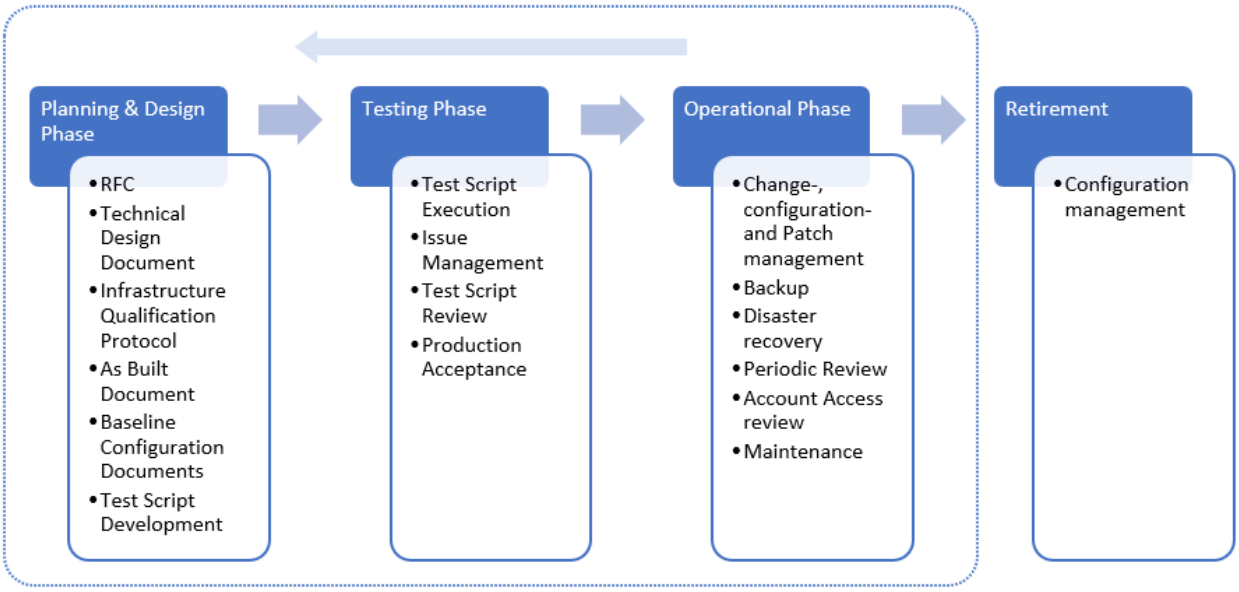
6.1.2 In cases where Kneat is not used but DocuSign is used, the DocuSign Use and Administration SOP-GLBL-SOP-00016 apply. All qualification deliverables, including but not limited to the IQR, IQP, As Built, and test scripts, must conform to the following requirements:

- All dates are in format dd-mmm-yyyy.
- Documents have a header/footer on all pages that indicates:
- Document title
- Qualification project number
- Document version

- Pagination in **Page x of y** format
- Documents will be initialed and dated or signed and dated.

6.2 Overview

An overview of the qualification process is below. Phases and specific deliverables are detailed below.



In scope of the SOP

6.3 Process

The qualification methodology will follow a typical lifecycle for infrastructure components as outlined below (adherence is determined by project requirements and outlined in the IQP):

6.3.1 Planning and Design Phase

Decisions made on infrastructure components to procure based on business requirements, ensure build and user acceptance requirements, and ensure adequate processes and support structures are in place.

6.3.1.1 RFC follows GIT-SOP-00001, Change Management Process.

6.3.1.2 A protocol (IQP) will be used to define the plan to qualify the infrastructure including roles and responsibilities, tasks to be accomplished, and responsible parties for each task. The level of detail for the IQP will be determined during the project

requirements gathering phase; however specific requirements are detailed below.

6.3.1.3 Test scripts are developed based on components and configuration in the As Built document .

6.3.1.4 The IQP and As Built Document must be approved prior to the commencement of any testing.

6.3.1.5 Baseline Configuration documents must be created prior to the commencement of any testing.

6.3.2 Testing Phase

6.3.2.1 Testing is performed using test scripts, including creation of as-built documents to show final configuration.

6.3.2.2 Vendor provided qualification or validation documents may also be used and detailed in the IQP and IQR, where appropriate.

6.3.2.3 Management of any issues found during testing are identified with documented rationale or corrective actions taken to remedy the issue.

6.3.2.4 Test script review is performed to ensure test script(s) were executed to meet the scope and meet good documentation practices.

6.3.2.5 Production Acceptance

Production acceptance may not be applicable or possible for all deployments and/or changes. In cases where production acceptance and “go-live” milestones are required, a completed qualification package with the following documents serve as acceptance and release to production.

