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Short communication

Risk-based validation of a spectrophotometric data system in a GMP-regulated environment

Elena Pacheshkoska*, Natasha Uroshevikj, Sanja Despotovska

Quality Control Pharmaceuticals, ALKALOID AD Skopje, Blvd. A. Makedonski 12, 1000 Skopje, N. Macedonia

Introduction

Spectrophotometric analysis is a fundamental analytical technique used in pharmaceutical quality control laboratories for identity testing, assay determination, and stability studies. The reliability of analytical results depends not only on instrument performance but also on the computerized data systems responsible for instrument control, data acquisition, processing, storage, and reporting.

Because these systems support GMP-relevant decisions, they must be validated. EU GMP Annex 11, FDA 21 CFR Part 11, and GAMP 5 recommend a lifecycle- and risk-based approach to ensure validation effort is proportionate to impact on product quality and data integrity (European Commission, 2011; FDA, 2003; ISPE, 2018). This communication describes the application of that approach to software used with a spectrophotometric system in a GMP-regulated quality control laboratory.

Materials and methods

Validation planning and system classification

Validation activities were initiated with the preparation of a Validation Plan defining system scope, intended use, applicable regulatory requirements, and overall validation strategy. Based on its functionality and configurability, the software was classified as a GAMP 5 Category 4 system (configured product), leading to a validation strategy primarily focused on verification of GMP-relevant configuration elements rather than comprehensive testing of standard software functionality (ISPE, 2018).

User and system specifications

A User Requirements Specification (URS) was developed to formally define the functional, business, regulatory, and data integrity requirements applicable to the spectrophotometric data system.

A Design Specification described system architecture, key functions, and data flow. A Configuration Specification documented GMP-relevant setting such as user roles, access controls, audit trails, electronic records, and data storage, ensuring traceability between requirements and implementation (European Commission, 2011).

Risk assessment

A structured Functional Risk Assessment was conducted based on the URS in order to evaluate the potential impact of system functions on product quality and data integrity. Each requirement was assessed in terms of severity, probability of occurrence, and detectability of failure, resulting in an overall risk classification (ICH, 2005).

Functions identified as GxP-critical were associated with defined risk mitigation measures and assigned enhanced verification activities. The outcomes of the risk assessment were used to determine the scope, depth, and focus of qualification

*epaceskoska@alkaloid.com.mk

testing, ensuring that the validation effort was proportionate to the identified risks.

Qualification activities

Installation Qualification (IQ) activities were performed to verify that the software, hardware components, operating system, and supporting infrastructure were installed and configured in accordance with predefined specifications and manufacturer recommendations. Successful IQ execution confirmed system readiness for operational testing.

Operational Qualification (OQ) verified the correct functioning of critical and high-risk features under controlled conditions using a black-box approach reflecting routine laboratory workflows (ISPE, 2018). Test scenarios covered user access, data acquisition and processing, audit trails, electronic records, and security, with direct traceability to URS requirements and risk assessment results.

Validation completion and production release

All executed validation activities, test results, deviations, and corrective actions were formally documented in the Validation Report. Upon confirmation that all acceptance criteria were met and no unresolved critical issues remained, the system was formally approved for GMP use. Following validation approval, the software was released into a controlled production environment, enabling routine use by trained analysts for spectrophotometric analysis within the quality control laboratory.

Results and discussion

The risk assessment identified functions with direct relevance to data integrity and regulatory compliance, including user access management, audit trail generation and review, analytical data processing, and secure data storage. Linking URS requirements with identified risks ensured that validation activities were focused on GMP-relevant areas.

Execution of IQ and OQ demonstrated that the software performed as intended under simulated routine operating conditions. The applied risk-based approach enabled optimized allocation of validation effort while maintaining full regulatory compliance. Traceability between requirements, risk assessment outcomes, mitigating controls, and executed test cases was maintained throughout the validation lifecycle, and all deviations were assessed and resolved prior to final system approval.

The URS comprised 67 requirements covering administrative, functional, data, technical, interface, user role, performance, security, and lifecycle aspects. OQ included four test cases covering the analytical process, administration, remote login, and user administration. Several GMP-relevant requirements showed initially high risk, especially user administration, access control, data integrity, authorized access, and audit trails. All deviations were resolved before final approval, with no open corrective actions remaining.

Conclusion

A structured, risk-based validation approach for spectrophotometric software effectively controls GMP-relevant risks and supports data integrity. Focusing validation on critical functions identified through risk assessment enables efficient, scientifically sound regulatory compliance in pharmaceutical quality control laboratories.

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