

Overview

Validation is the process of providing documented evidence that equipment, computer systems and processes are installed, operate and perform as specified providing consistent results. The necessary documented evidence is provided through the development of two primary groups of documents. They are specification documents and Validation Protocols:

Specification Documents – There are 3 primary specification documents:

- 1) **Functional Requirements Specifications** – This is a controlled document defining the top-level functional business rules and user requirements for each business process with Quality System or GMP impact.
- 2) **Functional Design Specifications** – This is a controlled document defining the configuration of the system in order to support the business requirements defined in the Functional Requirements Specification.
- 3) **Data Migration Specifications** – This is a controlled document defining the process and data to be manually or electronically loaded into the new or upgraded system and how this data will be verified accurate.

Validation Protocols – These are tests executed during the formal testing phase to validate and/or prove that each requirement can consistently be met and provide consistent results.

RCM offers three service options for the computer systems validation of the QAD ERP System:

1) PURCHASE

The full suite of validation documents and protocols are available for sale. The validation activities will be performed by corporate staff.

2) TEAM APPROACH

The Team approach utilizes a combination of RCM and corporate staff. During this process the corporate staff will gain the knowledge to perform additional validation without third party involvement.

3) TURNKEY APPROACH

This approach utilizes RCM Staff to perform all validation activities with a minimal impact on corporate staff. This approach will require third part involvement for future validations/revalidations.

The RCM QAD Validation Practice has the knowledge and experience to ensure that your QAD ERP System will be and remain FDA (21 CFR Part 11) and GMP compliant.



Enterprise QAD Solutions

Built on QAD® applications, RCM Technologies' Enterprise QAD Solutions unit provides high quality, cost-effective business solutions and services that enable customers to meet and exceed their objectives. QAD® applications manage the core business processes of your enterprise, with industry-specific design functionality. As an authorized Sales and Services Channel Partner of QAD®, RCM leverages the expertise of their staff and proven methodologies to assist clients in implementing QAD® applications.

For almost two decades, RCM has been recognized as a leader in providing QAD® applications for business solutions. By understanding industry trends, challenges, and issues, RCM extends the capability of QAD® Enterprise Applications and maximizes a client's investment.

North American Channel Alliance “Partner of the Year”

~ for five consecutive years

RCM has certified consultants that have documented and mastered the best training techniques that are now readily available to you and your team. RCM will train your organization or perform validation activities such as:

- 1) Validation Project Management
- 2) Validation Team Building
- 3) Preparation of all required documents including:
 - **Project description:** a comprehensive document describing the validation project.
 - **System Validation Master Plan:** a comprehensive document detailing the validation activities to be completed for the particular hardware and software and the plan to meet those activities (basically what we are going to do and how we are going to do it).
 - **Functional Requirements Specification:** a comprehensive document detailing the functional business requirements required to ensure the QAD system operates as required.
 - **Functional Design Specification:** a comprehensive document detailing the design required to ensure the functional requirements are met.

- **Server and Software Installation Qualifications:** a document describing the qualifications and a series of protocols that detail the steps required to verify that the server(s) and software have been properly installed per vendor and corporate requirement including information such as climate controlled room, secure environment and adhere to vendor specifications.
- **Server and Software Operational Qualifications:** a document describing the operational qualifications and a series of protocols designed to verify that the server and software operate in accordance to vendor and corporate requirements.
- **QAD Application Operational Qualification:** a document describing the application operational qualifications and a series of functional protocols that will provide documented evidence that the requirement and design specifications are met and can produce consistent results.
- **Data Migration Specifications:** a document detailing what data is to be manually or electronically loaded into the new/upgraded system from a legacy system.
- **Trace Matrix:** a document cross referencing the requirement and design specifications to the individual protocols executed to prove the specification.

- **Final Validation Report:** a report that summarizes the activities performed and details the validated status of the system.
- **Instructions for Protocol Execution:** a document detailing specific instructions on the execution of the protocols, how changes are to be made and how to record defects.

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