1. PURPOSE

1.1 The purpose of this work instruction is to define the requirements, processes, and responsibilities for management of Corrective Actions and Preventive Actions (CAPA) Company Name and its subsidiaries.

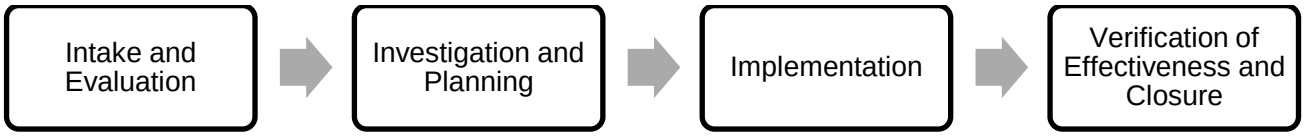
2. SCOPE

2.1 This work instruction applies to all groups, sites, and functions within the organization.

2.2 This work instruction includes instructions for:

- CAPA Intake and Evaluation
- CAPA Investigation and Planning
- CAPA Implementation
- CAPA Verification of Effectiveness and Closure

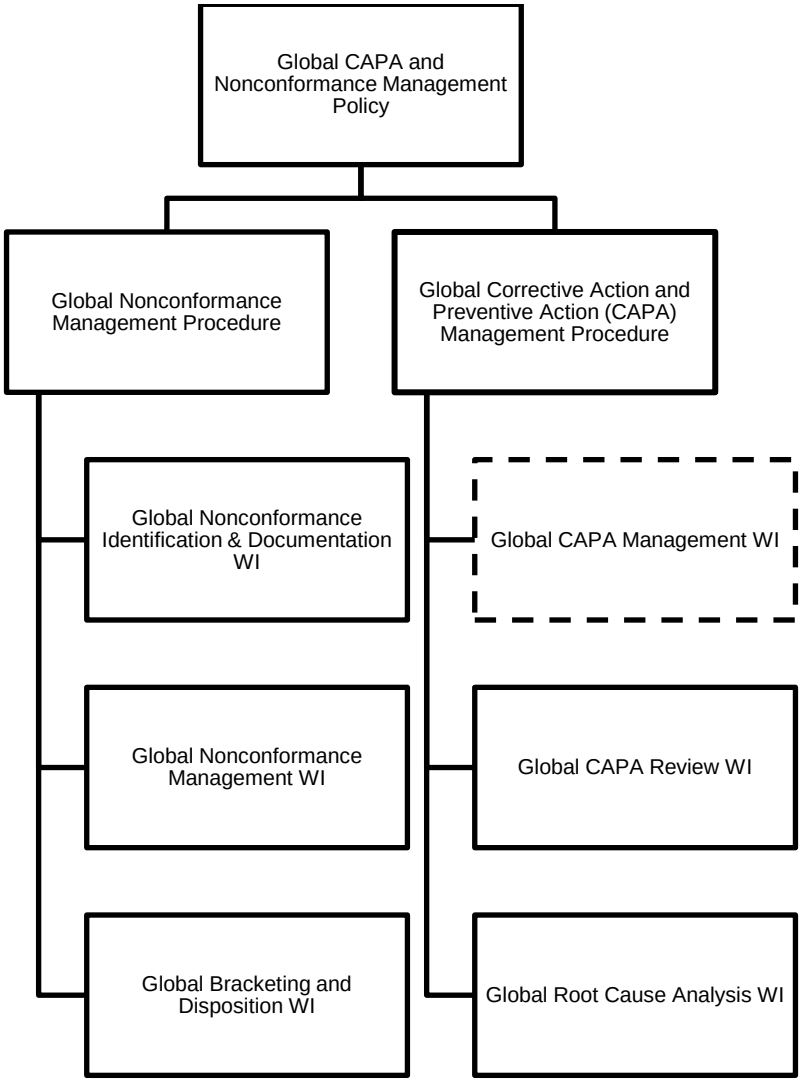
Figure 1: Procedure Overview



2.3 This work instruction does not include instructions for:

- Review of CAPA
- Root Cause Analysis

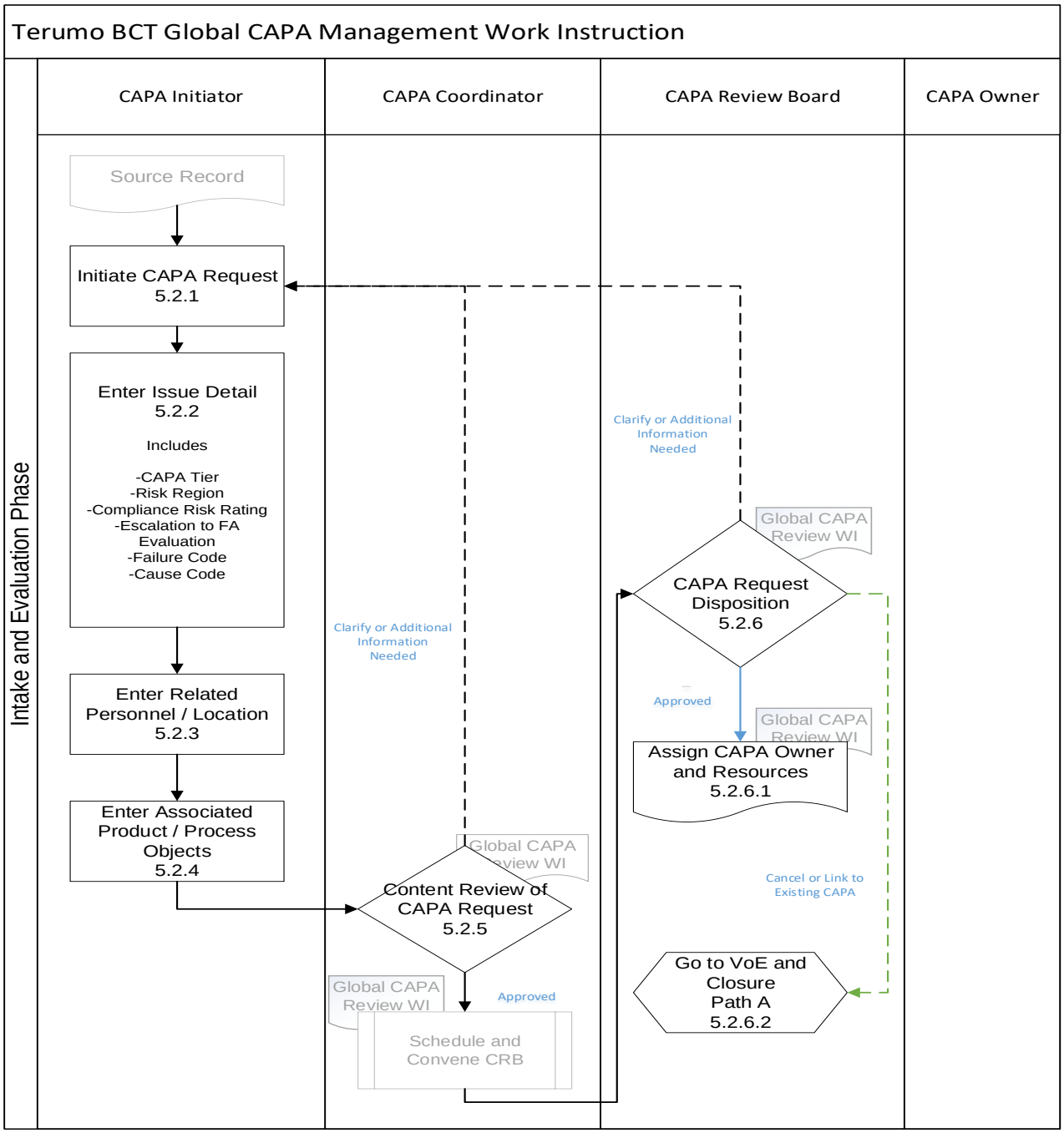
3. DOCUMENT HIERARCHY



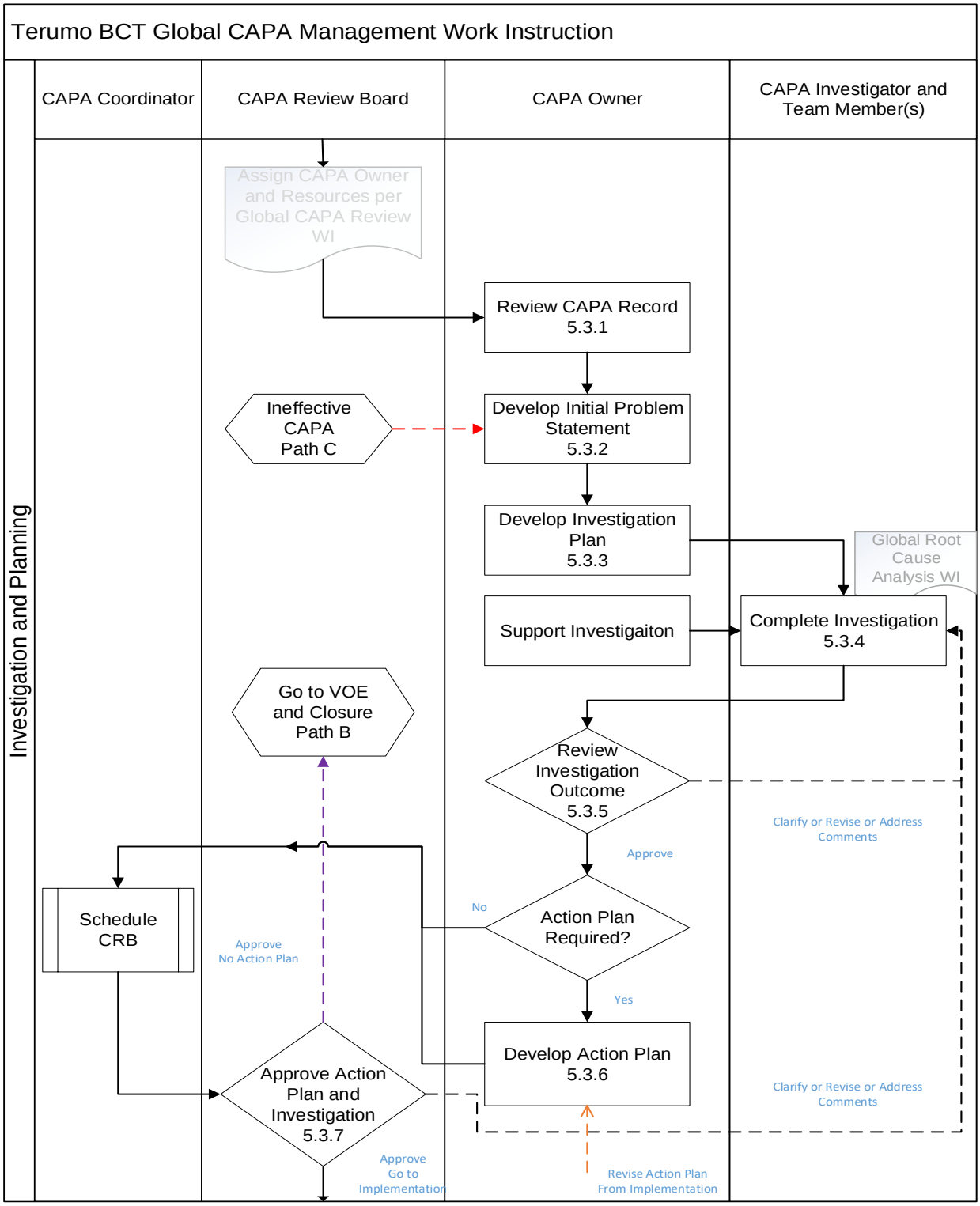
4. PROCESS MAP

The process map below is a high-level description of the Global CAPA Management Work Instruction.

