QAD Adaptive Applications

User Guide

QAD EQMS Applications: Adverse Events

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Adverse Events User Guide Change Summary

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

Date/Version	Description	Reference	Changed By
APR 2019/v2019	Initial upload	--	RQT
SEPT 2019/v2019	Updated links, styling, and copyright	--	RQT
MAY 2020/v2020	Removed all references to automated submissions from the guide	--	RQT
OCT 2020/v2020.1	Updated versioning	--	RQT
MAR 2021/v2021	Updated linkage	--	RQT
MAY 2021/v2021	Added a section for Commands	p. 61	RQT
JULY 2021/v2021.1	Updated Adverse Events; Updated Adverse Events Suspect Items; Updated State Change Security.	p. 22, p. 30, p. 51	RQT
FEB 2022/v2022	Updated versioning	--	RQT
SEPT 2022/v2022.1	Updated versioning; Updated Complaints; Removed MDR Reportability Questions; Removed Adverse Events Reportability Assessment Response	p. 22	RQT
MAR 2023/v2023	Updated versioning; Added a process: MDR Remedial Action Types	p. 14	RQT
MAR 2024/v2024	Updated versioning	--	RQT
SEPT 2024/2024.1	Updated versioning	--	RQT
MAR 2025/v2025	Updated versioning	--	RQT

Chapter 1

Introduction

Overview

Adverse events must be resolved quickly, or the problem can cause irreparable damage to the company's reputation and brand. A central adverse event repository is needed so every record is gathered in one place. This repository helps ensure you take corrective actions, and centralizing the information helps you recognize trends and emerging problems.

The QMS system includes a complete adverse event management system integrated to the Customer Complaints and CAPA systems, so you not only record events but can ensure the situation is quickly resolved.

About This Guide

This user guide focuses on:

- Setup required for the Adverse Events module
- Different forms of document organization in the Adverse Events module
- Security and roles for the Adverse Events module
- Instructions for the various Adverse Events tasks

Note: This guide does not provide field descriptions for the Adverse Events module fields. Field help is provided in the software.

Many fields in the Adverse Events module come from pre-made processes in order to fit within specific regulations; therefore, the options in these fields will remain static.

Adverse Events Module Setup Guide

This section describes the processes of the Adverse Events Management module. The list below is arranged by the order in which the processes should be completed, starting with the setup operations and continuing with the main functions.

Setting Up the Adverse Events Module

Reporting Agencies

Use Reporting Agencies to identify which organizations must be notified of an adverse event, should the situation require a report to be made. See "Reporting Agencies" on page 13.

MDR Remedial Action Types

Use MDR Remedial Action Types to identify if any remedial action has been initiated based on the complaint. See "MDR Remedial Action Types" on page 14.

MDR Reportable Event Types

Use MDR Reportable Event Types to add reportable situations to the QMS system and determine the severity of each event .See "MDR Reportable Event Types" on page 15.

MDR Event Outcomes

Use MDR Event Outcomes to identify what actions were taken by the reporting person or associated team in response to the event that caused an adverse event. See "MDR Event Outcomes" on page 16.

MDR Library Tasks Categories

Use MDR Library Tasks Categories to classify types of library tasks for organizational purposes. See "MDR Library Tasks Categories" on page 17.

MDR Reportability Questions

Use MDR Reportability Questions to assist the Adverse Events team in determining the reportability of any given adverse event. See "MDR Reportability Questions" on page 1.

MDR Library Tasks

Use MDR Library Tasks to provide categorization, description, and structure to an adverse event task. See "MDR Library Tasks" on page 18.

Using The Adverse Events Module

Adverse Events

Use Adverse Events to assess, investigate, and submit a medical device or product adverse event. See "Adverse Events" on page 22.

Adverse Events Suspect Items

Use Adverse Events Suspect Items to document the item or items that are thought to have caused an event. See "Adverse Events Suspect Items" on page 30.

Adverse Events Reportability Assessment Response

Use Adverse Events Reportability Assessment Responses to respond to reportability assessment questions during the Adverse Events process. See "Complaints Reportability Assessment Response" on page 1.

Adverse Events Tasks

Use Adverse Events Tasks to log action items that must be performed to complete an adverse event investigation. See "Adverse Events Tasks" on page 33.

Adverse Events Submissions

Use Adverse Events Submissions to record that an adverse event has been submitted to a reporting agency. See "Adverse Events Submissions" on page 36.

Getting Started

Before you can begin using the Adverse Events module, it is important to understand the basics of how to navigate and use the QMS system. The system is intuitive, but some layouts, features, and best practices require a more thorough understanding. See the User Interface user guide for additional information about the QMS software.

Chapter 2

Setting Up the Adverse Events Module

Introduction

Some preparation is required before you can create or submit adverse events.

Adverse Event preparation involves setting up the organization of events, tasks, and reports; listing reporting agencies; and ensuring that all data conforms to proper FDA standards. These tasks are generally performed by the Complaints Administrator.

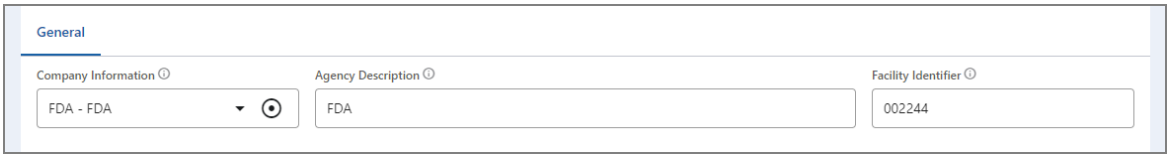
Reporting Agencies

Reporting agencies are organizations that must be notified of an adverse event, should the situation require a report to be made. Perhaps one of the biggest reporting agencies is the Food and Drug Administration (FDA), which is a federal agency of the United States Department of Health and Human Services. The Adverse Events module was designed to fit the FDA's regulations, but other reporting agencies can be added to the system for event submission.

Reporting Agencies are used in the following processes of the Adverse Events module:

- By Adverse Events to list which reporting agencies may need to be notified of the adverse event, based on the answers given during the reportability assessment. See "Adverse Events" on page 22.
- By Adverse Events Submissions to show which reporting agency an adverse event was submitted to. See "Adverse Events Submissions" on page 36.

Fig. 1: Reporting Agencies screen

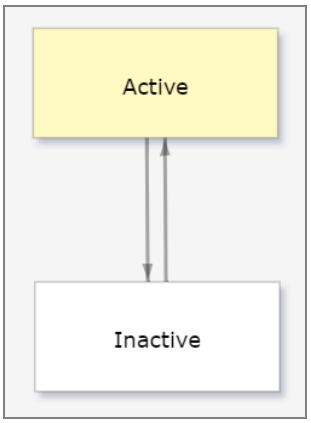


Reporting Agencies States

This section defines each state available in the workflow for the Reporting Agencies process. See "State Change Security" on page 51 to learn more about how these states transition.

Active (Default). A reporting agency that is actively used.

Inactive. A reporting agency that is no longer in use.



Reporting Agencies Tasks

Adding a New Reporting Agency

1. Select Reporting Agencies from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Select a company record from the Company Information drop-down field.
3. Enter a short description of this reporting agency, i.e. FDA or MDR.
4. Enter the facility identifier assigned to the company by the reporting agency.
5. Click Save to save the new record. When selecting the next state, click Active.

   Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the reporting agency cannot be used for new records.

MDR Remedial Action Types

The MDR Remedial Action Types process is used to identify if any remedial action has been initiated based on the complaint. Examples of remedial action types include Inspection, Patient Monitoring, Notification, and Relabeling.

MDR Remedial Action Types are used in the Adverse Events process. See "Adverse Events" on page 22 for more information.

Fig. 2: MDR Remedial Action Types process screen

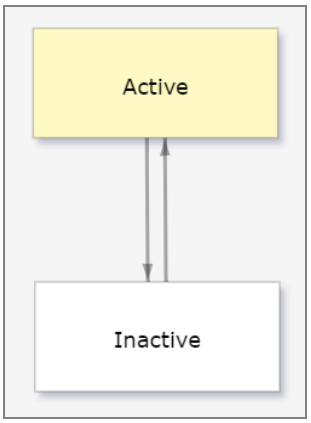
MDR Remedial Action Types States

This section defines each state available in the workflow for the MDR Remedial Action Types process. See "State Change Security" on page 51 to learn more about how these states transition.

Active (Default). An MDR remedial action type that is actively used.

Inactive. An MDR remedial action type that is no longer in use.

Locked. The MDR remedial action type's state cannot be moved, but is still active.



MDR Remedial Action Types Tasks

Adding a New MDR Remedial Action Type

1. Select MDR Remedial Action Types from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter the name of the remedial action type.
3. Click Save to save the new record. When selecting the next state, click Active.

   Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the remedial action type cannot be used for new records.

MDR Reportable Event Types

The MDR Reportable Event Types process allows you to add reportable situations to the QMS system and determine the severity of each event. When the system determines the reportable event type on an adverse event, the highest severity will be used.

MDR Reportable Event Types are used in the following processes of the Adverse Events module:

- By MDR Reportability Questions to help describe why the question is reportable if answered with "Yes". See "MDR Reportability Questions" on page 1.
- By Adverse Events to determine the type of reportable event that should be coded to the reporting agency when the event is submitted. See "Adverse Events" on page 22.

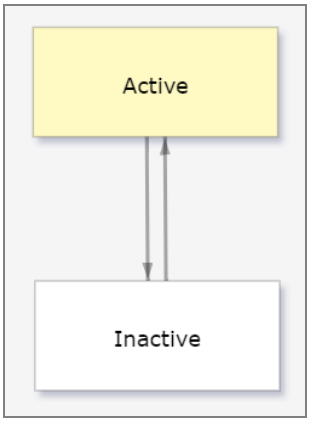
Fig. 3: MDR Reportable Event Types screen

MDR Reportable Event Types States

This section defines each state available in the workflow for the MDR Reportable Event Types process. See "State Change Security" on page 51 to learn more about how these states transition.

Active (Default). An MDR reportable event type that is actively used.

Inactive. An MDR reportable event type that is no longer in use.



MDR Reportable Event Types Tasks

Adding a New MDR Reportable Event Type

1. Select MDR Reportable Event Types from the left navigation panel. Then, click the Add Item ⊞ button in the toolbar.
2. Enter the event type. The value should match an FDA 3500A reportable event type.
3. Select the severity of the event type.
4. Click Save to save the new record. When selecting the next state, click Active.

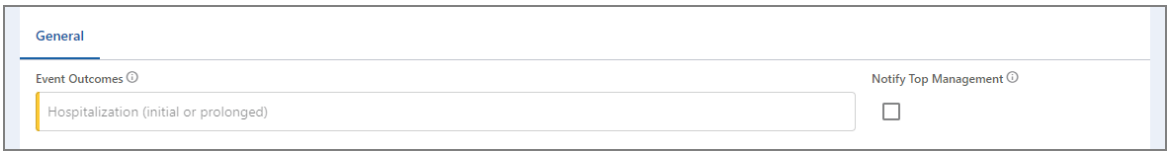
Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the event type cannot be used for new records.

MDR Event Outcomes

The MDR Event Outcomes process identifies what actions were taken by the reporting person or associated team in response to the event that caused an adverse event. Depending on the outcome, top levels of management may need to be notified.

MDR Event Outcomes are used in the Adverse Events process to describe all outcomes that occurred for an adverse event. See "Adverse Events" on page 22.

Fig. 4: MDR Event Outcomes screen

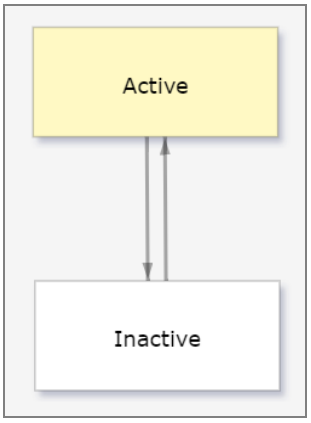


MDR Event Outcomes States

This section defines each state available in the workflow for the MDR Event Outcomes process. See "State Change Security" on page 51 to learn more about how these states transition.

Active (Default). An MDR event outcome that is actively used.

Inactive. An MDR event outcome that is no longer in use.



MDR Event Outcomes Tasks

Adding a New MDR Event Outcome

1. Select MDR Event Outcomes from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a descriptive name for the event outcome.
3. Select a unique identifier in the SystemID field. This number is optional, and is used for reporting and other system logic.
4. If the outcome requires notifying top levels of management, then select the "Notify Top Management" check box.
5. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the event outcome cannot be used for new records.

MDR Library Tasks Categories

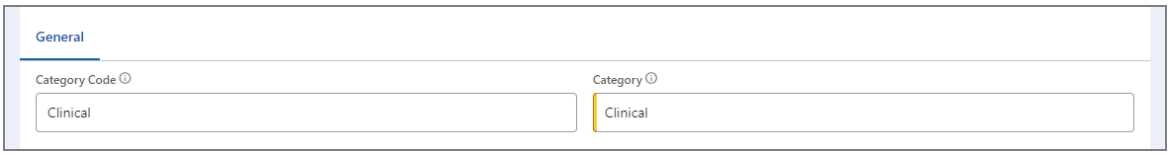
MDR Library Tasks Categories classify types of library tasks for organizational purposes. Examples of task categories include Clinical, Administrative, and Regulatory Affairs.