6.3.2.5.1 An approved IQP

6.3.2.5.2 An approved As Built document and Baseline Configuration documents (if applicable)

6.3.2.5.3 Completed test scripts

6.3.2.5.4 An approved IQR

Acceptance criteria are based on the provided proof the infrastructure being qualified was built per original specifications and is operating per specifications. Once accepted, the item is entered into the CMDB.

6.3.3 Operational Phase

Production use, control and maintenance occurs in this phase and may include, but are not limited to the following:

6.3.3.1 Change, Configuration and Patch Management

6.3.3.2 Backup and Restore

6.3.3.3 Disaster Recovery

6.3.3.4 Annual Review (see 6.3.5)

6.3.3.5 Annual account access review

6.3.4 Ongoing Maintenance

Technical work instructions may be developed to describe commonly repeated tasks for qualified infrastructure including for example patching, monitoring, capacity and lifecycle management.

6.3.5 Requalification

6.3.5.1 When there is a change to a qualified infrastructure, checks must be conducted to determine if requalification is needed. If required, the system should be requalified as before, either individually or as part of group of components. Annual review may also be triggered to evaluate the need for requalification. The System Owner will review and decide if there is a need for requalification. The following points are factors for consideration as part for overall decision:

- Has the current configuration changed from the baseline documents referenced in the Infrastructure Qualification Report?
- Has any configuration item of the qualified system had a software (major version only) or hardware upgrade (not break/fix) since the last qualification?
- Has the design specified in the As Built document changed since the last qualification?
- Have there been any documented Data Integrity incidents for the qualified system?
- Have any incidents, deviations or issues remained open/occurred for the system since the last qualification?
- Has the system undergone Change Management since the last qualification?
- If an Audit Trail review is required, have any system issues been identified as a result?
- Are there issues with the existing Qualification Package documentation (e.g. missing documents/approvals or not closed/retained properly)?
- Annual account access review

6.3.5.2 If requalification Is needed, the change will be described in the Scope and Process sections of the IQP.

6.3.6 Deliverable Requirements

6.3.6.1 Installation Qualification Protocol Requirements

The IQP is a controlled and versioned document that specifies requirements of the qualification and is a basic element of a qualified infrastructure component. The format may vary and will be considered acceptable for use as long as the IQP contains the following required information:

- Purpose: Detail the strategy and scope for the qualification to show the system operates as intended and is configured correctly.
- Scope: Detail what components are included in the qualified system.
- Process – Detail how the qualification will be completed including a list of deliverables, any document control, any significant project risks with mitigation, issue management and acceptance criteria.
- Assumptions, Limitations and Exclusions – list any assumptions, limitations and exclusions made during the qualification.
- Definitions: This is optional.
- References: This should include SOPs and the IQR.
- List of Appendices: This is optional.

6.3.6.2 As Built Document Requirements

The As Built Design Document shows the detailed, final equipment list and system configuration. Qualification testing occurs against the information in this document.

6.3.6.3 Baseline Configuration Document Requirements

Baseline Configuration Documents show the configuration of each device when the qualification is performed. All Baseline Configuration Documents must meet the following electronic requirements:

- Filename must indicate device
- File must indicate versioning or date
- Digitally signed in Kneat or on first or last page using DocuSign

6.3.7 Test Script Requirements

Test script is a basic element of a qualified infrastructure component. The format may vary and will be considered acceptable for use as long as the test script contains the following required information:

- Test Script Title
- Test Script Number: Test scripts must be numbered sequentially. Test script numbers must include the type of testing (e.g., IQ, UAT) designation as part of the number.

- Test Objective: The purpose of the test or what it is expected to demonstrate (e.g., to verify that the software was installed according to the vendor's specifications).

  Preparation and Setup – A description of any 1) prerequisites required prior to executing the script, 2) test data required to perform the test, and/or 3) instructions the tester requires to execute the script.

- Step Number: Each test step is numbered sequentially in whole numbers to ensure repeatability, and that tests are carried out in a consistent manner in the appropriate sequence.

- Test Procedure: Instructions for performing the test step should reflect the work process. Instructions for capturing screen shots must be included in the test procedure. Additional screen shots may be taken as needed during execution to clarify test step results. Expected results should not be described in the procedure.

- Expected Results: The results that are expected when the instructions in the test step are executed.

- Actual Results or Results Location: This column is provided for entry of the actual results that are obtained when the test is performed or to provide a location of the actual results. This column must be completed by either stating the results obtained or referencing supporting test documentation. Actual results must not be pre-populated.

- Pass/Fail: These columns are used to indicate "Pass" or "Fail" when the test is performed. If the result obtained is as expected in the expected results column, the step will be marked as "Pass". Otherwise, the step will be marked as "Fail".