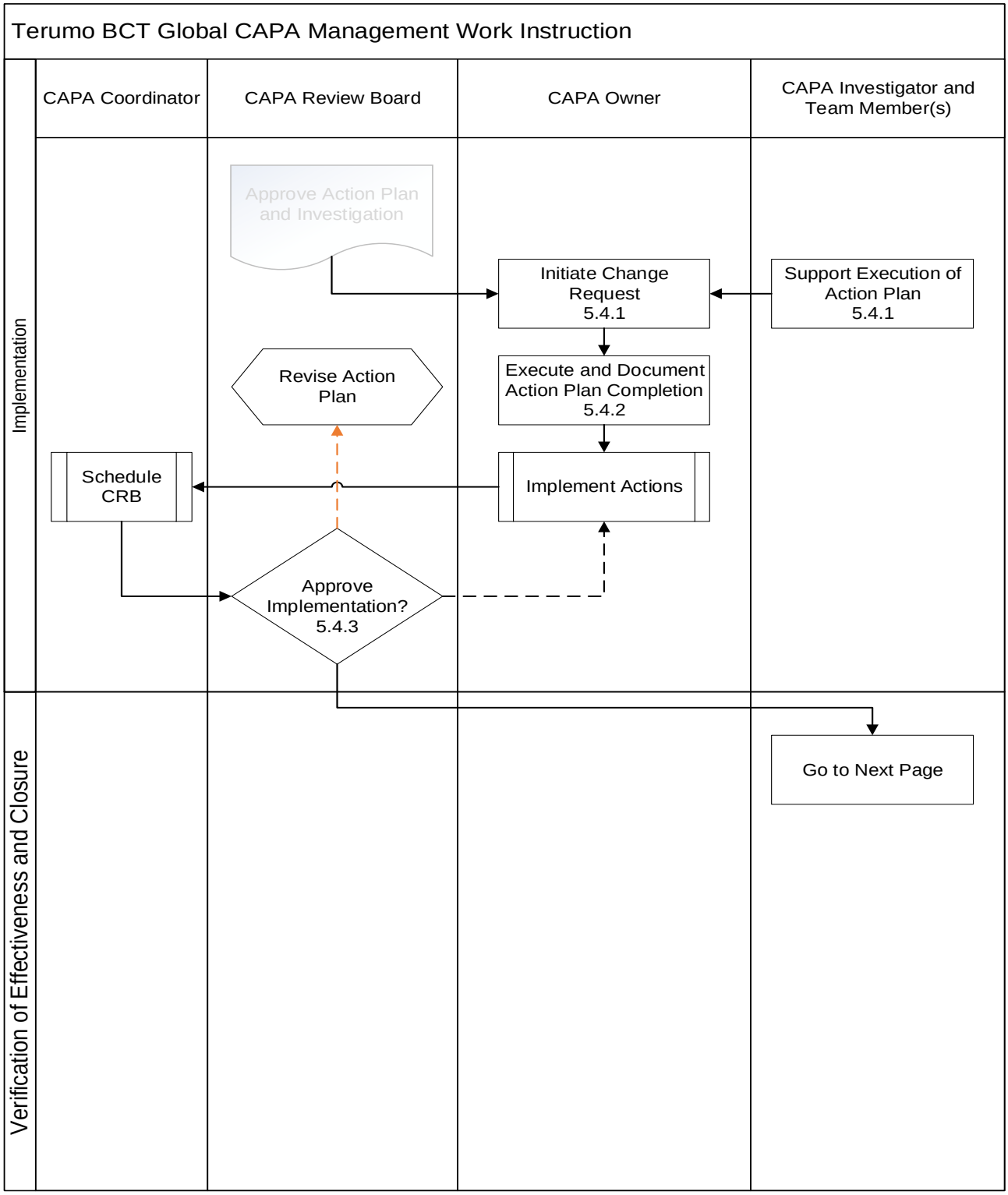
Intake and Evaluation



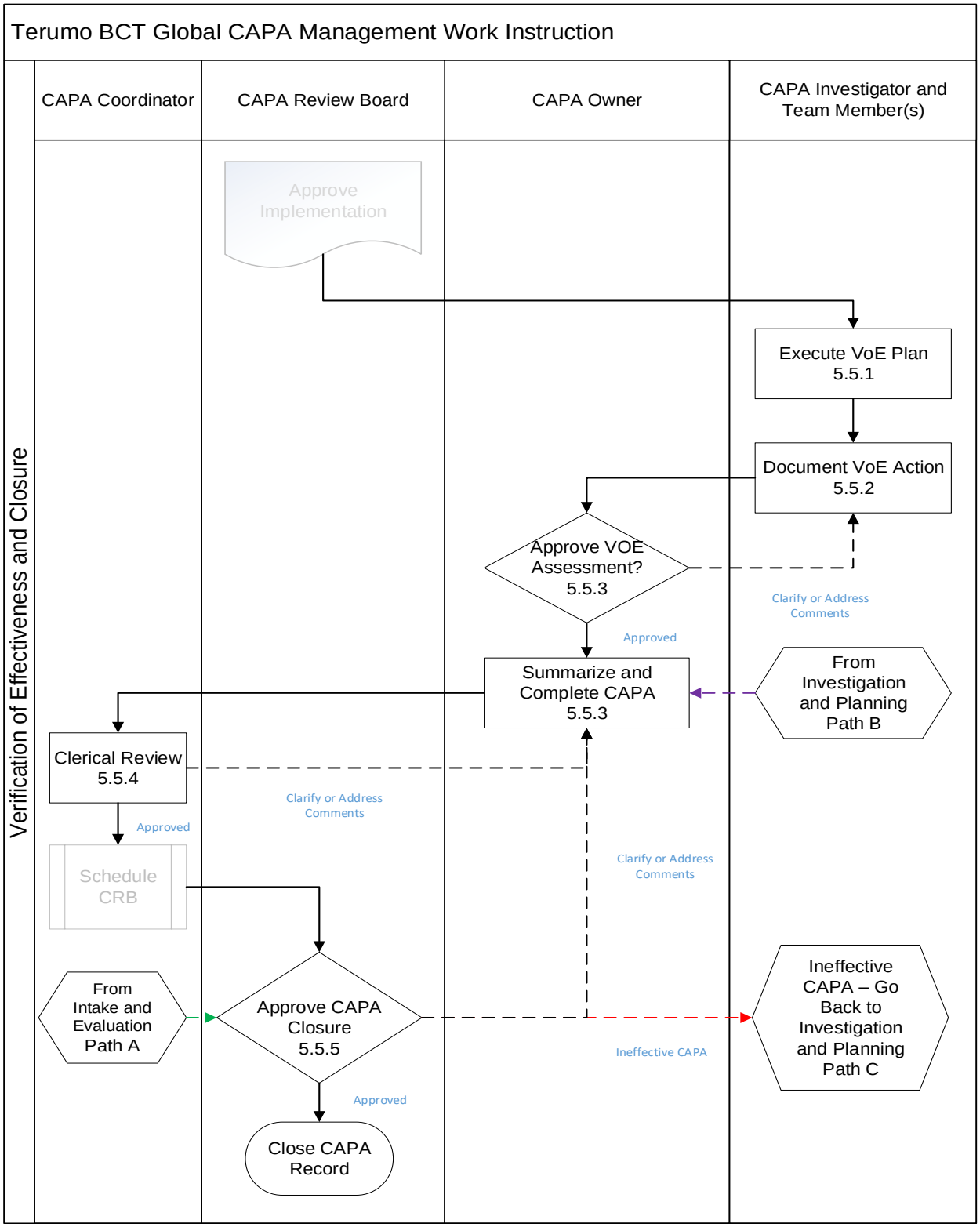
Investigation and Planning



Implementation



Verification of Effectiveness and Closure


Terumo BCT Global CAPA Management Work Instruction
Verification of Effectiveness and Closure
CAPA Coordinator
CAPA Review Board
CAPA Owner
CAPA Investigator and Team Member(s)
Approve Implementation
Execute VoE Plan 5.5.1
Document VoE Action 5.5.2
Approve VOE Assessment? 5.5.3
Clarify or Address Comments
Approved
Summarize and Complete CAPA 5.5.3
From Investigation and Planning Path B
Clerical Review 5.5.4
Clarify or Address Comments
Approved
Schedule CRB
Clarify or Address Comments
From Intake and Evaluation Path A
Approve CAPA Closure 5.5.5
Ineffective CAPA – Go Back to Investigation and Planning Path C
Ineffective CAPA
Approved
Close CAPA Record

5. INSTRUCTIONS

5.1 General Requirements

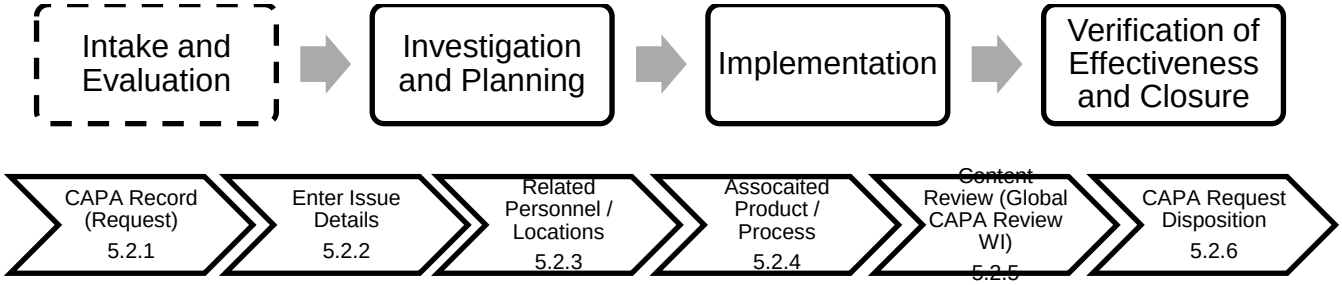
5.1.1 The CAPA Owner shall ensure escalation to Field Action Evaluation, during any phase of the CAPA process if escalation is required as defined by Field Action Evaluation escalation in the appendix of the Global Field Action Procedure.

5.1.2 The CAPA Owner shall ensure escalation of a CAPA for a new issue in any phase of the CAPA process if escalation is required as defined by the CAPA escalation in the appendix of the Global Corrective Action and Preventive Action (CAPA) Management Procedure.

5.1.3 If a new nonconformance is identified in any phase of the CAPA process, the CAPA Owner shall ensure initiation of a nonconformance as defined in the Global Non-conformance Management Procedure and then the subsequent escalation to CAPA, if warranted, per the Global Corrective Action and Preventive Action (CAPA) Management Procedure.

5.1.4 CAPA Owner shall initiate additional containment or corrections activities when new information warrants such actions per this work instruction.