MDR Library Tasks Categories are used in the following processes of the Adverse Events module:

- By MDR Library Tasks to group the library task with other similar library tasks. See "MDR Library Tasks" on the next page.

- By Adverse Events Tasks as a category inherited from the Library Task field. See "Adverse Events Tasks" on page 33.

Fig. 5: MDR Library Tasks Categories screen

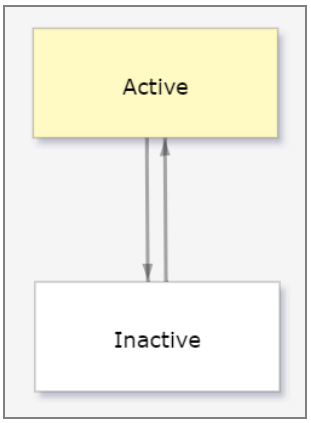


MDR Library Tasks Categories States

This section defines each state available in the workflow for the MDR Library Tasks Categories process. See "State Change Security" on page 51 to learn more about how these states transition.

Active (Default). An MDR library task category that is actively used.

Inactive. An MDR library task category that is no longer in use.



MDR Library Tasks Categories Tasks

Adding a New MDR Library Tasks Category

1. Select MDR Library Tasks Categories from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a short-form code.
3. Enter the name of the category.
4. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the task category cannot be used for new records.

MDR Library Tasks

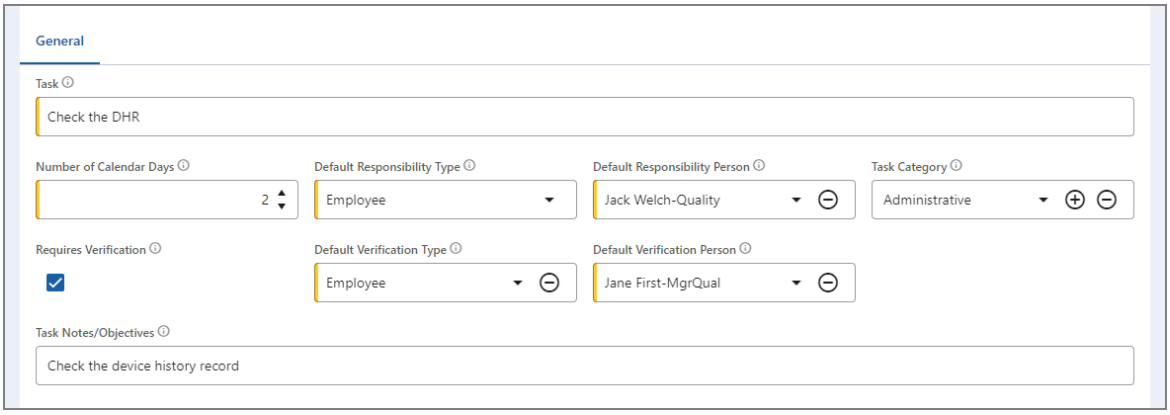
As an adverse event is processed, tasks will be assigned for completion during the investigation. These tasks, intended to process and remedy the issue, use MDR library tasks to provide categorization, description, and structure for security and system behavior.

You must assign a default responsibility user and a default verification user to the MDR library task. These users can be selected from the following options:

- Complaint Coordinator role
- Complaint Specialist role
- A specific employee
- A specific security role

Adverse Events Tasks inherit the information from an MDR library task for structure and categorization. See "Adverse Events Tasks" on page 33.

Fig. 6: MDR Library Tasks screen

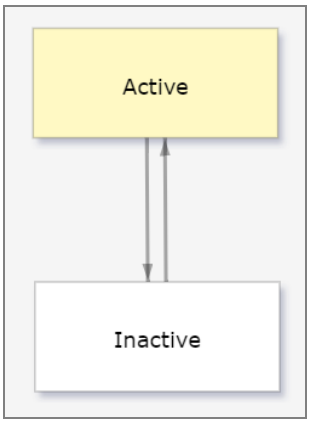


MDR Library Tasks States

This section defines each state available in the workflow for the MDR Library Tasks process. See "State Change Security" on page 51 to learn more about how these states transition.

Active (Default). An MDR library task that is actively used.

Inactive. An MDR library task that is no longer in use.

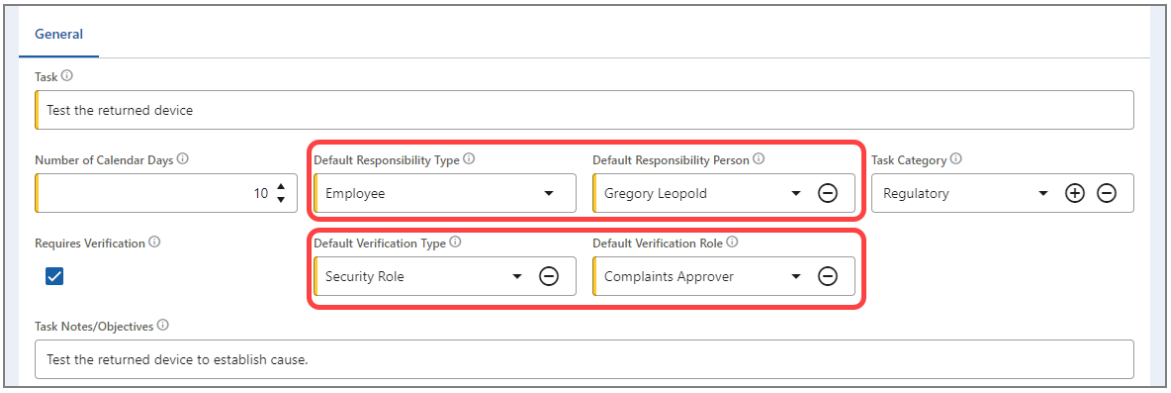


MDR Library Task Tasks

Adding a New MDR Library Task

1. Select MDR Library Task from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a descriptive name for the library task.
3. Enter the number of calendar days an employee has to complete the task.
4. Select the default responsibility and verification types. If you select Employee or Security Role in either field, then an additional field appears so you can select the specific employee or role.

Fig. 7: MDR Library Tasks screen, additional fields



5. Select a task category.
6. If the task will require verification before closure, then select the "Requires Verification" check box.
7. Enter any task notes or objectives.
8. Click Save to save the new record. When selecting the next state, click Active.

Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the library task cannot be used for new records.

Chapter 3

Using the Adverse Events Module

Adverse Events

The FDA requires that manufacturers, importers, and device use facilities report adverse events per the requirements of 21 CFR 803. The Adverse Events process allows you to assess, investigate, and document the submission of an adverse event. The format of this process is based off of the MedWatch FDA Safety Information and Adverse Event Reporting Program form. The process report "Adverse Events FDA 3500A Report" allows you to view the adverse event in this format. See "Reports" on page 46 for more information.

As the main process for the Complaints module, Adverse Events is the process from which you will complete all work or initiate a supporting process to complete work. A majority of the fields in this process come from processes that users will not see because they are pre-made to fit within specific regulations; therefore, the options in these drop-down fields will remain static.

There are three levels of approval for adverse events:

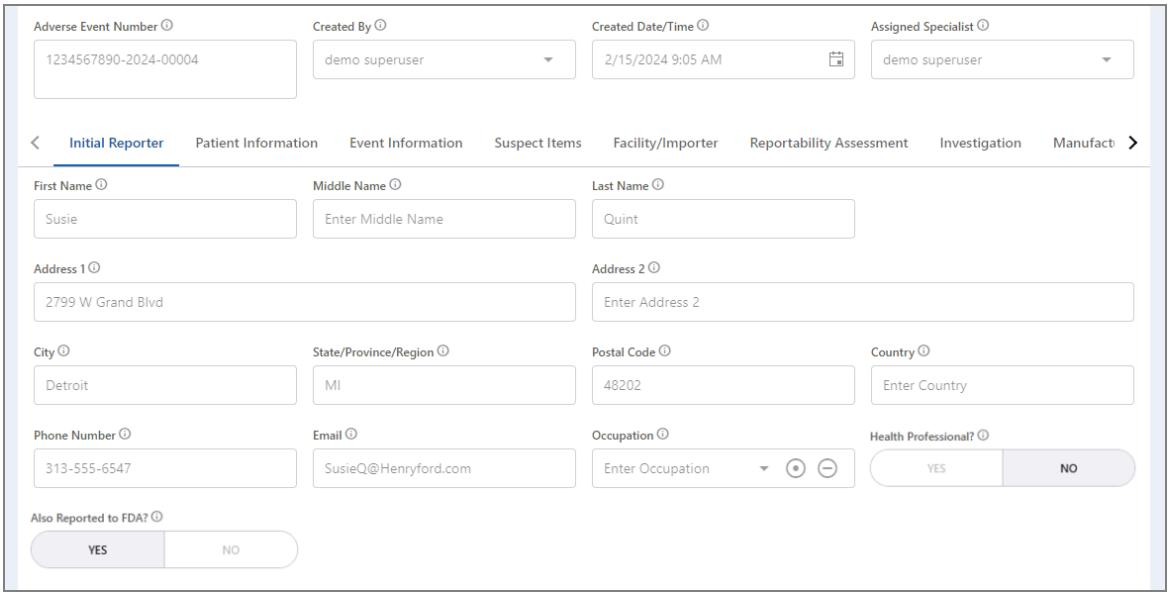
- **Level 1** – Complaints Coordinator
- **Level 2** – Complaints Approval
- **Level 3** – Adverse Events Complaints Specialist

The following processes are typically created directly from the Adverse Events process:

- "Adverse Events Suspect Items" on page 30.
- "Adverse Events Tasks" on page 33.
- "Adverse Events Submissions" on page 36.

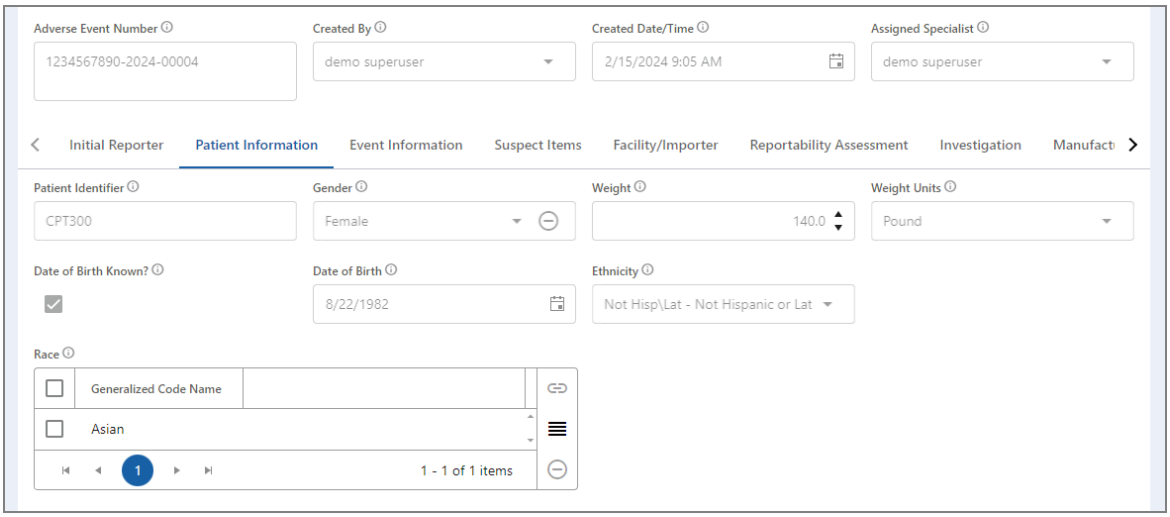
Adverse events are created from the Complaints process when the complaint is related to a life sciences issue. See the Complaint Management user guide for more information.

Fig. 8: Adverse Events screen, Initial Reporter tab



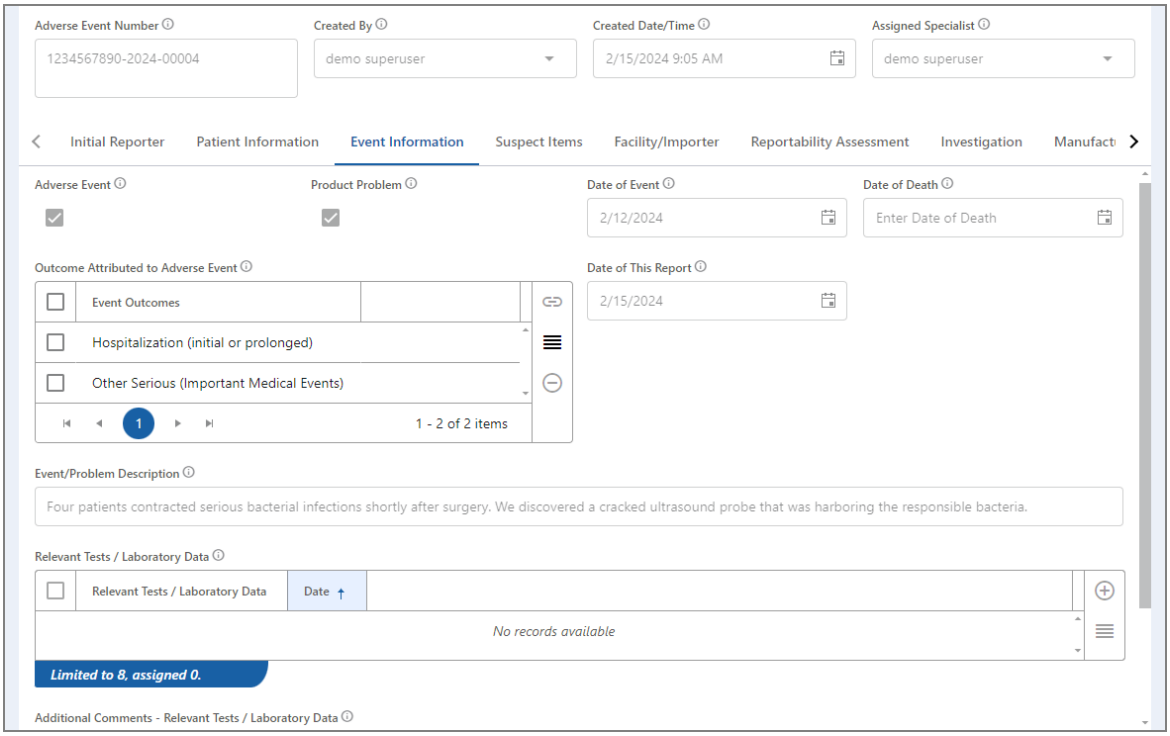
The Initial Reporter tab supplies information about the contact that initially reported the issue.

