



QAD Adaptive Applications

User Requirements Specifications QAD EQMS Applications Auditing

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	1
Confidentiality	4
Purpose	5
Scope	5
Auditing	6
Audits	6
Layered Process Audits	7
Setup	7
Metrics	8
Reports	8
General	8

Auditing 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. 8	RQT
MAR 2021/v2021	Updated versioning.	--	RQT
AUG 2021/v2021.1	Updated versioning	--	RQT
MAR 2022/v2022	Updated versioning; Updated the Audits section	p. 6	RQT
SEPT 2022/v2022.1	Updated versioning; Updated the General section	p. 8	RQT
MAR 2023/v2023	Updated versioning; Updated the Audits section; Updated the General section	p. 6, p. 8	RQT
MAR 2024/v2024	Updated versioning; Updated the General section	p. 8	RQT
SEPT 2024/v2024.1	Updated versioning; Updated the General section	p. 8	RQT
MAR 2025/v2025	Updated versioning; Updated the Audits section; Updated the General section	p. 6, p. 8	RQT
SEPT 2025/v2025.1	Updated versioning; Updated the Audits section; Updated the General section	p. 6, p. 8	RQT
SEPT 2026/v2026	Updated versioning	--	F6J

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Purpose

This requirements specification includes the documentation of the EQMS Applications business requirements for the EQMS Auditing Module version 2026.

This document was used as the basis for the configuration of the Auditing 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 Auditing Module version 2026.

Auditing

Facilitates strategic audit planning, automatic audit scheduling, and findings management.
Configurable checklists/questions. Integration with non-conformance.

Audits

1. The system shall have the ability to maintain an audit schedule using a manual scheduling system or a recurring pattern.
2. The system shall have the ability to use one or more audit checklists as part of the audit for the purposes of identifying questions and/or concepts that auditors should respond to.
3. The system shall have the ability to insert ad hoc questions into an audit.
4. The system shall have the ability to define the audit team, including auditors and auditees.
5. The system shall have the ability to define the organization coverage for an audit for the purposes of proving that all organization levels (domains, sites, departments, work centers, and/or shifts) have been audited.
6. The system shall have the ability to define the reference coverage for an audit for the purposes of proving that audits were completed covering the appropriate standards and/or customer-specific requirements.
7. The system shall have the ability to document the results of the audit including any audit findings.
8. The system shall have the ability to score audits using various methods, including weighting of questions.
9. The system shall have the ability to create one or more non-conformances based on an audit.
10. The system shall have the ability to integrate with Document Management, including identifying which document(s) were reviewed as part of an audit.
11. The system shall have the ability to reference a documentation set and specific process control plan rows for the purposes of conducting a part audit.
12. The system shall have the ability to notify the lead auditor of a scheduled audit.
13. The system shall have the ability to notify an audit organizer of a past due audit.
14. The system shall have the ability to notify an audit organizer that an audit has been completed.
15. The system shall have the ability to display previous audits for the purposes of quickly identifying items that should be followed up on during the next audit.
16. The system shall copy the related document links for an audit checklist question into the Audit—Reviewed Document(s) list (added in 2022).
17. The system shall allow an audit creator to specify the audit recurrence and scheduling for subsequent audits in the series (added in 2023).
18. The system shall allow the user to specify the Domain, Entity, and Site(s) to which the following apply: Audit Finding Types, Audit Types, Audit Questions, and Audit Question Categories (added in 2023).
19. The system shall provide a place to specify the audit organizer (in addition to auditors) (added in 2023).
20. The system shall send notifications to the audit organizer when an audit is completed or becomes past due (added in 2023).

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21. The system shall provide a report that allows the organizer to see audit findings for audits they organize (added in 2023).
 22. The system shall require all audit questions to be completed or specifically marked as skipped before closing an audit (added in v2025).
 23. The system shall allow the ability to create audit findings from the audit result (added in v2025.1).
 24. The system shall allow the ability to escalate to CAPA or escalate to NCR from the audit finding (added in v2025.1).

Layered Process Audits

1. The system shall have the same abilities identified for audits to be used for layered process audits (LPAs).
2. The system shall allow LPA groups and LPA layers to be defined.
3. The system shall allow the requirements for number of audits to be completed to be defined per LPA layer.
4. The system shall have the ability to generate LPAs based on an LPA group.
5. The system shall have the ability to determine which group and which layer an audit was completed for.

Setup

1. The system shall have the ability to define standards and the related sections or requirements, including customer-specific requirements, for the purposes of ensuring adequate auditing coverage.
2. The system shall have the ability to document the details of manufacturing and business processes for the purposes of more quickly reviewing key information during process audits.
3. The system shall have the ability to version process information, including approval prior to changes being official.
4. The system shall have the ability to develop a question library that can be associated with one or more checklists.
5. The system shall have the ability to categorize and sequence checklist questions.
6. The system shall have the ability to create an audit checklist that can be easily copied and modified for the next audit with no retyping.
7. The system shall have the ability to define one or more audit types for the purposes of categorizing audits.
8. The system shall have the ability to integrate with Training Management, to allow one or more skills to be required per audit type.
9. The system shall have the ability to identify which processes help comply with which management system standards, standard sections, and/or standard requirements.
10. The system shall have the ability to define one or more audit finding types.
11. The system shall have the ability to document risks associated with a process that can default based on a risk library only for processes.

Metrics

1. The system shall have a metric for Audit Average Score. The average score of an audit by audit type and site.
2. The system shall have a metric for Audit On-time Completion. A percent that identifies how often audits are completed on time.

Reports

1. The system shall have a report to print an audit detail report.
2. The system shall have a report to print the LPA compliance that ensures layers that are defined are completing the required number of audits on a weekly or monthly basis.
3. The system shall have a report to print an LPA detail report.
4. The system shall have a report to print an LPA question report for the purposes of completing and documenting an audit in a non-electronic manner.
5. The system shall have a report to print audit scoring analysis by several categories such as audit type, site, and time frame.
6. The system shall have a report to print an audit summary report.
7. The system shall have a report to print a list of past due audits.
8. The system shall have a report to print a list of open audits.
9. The system shall have a report to print the number of NCRs created/found during an audit.
10. The system shall have a process card and turtle diagram reports to allow auditors to visually see the details of a process in order to more quickly and accurately conduct a process audit regarding the business/manufacturing processes.
11. The system shall have a cross-tab report to help identify processes that may be missing for a given management system standard. Since management system standards could also include customer-specific standards, this will also provide a method to ensure customer-specific requirements are being met.
12. The system shall have a report to show the assignment matrix for a layered process audit.
13. The system shall have a layered process audit summary report for a selected year and site.
14. The system shall have a report to support VDA reporting.

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).

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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).
 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).
 18. The system shall provide the ability for Semantic Search to apply to search screens and global search results (added in v2025.1).