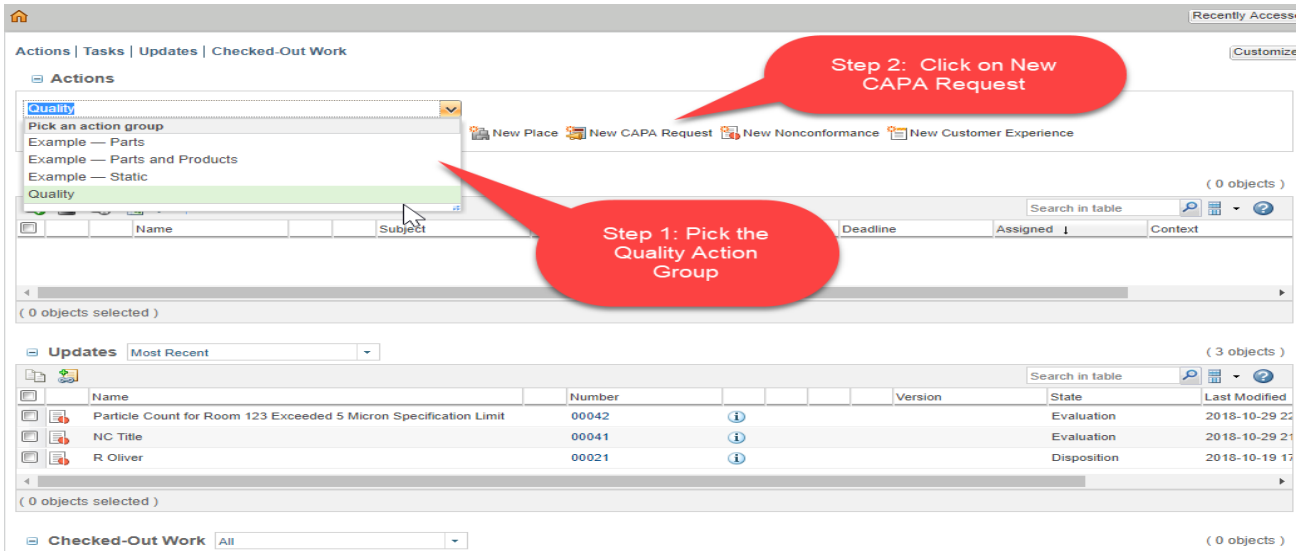
5.2 Intake and Evaluation



5.2.1 The CAPA Initiator shall initiate a CAPA Record (Request) if an existing or potential issue meets the criteria defined in Appendix 1: CAPA Escalation Criteria in Global Corrective Action and Preventive Action (CAPA) Procedure.

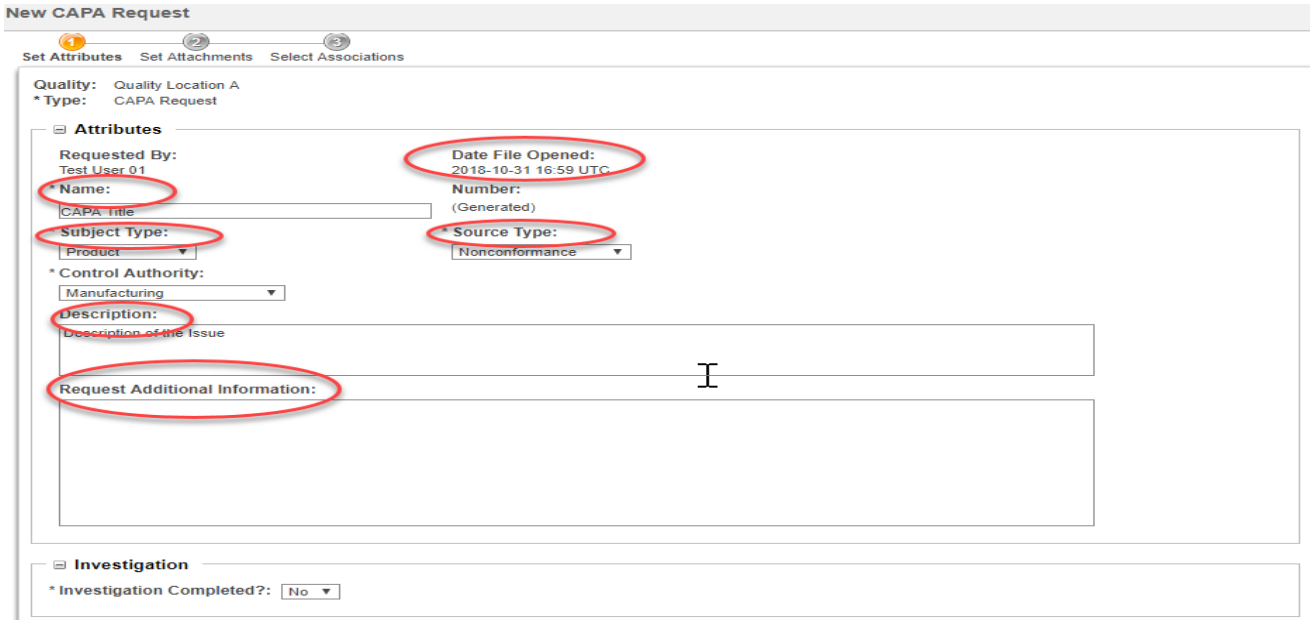
5.2.1.1 Initiate the CAPA Request in WindChill per Figure 2.

Figure 2: Initiate A CAPA Record (Request)



5.2.2 CAPA Initiator shall complete the attribute fields in Figure 3 per Table 1.

Figure 3: New CAPA Request



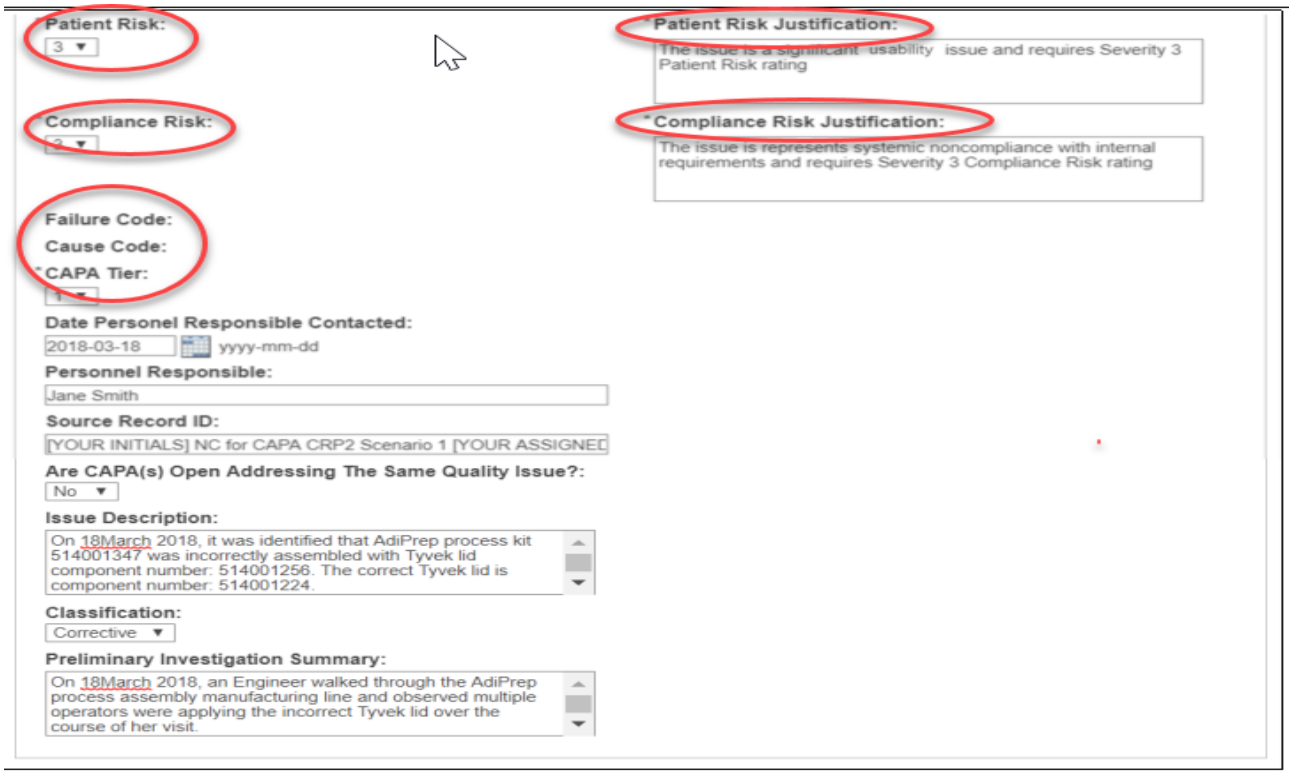


Table 1: Attribute Fields for CAPA Request

Attribute Field	Action and Details	Optional or Required
Name (Title)	Document a title of the CAPA	Required
Requested By	The individual who is requesting the CAPA Request. Autogenerated upon Initiation of Request	Required
Date File Opened (CAPA Request Date)	Date the CAPA Request was initiated • Formatted DD/MMM/YYYY Autogenerated	Required
Issue Description	Document the detailed description of the escalated issue. Should answer: who, what, where, when, to what extent, and why. Should support a development of a problem statement or contain a problem statement.	Required
Risk Region - Expected	Document the risk region associated with the escalated issue: Select:	Required (Editable)

Attribute Field	Action and Details	Optional or Required
	• **High** • **Medium** • **Low** Refer to the Global Risk Assessment Procedure.	
Risk Region – Expected Justification	Document the rationale for the selected risk region - expected	Required (Editable)
Risk Region - Actual	Document the Actual Risk Region associated with the escalated issue: Select: • **High** • **Medium** • **Low** Refer to the Global Risk Assessment Procedure.	Required (Editable)
Risk Region – Actual Justification	Document the rationale for the selected risk region- Actual	Required (Editable)
Compliance Risk	Enter Compliance Risk Rating as defined in the Risk Management WI. Select Rating: ▪ 1 – 5	Required (Editable)
Compliance risk rating Justification	Document the rationale for the selected compliance risk	Required (Editable)
Subject Type (CAPA Issue Type)	Select the most applicable CAPA Issue Type that best describes the escalated issue: • Product • Process • Quality Management System (QMS) Refer to the Global Glossary for Issue definition.	Required

Attribute Field	Action and Details	Optional or Required
Source Type	Select the process/element from which the CAPA was escalated. • **Design Controls** • **Risk Management** • **Labels & Promotional Materials** • **Statistical Techniques** • **Management Responsibility** • **Personnel/Training** • **Quality Audits** • **Document Controls** • **Records Controls** • **Change Controls** • **Non-Conformance** • **CAPA** • **Trending** • **Complaints & AER** • **Field Actions** • **Periodic Reporting** • **Supplier Controls** • **Distribution** • **Storage** • **Equipment Controls** • **Validation** • **Facilities Controls** • **Installation & Service** • **Identification & Traceability** • **Process Controls** • **Acceptance Activities**	Required ▪ NC ID ▪ Complaint ID ▪ Audit ID
CAPA Tier	Select the CAPA Tier based on risk in accordance with Global Corrective Action and Preventive Action Procedure. • **Tier 1** • **Tier 2** • **Tier 3**	**Required (Editable)**
CAPA Tier Rationale	Document the rationale for selecting the CAPA Tier.	Required
Escalation to Field Action	Answer the Field Action Evaluation Escalation Questions per the Global Field Action Procedure and based on the response, select Yes if the criteria for	Required – if Known

Attribute Field	Action and Details	Optional or Required
	escalation has been met or No if the criteria was not met: • **Yes** • **No** If the answers to the Field Action Evaluation Escalation questions are not known, leave the answers blank.	
Failure Code (Initial)	Document the codes linking potential failure to the associated risk file failure mode. Refer to the Global Risk Assessment Procedure. If the Failure Code is not known, leave the answers blank	Required – if Known (Editable)
Cause Code (Initial)	Document the quality code that describes the cause of the issue. Refer to the Global Risk Assessment Procedure. If the Cause Code is not known, leave the answers blank	Required – if Known (Editable)

5.2.3 CAPA Initiator shall complete and / or confirm the Attribute Fields in Figure 4 associated with Related Personnel and Locations per Table 4 and Table 5.