Fig. 9: Adverse Events screen, Patient Information tab



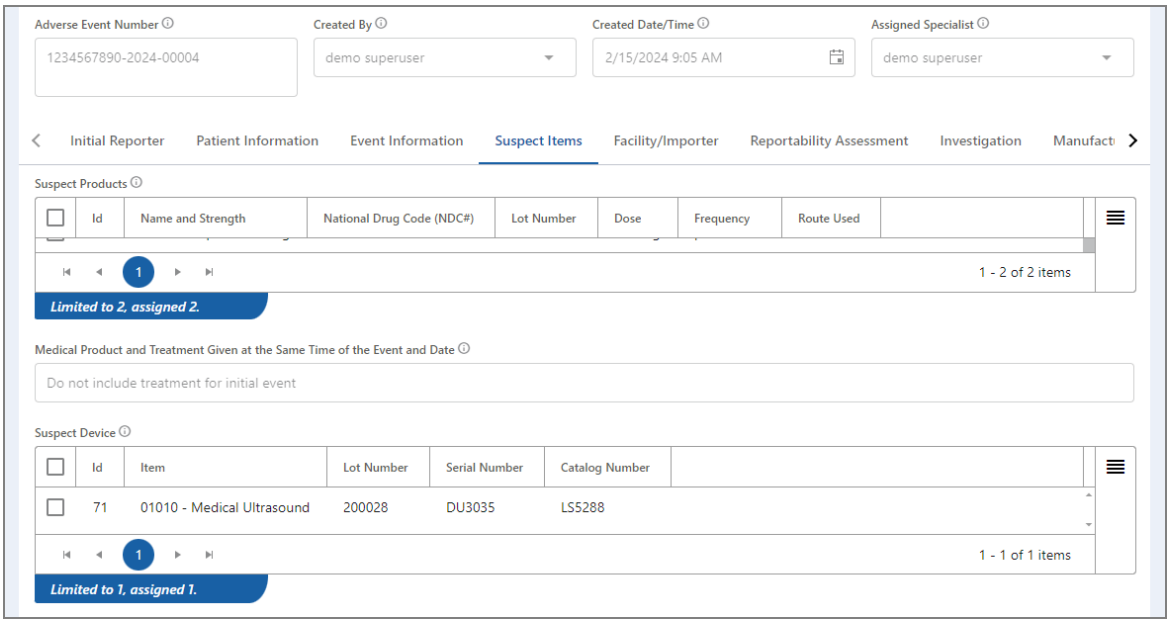
The Patient Information tab contains all the basic information about the affected patient, including their gender, age, and ethnicity. The drop-down fields are pre-made to fit within specific regulations; therefore, the options in these fields will remain static.

Fig. 10: Adverse Events screen, Event Information tab



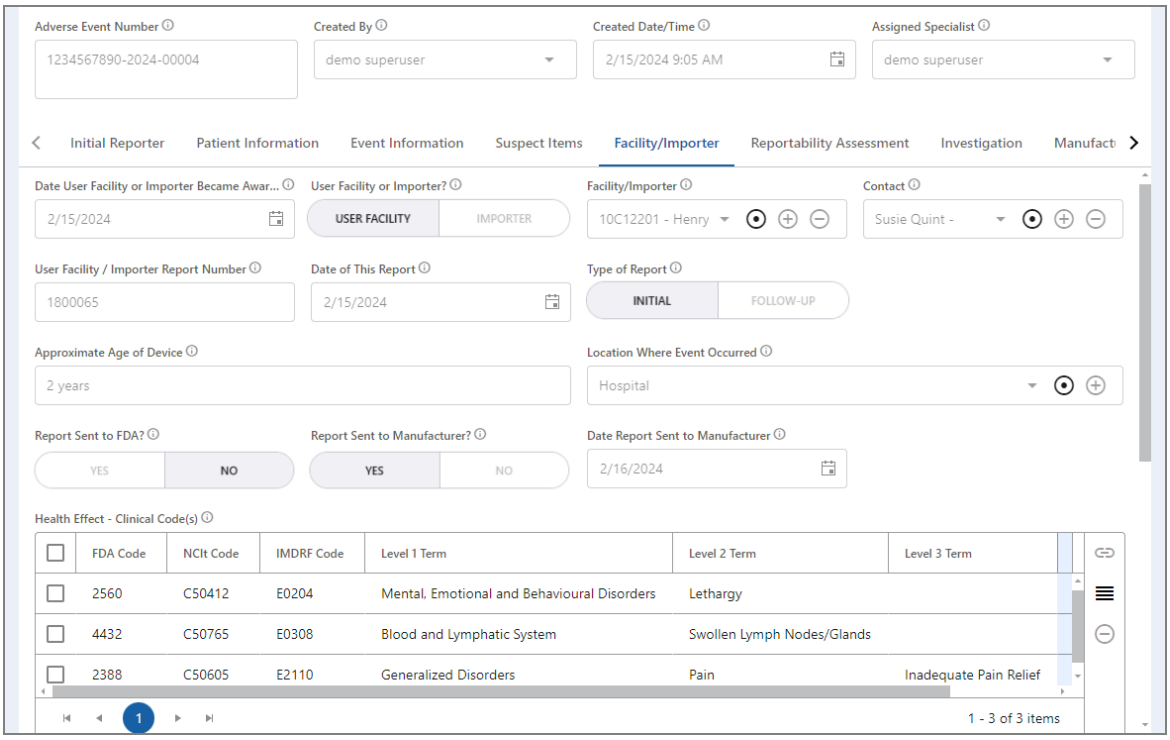
Use the Event Information tab to describe the event, including the dates surrounding the event, the outcomes, relevant tests and laboratory data, and more.

Fig. 11: Adverse Events screen, Suspect Items tab



Use the Suspect Items tab to list the products and/or device that are suspected to play a role in the event.

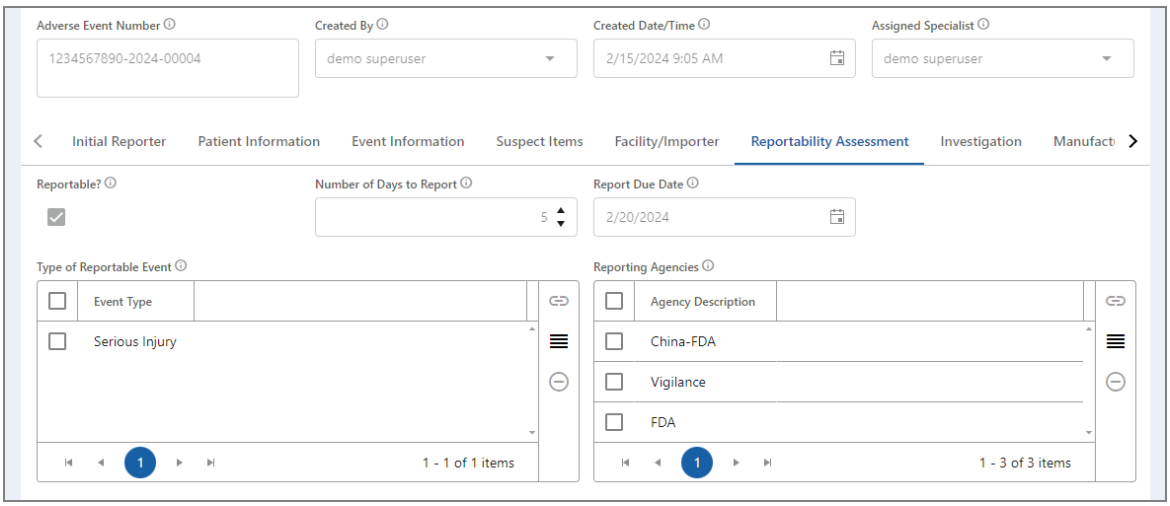
Fig. 12: Adverse Events screen, Facility/Importer tab



Use the Facility/Importer tab to provide information about the facility or importer, as well as additional data regarding the report, including health effects, medical device problem, and

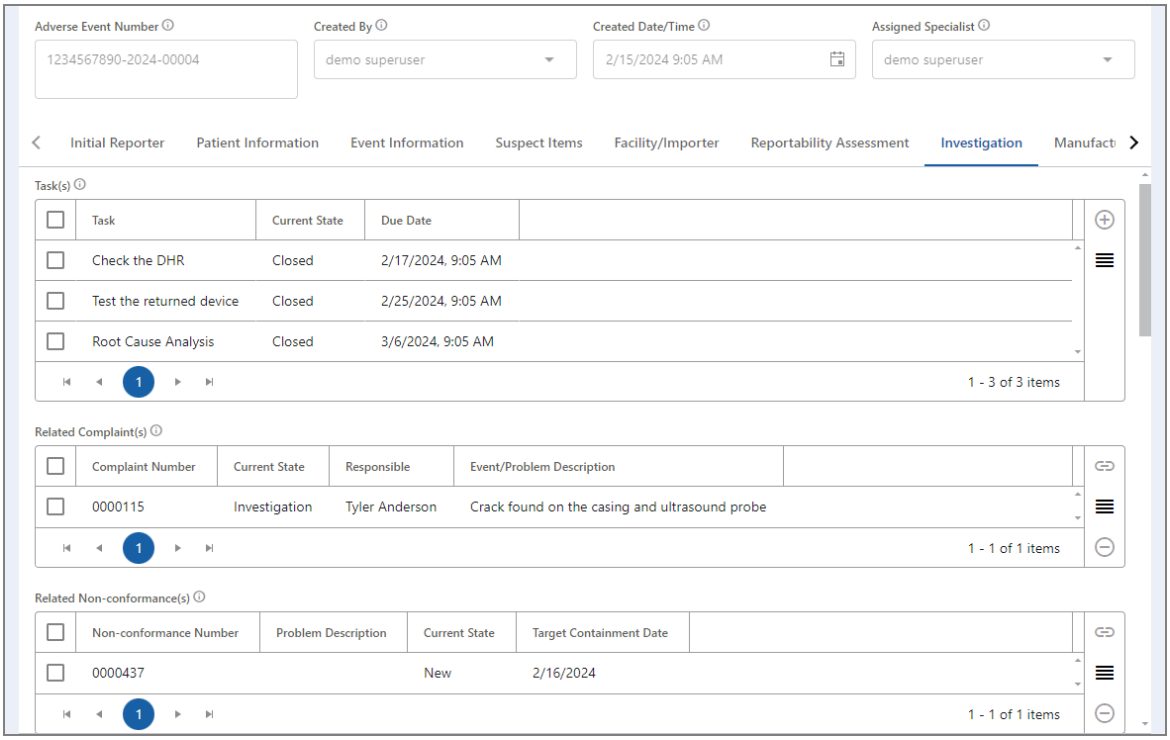
component codes. Once this tab is completed, the Adverse Events Specialist saves the record and the Reportability Assessment tab appears.

Fig. 13: Adverse Events screen, Reportability Assessment tab



The Reportability Assessment tab appears when the adverse event is reportable to a reporting agency, which is defined in the Complaints process. This tab provides the number of days to report and the report due date, as well as the type of reportable event and the reporting agencies that may need to be notified of the adverse event.

