



QAD Adaptive Applications

User Requirements Specifications
QAD EQMS Applications
Risk Management

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Risk Management User Requirements Specification Change Summary

The following table summarizes significant differences between this document and previous versions.

Date/Version	Description	Reference	Changed By
JULY 2020/v2020	Initial upload	--	RQT
NOV 2020/v2020.1	Updated versioning; Added a General section	p. 7	RQT
MAR 2021/v2021	Updated versioning	--	RQT
AUG 2021/v2021.1	Updated versioning	--	RQT
MAR 2022/v2022	Updated versioning	--	RQT
SEPT 2022/v2022.1	Updated versioning; Updated the General section	p. 7	RQT
MAR 2023/v2023	Updated versioning; Updated the General section	p. 7	RQT
MAR 2024/v2024	Updated versioning; Updated the General section	p. 7	RQT
SEPT 2024/v2024.1	Updated versioning; Updated the General section	p. 7	RQT
MAR 2025/v2025	Updated versioning; Updated the General section	p. 7	RQT

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Purpose

This requirements specification includes the documentation of the EQMS Applications business requirements for the EQMS Risk Management Module version 2025.

This document was used as the basis for the configuration of the Risk Management Module and shall be used in the definition of testing criteria for operational qualification.

Scope

The scope of this document is to define the EQMS Applications business requirements for the Risk Management Module version 2025.

Risk Management

An electronic risk management application facilitates the management of risk and enables the definition, prioritization, and mitigation of risks that require investigation or monitoring.

Risk Assessments

1. The system shall have the ability to document one or more risk assessments for the purposes of identifying and organizing risks for a particular group.
2. The system shall have the ability to generate a risk assessment for different levels within the organization, including domain, site, and/or department.
3. The system shall have the ability to generate a risk assessment for a particular process and/or standard (including customer-specific requirements).
4. The system shall have the ability to set up a review frequency for a risk assessment and notify the coordinator upon reaching the next review date.
5. The system shall have the ability to define risks for the following system-based contexts: APQP Projects, Change Requests, Manufacturing Documents, Objectives, Processes, and Suppliers.

Risks

1. The system shall have the ability to identify a risk including: number, title, type, and description.
2. The system shall have the ability to analyze and evaluate a risk using the standard likelihood and consequence methodology that ultimately automatically produces a risk score.
3. The system shall have the ability to document a bow-tie analysis as part of determining the likelihood and consequence.
4. The system shall have the ability to document the treatment options and current treatment controls for a risk.
5. The system shall have the ability to monitor and review a risk.
6. The system shall have the ability to generate a non-conformance for a risk.
7. The system shall have the ability to generate a lessons learned from a risk.
8. The system shall have the ability to define a library of risks associated with one of the system contexts for the purposes of quickly applying risks to a new item within the context.
9. The system shall have the ability to define key risk indicators for a risk.

Incidents

1. The system shall have the ability to identify risk events or incidents.
2. The system shall have the ability to track risk events or incidents to resolution using actions.
3. The system shall have the ability to escalate a risk event or incident to a non-conformance or complaint.
4. The system shall have the ability to associate a risk event or incident with one or more cause codes and one or more risks.

Setup

1. The system shall have the ability to maintain a list of risk drivers for the purposes of organizing risks.
2. The system shall have the ability to build a hierarchy of risk types.
3. The system shall have the ability to define one or more risk ratings for likelihood.
4. The system shall have the ability to define one or more risk ratings for consequence.
5. The system shall have the ability to define a risk acceptability matrix.
6. The system shall have the ability to define one or more library controls for the purposes of easily reusing controls on more than one risk.

Metrics

None defined.

Reports

1. The system shall have a report to print a risk summary.
2. The system shall have a report to print the risk acceptability matrix.

General

1. The system shall support Coordinated Universal Time (UTC), which adjusts Date/Time fields to represent the Date/Time in the current user's timezone (added in 2020.1).
2. The system shall have a global search feature to search for records within the system that have the search term in applicable fields and within files linked to File fields (added in 2020.1).
3. The system shall have the ability to create URLs to other systems in the Navigation menu (added in 2020.1).
4. The system shall provide audit trail reports for all records (added in 2022.1).
5. The system shall have an option to disable the ability to approve a record without opening it (added in 2022.1).
6. The system shall allow checklist responses to have the same score among different responses—e.g. to allow all wrong answers to have a zero value (added in 2023).
7. The system shall allow users to easily move to the next detailed record based on the search screen initiating the detailed screen view (added in 2023).
8. The system shall provide a web-based report designing tool (added in 2023).
9. The system shall provide an option to limit users to be able to only view records associated with the sites specified in their employee record (added in 2023).
10. The system shall have an option to see the prior rejection comments during a re-approval of a record (added in 2023).
11. The system shall provide the ability to report on the security configured for each process including customer extensions/changes to security setup (added in 2024).
12. The system shall allow the user to cancel the generation of a report (added in 2024).
13. The system shall provide the ability to open multiple EQMS windows in the same browser tab (added in 2024).
14. The system shall provide the ability to embed video in key areas (added in 2024.1).

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15. The system shall provide the ability to support arrays of images in key areas (added in 2024.1).
 16. The system shall provide (for critical workflow processes) a visual indicator of the progress of a record through its life-cycle (added in v2025).
 17. The system shall provide a mechanism to socialize a record with others including @mentions that notify those individuals mentioned (added in v2025).