Figure 4: Attribute Fields for Related Personnel and Locations

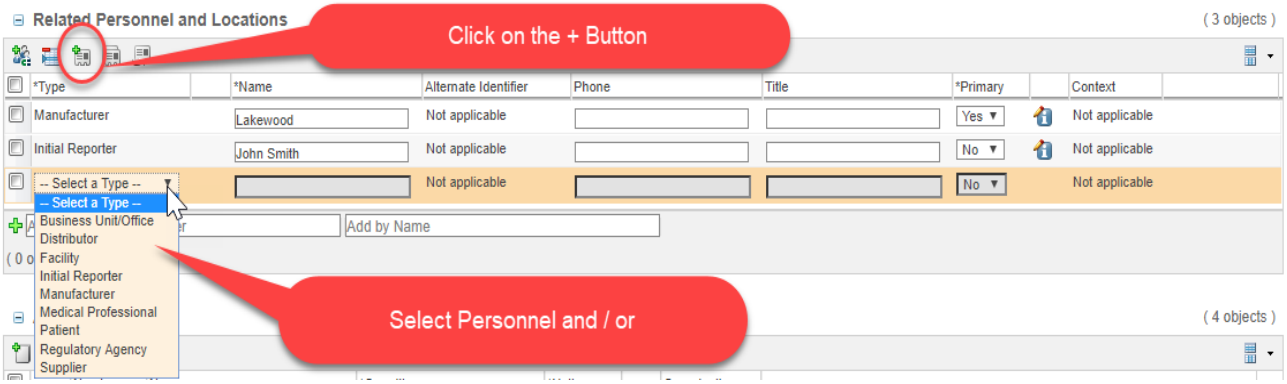


Table 2: Related Personnel Selections

Related Personnel Type	Action and Field Description	Optional or Required
CAPA Initiator	Document the name of the personnel initiating the CAPA. This is autogenerated by the system	Required
Product/Process Owner	Document the owner or responsible personnel / entity of the product or process related to the escalated issue	Required (Editable)
Lead Auditor	Document the lead auditor associated with the escalated issue	Required- Audit Only
Validation Owner	Document the validation owner associated with the escalated issue	Required- Validation Only
Supplier Contact	Document the name of the contact at the supplier	Required-Supplier Only

Table 3: Related Location Selections

Related Location Type	Action and Related Location Description	Optional or Required
Site	Document the area where the escalated issue was found and the site(s) impacted by the issue: Select Site: • Lakewood • Penpol • Vietnam • Larne • Leuven • Singapore • Australia • Brazil • Chile • Colombia • Peru	Required (Editable)

	• Uruguay • Mexico • Argentina • Venezuela • China • Spain • Global For each site selected answer if Primary Site: • Yes • No	
Supplier	Document the facility where manufacturing of the associated product/process is made	Required-Supplier Only (Editable)
Manufacturing Site	Site where the manufacturing of the product occurred. Record if the site of the manufacturing is different than the site where the escalated issue is found. Do not enter manufacturing site if unknown.	Optional (Editable)
Distributor	Distributor associated with the escalated issue	Optional (Editable)

5.2.4 CAPA Initiator shall complete and / or confirm the Attribute Field in Figure 5 for associated product(s), part(s), and process(es). Enter details for associated part(s) and product(s) by completing the Attribute Fields in Figure 6 per Table 4.

Figure 5: Attribute field to add Affected Objects

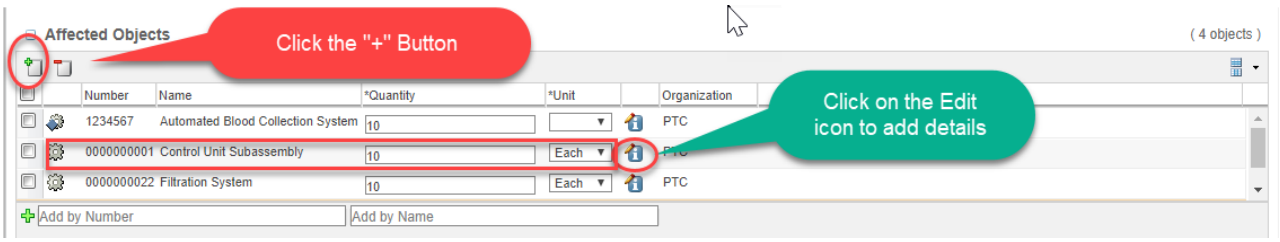


Figure 6: Attribute Fields within Edit details for Affected Objects – Part(s) and Product(s)

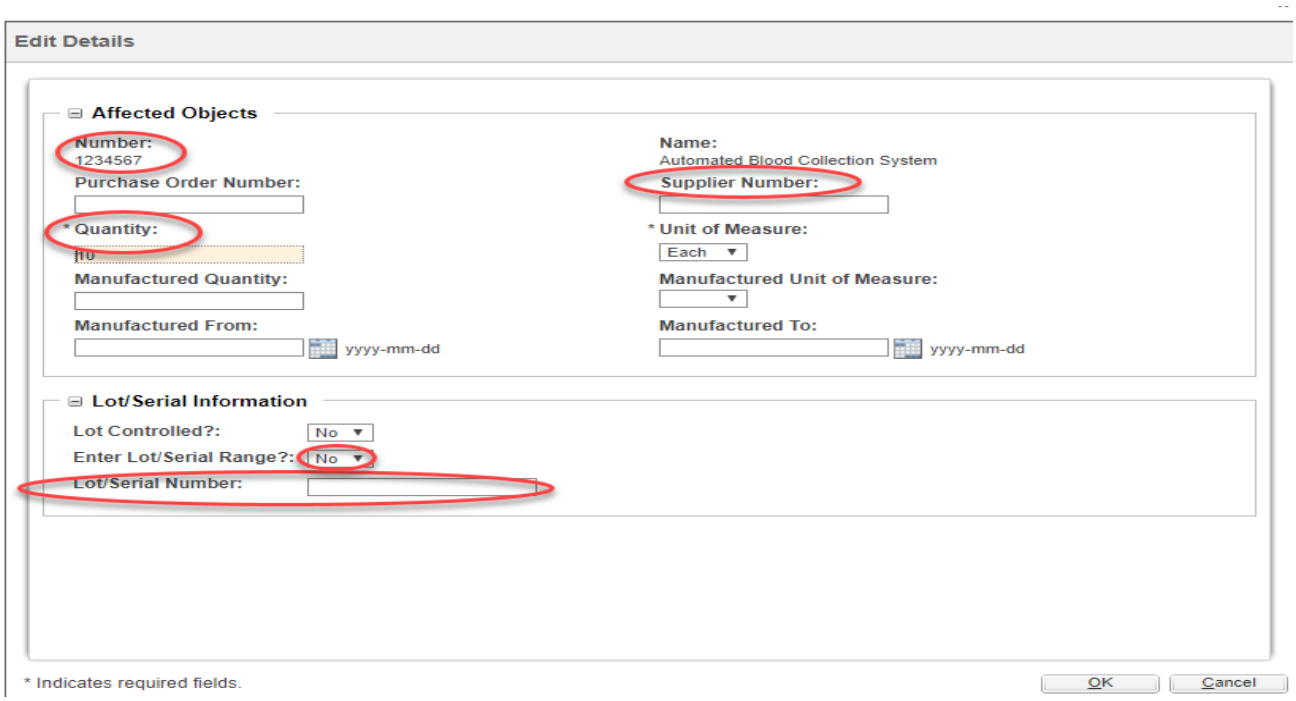


Table 4: Attribute Field for Affected Objects

Attribute Field	Action and Affected Object Field Description	Optional or Required
Name	Autogenerated by WindChill	Required
Number	Autogenerated by WindChill	Required
Quantity	Record the quantity of parts or product associated with the nonconformance	Required
Lot	Document the Lot number associated with the nonconforming product	Required-for parts
Serial Number	Document the Serial number associated with the nonconforming product	Required-for parts
Enter Lot/Serial Range	Select **Yes** if there are multiple lots that are associated, and the range is known or else Select **No**.	Required-for process(es)

5.2.4.1 After completion of the CAPA Record (Request) Attribute Fields, the CAPA Initiator shall submit the record to the CAPA Coordinator.

5.2.5 CAPA Coordinator shall review the submitted CAPA record (Request) for content completeness per the Global CAPA Review Work Instruction.

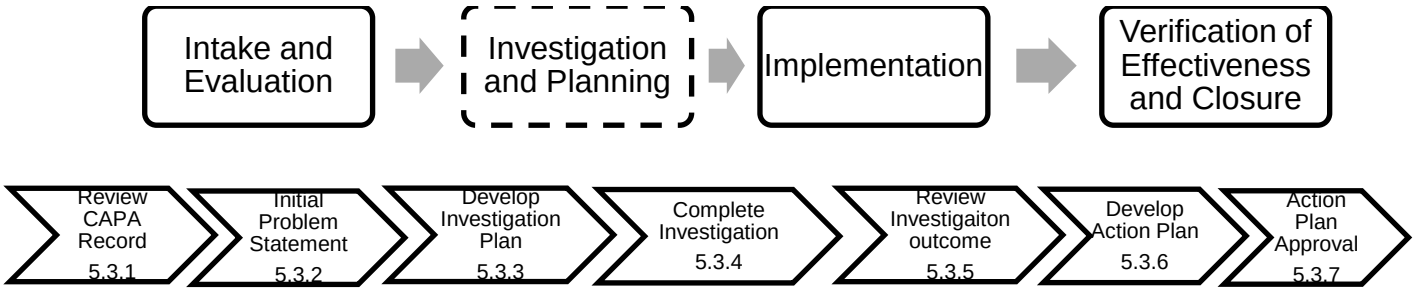
5.2.5.1 CAPA Coordinator shall perform the historical review on the submitted CAPA record (Request) per the Global CAPA Review Work Instruction.

5.2.6 CAPA Coordinator shall submit the record to the intended CAPA Review Board (CRB) members for record disposition decision per the Global CAPA Review Work Instruction.

5.2.6.1 Approved CAPA Requests creates a formal CAPA and moves the record to Investigation and Planning Phase

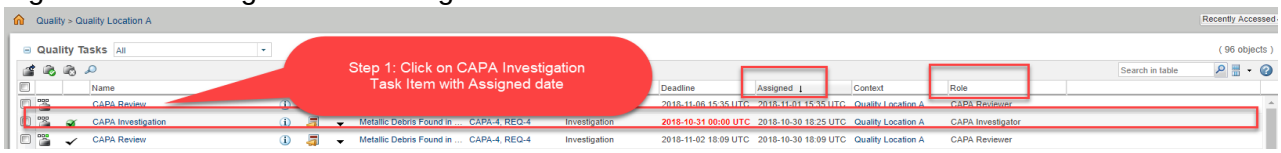
5.2.6.2 Rejected CAPA Requests are closed or sent back to the CAPA Initiator for clarifying details/CRB comments.