Fig. 14: Adverse Events screen, Investigation tab

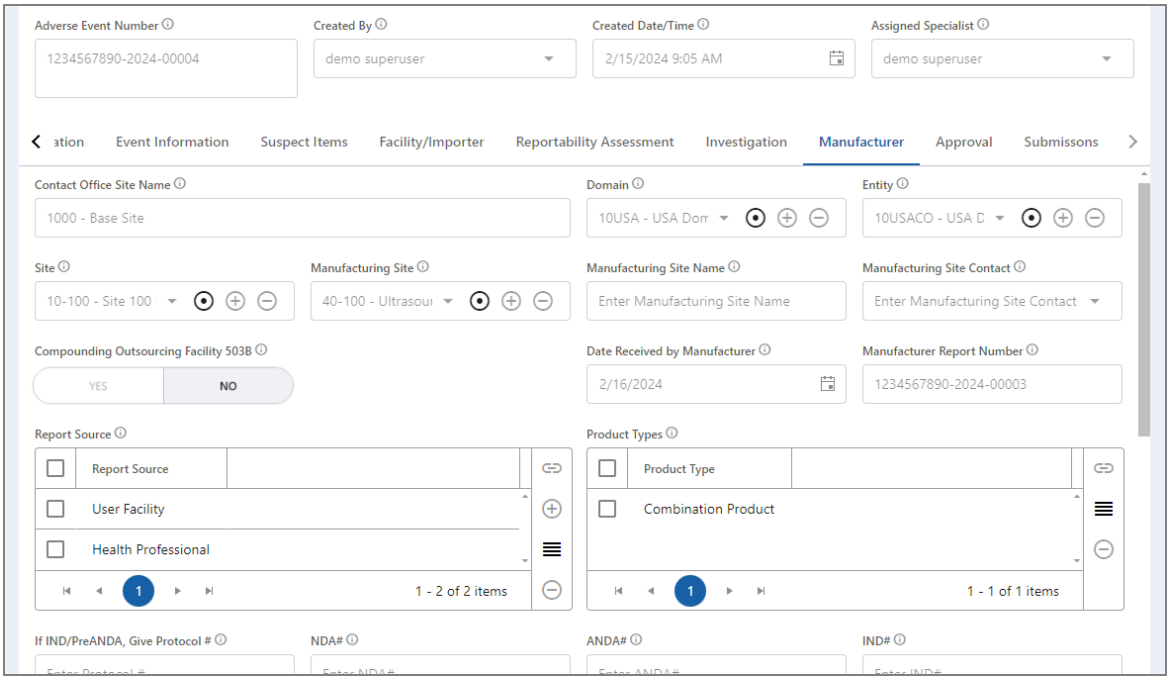


The Investigation tab houses the adverse events tasks and non-conformances, as well as device manufacturer codes and investigation findings.

The Tasks field is automatically populated with all MDR library tasks that are in the Active state. You can also create a new adverse event task. See "MDR Library Tasks" on page 18 and "Adverse Events Tasks" on page 33.

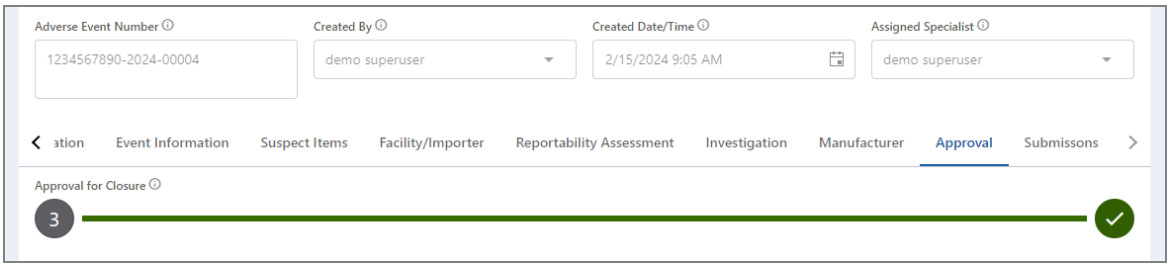
If the "Create Non-Conformance" check box was selected on any of the suspect items added in the Event Information tab, then the Non-Conformances field is automatically populated with that non-conformance.

Fig. 15: Adverse Events screen, Manufacturer tab



The Manufacturer tab contains manufacturer information about the product or device.

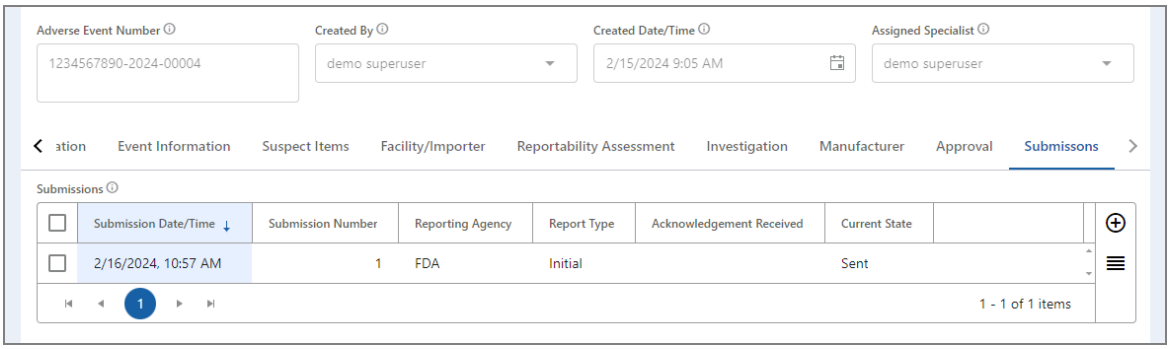
Fig. 16: Adverse Events screen, Approval tab



The Approval tab appears when the current state is Ready for Approval, and lists the employees responsible for approving the adverse event. Approvers can approve directly from this tab.

Once all approvers have signed off, the state moves to Submission.

Fig. 17: Adverse Events screen, Submissions tab



The Submissions tab contains a list of adverse event submissions sent to the reporting agencies specified in the Reportability Assessment tab.

Note that the submission records are a notation that a submission activity was made, and **not** the submission itself.

Adverse Events States

This section defines each state available in the workflow for the Adverse Events process. See "State Change Security" on page 51 to learn more about how these states transition.

New (Default). A newly created adverse event.

Ready for Approval. Move the adverse event to this state for approval. If the event is approved, it will be moved to the Submission state.

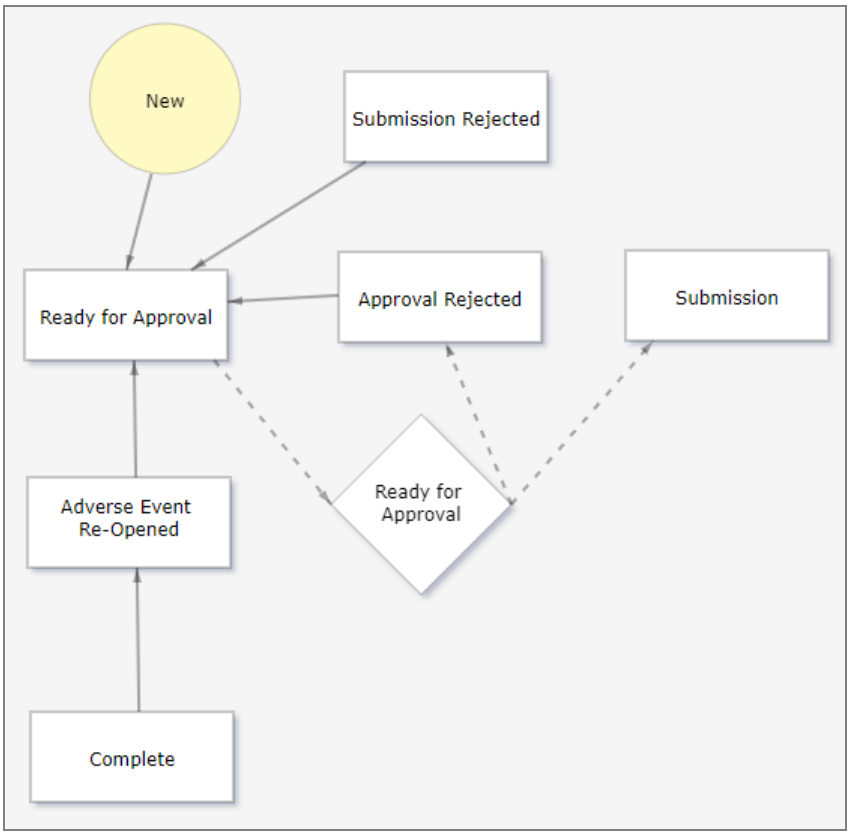
Approval Rejected. The approval of this adverse event was rejected.

Submission. The adverse event is ready to have the submission sent, or the submission has been sent and this event is waiting for acknowledgment to be complete.

Submission Rejected. The submission was rejected. Review the submissions for any failures that need to be resolved.

Complete. The adverse event is completed and has been submitted to a reporting agency. The adverse event transitions to this state when the submission is in the Final Submission state, was accepted, and is not reportable.

Adverse Event Re-Opened. The adverse event needs to be re-opened by an Adverse Event Administrator.



Adverse Events Tasks

Documenting a New Adverse Event

Adverse events are created from the Complaints process when the complaint is related to a life sciences issue. See the Complaint Management user guide for more information.

1. Select Adverse Events from the left navigation panel. Find the appropriate record, then double-click the line item to open the record.
2. Review the initial reporter's information. Select whether the contact is a health professional, and whether the patient or initial reporter also reported the adverse event to the FDA.
3. Navigate to the Event Information tab. If the event caused an adverse condition or was a product problem, then select the appropriate check boxes.
4. Select when the event occurred and when it was reported.
5. Click the Link button in the Outcome Attributed to Adverse Event field to select all applicable outcomes that occurred from this event, then click OK.
6. Use the fields that follow to describe the event or problem, list relevant tests or laboratory data, and supply any other relevant history or pre-existing conditions.
7. Navigate to the Suspect Items tab. See "Adverse Events Suspect Items" on page 30 for information on how to document what is thought to be the items that caused the event.
8. Navigate to the Facility/Importer tab. Use the fields that follow to provide more information regarding the facility/importer and report. Then, in each code field, use the

Link button to select the appropriate codes for health effects, medical device problems, and components.

9. Navigate to the Investigation tab. Note that the Tasks field is populated with all MDR library tasks that are in the Active state. You can also create a new adverse event task with the Add New Item button.
    - See "Adverse Events Tasks" on page 33 for more information about completing an adverse event task.
10. If you selected the "Create Non-Conformance" check box when adding suspect items in the Suspect Item tab, then the Non-conformances field is populated with a new non-conformance.
    - See "Non-Conformances" in the NCR & CAPA Management user guide for more information about completing a non-conformance.
11. If you have any physical files related to the event investigation that you would like to attach, then follow the instructions in the task "Adding an Attachment to the Adverse Event Investigation" on the facing page.
12. Navigate to the Manufacturer tab. There are several fields for describing details about the device, such as whether it is labeled for single use, whether it is an over-the-counter product, and so on. Fill out all fields that apply.
13. If the device has been evaluated for the cause of the event, then select YES in the "Device Evaluated" toggle field. If it was not evaluated, then explain why in the designated explanation field below.
14. Click Save to save the record. When selecting the next state, click Ready for Approval.

Note: The tasks listed in the Investigation tab must be completed before the state can be moved. See "Completing an Adverse Events Task" on page 35 for more information.

Approving an Adverse Event

1. The users responsible for approving an adverse event are automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the complaint for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Complaints group to show the action icons. Then click the Open icon. The screen navigates to the adverse event's detail screen.
4. In the detail screen, navigate to the Approval tab.
5. Click the Approve/Reject button. A small window appears.
6. In the Sign Off window, enter your password and either approve or reject the event. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the event moves to the next state.

- If you were conducting an initial approval, then the event moves to Submission.
- If you were conducting a final approval, then the event moves to Final Submission.

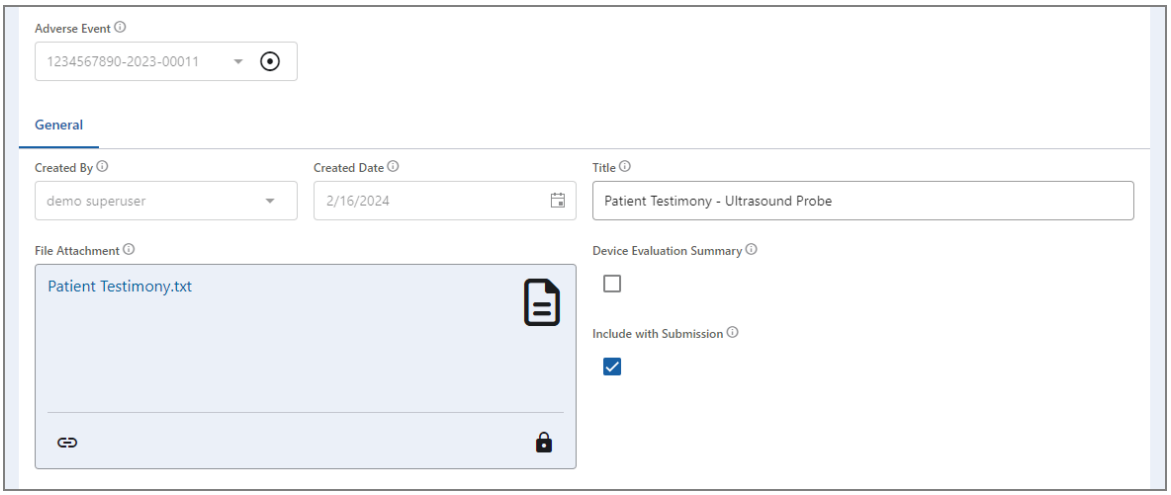
Adding an Attachment to the Adverse Event Investigation

1. In the Adverse Events process screen, navigate to the Investigation tab.
2. Click the Add New Item button in the Attachments field. A new screen opens.
3. Enter a descriptive title of the attachment.
4. Click the Select File to Upload button. A desktop window appears.
5. Navigate to the folder on your computer, then double-click or single-click it and select the Open button.
6. Back in the Attachments screen, select the "Include with Submission" check box to include the attachment with the electronic submission.

   Note: The electronic submission will be available in a future release.

7. Select the "Device Evaluation Summary" check box if the attached file is an evaluation summary from the device manufacturer.
8. Click the Save button.

