



QAD Adaptive Applications

User Requirements Specifications
QAD EQMS Applications
NCR & CAPA

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NCR & CAPA 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. 10	RQT
MAR 2021/v2021	Updated versioning; Updated the Non-conformances section.	p. 7	RQT
AUG 2021/v2021.1	Updated versioning; Updated the Non-conformances section.	p. 7	RQT
MAR 2022/v2022	Updated versioning.	--	RQT
SEPT 2022/v2022.1	Updated versioning; Updated the Non-conformances section; Updated the General section	p. 7, p. 10	RQT
MAR 2023/v2023	Updated versioning; Updated the Non-conformances section; Updated the General section	p. 7, p. 10	RQT
MAR 2024/v2024	Updated versioning; Updated the Non-conformances section; Updated the Quality Alerts / Deviations section; Updated the General section; Added a new section: Incident Investigations	p. 7, p. 8, p. 10, p. 9	RQT
SEPT 2024/v2024.1	Updated versioning; Updated the Incident Investigations section; Updated the General section	p. 9, p. 10	RQT

Date/Version	Description	Reference	Changed By
MAR 2025/v2025	Updated versioning; Updated the Non-conformances section; Updated the Quality Alerts / Deviations section; Updated the General section	p. 7, p. 8, p. 10	RQT

Confidentiality

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Purpose

This requirements specification includes the documentation of the EQMS Applications business requirements for the EQMS NCR & CAPA Module version 2025.

This document was used as the basis for the configuration of the NCR & CAPA 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 NCR & CAPA Module version 2025.

NCR & CAPA

A workflow engine to create and track all non-conformances and escalate them into corrective action workflows. Incorporates effective problem solving strategies such as Fishbone and 5 Why tools. Easy-to-use input screens for company-wide engagement in NCR creation. Real time metrics and reporting capabilities. Action notifications ensure workflow completion.

Non-conformances

1. The system shall have the ability to support the 8D problem solving technique.
2. The system shall have the ability to support the A3 problem solving technique.
3. The system shall have the ability to configurable electronic workflow routing for review, approval, and distribution.
4. The system shall have the ability to document one or more non-conformances relating to process, product, or other.
5. The system shall have the ability to escalate a non-conformance to a corrective action.
6. The system shall have the ability to define one or more containment actions for the purposes of defining and tracking the actions that must be completed to contain a problem.
7. The system shall have the ability to define a disposition including approval of that disposition.
8. The system shall have the ability to define the problem associated with a non-conformance.
9. The system shall have the ability to conduct root cause analysis using 5 Why.
10. The system shall have the ability to conduct root cause analysis using Fishbone.
11. The system shall establish links between the process FMEA and non-conformances.
12. The system shall have the ability to define one or more problem solving tasks to help drive the root cause.
13. The system shall allow metrics to be defined for each non-conformance for the purposes of taking a baseline reading of the metric as compared to readings after implementation to help ensure the problem has been resolved.
14. The system shall allow for an approval process to close a corrective action.
15. The system shall have the ability to capture the cost of quality associated with problem solving activities.
16. The system shall have the ability to identify a repeat issue.
17. The system shall have the ability to notify a group of employees when a non-conformance is created.
18. The system shall notify the Notification List when the current state is Corrective Action Complete (added in 2021).
19. The system shall notify the Champion when past the Target Corrective Action Date and the corrective actions are not complete (added in 2021).
20. The system shall have the ability to allow a risk-based assessment of the non-conformance in the form of a standard checklist (added in 2021).
21. The system shall have the ability to generate a change request from a Non-conformance record (added in 2021).
22. The system shall protect ITAR Non-conformance information from non-ITAR persons' view (added in 2021.1).

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23. The system shall provide embedded guidance (Guide Me) to direct users through the Non-conformances process (added in 2022.1).
 24. The system shall provide the ability to capture an image of the problem on a non-conformance (added in 2022.1).
 25. The system shall notify the champion of a CAPA when verification is required (added in 2023).
 26. The system shall provide the ability to have non-conformances separated from Corrective Action Preventive Actions to provide more flexibility (added in 2024).
 27. The system shall show any Quality Alerts created from the NCR on the NCR record (added in v2025).

Supplier Corrective Actions

1. The system shall have the ability to include supplier participation in the problem solving process as appropriate, with notifications and the ability for them to document their responses, as well as participate in the workflow.
2. The system shall have the ability to escalate a non-conformance to a Supplier Corrective Action (SCAR).
3. The system shall have the ability to notify a supplier of a new SCAR.
4. The system shall have the ability for a supplier to sign into the system and complete the SCAR information.
5. The system shall have the ability to verify SCARs on Supplier Audits using the Supplier Management application.