5.3 Investigation and Planning

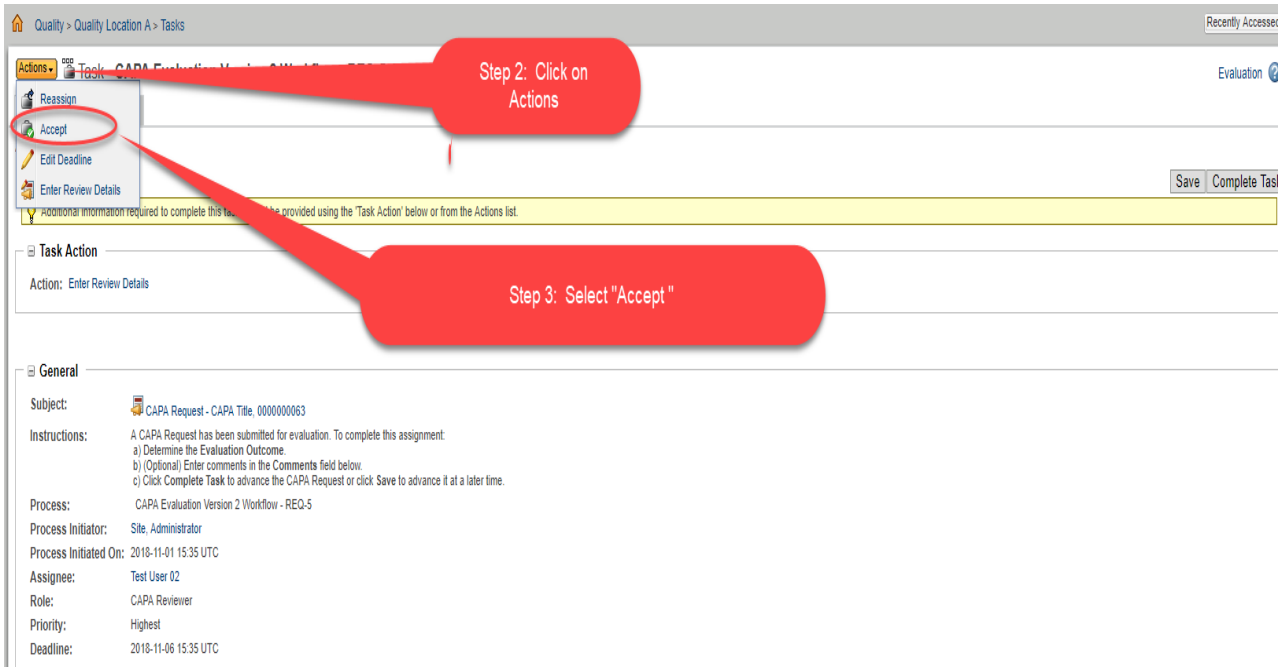


5.3.1 CAPA Owner shall select the assigned CAPA Investigation Task for review per steps provided in Figure 7.

Figure 7: Selecting CAPA Investigation

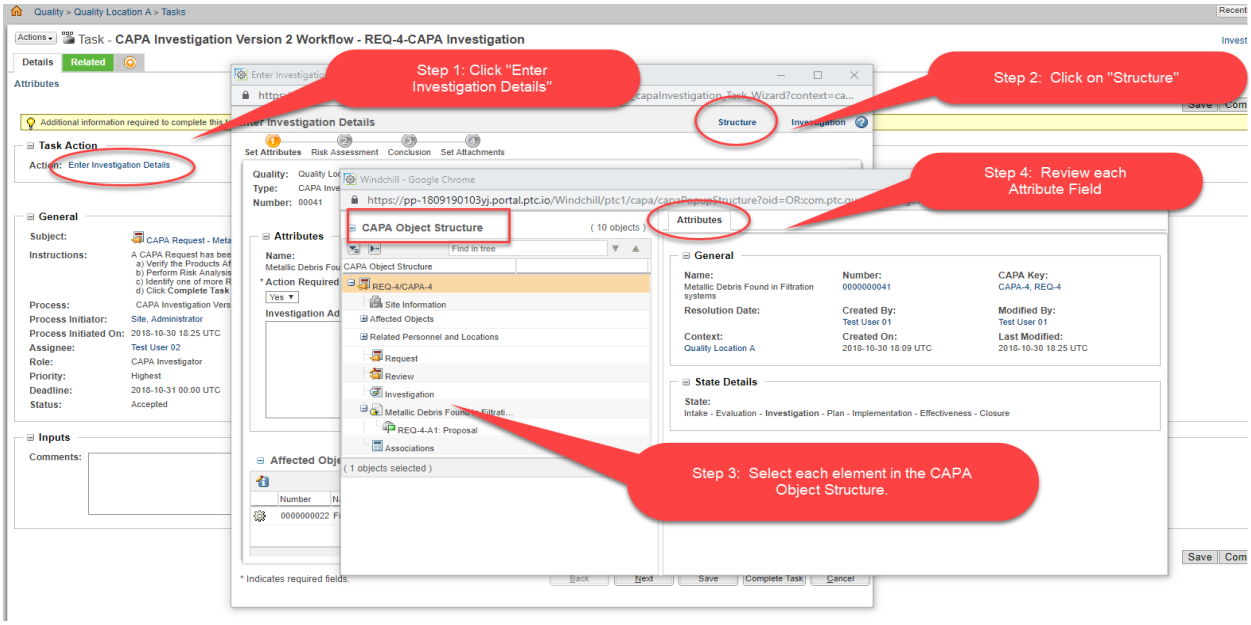


Item for Review

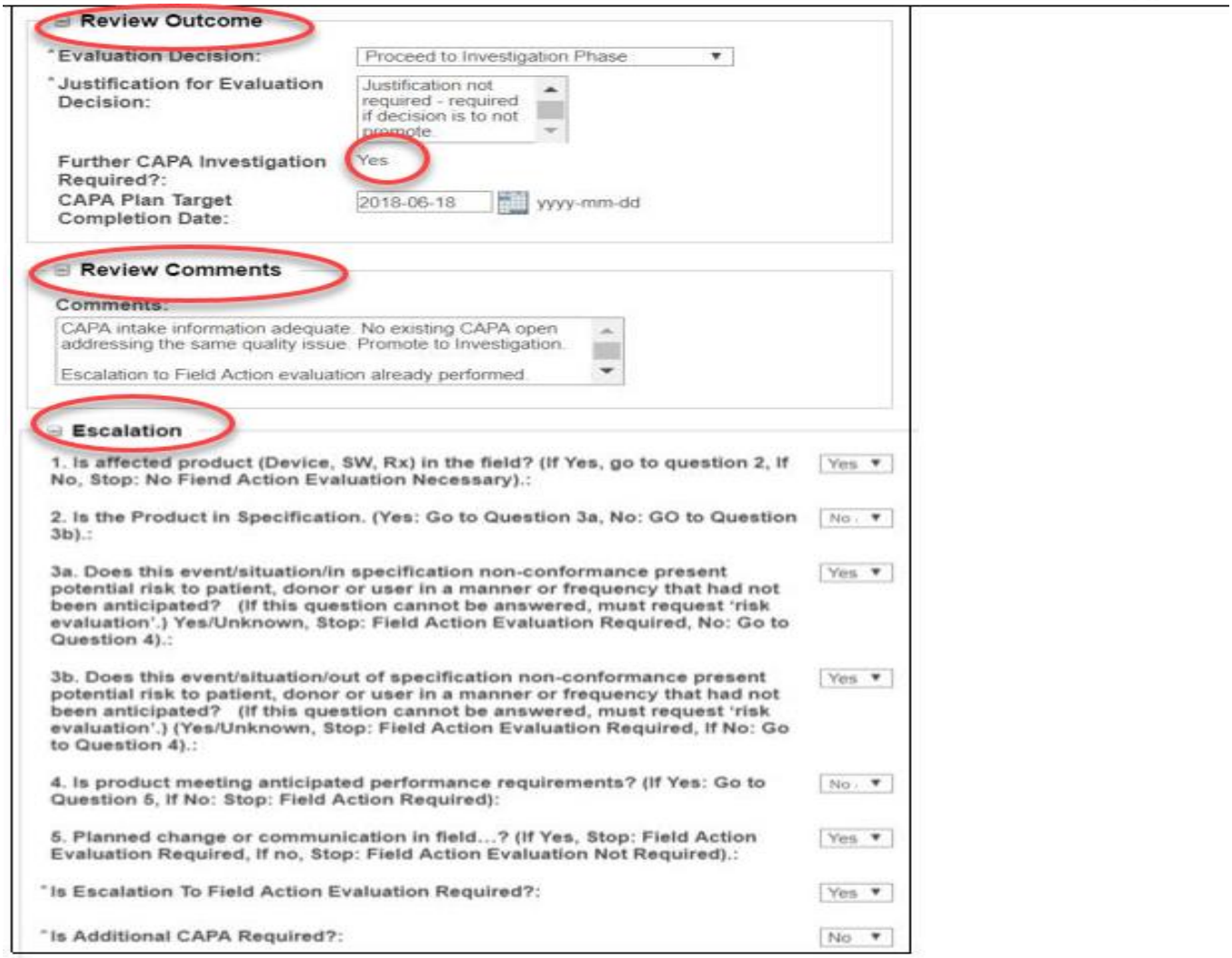


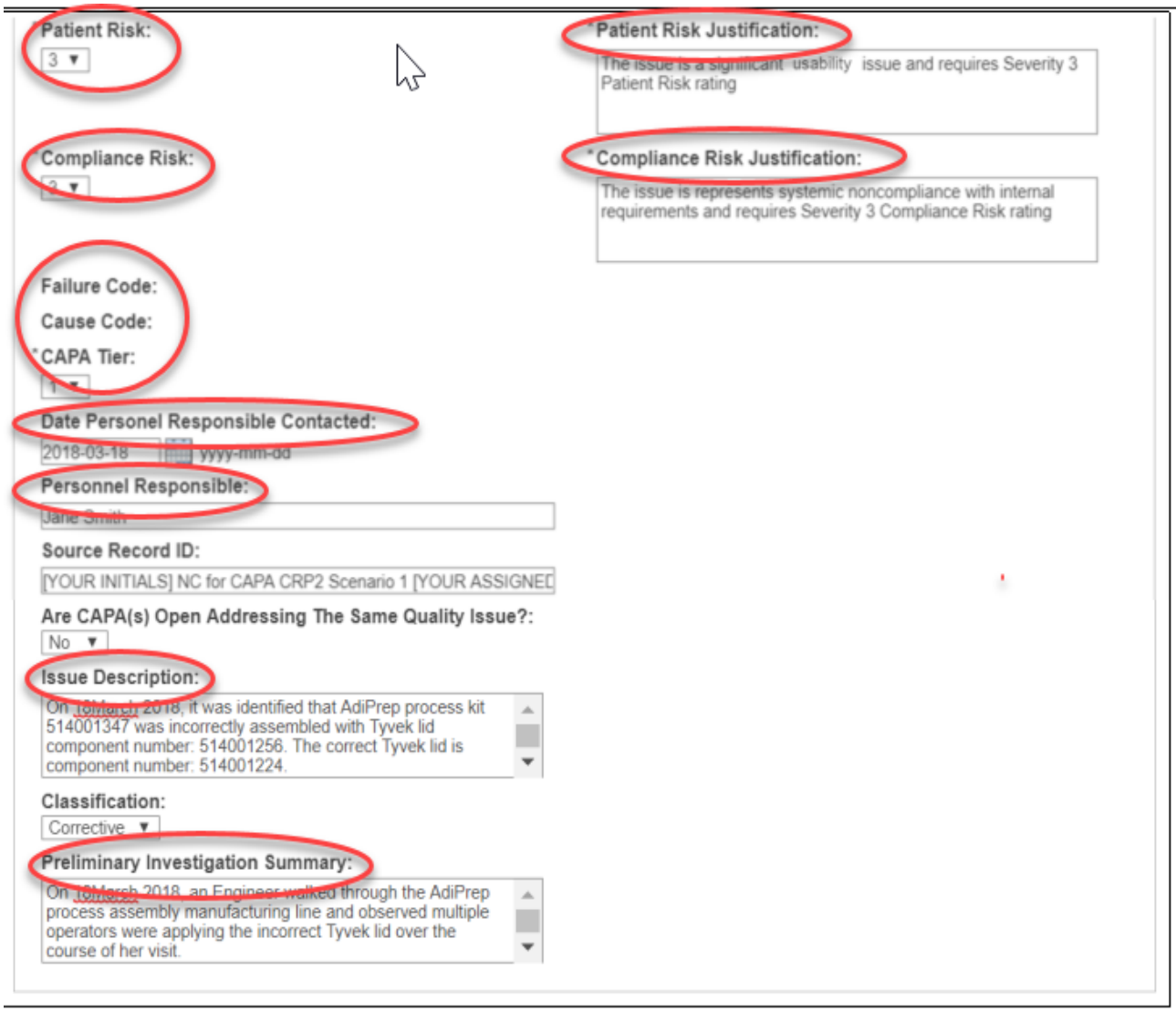
5.3.1.1 CAPA Owner shall review the CAPA information prior to leading an investigation into the issue by reviewing each attribute (listed in Table 1 through Table 4) in the selected object structure in Figure 8.

Figure 8: Steps to Object Structure for detailed information about the CAPA




Enter Evaluation Details
Structure
Evaluation
Information
Requested By:
Mark Zhong
Name:
Created from [YOUR INITIALS] NC for CAPA CRP2 Scenario 1
Issue Description:
On 18March 2018, it was identified that AdiPrep process kit 514001347 was incorrectly assembled with Tyvek lid (component number: 514001256), rather than Tyvek lid (component number: 514001224).
*Patient Risk:
3
*Compliance Risk:
3
Date File Opened:
2018-03-12 19:34 GMT
Number:
0000000486
*Patient Risk Justification:
The issue is a significant usability issue and requires Severity 3 Patient Risk rating
*Compliance Risk Justification:
The issue is represents systemic noncompliance with internal requirements and requires Severity 3 Compliance Risk rating
*Failure Code:
TBD
*Cause Code:
TBD
CAPA Tier:
1
Classification:
Corrective
Issue Type:
Product


Review Outcome
*Evaluation Decision:
Proceed to Investigation Phase
*Justification for Evaluation Decision:
Justification not required - required if decision is to not promote
Further CAPA Investigation Required?:
Yes
CAPA Plan Target Completion Date:
2018-06-18
yyyy-mm-dd
Review Comments
Comments:
CAPA intake information adequate. No existing CAPA open addressing the same quality issue. Promote to Investigation.
Escalation to Field Action evaluation already performed.
Escalation
1. Is affected product (Device, SW, Rx) in the field? (If Yes, go to question 2, If No, Stop: No Fiend Action Evaluation Necessary).:
Yes
2. Is the Product in Specification. (Yes: Go to Question 3a, No: GO to Question 3b).:
No
3a. Does this event/situation/in specification non-conformance present potential risk to patient, donor or user in a manner or frequency that had not been anticipated? (If this question cannot be answered, must request 'risk evaluation'.) Yes/Unknown, Stop: Field Action Evaluation Required, No: Go to Question 4).:
Yes
3b. Does this event/situation/out of specification non-conformance present potential risk to patient, donor or user in a manner or frequency that had not been anticipated? (If this question cannot be answered, must request 'risk evaluation'.) (Yes/Unknown, Stop: Field Action Evaluation Required, If No: Go to Question 4).:
Yes
4. Is product meeting anticipated performance requirements? (If Yes: Go to Question 5, If No: Stop: Field Action Required):
No
5. Planned change or communication in field...? (If Yes, Stop: Field Action Evaluation Required, If no, Stop: Field Action Evaluation Not Required).:
Yes
*Is Escalation To Field Action Evaluation Required?:
Yes
*Is Additional CAPA Required?:
No



5.3.1.2 CAPA Owner shall review the circumstances of issue occurrence and identification based on information provided in the source record, including considerations such as any changes made to affected product, process, or QMS element, procedures or controls in place to identify issue, and shift during which issue occurred.

5.3.1.3 CAPA Owner shall review initial scope determination, including impact of issue on:

5.3.1.4

- Product, including batch / quantity impacted
- Processes
- Company sites
- Equipment
- Utilities

5.3.1.5 CAPA Owner shall review the source record and supporting documentation.

5.3.1.6 CAPA Owner shall confirm the scope remains the same per the Global Bracketing and Disposition Work Instruction

5.3.1.7 CAPA Owner shall confirm any action(s) (immediate containment and corrections) have been completed and supported by objective evidence

5.3.1.8 CAPA Owner shall review adequacy of containment and corrections to prevent further propagation of the issue by evaluating the affected QMS for similar reoccurring events post implementation of planned actions.

- For example: CAPA owner shall generate Open NC report per Windchill Technology Work Instruction and evaluate if similar NC have been initiated post planned action implementation if the escalated issue affects NC.

5.3.1.9 CAPA Owner shall ensure information about the CAPA is communicated to Product/Process Owner responsible by reviewing the attribute field completion in Table 5 below.

- Ensure the source record, details of scope and impact of issue, containment and corrections taken, and CAPA escalation criteria met are communicated, at minimum.
- Ensure communications are recorded, including date of communication, name of recipient, and responsibilities or relationship of recipient to assuring the quality of the affected product, process, or QMS element.

5.3.1.10 CAPA Owner shall ensure the CAPA Team Members assigned by the CRB have the subject matter expertise to support the investigation tasks related to the escalated issues.