Fig. 18: Adverse Events Attachments



Adverse Events Suspect Items

Suspect items are used during the Adverse Events process to document what is thought to be the item or items that caused the event. Note that items could be a suspected medical device or other suspected product, and the screens are different for each choice. See "Adverse Events" on page 22.

Fig. 19: Adverse Events Suspect Items - Product screen, General tab

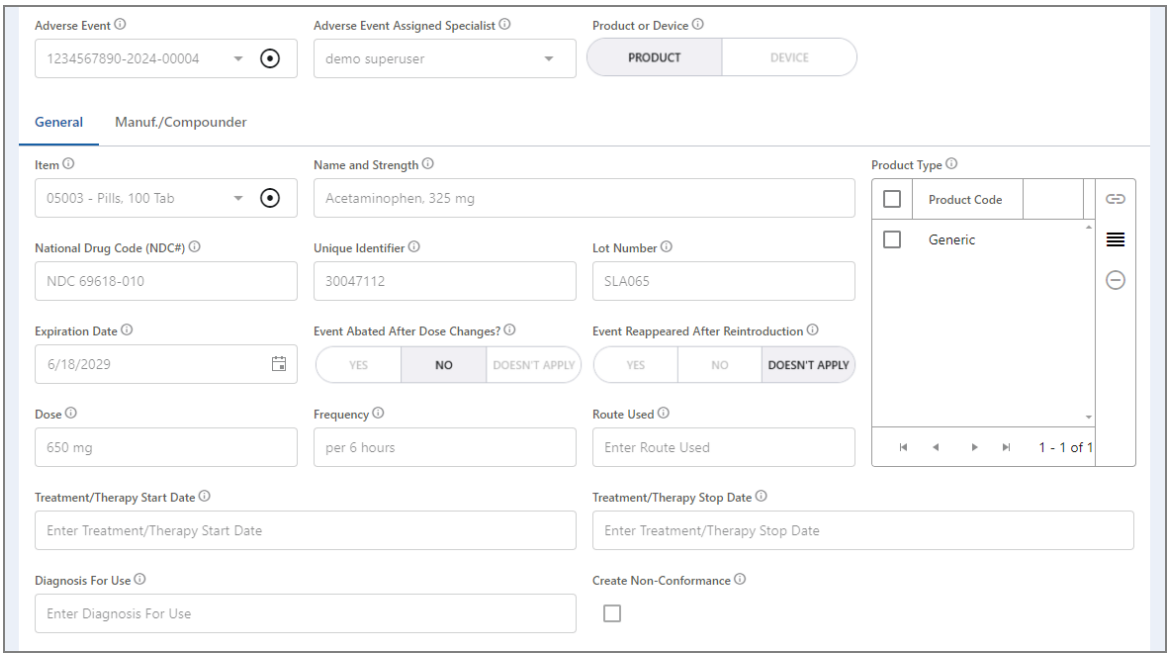
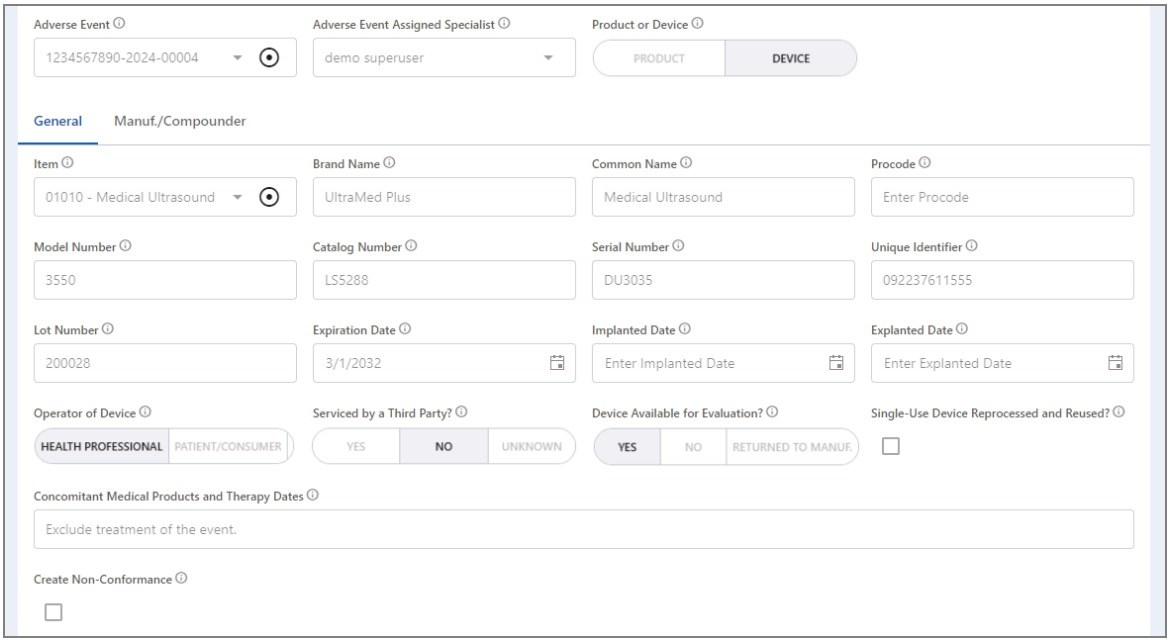


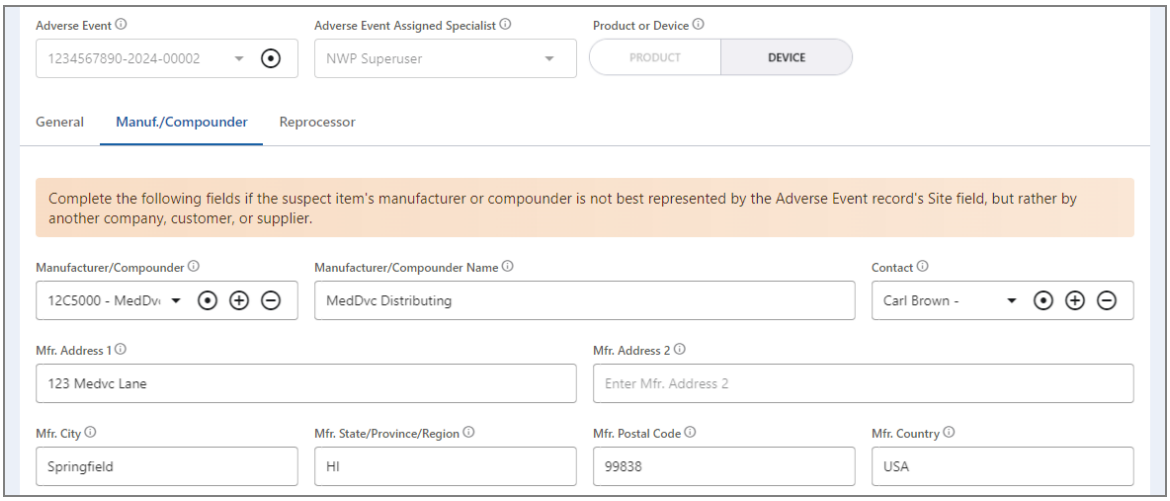
Fig. 20: Adverse Events Suspect Items - Device screen, General tab



The General tab is used to define the basic details of a suspect item, including , the lot and serial numbers, whether the device is available for evaluation, the dates involved, and more.

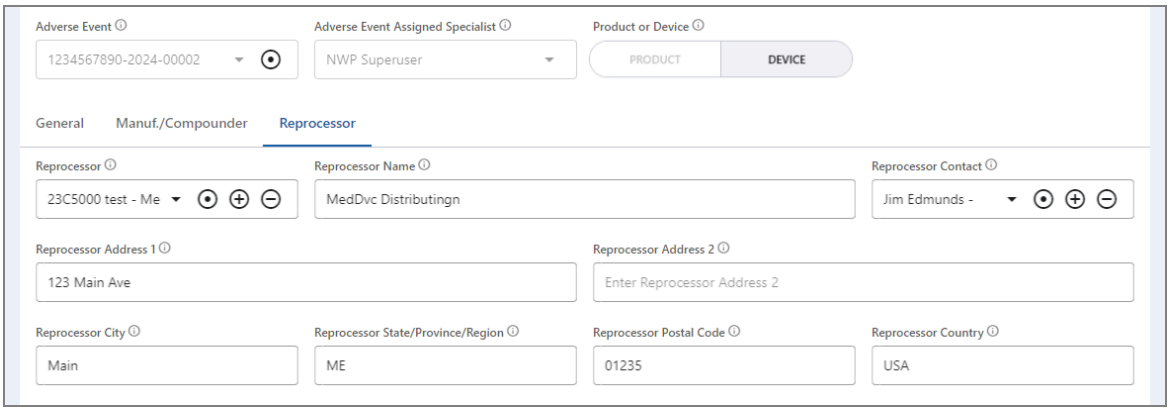
If the "Create Non-Conformance" check box is selected, then a non-conformance is created from this suspect item and added to the adverse event during the investigation phase. See "Adverse Events" on page 22.

Fig. 21: Adverse Events Suspect Items screen, Manuf./Compounder tab



The Manuf./Compounder tab contains information about the company who manufactured or compounded the suspect item. Selecting the company in the Manufacturer/Compounder field automatically populates the rest of the tab upon saving the record.

Fig. 22: Adverse Events Suspect Items screen, Reprocessor tab



The Reprocessor tab contains information about the company that reprocessed the suspect item. Selecting the company in the Reprocessor field automatically populates the rest of the tab upon saving the record.

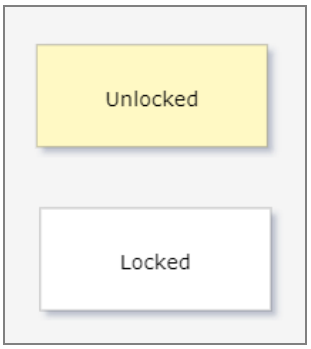
Note that the Reprocessor tab is only available in the Device screen, if the "Single-Use Device Reprocessed and Reused?" check box is selected on the General tab.

Suspect Items States

This section defines each state available in the workflow for the Suspect Items process. See "State Change Security" on page 51 to learn more about how these states transition.

Unlocked (Default). The suspect item record is open and available for edits.

Locked. The suspect item record is locked. It cannot be used or edited.



Suspect Items Tasks

Adding a New Suspect Item

Suspect Items are added from the Adverse Events process.

1. In the Adverse Events detail screen, navigate to the Suspect Items tab. Determine whether you are inserting a product (limited to two) or a device (limited to one), then click the corresponding command button. A line item appears in the appropriate field.
2. Double-click the new line item. A new screen opens.
3. Select the specific item from the Item drop-down field. Then manually add additional details, such as the brand name, lot number, and more.
4. If you want to create a non-conformance for the suspect item, then select the "Create Non-Conformance" check box and select a non-conformance category.
5. Navigate to the Manuf./Compounder tab. Select the company in the Manufacturer/Compounder field. The rest of the fields will automatically populate after you save.
6. Navigate to the Reprocessor tab, if applicable. Select the company in the Reprocessor field. The rest of the fields will automatically populate after you save.
7. Click Save to save the new record.

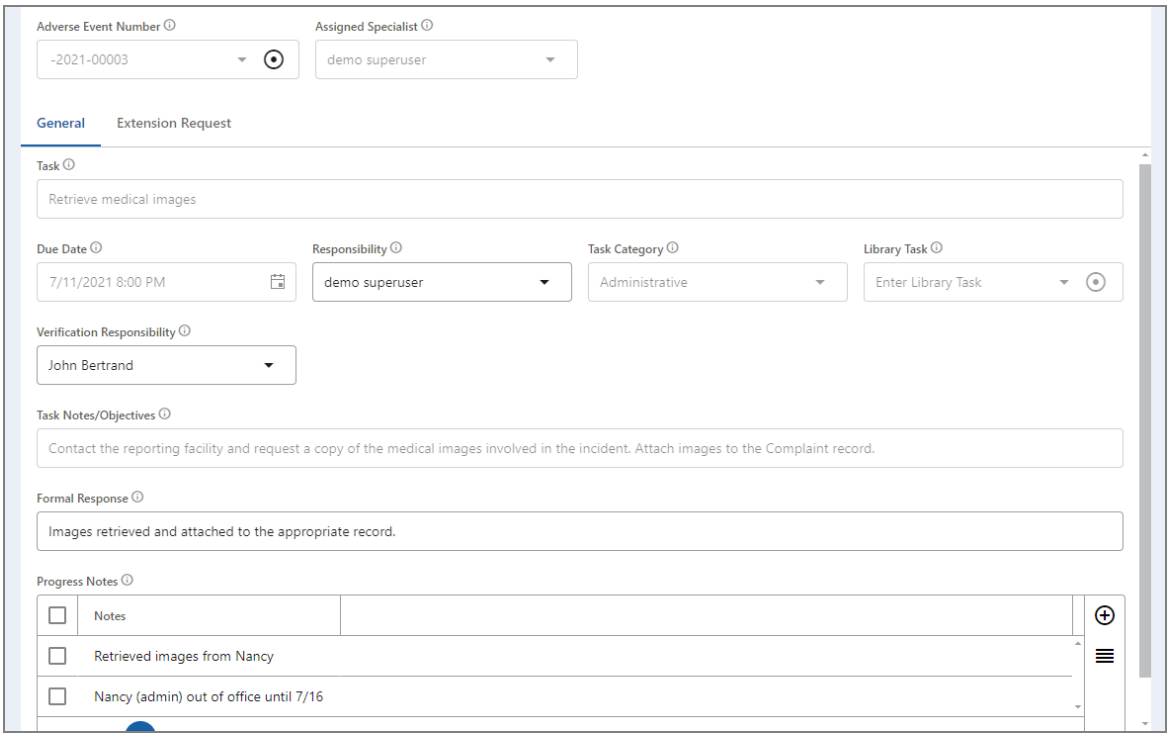
Adverse Events Tasks

Adverse events tasks are used as assignment trackers to log action items that must be performed to complete the investigation. The task inherits its basic information, such as description and responsibilities, from an MDR library task. Once the task is assigned, the responsible user must follow the task notes and enter progress notes for completion. While the task includes a due date, the responsible user may request an extension.