- Comments: This section is an optional field used to provide additional information. The tester may use this area to provide a description of any errors (e.g., data entry error that can be used where space on the test script is limiting). All comment entries must be initialed and dated or signed electronically using Kneat or DocuSign.The comment section must not be left blank. If there are no comments, the text "None" should be entered then initialed and dated or signed electronically using Kneat or DocuSign.

- Supporting Documentation (Attachments): When using Kneat all supporting documentation can be pasted directly into the test scripts. If not using Kneat all supporting documentation must be labeled with the associated test script identification number and test step number(s). Initials/date of the tester are required on the first or last page. If several attachments are captured for a single test step, they should be labelled sequentially (e.g., Step 2a, 2b, 2c).

- Post Execution Signatures: Post execution, the tester will complete each test script with their printed name, signature and date. Electronic signatures can be used within Kneat or DocuSign where the date will be added automatically. The test scrips must be routed for review to a reviewer who is qualified and trained on the process and system
- A reviewer will review each test script and its supporting documentation with their printed name, signature, and date. Electronic signatures can be used within Kneat or DocuSign where the date will be added automatically. An individual cannot review a test script that he/she has executed.

6.3.7.1 Installation Qualification Report Requirements

The IQR is a controlled and versioned document that summarizes the project and is a basic element of a qualified infrastructure component. Approval of the IQR closes the project. The format may vary and will be considered acceptable for use as long as the IQP contains the following required information:

- Purpose of Qualification: To confirm that the IT infrastructure components are configured as detailed in the Protocol and that they meet the required business needs and operate as originally intended.
- Results of Testing: Details of test scripts including when they were executed and whether they were successful.
- Discrepancies: Discrepancies are any situation in which expected results are not met.
- Deviations: Deviations are any situation in which the protocol or procedure was not followed.
- Special Considerations: Any special considerations noted during the qualification.
- Conclusion: This should summarize the qualification and confirm that the test scripts were run successfully, and the IT infrastructure components have been qualified as detailed in the Infrastructure Qualification Protocol.
- References: This should include SOPs, the IQP, the As Built document, all Baseline Configuration documents, test scripts and, if applicable, Offshore Monitoring reports.

6.3.8 DocuSign Usage Requirements

To comply with Data Integrity requirements, the following processes need to be followed while using DocuSign for test script execution.

- A DocuSign Sender must set up test scripts for a single user only on a single day

- The test script template must be appropriately set-up by the sender to ensure that data is entered by the individual attesting the activity (e.g., executor, reviewers, and approvers).
- Only a single tester must control a test script and this is indicated by the tester's signature to attribute the entered data
- The executor must reject the form prior to entering the data if they cannot attest the activity for attribution and contact the DocuSign router or GT management.
- If multiple testers are required, the test steps must be split into multiple test scripts, each with a single tester.
- Screenshots for critical steps will be provided to support accuracy of the results.
- Review and approval of QA will be documented by the QA Approval signature in the Infrastructure Qualification Report. If the quality or integrity of the test scripts are in doubt, appropriate actions are required (e.g., deviation, re-testing).
- Use of "Finish Later" is not permitted.
- If testing cannot be performed within a single day, the tester must attest to the executed steps and make comments in mandatory fields as ‘’Test could not be executed today, execution will be done in the next version of the test script’’. The remaining test steps must be executed in the next version of the executed test script at a different date
- The test script format requires clear designation of where the tester, reviewer, and approver must sign.
- The table below is acceptable signature reasons for test script actions, where appropriate. The tester must use the "Approve" signature reason to attest to execution and approval of the results recorded.

DocuSign Reason	Test Script Use
Author	Not used
Review	Post-execution test script review by non-tester SME.
Approve	Pre- and post-execution approval of the test script, when required. Tester's execution of test script must use this signature reason. Includes attestation and attribution for the data.

7.0 REFERENCES

7.1 SOPs

7.1.1 GLBL-SOP-00016 DocuSign Use and Administration

7.1.2 GIT-SOP-00001 Change Management Process

8.0 REVISION HISTORY

Revision	Effective Date	Reason for Revision
1.0	17 FEB 2020	Initial release of SOP
2.0	23 AUG 2021	1) Updated to add clarification of the following: - Required qualification documentation - Test script details - Requalification event questions 2) Added in scope infrastructure
3.0	28 Nov 2022	Amended paragraph in Sec. 3 ‘’System Owner Role’’ to clarify responsibility of a system owner.
4.0	24 Jul 2023	Updated section 6.4.3. Added section 6.4.3.2 to capture processes need to be followed while using DocuSign for test script execution.
5.0	06 Jul 2024	Updated entire document to include details of how Kneat can be used to perform IT Infrastructure qualifications. Also added details of Baseline Configuration documents.
6.0	See Cover Page for Effective Date	SOP updated throughout to include cloud services within the scope. Necessary amendments made to baseline configuration documentation requirements to align SOP with the practical workflow. Added reference to GLBL-SOP-00016 for additional context.