5.3.2 After review of the CAPA Record, CAPA Owner shall develop an initial problem statement based on the issue description and supporting documentation.

5.3.2.1 A problem statement is a clear, concise description of the issue that is to be addressed by the investigator / investigation team.

5.3.2.2 A problem statement answers the what, where, when, how much, and who. For example: “Monthly trending of Nonconformances at Lakewood for November identified a trend associated with the use of incorrect power unit on Trima product. Between 10 October 2018 to 19 November 2018, a total of 10 nonconformances on 8 different batches impacting 52 devices was identified by Manufacturing.”

5.3.2.3 CAPA Owner shall complete and/or confirm the Attribute Fields in Figure 9 and Table 5 based on the review of the CAPA record:

Figure 9: Document the Problem Statement and Planned Actions

Example has been removed for company confidential information.

Table 5: Attribute Fields completed by the CAPA Owner Prior to Investigation

Attribute Field	Action and Field description	Optional or Required
Initial Problem Statement	Document Enter the initial (unconfirmed) problem statement based on the issue description and supporting evidence.	Required
Risk Region - Expected	Document the expected risk region associated with the escalated issue: Select: • **High** • **Medium** • **Low** Refer to the Global Risk Assessment Procedure.	Required (Editable)
Risk Region – Expected Justification	Document the rationale for the selected risk region - expected	Required (Editable)
Risk Region - Actual	Document the risk region associated with the escalated issue: Select: • **High** • **Medium** • **Low** Refer to the Global Risk Assessment Procedure.	Required (Editable)
Risk Region – Actual Justification	Document the rationale for the selected risk region- Actual	Required (Editable)
Escalation to Field Action	Answer the Field Action Evaluation Escalation Questions per the Global Field Action Procedure: • **Yes** • **No** If the answers to the escalation questions are not known, leave the answers blank.	Required – if Known (Editable)

Attribute Field	Action and Field description	Optional or Required
Date Product/Process Owner Contacted/Notified	Document the date on which the Product/Process Owner for the affected product, process or QMS issue was contacted if not already performed. DATE FORMAT: DD/MMM/YYYY	Required (Editable)
Product/Process Owner	Select the Product/Process Owner for the affected product, process, or QMS issue was notified if not already performed and the method of notification.	Required (Editable)
Historical Review – Open CAPAs	Are CAPAs Open Addressing the Same Quality Issue?	Required (Referenced)
Historical Review – Closed CAPAs	Did CAPAs Addressing the Same Quality Issue close in the last 24 months?	Required (Referenced)
Are additional Actions Required?	Assess if additional actions (containment and/or corrective) are required based on the review and Select: • **Yes** • **No**	Required
If Additional Actions required, what steps taken?	Select: • Action(s) **Link to Associated Nonconformance** • **Initiated New Nonconformance** Provide Reference Record # for Traceability	Required
Investigation Tasks	Select the following Task Type: • Problem Statement Confirmation • Root Cause Analysis • Root Cause Confirmation For each Task Assign: • Task Owner (CAPA Team Member/CAPA Investigator) • Due Date	Required

5.3.3 The CAPA Investigator, with support from the CAPA Owner, shall develop the High-Level Investigation Plan per the Global Root Cause Analysis Work Instruction and document within the task associated with Root Cause Analysis.

5.3.4 The CAPA investigator shall execute the High-Level Investigation Plan and perform root cause analysis per the Global Root Cause Analysis Work Instruction.

5.3.4.1 The CAPA Investigator and/or CAPA Team Member shall facilitate and confirm the Problem Statement per the Global Root Cause Analysis Work Instruction.

5.3.5 After completion of the three assigned tasks, the CAPA Owner shall review and approve the assigned tasks per the following:

5.3.5.1 Ensure all required fields for the CAPA Investigation Task are completed per the Global Root Cause Work Instruction.

5.3.5.2 Ensure the escalated issues was investigated per the Global Root Cause Analysis Work Instruction and all templates were used as instructed.

5.3.5.3 Ensure investigation details the method for confirmation of the selected root cause and objective evidence is present to support the identified root cause.

5.3.5.4 Based on investigation findings and the identified root cause(s) of the issue, reevaluate the scope of the issue and determine the need for additional containment and / or corrections if scope changed.

5.3.5.5 Based on investigation findings, review and revise, if necessary, Risk Region - Actual and Compliance Risk Ratings in accordance with the Global Risk Management Procedure.

5.3.5.6 Review and revise, if necessary, initial determination of CAPA Tier in accordance with Global Corrective Action and Preventive Action Procedure.

5.3.5.7 After review and approval of the Investigation Tasks, the CAPA Owner shall complete and/or confirm the Investigation Findings Attribute Fields as shown in Figure 10 per Table 6.