After the task is complete, the responsible user moves the state to Task Complete. The user assigned to verification responsibility then receives a notification to review the task and ensure it was completed appropriately and on time. The verification responsibility then moves the task to the Complete state.

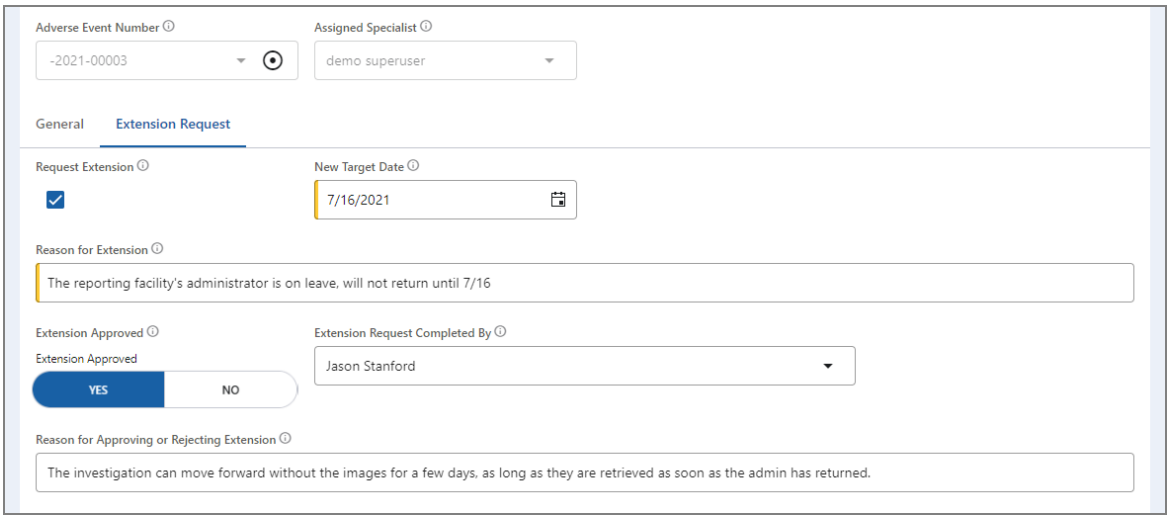
When an Adverse Events record enters the Adverse Events Investigation state, all active MDR Library Task records are inserted in the adverse event and assigned for completion. See "MDR Library Tasks" on page 18 and "Adverse Events" on page 22.

Fig. 23: Adverse Events Tasks screen, General tab



The General tab is used to define the basic details of an adverse event task, including the task description, due date, responsibility, objectives and more.

Fig. 24: Adverse Events Tasks screen, Extension Request tab



The Extension Request tab allows you to request an extension on the task due date. Once the "Request Extension" check box is selected, other fields appear in the tab so you may select a new target date and supply a reason for the extension request.

Adverse Events Tasks States

This section defines each state available in the workflow for the Adverse Events Tasks process. See "State Change Security" on page 51 to learn more about how these states transition.

New (library task). A newly created adverse event task. This is the default state when the system generates the task from the library.

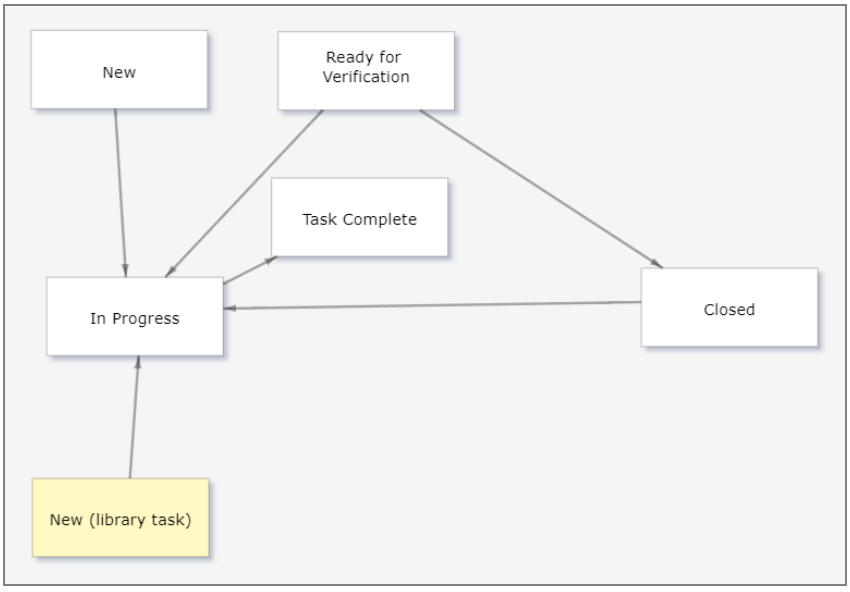
New. A newly created adverse event task. This is the default state when the task is created manually.

In Progress. The task is in the process of being completed.

Task Complete. The Task Responsibility user has completed the task and wants it to be verified for official completion. If the completion approval is rejected, then the state will return to In Progress. If the completion approval is approved, then the state will proceed to Closed.

Ready for Verification. The task is ready for the default verifier to change the state to Closed. The system changes to this state if the adverse event task contains a Verification Responsibility. Otherwise, the state will proceed to Closed upon the completion approval.

Closed. The adverse event task is closed. This state is reached after verification when the work is complete.



Adverse Events Task Tasks

Completing an Adverse Events Task

Adverse Events Tasks are typically added from the Adverse Events process. This task occurs parallel to "Completing a Complaint Investigation" on page 1.

1. There are two ways to open an adverse events task:
    a. In the Adverse Events process screen, navigate to the Investigation tab. Then open the relevant task in the Tasks field.
    b. In the Inbox panel, navigate to Assignments and open the Complaints section. Click the assignment “You are responsible to complete the task *** for Adverse Event ***”. Then click Open.
2. Observe the Task Notes/Objectives field, which contains notes that may assist in completing the task, as well as objectives that must be performed to complete the task.
3. As you complete the task, save the task record to the state In Progress.
4. Add entries to the Progress Notes field as you complete the task:
    a. Click the Add New Item button. A new screen opens.
    b. Select your name from the Notes Author drop-down field, if necessary.
    c. Enter information pertaining to the task in the Notes field.
    d. Click Save.
5. Once the task is complete, enter a description of the context, steps performed and other important closing details in the Formal Response field.
6. Click Save to save the new record. When selecting the next state, click Task Complete.

    Note: If a Verification Responsibility is assigned to the task, then the state moves to Ready for Verification and the verification responsibility must move the state the rest of the way to Closed.

Requesting and Approving a Due Date Extension for an Adverse Events Task

1. In the Adverse Events Task detail screen, navigate to the Extension Request tab.
2. Select the "Request Extension" check box. Several fields appear.
3. Select a new target date and enter your reason for requesting an extension.
4. Click Save to save the record. When selecting the next state, click In Progress.

    The Adverse Events Complaint Specialist receives a notification that an extension was requested and they must approve or reject it. Additionally, the system creates an entry in the Progress Notes field that describes the request.

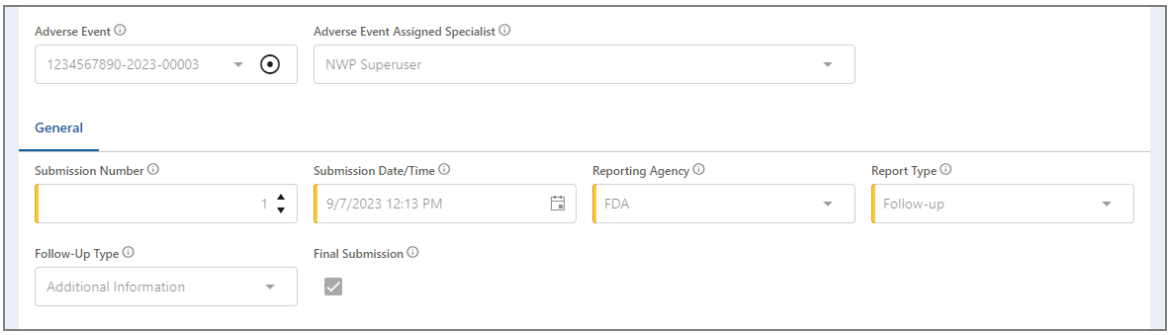
5. Upon opening the record from the notification, review the extension request information and select "Yes" or "No" in the Extension Approved toggle field.
6. Describe your reason for approving or rejecting the extension.
7. Click Save to save the record. When selecting the next state, click In Progress.

Adverse Events Submissions

The Adverse Events Submissions process is typically initiated during the submission phase of an adverse event, and is created within the Adverse Events process itself. Submissions are sent to the specified reporting agencies; the process' search screen is then used to filter and sort for metrics. See "Reporting Agencies" on page 13 and "Adverse Events" on page 22.

Note that the submission records are a notation that a submission activity was made, and are **not** the submission itself.

Fig. 25: Adverse Events Submissions screen



Adverse Events Submissions States

This section defines each state available in the workflow for the Adverse Events Submissions process. See "State Change Security" on page 51 to learn more about how these states transition.

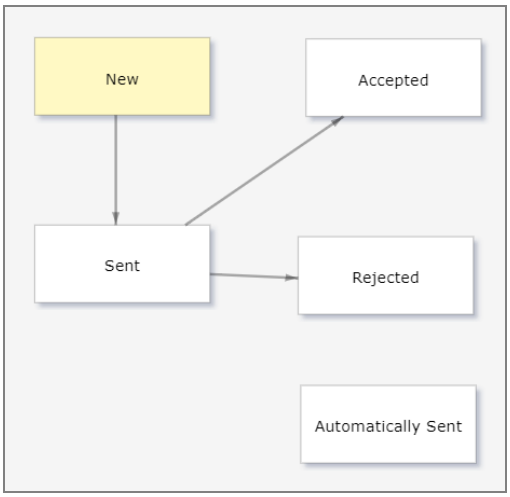
New (Default). A newly created adverse event submission.

Sent. The submission has been sent to the agency.

Accepted. The agency has approved the data submitted.

Rejected. The agency has rejected the data submitted.

Automatically Sent. This state is a placeholder for a future functionality.



Adverse Events Submissions Tasks

Adding a New Adverse Events Submission

1. In the Adverse Events process detail screen, navigate to the Submissions tab.
2. Click the Add New Item button in the Submissions field. A new screen appears.
3. Select a submission number, the reporting agency, and the report type.
4. If the submission is a follow-up, then select a follow-up type.

5. If this is the final submission to the reporting agency, then select the "Final Submission" check box.
6. Click Save to save the new record. When selecting the next state, click Sent.

   Note: Once the reporting agency responds to the submission, you may return to the submission record and move the state to Accepted or Rejected, depending on the response.

Chapter 4

Inbox Messages

Introduction to Inbox Messages

Most processes in the system require multiple people, departments, or groups to coordinate on completing a process. The inbox automates notifications sent to the appropriate users at specific times in the process.

An individual action item represents a single task, approval, or notification that has been sent to you. This task will remain in your inbox until the necessary steps have been taken for completion.

Inbox messages can be separated into three different action types:

- **Assignment.** You are required to take some action in the system to move it beyond your workflow.
- **Approval.** Your approval is requested. You must approve or reject the process item.
- **Acknowledgment.** This is only for your information. You can acknowledge the notification to remove it from your inbox.

See the User Interface user guide to learn how to access inbox messages.

Inbox Messages

The table below describes each inbox action item involved in the Adverse Events module. In addition to title and description, the table indicates which process each item comes from, who receives the message, and when it is sent. See the User Interface user guide to learn more about inbox messages.

Process	Title	Message	Action Type	Sent To / Sent When
Adverse Events	Investigation Complete	The investigation for Adverse Event {ComplaintNumber_f} has been completed. This Adverse Event was filed by {ReporterFacility_f} with the following details: {EventProblemDescription_f}	Assignment	Sent to the Assigned Specialist when the adverse event investigation has completed.

