

Datex Software Validation Services

Datex works closely with our pharmaceutical and life science clients to provide exceptional service and support in a cost-effective manner. Working in regulated industries usually requires that companies follow tightly controlled processes for the development and manufacturing of products required to meet the strictest quality standards. This often necessitates the use of enterprise systems, including software to monitor the production, purchasing, documentation and traceability of goods. In addition, compliance requirements management is essential.

Pharmaceutical, Medical Device and Life Sciences Clients

The FDA requires that software systems used for quality purposes in place of paper records be validated for their intended use Title 21 CFR Part 820(i). This means that when using systems, companies must verify that the software is configured correctly to meet their business needs. Even if you are intending to do a relatively “basic” or “standard” implementation, you need to have documented evidence verifying that the system was correctly installed and configured for your intended use.

Datex Validation Services for Expert Assurance

- ✓ **Validation Plan**
- ✓ **Installation Specification**
- ✓ **Installation Qualification (IQ)**
- ✓ **Operational Qualification (OQ)**
- ✓ **User Acceptance Testing (UAT)**
- ✓ **Trace Matrix**
- ✓ **Validation Summary**

Overview of Datex Validation Services

Validation Plan

The Validation Plan outlines the targeted testing areas as well as the testing deliverables. Datex works hand-in-hand with clients to ensure that only those areas being utilized are tested as well as to provide justifications for those areas that may need more or less testing.

Installation Qualification (IQ)

The Installation Qualification verifies the Installation Specification as well as the required settings that are turned on and performing as expected. In addition, the IQ verifies the visibility of each role and the functionality that can be viewed.

Installation Specification

The Installation Specification document outlines the Datex FootPrint® WMS installation requirements. One of the important elements of regulatory compliance often involves limiting the access of records to authorized users only. The Installation Specification document provides information on how user roles and specific permissions are defined by the client as well as information on settings that are related to more security-driven regulations.

Operational Qualification (OQ)

In the Operational Qualification, the Datex team provides tests for the requirements that were gathered during the business process analysis and focuses on the system functionality consistently performing as expected. The Datex team will customize the test cases within the OQ to meet the client's specific system use. Within the OQ, testing is of a more granular nature, made up of multiple different test plan documents which cover different functional areas.

User Acceptance Testing (UAT)

Within the User Acceptance Testing phase of validation, generalized, the validation effort concentrates on executing higher level testing designed for use in ensuring that users test the customizations applied to the system. Test cases and provided documents will allow the users to verify the customizations meet their business needs from a day-to-day use perspective.

Using the agile process, User Acceptance Testing drives the testing-delivered functionality to enable changes to be made in later iterations if needed. It is important to note that the Operational Qualification may be impacted if custom changes are made after testing change functionality has been completed.

Trace Matrix

During the Trace Matrix phase of the validation process, the Datex team will verify that all requirements either have test case coverage or a justification has been provided for those requirements which have not been covered. The Trace Matrix shows the connectivity between the test plans and the requirements.

Validation Summary

The final phase of the Validation process involves providing a Validation Summary of all the testing that has been completed. This provides an easy-to-use document that can help facilitate the client to highlight any findings that need to be addressed over the course of the Validation Process.

Datex Validation Services are billed on a professional service per hour basis. An estimate of the hours needed for completion of this service will be provided based on the information gathered through discussions and communications with the client.



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