Figure 10: Documentation of Investigation Findings

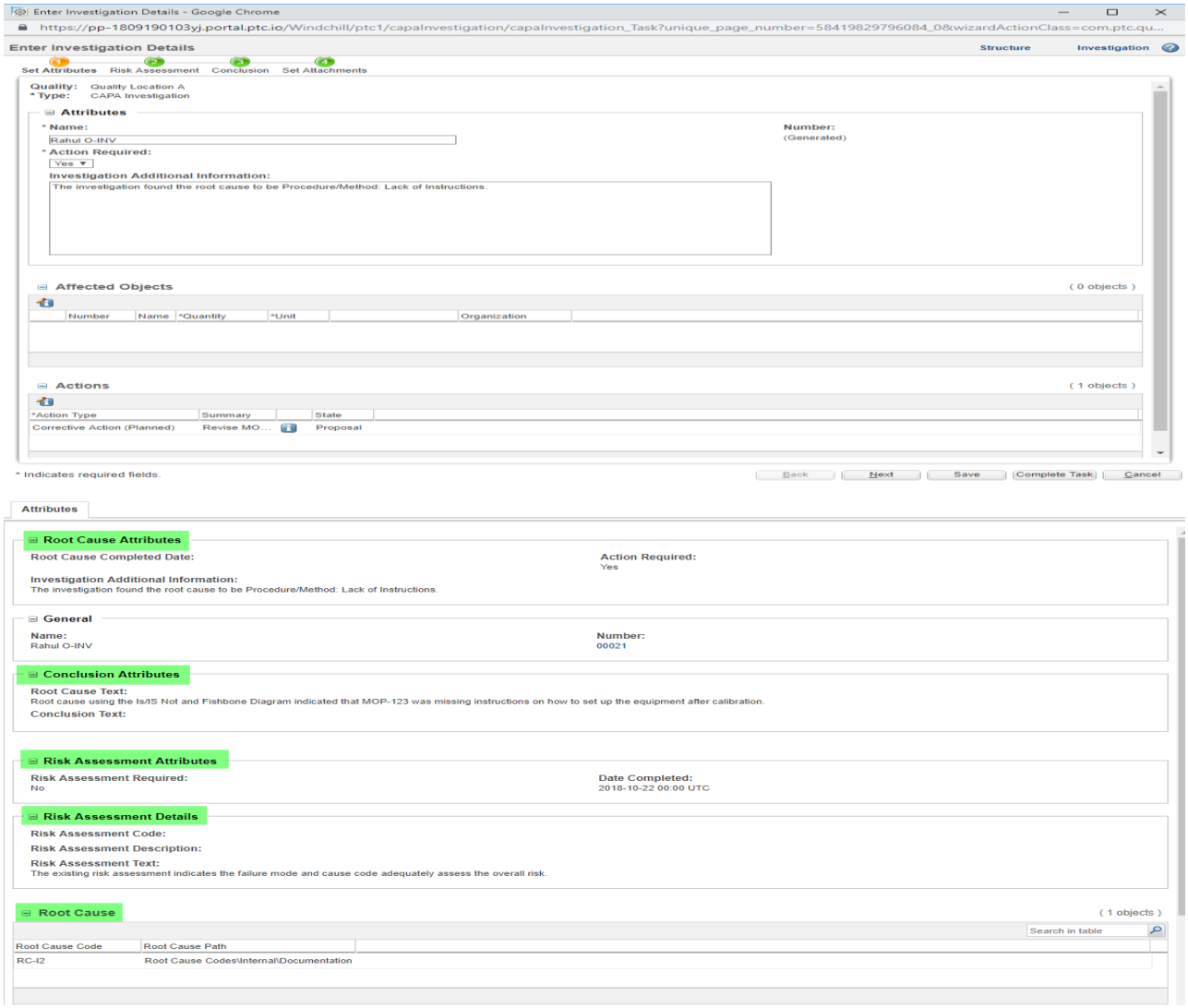


Table 6: Attribute Field for Investigation Details

Attribute Field	Action and Field Description	Optional or Required
Problem Statement (Confirmed)	Document the confirmed problem statement based on escalated issue and supporting document	Required (Reference)
Root Cause Statement	Document the root cause statement in accordance with the Global Root Cause Work Instructions for each RC category selected	Required (Editable)

Attribute Field	Action and Field Description	Optional or Required
Root Cause Category	Select the all applicable Root Cause Categories: • **Method** • **Equipment** • **Material** • **Measurement** • **Environment** • **Personnel**	Required (Editable)
Root Cause Analysis Tools Used in Investigation	Document the RCA tool used for investigation. Select all that apply: • **Is / Is Not Analysis** • **Fishbone Analysis** • **Affinity Diagram** • **5 Why's Analysis** • **Relations Diagram**	Required (Reference)
Risk Assessment Required	Select one of the options based on the investigation finds dictating if risk assessment is required or was required to be performed to better understand patient and compliance risk. • **Yes** • **No**	Required (Reference)
Risk Assessment	If risk assessment was performed or is required link to the appropriate Risk File	Required (Editable)
Risk Assessment Text	Document the findings of the risk assessment performed to support the investigation.	Required
Did the Failure Code-Initial Change?	Select • **Yes** • **No**	Required
Failure Code (Final)	Document the codes linking potential failure to the associated risk file failure mode. Refer to the Global Risk Assessment Procedure.	Required (Editable)
Did the Failure Code Initial Change?	Select • **Yes** • No	Required
Cause Code (Final)	Document the quality code that describes the cause of the issue. Refer to the Global Risk Assessment Procedure.	Required (Editable)

Attribute Field	Action and Field Description	Optional or Required
Did the Risk Region Action Change After Investigation?	Select • **Yes** • **No**	Required
Risk Region - Actual	Document the risk region associated with the escalated issue: Select: • **High** • **Medium** • **Low** Refer to the Global Risk Assessment Procedure.	Required (Editable)
Risk Region – Actual Justification	Document the rationale for the selected risk region-Actual	Required (Editable)
Did the Compliance Rating Change after Investigation?	Select • **Yes** • **No**	Required
Compliance Risk	Enter Compliance Risk Rating as defined in the Risk Management WI. Select Rating: 1 - 5	Required (Editable)
Compliance Risk Rating Justification	Document the rationale for the selected compliance risk	Required (Editable)
Did CAPA Tier change after investigation?	Select • **Yes** • No	Required
CAPA Tier	Select and / or confirm CAPA Tier based on risk in accordance with Global Corrective Action and Preventive Action Procedure. • **Tier 1** • **Tier 2** • **Tier 3**	Required (Editable)
Escalation to Field Action after investigation?	Answer the Field Action Evaluation Escalation Questions per the Global Field Action Procedure: • **Yes** • **No** If the answers to the escalation questions are not known, leave the answers blank.	Required – if Known

Attribute Field	Action and Field Description	Optional or Required
Investigation Summary	Document the summary of the investigation findings.	Required

5.3.6 Based on the Investigation Findings, the CAPA Owner shall determine the need for a CAPA Action plan and complete the Attribute Fields in Figure 10 per Table 7.

5.3.6.1 If a CAPA Action Plan is not required, the CAPA owner shall document in the “If no Action Plan Required, Provide Rationale” Attribute Field the justification and include:

5.3.6.1.1 Rationale substantiating criteria for no CAPA Acton Plan was met per Appendix A in this work instruction

5.3.6.1.2 Summary of actions taken to address the issue (i.e. Field Action)

5.3.6.1.3 Confirmation that not implementing corrective and / or prevention actions does not increase risk to patient safety or product quality

5.3.6.1.4 Confirmation of the absence of safety issues associated with the CAPA

5.3.6.1.5 Confirmation that regulatory requirements are met by the CAPA

5.3.6.2 If CAPA Action Plan is required, the CAPA Owner shall perform the following actions and enter selected action information in Attribute Fields shown in Figure 11 per Table 7:

5.3.6.2.1 Identify corrective actions and / or preventive actions with the aid of CAPA Investigator and CAPA Team Member.

5.3.6.2.2 The actions selected shall address confirmed root cause(s) or most probable cause(s)

5.3.6.2.3 Conduct high-level assessment to identify potential impact of implementation of corrective actions, preventive actions, and / or corrections on other product, processes, or QMS elements.

5.3.6.2.4 Corrective and / or preventive actions shall be assigned based on categories and considering the following order of preference in accordance with Appendix B.

5.3.6.2.5 The most preferred to least preferred corrective and / or preventive actions are:

- Error proof
- Error prevention
- Detect and Recover
- Duplication

5.3.6.2.6 Document the rationale for the selection of the corrective and / or preventive actions including, at minimum:

- Details of how the action will address the root cause(s) and / or most probable cause(s), including supporting objective evidence, if applicable.
- How the action meets the description of its designated categorization.

Figure 11: Action Plan Required Selection

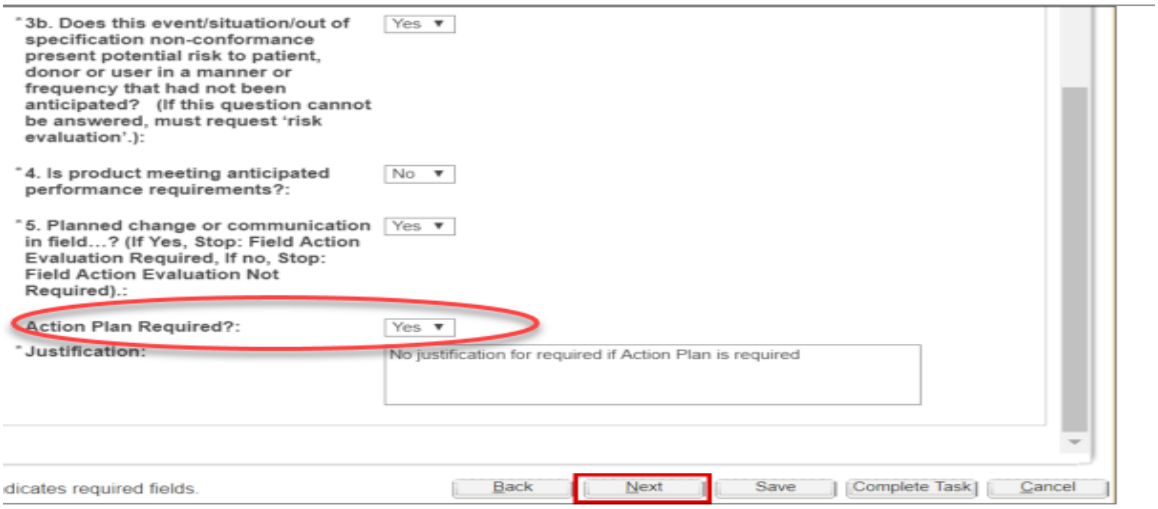


Table 7: Attribute Fields Associated with CAPA Action Plan

Attribute Field	Field Description	Optional or Required
Action Plan Required	Select, based on the investigation findings, if action plan is required to address the root cause or probable root cause: • **Yes** • **No**	Required
If Action Plan not required provide rationale:	Document rationale and justification to support No Action is Required post investigation.	Required-No Action Required
If Action Plan required	Document the CAPA Plan summary	Required – Action Plan Required

5.3.6.3 CAPA Owner shall add action and details including Action Owners and target due dates per steps in Figure 12 and complete associated Attribute Fields per Table 8.