Process	Title	Message	Action Type	Sent To / Sent When
Adverse Events	Final Submission Rejected	The Final Submission for Adverse Event {ComplaintNumber_f} has been rejected. Please review this Adverse Event and the final submission for this Adverse Event for accuracy before re-submitting the Adverse Event to the reporting agency. This Adverse Event was filed by {ReporterFacility_f} with the following details: {EventProblemDescription_f}	Assignment	Sent to the Assigned Specialist when the final submission is rejected.
Adverse Events	Adverse Event Reopened	Adverse Event {ComplaintNumber_f} has been re-opened by a Complaint Administrator. Please review the Adverse Event and contact your Complaint Administrator for further details.	Assignment	Sent to the Assigned Specialist when an adverse event record is re-opened.
Adverse Events	Notify Top Management	Adverse Event {ComplaintNumber_f} has been created and is awaiting initial approval. This Adverse Event was created on {CreatedDateTime_f} and reported by {ReporterFacility_f}	Assignment	Sent to employees in the Top Management Notification Group that an adverse event record has been created and is ready to be approved.
Adverse Events	Initial Approval Rejected	The Initial Approval of Adverse Event {ComplaintNumber_f} has been rejected.	Assignment	Sent to the Assigned Specialist when the initial approval is rejected.
Adverse Events	Final Approval Rejected	The Final Approval of Adverse Event {ComplaintNumber_f} has been rejected.	Assignment	Sent to the Assigned Specialist when the final approval is rejected.
Adverse Events	Adverse Event Complete	Adverse Event {ComplaintNumber_f} has been completed. This Adverse Event was regarding the following problem: {EventProblemDescription_f}	Assignment	Sent to the Assigned Specialist when the state is Complete.

Process	Title	Message	Action Type	Sent To / Sent When
Adverse Events	A New Adverse Event Has Been Created	A new Adverse Event has been created that you are responsible for investigating. Adverse Event Number: {RecordID_f} This Adverse Event was filed by {ReporterFacility_f} with the following details: {EventProblemDescription_f}	Assignment	Sent to the Assigned Specialist when the current state is either New, Intake Information, or Assign Specialist and the current state has not been assigned.
Adverse Events	New Adverse Event Specialist Assigned	Adverse Event {ComplaintNumber_f} has been re-assigned to you. You are tasked with investigating and coordinating this Adverse Event further. This Adverse Event was filed by {ReporterFacility_f} with the following details: {EventProblemDescription_f}	Assignment	Sent to the Assigned Specialist when they are assigned to an adverse event.
Adverse Events	Initial Approval	The following Adverse Event is ready for Initial Approval and is awaiting sign-off. Adverse Event {ComplaintNumber_f} has been filed by {ReporterFacility_f} with the following details: {EventProblemDescription_f}	Approval	Sent to the Adverse Event and Reportability Approval user when an adverse event is ready for initial approval.
Adverse Events	Final Approval	You are responsible for signing-off on Adverse Event {ComplaintNumber_f}. Adverse Event {ComplaintNumber_f} has been filed by {ReporterFacility_f} with the following details: {EventProblemDescription_f}	Approval	Sent to the Final Approval for Closure user when an adverse event is ready for final approval.

Process	Title	Message	Action Type	Sent To / Sent When
Adverse Events Tasks	Extension Requested on Adverse Events Task	{Responsibility_f} has requested an extension for Task "{Task_f}" on adverse event {Complaint_f} has been requested. The extension requests the due date being changed from {DueDate_f} to {NewTargetDate_f}. {Responsibility_f} is requesting this extension for the following reason: {ReasonforExtension_f}	Assignment	Sent to the Adverse Events Specialist when the "Request Extension" check box is selected and the adverse events task is saved.
Adverse Events Tasks	An Adverse Event Task Has Been Assigned	You are responsible to complete the task {Task_f} for adverse event {Complaint_f} This task is due on {DueDate_f} The notes or objectives for this task are as follows: {TaskNotesObjectives_f}	Assignment	Sent to the Responsibility role when the task is saved and an action was not previously sent.
Adverse Events Tasks	Obsolete: A. Extension Complete	You have requested an extension for Task {Task_f} on Complaint {Complaint_f}. The Extension was {ExtensionApproved_f} by {ExtensionRequestCompletedBy_f} for the following reason: {ExtensionApprovalNotes_f}	Assignment	Sent to the Responsibility role when the extension approval is complete, whether it is approved or denied.
Adverse Events Tasks	Task Ready for Verification	Adverse event task {Task_f} for adverse event {Complaint_f} is ready for verification.	Assignment	Sent to the user in the Task Verification field when the task is ready for verification.
Adverse Events Tasks	Task Has Been Re-opened	Adverse event task {Task_f} for adverse event {Complaint_f} has been re-opened.	Assignment	Sent to the Responsibility role when an adverse event task is re-opened.

Process	Title	Message	Action Type	Sent To / Sent When
Adverse Events Tasks	An Extension Complete Denied	You have requested an extension for task {Task_f} on adverse event {Complaint_f}. The extension was denied by {ERCompletedBy_f} for the following reason: {ReasonforApprovingRejecting_f}	Assignment	Sent to the Responsibility user when the extension approval is denied.
Adverse Events Tasks	An Extension Complete Approved	You have requested an extension for task {Task_f} on adverse event {Complaint_f}. The extension was approved by {ERCompletedBy_f} for the following reason: {ReasonforApprovingRejecting_f}	Assignment	Sent to the Responsibility user when the extension approval is approved.
Adverse Events Tasks	An Adverse Event Task Has Failed the Verification	Adverse event task {Task_f} for adverse event {Complaint_f} has been re-opened due to failed verification.	Assignment	Sent to the Responsibility role when the adverse event task has failed the verification.
Adverse Events Submissions	Submission Was Rejected	The Submission for Adverse Event {Complaint_f} has been Rejected. This submission was sent to {ReportingAgency_f} on {SubmissionDateTime_f}	Assignment	Sent to the Adverse Event Assigned Specialist when the submission record is in the Rejected state.

Chapter 5

Metrics and Reports

Introduction to Metrics and Reports

The QMS system includes reporting and metric features that let you analyze the data in each process, measuring efficiency and effectiveness. The metrics and reports available differ between each process.

Report are generated within each process, either from the search screen or the detail screen. Metrics and key process indicators (KPIs) are gadgets that can be placed on one of your dashboards.

See the User Interface user guide to learn how to generate reports, metrics, and KPIs.

Reports

Pre-set reports have been set up to be pulled on a process by process basis, though not every process has a pre-set report. Certain reports require additional parameters in order to be previewed. The parameters are listed on the right side of the preview window. If a report requires parameters, then this pane will automatically appear. Once you have selected the desired parameters, click the Preview button to see the report preview.

Below is a table that describes each report available in the Adverse Events module. In addition to title and description, the table indicates which process each report comes from and whether it is pulled from the search screen or detail screen. Lastly, if the report requires specific parameters in order to be generated properly, a description of those parameters is included below that report. See the User Interface user guide to learn how to access reports.

Process	Pulls From	Title	Description
Reporting Agencies	Detail Screen	Audit Trail – Reporting Agencies	Provides a path of how the record has progressed over time with changes (who, what, and when).
MDR Reportable Event Types	Detail Screen	Audit Trail – MDR Reportable Event Types	Provides a path of how the record has progressed over time with changes (who, what, and when).
MDR Event Outcomes	Detail Screen	Audit Trail – MDR Event Outcomes	Provides a path of how the record has progressed over time with changes (who, what, and when).
MDR Library Tasks Categories	Detail Screen	Audit Trail – MDR Library Tasks Categories	Provides a path of how the record has progressed over time with changes (who, what, and when).
MDR Library Tasks	Detail Screen	Audit Trail – MDR Library Tasks	Provides a path of how the record has progressed over time with changes (who, what, and when).
Adverse Events, Adverse Events Submissions	Detail Screen	Adverse Events FDA 3500A Report	FDA 3500A used for mandatory reporting. This report is only for reference purposes.
Adverse Events	Search Screen	Adverse Events Provider Summary	Provides a summary of adverse events for a selected provider (any reporting facility that has

Process	Pulls From	Title	Description
			at least one adverse event created for that provider).
Adverse Events	Detail Screen	Audit Trail – Adverse Events	Provides a path of how the record has progressed over time with changes (who, what, and when).
Adverse Events Suspect Items	Detail Screen	Audit Trail – Adverse Events Suspect Items	Provides a path of how the record has progressed over time with changes (who, what, and when).
Adverse Events Tasks	Detail Screen	Audit Trail – Adverse Events Tasks	Provides a path of how the record has progressed over time with changes (who, what, and when).
Adverse Events Submissions	Detail Screen	Audit Trail – Adverse Events Submissions	Provides a path of how the record has progressed over time with changes (who, what, and when).

Metrics

Below is a table that describes each metric available in the Adverse Events module. In addition to title and description, the table indicates which process each metric comes from. Lastly, if the metric requires specific parameters in order to be generated properly, a description of those parameters is included below that metric. See the User Interface user guide to learn how to access reports.

Process	Pulls From	Title	Description
Adverse Events	Gadgets	Open Adverse Events by State	Open adverse events by state that are not complete.

KPIs

See the User Interface user guide to learn more about KPIs.

There are no KPIs available for this module.

Chapter 6

Security Settings

Security Roles

Security roles define how various users access and control different types of processes and data. These roles are then assigned to each user. Some roles are used by many users, while others may only be applied to one or two individuals.

The following security roles apply in the Adverse Events module.

Adverse Events Complaints Specialist

The complaints specialist is responsible for entering or verifying the intake information, as well as managing the compliant through completion. This security role allows you to add new complaint records and modify complaint records that you are assigned to as the specialist.

All Roles

System-controlled All Roles Value. Any security applied to this special system role grants that security access to all users of the system.

Complaints Administrator

The complaints administrator is responsible for setting up and maintaining the Complaint Management module. This security role has access to add/modify/remove records of the following processes: MDR Library Tasks, MDR Reportability Questions, MDR Library Tasks Categories, MDR Reportable Event Types, MDR Event Outcomes, and Reporting Agencies. The complaints administrator security role is also the only security role that is allowed to re-open a completed complaint.

Complaints Approver

Members of the of the complaints approver security role are level 2 approvers for both the initial and final approval of a complaint.

Complaints Coordinator

The complaints coordinator is responsible for managing the overall complaints process, including assigning a complaint specialist to complaints where one has not been assigned. This security role allows you to add new compliant records, modify complaint records, and remove compliant records that are not yet complete.

Complaints Maintenance

The Complaints Mainteance role can modify setup processes for the Complaints process.

Complaints Navigation

Members of this security role have access to navigate to the Complaints and Complaints Tasks process.

System View

System view is a generic role that most users and modules use. This role allows you to view (but in most cases not edit) much of the non-sensitive data in the system. Being able to view the data is still subject to you having the ability to navigate to, and open, a process.

Every user should have this security role because it allows users to view non secure data for most processes. For users who typically only have to approve data, but do not have to add or edit data, this System View role is what they need.

Process Security Roles

Each list below displays the security roles that provide you with permissions to add items for the indicated individual process.

Reporting Agencies

- Complaints Administrator

MDR Remedial Action Types

- Complaints Administrator

MDR Reportable Event Types

- Complaints Administrator

MDR Event Outcomes

- Complaints Administrator

MDR Library Tasks Categories

- Complaints Administrator

Adverse Events

There are no security roles for this process.

Adverse Events Tasks

- Adverse Events Complaint Specialist
- Complaints Administrator
- Complaints Coordinator

Adverse Events Submissions

- Adverse Events Complaint Specialist
- Complaints Administrator
- Complaints Coordinator

State Change Security

As you complete tasks in the system, changes occur based on your activities (such as changing a record's state) and when other events occur (such as a specific amount of time passing). The changes based on your activities are called **actions**, while the event-based changes are called **transactions**. The main difference between the two is the initiator: actions are performed by users, and transactions are managed by the system.

Each system change may depend on a number of factors, including where you are in the system, who is involved, which fields are populated, and more. It is important to know the actions and transactions for each process because these affect your ability to complete a task.

The state change security for each process is separated into two sections:

1. **Security.** Which users (by security role or field role) can change the state of a record. Field roles are indicated with an asterisk*.
2. **Transactions.** The conditions that must be met to initiate a transactions.

Security

Reporting Agencies

Transactions	Complaints Administrator
Active >> Inactive	✓
Inactive >> Active	✓

MDR Remedial Action Types

Transactions	Complaints Administrator
Active >> Inactive	✓
Inactive >> Active	✓

MDR Event Outcomes

Transactions	Complaints Administrator
Active >> Inactive	✓
Inactive >> Active	✓

MDR Reportable Event Types

Transactions	Complaints Administrator
Active >> Inactive	✓
Inactive >> Active	✓

MDR Library Tasks Categories

Transactions	Complaints Administrator
Active >> Inactive	✓

Transactions	Complaints Administrator
Inactive >> Active	✓

Adverse Events

Transitions	Adverse Events Complaint Specialist	Complaints Administrator	Complaints Coordinator
Adverse Event Re-Opened >> Ready for Approval	✓	✓	✓
Approval Rejected >> Ready for Approval	✓	✓	✓
Complete >> Adverse Event Re-Opened	X	✓	X
New >> Ready for Approval	✓	✓	✓
Submission Rejected >> Ready for Approval	✓	✓	✓

Adverse Events Tasks

Transitions	Adverse Events Complaint Specialist	Responsibility*	Verification Responsibility*	Complaints Administrator	Complaints Coordinator
Closed >> In Progress	X	X	X	✓	X
In Progress >> Task Complete	✓	✓	X	✓	✓
New (library task) >> In Progress	✓	✓	X	✓	✓
New >> In Progress	✓	✓	X	✓	✓
Ready for Verification >> Closed	X	X	✓	✓	X
Ready for Verification >> In Progress	✓	✓	✓	✓	✓

Adverse Events Submissions

Transitions	Adverse Events Complaint Specialist	Complaints Administrator	Complaints Coordinator
New >> Sent	✓	✓	✓
Sent	✓	✓	✓

Transitions	Adverse Events Complaint Specialist	Complaints Administrator	Complaints Coordinator
>> Accepted			
Sent >> Rejected	✓	✓	✓

Transactions

MDR Library Tasks

Default Resp = 1 or 2

When the Default Responsibility field is set to Complaint Specialist or Complaint Coordinator, the following fields are hidden:

- Default Responsibility Person
- Default Responsibility Role

Default Resp = 3

When the Default Responsibility field is set to Security Role, the Default Responsibility Person field is hidden.