Quality Alerts / Deviations

1. The system shall have the ability to create a quality alert from a non-conformance, which shall create a link from the non-conformance to the new quality alert.
2. The system shall have the ability to document one or more quality alerts for a combination of one or more items, one or more customers, and/or one or more suppliers.
3. The system shall have the ability to notify people of a quality alert based on a distribution list.
4. The system shall allow a quality alert to be defined using a description and an image.
5. The system shall allow a quality alert to define the action required.
6. The system shall have the ability to create a deviation from a non-conformance, which shall create a link from a non-conformance to the deviation.
7. The system shall have the ability to create a deviation for a supplier or from a customer.
8. The system shall have the ability to notify people of a deviation based on a distribution list.
9. The system shall have the ability to define a deviation expiration based on date or quantity.
10. The system shall have the ability to define an approval prior to a deviation becoming active.
11. The system shall have a method to provide proof of customer approval for a deviation.
12. The system shall have the ability to document training on a quality alert.
13. The system shall have the ability to create an incident investigation from a deviation (added in 2024).

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14. The system shall notify the initiator of a quality alert that the quality alert will not be distributed until it is moved to the Active state (to accommodate those generated from an NCR) (added in v2025).

Lessons Learned

1. The system shall have the ability to document lessons learned grouped by lessons learned category.
2. The system shall have the ability to summarize a lesson learned in terms of the problem or success, impact, and recommendation.
3. The system shall have the ability to set up a review frequency for a lesson learned and notify the owner upon reaching the next review date.
4. The system shall have the ability to link lessons learned to non-conformances, APQP projects, issues, risks, and/or improvements.

Improvements

1. The system shall have the ability to document improvement ideas grouped by an improvement category.
2. The system shall allow improvements to be documented as anonymous.
3. The system shall allow an improvement to document the potential impacts of the improvement.
4. The system shall allow tasks to be associated with an improvement to support implementation of the improvement.
5. The system shall allow the resolution of an improvement to be documented, including the achieved impacts.

Incident Investigations

1. The system shall have the ability to document and manage an incident investigation (added in 2024).
2. The system shall allow incident investigations to have an incident type that determines the default lead investigator or additional investigators, default target days to completion, possible situation types, and investigation questions to be answered (added in 2024).
3. The system shall allow the selection of notification groups that would be notified when an incident investigation is created and moves to the plan investigation state (added in 2024).
4. The system shall allow incident investigations to have a situation type to further classify the investigation (added in 2024).
5. The system shall allow for the documentation of person(s) of interest with a comment to describe why they are of interest to the investigation (added in 2024).
6. The system shall provide a way to link relevant controlled documents to an investigation (added in 2024).
7. The system shall provide the option to create either an associated NCR OR a CAPA (added in 2024).
8. The system shall provide the option to create an associated SCAR (added in 2024).
9. The system shall allow for the documentation of whether the incident requires 3rd party reporting (added in 2024).

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10. The system shall provide for the documentation of assigned tasks as part of the investigation to manage the investigation needs (added in 2024).
 11. The system shall provide an incident type-driven investigation checklist to enforce corporate standards for incident types (added in 2024).
 12. The system shall allow for the documentation of lessons learned from the incident (added in 2024).
 13. The system shall provide approval of the closure of an incident (added in 2024).
 14. The system shall provide the ability to produce OSHA forms 300, 300A, and 301 on Incident Investigations (added in 2024.1).

Setup

1. The system shall have the ability to define a list of categories for non-conformances.
2. The system shall have the ability to define a list of sources for non-conformances.
3. The system shall have the ability to define a list of severities for non-conformances that drive the default target dates for containment, root cause, correction action, and overall completion.
4. The system shall have the ability to define a list of dispositions for non-conformance that also drive the team for the disposition.
5. The system shall have the ability to define a list of symptoms for non-conformances for the purposes of providing a way to analyze the data based on symptom.
6. The system shall have the ability to define a list of causes for non-conformances for the purposes of providing a way to analyze the data based on cause.

Metrics

1. The system shall have a metric for corrective action (non-conformance) on-time completion.
2. The system shall have a metric for non-conformances by customer and item.
3. The system shall have a metric for number of past due corrective actions by site.

Reports

1. The system shall have a report to print a problem solving tool.
2. The system shall have a report to print the AIAG EPS (Effective Problem Solving) report format.
3. The system shall have a report to print an open corrective action list.
4. The system shall have a report to print an open non-conformance list.
5. The system shall have a report to print a past due corrective action list.
6. The system shall have a report to print a past due non-conformance list.
7. The system shall have a report to print a 5 Why analysis.
8. The system shall have a report to print an 8D (disciplines) format.
9. The system shall have a report to print a quality alert.

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).

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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).
 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).