QAD Adaptive Applications

User Requirements Specifications

QAD EQMS Applications Complaint Management

70-3458-2025

QAD EQMS 2025

March 2025

Complaint 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. 9	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 Complaints section; Updated the General section	p. 6, p. 9	RQT
MAR 2023/v2023	Updated versioning; Updated the General section	p. 9	RQT
MAR 2024/v2024	Updated versioning; Updated the Complaints section; Updated the General section	p. 6, p. 9	RQT
SEPT 2024/v2024.1	Updated versioning; Updated the General section	p. 9	RQT
MAR 2025/v2025	Updated versioning; Updated the General section	p. 9	RQT

Confidentiality

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Purpose

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

This document was used as the basis for the configuration of the Complaint 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 Complaint Management Module version 2025.

Complaints

Facilitates the management of customer complaints, including initial reporting, complainant information, event information, assessment, action plan, and closure approval. During the assessment phase, a complaint can be escalated to a CAPA, SCAR, or Adverse Event.

Complaints

1. The system shall be able to capture required information about complaints in a single system, including any necessary file attachments.
2. The system shall be able to have defined owners for tasks that allow for those owners to be adjusted ad-hoc (with certain permissions).
3. The system shall be able to have task deadlines.
4. The system shall allow searching of complaint records by any of its key fields.
5. The system shall allow the view-only of complaint records based on security and/or the current workflow state of the complaint (for example, closed complaint records should not be modified).
6. The system shall allow multiple users (as designated) to work on a complaint at various stages.
7. The system shall have a standardized method for assigning approvers for a complaint.
8. The system shall generate a unique complaint ID when creating a new complaint.
9. The system shall have the ability to document the complainant reporter, including their contact information.
10. The system shall have the ability to document a patient identifier and related information.
11. The system shall have the ability to document the event information, including event date, reported date, and event details.
12. The system shall have the ability to track returned product.
13. The system shall have the ability to do a risk assessment of the complaint.
14. The system shall have the ability to document correspondence related to the complaint.
15. The system shall have the ability to document attachments related to the complaint.
16. The system shall have the ability to define one or more tasks to be completed as part of each complaint.
17. The system shall have integration with the Non-conformances/CAPA process to handle the manufacturing side of the complaint process.
18. The system shall have the ability to associate one or more file attachments as part of the investigation.
19. The system shall have the ability to approve assessment as part of the initial approval.
20. The system shall be able to notify the person responsible if the assessment approval was rejected.
21. The system shall have the ability to conduct a final approval of the complaint.
22. The system shall be able to notify the person responsible if the final approval was rejected.
23. The system shall allow the intake of patient information on a complaint for a Life Sciences customer (added in 2022.1).
24. The system shall provide a reportability assessment on a complaint for a Life Sciences customer (added in 2022.1).

25. The system shall provide a place to document investigation details on a complaint (added in 2022.1).
26. The system shall provide the ability to create an incident investigation from a complaint to be able to investigate before creating a non-conformance (added in 2024).

Setup

1. The system shall allow complaint specialists to be determined for complaint types.
2. The system shall allow a complaint review team to be determined for complaint types.
3. The system shall allow an assessment approval team to be determined for complaint types.
4. The system shall allow a final approval team to be determined for complaint types.
5. The system shall allow the severity of the complaint to drive need for a CAPA.

Adverse Events

Facilitates the management of life science complaint management, including initial reporting, patient information, event information, reportability assessment, investigation activities, approvals, and reporting agency submissions. Basing the complaint process on a single workflow using lessons learned via checklists and library tasks allows enforcement of a standardized process. Integrating complaints with non-conformances provides a seamless transition of workflow between complaint and manufacturing activities.

Adverse Events

1. The system shall be able to capture required information about complaints in a single system, including any necessary file attachments.
2. The system shall be able to have defined owners for tasks that allow for those owners to be adjusted ad-hoc (with certain permissions).
3. The system shall be able to have task deadlines extended upon approval by a user with a specific role.
4. The system shall allow searching of complaint records by any of its key fields.
5. The system shall allow the view-only of compliant records based on security and/or the current workflow state of the complaint (for example, closed complaint records should not be modified).
6. The system shall allow a closed complaint record to be re-opened under special circumstances.
7. The system shall allow multiple users (as designated) to work on a complaint at various stages.
8. The system shall have a standardized method for assigning approvers for a complaint.
9. The system shall generate a unique complaint ID when creating a new complaint.
10. The system shall have a way to notify senior management in cases where a death or serious public health threat is reported.
11. The system shall have checklists to support decision trees.
12. The system shall have the ability to document the initial reporter, including their contact information.
13. The system shall have the ability to document a patient identifier and related information.

14. The system shall have the ability to document the event information, including event date, reported date, awareness date, and event outcomes.
15. The system shall allow for entry of the affected serialized or lot based product.
16. The system shall have the ability to conduct a reportability assessment for each complaint based off of a pre-defined checklist.
17. The system shall have the ability to suggest if a complaint is reportable based on the reportability assessment.
18. The system shall have the ability to suggest the number of days to report, reporting agencies, and type of reportable event based on the reportability assessment.
19. The system shall allow a user to see the status of an investigation for a submitted complaint.
20. The system shall have the ability to define one or more tasks to be completed as part of each complaint.
21. The system shall have integration with the Non-conformances/CAPA process to handle the manufacturing side of the complaint process.
22. The system shall have the ability to document the information required for an FDA submission as part of the investigation.
23. The system shall have the ability to associate one or more file attachments as part of the investigation.
24. The system shall have the ability to approve the intake and reportability assessment as part of the initial approval.
25. The system shall be able to notify the complaint specialist if the initial approval was rejected.
26. The system shall have the ability to conduct a final approval of the complaint prior to submission.
27. The system shall be able to notify the complaint specialist if the final approval was rejected.
28. The system shall support the ability to produce an FDA Medwatch 3500A report (added in 2020.1).

Setup

1. The system shall have the ability to set up a reportability assessment checklist for the purposes of having a defined process for assessing reportability to various agencies.
2. The system shall have the ability to set up one or more library tasks that will automatically load into each complaint for the purposes of having a defined list of tasks for each complaint.
3. The system shall allow defining the list of event outcomes.
4. The system shall allow defining the list of follow-up types.
5. The system shall allow defining the list of reportable event types.
6. The system shall allow defining the list of remedial action types.
7. The system shall allow defining the list of submission types.
8. The system shall allow defining the list of evaluation codes for each of the types of conclusion, method, and result.
9. The system shall allow defining the list of problem codes for each of the types of component, device, and patient.
10. The system shall allow defining the list of reporting agencies.

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).
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).