Default Resp = 4

When the Default Responsibility field is set to Employee, the Default Responsibility Role field is hidden.

Default Verif = 1 or 2

When the Default Verification field is set to Complaint Specialist or Complaint Coordinator, the following fields are hidden:

- Default Verification Person
- Default Verification Role

Default Verif = 3

When the Default Verification field is set to Security Role, the Default Verification Person field is hidden.

Default Verif = 4

When the Default Verification field is set to Employee, the Default Verification Role field is hidden.

NOT Verification Required

If verification is not required for the library task, then the Default Verification Type field is hidden.

Adverse Events

A New Adverse Event is Created and Saved

When the record is initially added and the current state is New, Assign Specialist, or Intake Information, the following items occur:

- The assigned specialist receives a notification that a new adverse event has been created.
- The system uses the FEI number from System Parameters and combines the current year and sequence number to create the proper adverse event number according to the FDA.
- The system inserts a list of employees into the Top Management Group multi-cross-reference field so an action can be sent to people with the Top Management option assigned on their title.
- The ssytem inserts all active MDR library tasks into the Adverse Events Tasks process.

Adverse Event State is Complete

When the current state moves to Complete, a notification is sent to the Assigned Specialist role.

Age Checkbox = False (Supply Age and Age Unit)

When the "Date of Birth Known?" check box is not selected, the Date of Birth field is hidden.

Age Checkbox = True (Supply Date of Birth)

When the "Date of Birth Known?" check box is selected, the Age and Age Units fields are hidden.

Approval Rejected

When the current state is Approval Rejected, the Suspect Products and Suspect Device fields are unlocked. Additionally, a notification is sent to the Assigned Specialist to inform them that the approval was rejected.

Assigned Specialist Changed

When the Assigned Specialist changes, the newly selected user is updated in the following processes:

- Adverse Events Suspect items
- Adverse Events Tasks
- Adverse Events Submissions
- Adverse Events Reportability Assessment Response

Current State = Final Submission and Reportable is Not Checked

When the current state changes to Final Submission and the "Reportable?" check box is not selected, the system changes the state to Complete after the final submission is accepted.

Current State Changed to Adverse Event Re-Opened

When the current state moves to Adverse Event Re-Opened, a notification is sent to the Assigned Specialist.

Device Evaluated by Manufacturer or Not Returned for Evaluation

When a device is evaluated by a manufacturer or a device is not returned to the manufacturer for evaluation, the following fields are hidden:

- Not Evaluated Code
- Explanation for Not Evaluating Device

Facility Did Not Send Report to FDA

When the Report Sent to FDA? field is null, the Date Report Sent to FDA field is hidden.

Facility Did Not Send to Manufacturer

When the Report Sent to Manufacturer? field is null, the Date Report Sent to Manufacturer field is hidden.

Facility Report Type is Not Follow-Up

When the type of report is **not** Follow-Up, the Follow-up # field is hidden.

Final Submission = Accepted

When a final submission in the Submissions list is accepted, the system updates the adverse event record's state to complete.

Final Submission = Rejected

When the Submissions list contains a rejected final submission and not an accepted final submission, the current state becomes Final Submission Rejected.

Hide "Reportability Assessment"

When the reportability assessment is hidden, the following fields are also hidden:

- Number of Days to Report
- Report Due Date
- Reportable?
- Reporting Agencies
- Type of Reportable Event

Maximum Suspect Devices

When there is one record in the Suspect Device field, the "Insert Suspect Device" command button is hidden.

Maximum Suspect Products

When there is two records in the Suspect Products field, the "Insert Suspect Product" command button is hidden.

Mfg Not Outsourcing Facility

When the "Compounding Outsourcing Facility 503B" field is set to NO, the Outsourcing Facility field is hidden.

New Adverse Event Specialist Assigned

If the Assigned Specialist is changed while the state is New, Assign Specialist, or Intake Information, then a new Adverse Event Specialist is assigned.

Occupation is Not Other

When the Occupation field is **not** set to Other, the Occupation Other field is hidden.

Ready for Final Approval

When the current state is Ready for Final Approval, a notification is sent to the approvers to inform them that they must sign off.

Ready for Initial Approval

When the current state is Ready for Initial Approval, a notification is sent to the approvers to inform them that they must sign off.

Reportable is Not Checked

When the "Reportable?" check box is not selected, the following fields are hidden:

- Number of Days to Report
- Report Due Date
- Reporting Agencies

Reportable Is Not Checked and Final Approval Was Completed

When the "Reportable?" check box is not selected and the current state is changed to Final Submission, the state transitions to Complete once the final submission is accepted.

State = Ready for Approval

When the current state is Ready for Approval, the following changes occur:

- The Suspect Products and Suspect Device fields are locked.
- The current state of all linked Complaints Reportability Assessment Responses is updated to Locked.
- All linked Suspect Item records are updated so they create NCRs as expected.
- A notification is sent to the employees in the "Top Management Notification Group MCR" that an event was created and is ready to be approved.

State = Submission Rejected

When the current state moves to Submission Rejected, a notification is sent to the owner of the adverse event.

State is Not Equal to Ready for Approval

When the current state is **not**Ready for Approval, the "Tasks must be closed prior to approval" field is hidden.

Type of Reportable Event is Not Summary Report

When the reportable event type is **not** Summary Report, the No. of Events Summarized field is hidden.

Adverse Events Suspect Items

Adverse Events State = "Ready for Approval"

A new non-conformance record is created for the suspected item and the parent Adverse Events record is updated, given that it fits the following parameters:

- The "Create Non-Conformance" check box is selected.
- The Related Non-Conformance field is empty, meaning that no non-conformance has already been created.
- The parent Adverse Events state is Ready for Approval.

Create Non-Conformance not Checked

When the "Create Non-Conformance" check box is **not** selected, the following fields are hidden:

- Non-Conformance Category
- Related Non-Conformance

Item is Updated

When a new item is selected, the rest of the item data is defaulted.

Manufacturer / Compounder Updated

When a new manufacturer / compounder is selected, the rest of the manufacturer / compounder data is defaulted.

Not Returned to Manufacturer

When the "Device Available for Evaluation?" field is set to NO, the Returned Date field is hidden.

Operator is Not Other

When the operator is not set to Other, the Other Operator field is hidden.

Product or Device = Device

When the Product or Device toggle field is set to Device, the following fields are hidden:

- Diagnosis For Use
- Dose
- Event Abated After Dose Changes?
- Event Reappeared After Reintroduction
- Frequency
- Name and Strength
- National Drug Code (NDC#)
- Product Compounded
- Product Type
- Route Used
- Treatment/Therapy Start Date
- Treatment/Therapy Stop Date

Product or Device = Product

When the Product or Device toggle field is set to Product, the following fields are hidden:

- Brand Name
- Catalog Number
- Common Name
- Concomitant Medical Products and Therapy Dates
- Device Available for Evaluation?
- Explanted Date
- Implanted Date
- Model Number
- Operator of Device
- Other Operator
- Procode
- Reprocessor
- Reprocessor Address 1
- Reprocessor Address 2
- Reprocessor City
- Reprocessor Contact
- Reprocessor Country
- Reprocessor Name
- Reprocessor Postal Code
- Reprocessor State/Province/Region
- Returned Date
- Serial Number
- Serviced by a Third Party?
- Single-Use Device Reprocessed and Reused?

Related NCR is not null

When the Related Non-Conformance field contains a value, the Non-Conformance Category field is hidden.

Reprocessor is Not True

When the "Single-Use Device Reprocessed and Reused?" check box is **not** selected, the following fields are hidden:

- Reprocessor
- Reprocessor Address 1
- Reprocessor Address 2
- Reprocessor City
- Reprocessor Contact
- Reprocessor Country
- Reprocessor Name
- Reprocessor Postal Code
- Reprocessor State/Province/Region

Reprocessor is Updated

When a new reprocessor is selected, the rest of the reprocessor data is defaulted.

Submission Focus was Checked

When the "Submission Focus" check box is selected and the record is saved, the "Submission Focus" check box on all other Suspect Items for the same Adverse Event are de-selected. This ensures that only one suspect item per event can be the focus of a submission.

Adverse Events Tasks

Extension Approval "Approved"

The extension approval is approved and sent to the Task Responsibility when the following parameters are met:

- The Extension Approved toggle field was changed from "Undecided" to "Yes".
- The "Request Extension" check box is selected.
- The Extension Approved field contains a value.
- The record state is Complete.

Extension Approval "Denied"

The extension approval is denied and sent to the Task Responsibility when the following parameters are met:

- The Extension Approved toggle field was changed from "Undecided" to "No".
- The "Request Extension" check box is selected.
- The Extension Approved field contains a value.
- The record state is Complete.

Extension Approval Complete

When the Extension Approved field contains a value other than "Undecided", the "Request Extension" check box is selected, and the current state is Complete, the system performs the

following actions:

- Updates the ER Completed By and the Reason for Approving/Rejecting Extension fields.
- Updates the Due Date (if the extension was approved) and sets the name of the user who conducted the extension review.
- Creates a new system note in the Progress Notes field, which details why the extension was approved or rejected.
- Clears the Request Extension information.

Request Extension Changed to True

When the record is saved and the "Request Extension" check box was selected, a notification is sent to the Assigned Specialist that an extension was requested and they must approve or reject the extension. A detailed note of this is created in the Progress Notes field.

Request Extension is False

When the "Request Extension" check box is not selected, the following fields are hidden:

- Extension Approved
- Extension Request Completed By
- New Target Date
- Reason for Approving or Rejecting Extension
- Reason for Extension

Responsibility has Changed and Task Not Closed

If the responsibility has changed and the task state is NOT set to Task Complete or Closed, then a notification is sent to the new responsible user.

Send Initial Action

When the "Send Initial Assignment Action" check box is selected, a notification is sent to the responsible user.

Task Closed

When the current state is changed to Closed, the Update Date field in the parent Adverse Events record is updated to the current date.

Task Moved to Complete

When the current state is changed to Task Complete, the system updates the state to either Closed or Ready For Verification, depending on if the "Requires Verification" check box is selected.

Additionally, all records in the Progress Notes field are updated to the Locked state.

Task Ready for Verification

When the current state is changed to Ready for Verification, a notification is sent to the user or role in the Task Verification field that the task is ready for verification.

Verification Failed

When the current state is changed from Ready for Verification to In Progress, a notification is sent to the responsible user that the task failed the verification.

Adverse Events Submissions

Automated Submission is not Checked

When the Automated Submission check box is not selected, the following fields are hidden:

- Acknowledgment Received
- Automated Submission
- Submission Acknowledgments

> ***Note:*** Automated submissions are a future functionality.

Received 3 Acknowledgments

When the "Acknowledgments Received" of an adverse event submission is set to 3 and the previous value was not 3, the state becomes Accepted or Rejected based on the number of failures.

This trigger only occurs when there have been three acknowledgments, so if any failures exist on the third acknowledgment, the state becomes Rejected. If there are no failures, the state becomes Accepted.

State = Rejected

When the current state changes to Rejected, the Last Modified Date field is updated and the Adverse Events record is evaluated to determine if all submissions have been approved.

Submission = Accepted

When the current state changes to Accepted, the Last Modified Date field is updated and the Adverse Events record is evaluated to determine if all submissions have been approved.

Commands

Some processes utilize command buttons to perform pre-defined actions. Commands can be found under the Actions icon in the top toolbar of the appropriate process.

Below is a table that describes each command available in the Adverse Events module. In addition to title and description, the table indicates which process each command comes from, the roles that can execute the command, and the states when the command can be executed.

There are no commands available in this module.

Chapter 7

Module Frequently Asked Questions

Frequently Asked Questions

Why shouldn't I delete items?

Records should only be deleted when you are sure that they are no longer needed. Even though records use a soft delete mechanism, there is still work that must be done to restore an item once it has been deleted.

The best thing to do with an item that is no longer needed is to set it to Inactive, Retired, or Obsolete, whichever state is applicable. This way, the item historically remains in the system but cannot be used.

If you do need to delete an item for good, then use the Trash button in the toolbar. Typically, only the system administrator can delete items.

I just changed the state of a process. What happens now?

When a process' state makes a transition, the system typically takes some automated steps. Details about these steps are listed in the State Transitions section of each process in this user guide.

Typically, state transition steps perform one of three functions:

1. **Notifications.** Notifications are sent to the users that are responsible for the next state of a process.
2. **Field Update.** Fields that depend on a state, date, or action are updated.
3. **Another State Transition**. A process' state may be transitioned automatically by the system, depending on a state, date, or action update.

Some processes may not have any automatic state transitions. In that case, it is useful to check the States section (listed before the State Transitions section) to view the process' state map and read the definitions of each state.

You can also review the Task list for that process. Each list typically describes which state to select when saving a process record.