Figure 12: Steps to Enter Action Details

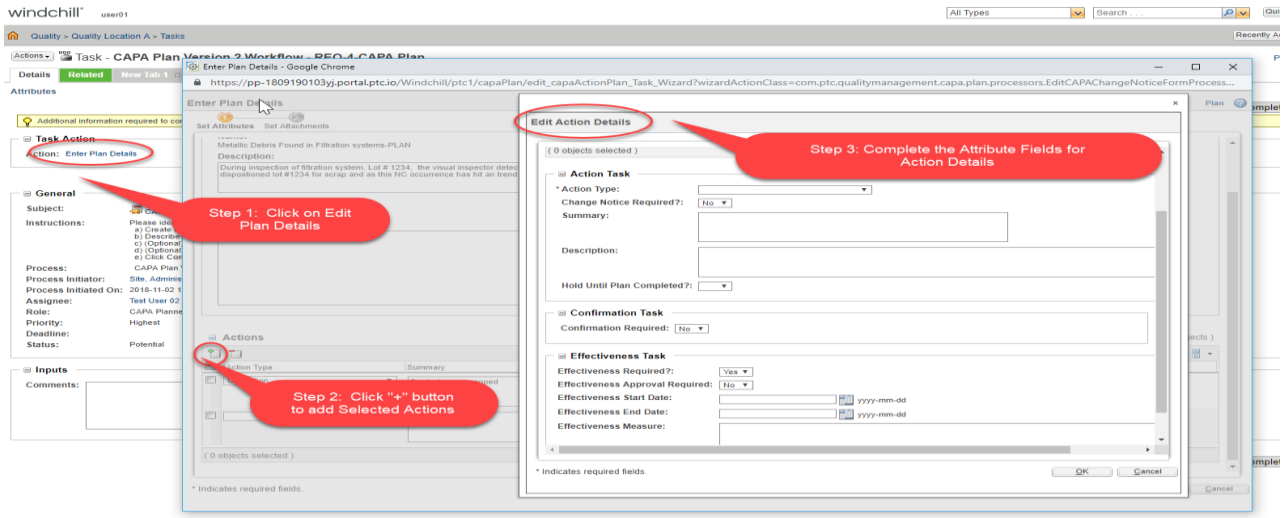


Table 8: Action Details Attribute Field

Attribute Field	Field Description	Optional or Required
Action Task	Select one of the action type for the proposed action: • **Corrective Action** • **Preventive Action** For each Task assign: • Task Owner (CAPA Team Member/CAPA Investigator) • Target Due Date	Required
Description	Document the details description of the action being proposed.	Required
Objective Evidence Required	Identify expected objective evidence of implementation	Required
Hold Until Plan Completed	All corrective and preventive actions required hold until CAPA Plan is approved by CRB.	Required (Always Yes)

5.3.6.4 CAPA Owner shall develop a Verification of Effectiveness (VoE) Plan and complete the associated Attribute Field in Figure 13 per Table 9. The VoE plan shall include the following:

5.3.6.4.1 Define VoE acceptance criteria based on improvement of the original issue that required escalation to CAPA to an acceptable level. For example, if issue was escalated from a complaint, then the VoE shall measure / verify there are no associate complaints due to same failure mode.

5.3.6.4.2 Determine VoE timeline based on considerations such as time required to collect statistically significant data samples to confirm effectiveness.

5.3.6.4.2.1 Define interim checks for VoE actions with timelines for completion of over 6 months to ensure ongoing monitoring.

5.3.6.4.3 Type of VoE monitoring shall be selected based on issue type:

5.3.6.4.3.1 VoE for product or process issues shall check effectiveness using statistical process monitoring or statistical techniques, in accordance to the Statistical Techniques Procedure to verify there has not been issue reoccurrence or that the statistical measurements indicate improvement to an acceptable level.

5.3.6.4.3.2 VoE for QMS issues shall check effectiveness after a statistically significant number of transactions has occurred to verify there has not been issue recurrence or that the issue frequency has been reduced to an acceptable level.

5.3.6.4.4 VoE acceptance criteria determination, data sampling, and data analysis shall be performed using statistical techniques in accordance with the Global Statistical Techniques Procedure.

5.3.6.4.5 Define VoE actions, including description of actions, instructions for performing actions, and expected objective evidence to support VoE results.

5.3.6.4.6 Link VoE actions to the corrective action(s) the VoE action verifies

Figure 13: Verification of Effectiveness Plan Summary

Example has been removed for company confidentialuality

Table 9: Verification of Effectiveness Attribute Fields

Attribute Field	Field Description	Optional or Required
Verification of Effectiveness Plan	Document and Summarize the required VoE to holistically assess the effectivity of the actions selected to address root cause. Include the items for the VoE Plan as described above.	Required
Verification of Effectiveness Task	For each task assign: • Task description Document detail description of the VoE tasks to execute the VOE plan post action implementation. • VoE Criteria • VOE Start Date: Autogenerated post all Action Implementation • VoE Period Select: ○ **3 Months** ○ **6 Months** ○ **9 Months** ○ **12 months** • Task Owner	Required
Hold VOE Until Plan Approval	All VOE tasks are on hold until CAPA Plan is approved by CRB.	Required (Always Yes)

5.3.7 CAPA Owner shall route the proposed CAPA Action Plan to the CAPA Review Board (CRB) for review and approval in accordance with Global CAPA Review Work Instruction.

5.3.7.1 Based on CRB review disposition per Global CAPA Review Work Instruction, the CAPA Owner shall perform the following actions:

5.3.7.1.1 If the CRB approves the CAPA Action Plan, advance to the Implementation phase.

5.3.7.1.2 If the CRB approves justification for no CAPA Action Plan, advance to summarize the CAPA in the VoE and Closure phase.

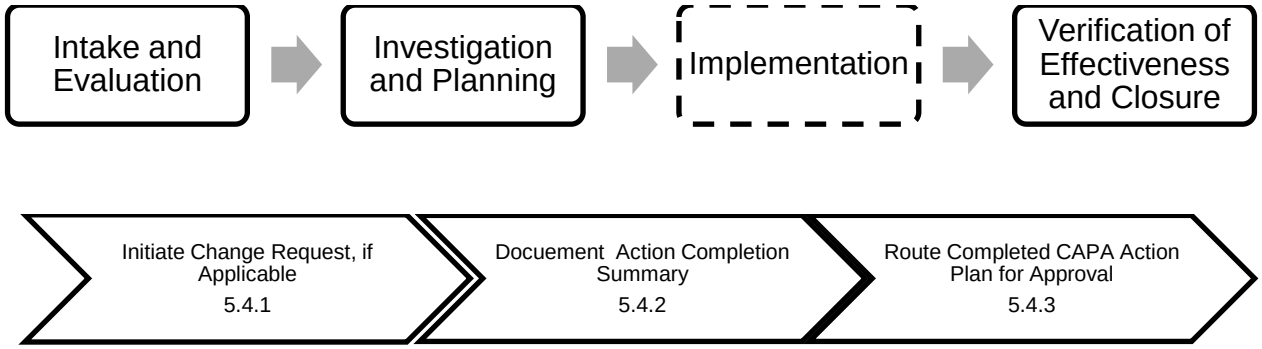
5.3.7.1.3 If the CRB rejects justification for no CAPA Action Plan, develop a CAPA Action Plan in accordance with this work instruction.

5.3.7.1.4 If the CRB requests resubmission of investigation, communicate with the CAPA Investigator to review CRB rationale, revise investigation plan, and initiate revised investigation.

5.3.7.1.5 If the CRB requests resubmission of CAPA Action Plan, review CRB rationale and initiate CAPA Action Plan revisions.

5.3.8 If Investigation and Planning cannot be completed by the phase due date, the CAPA Owner shall request a due date extension as defined in Section 5.6.

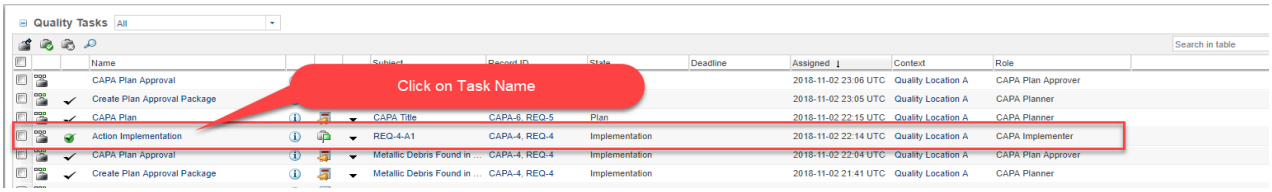
5.4 Implementation



5.4.1 Upon approval of the CAPA Action Plan, the CAPA Owner, or designee, shall initiate the selected Change Notice per Global Change Control Procedure.

5.4.2 CAPA Owner or designee shall select the assigned Action Implementation Task per Figure 14 and complete the Attribute Fields in Table 10.

Figure 14: Completing Action Implementation Task



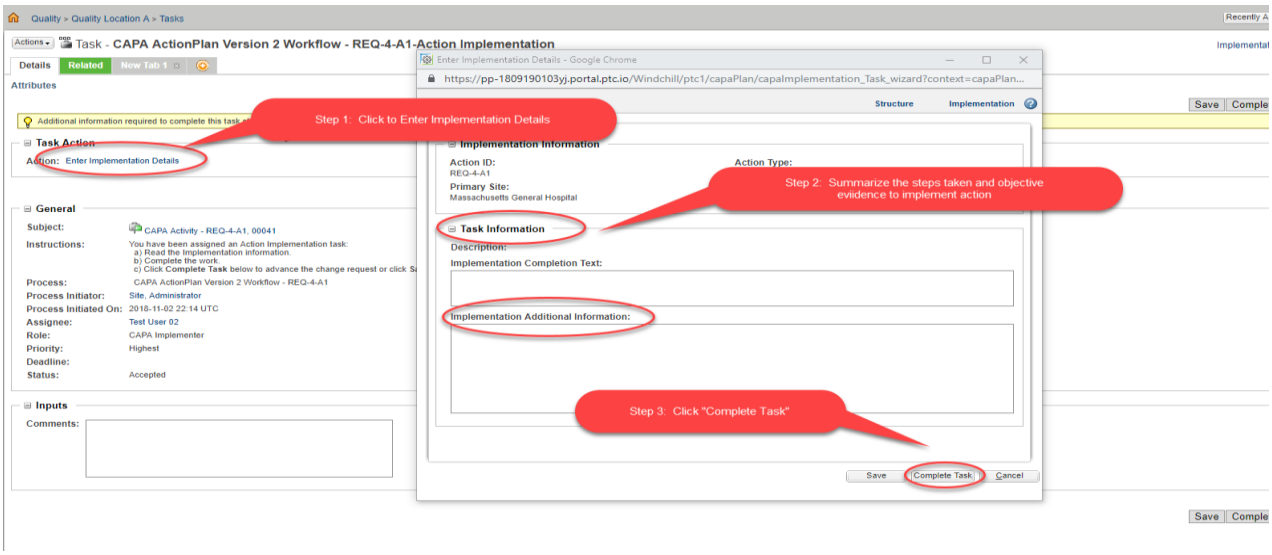


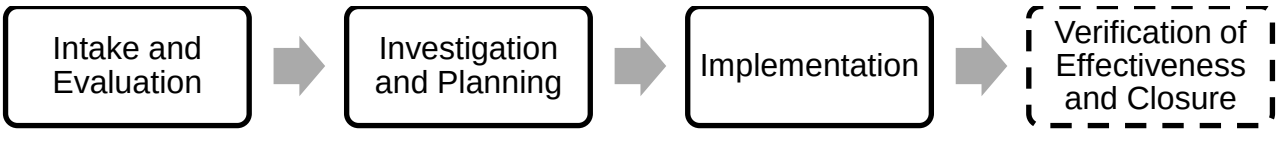
Table 10: Attribute Fields associated with Action Implementation Tasks

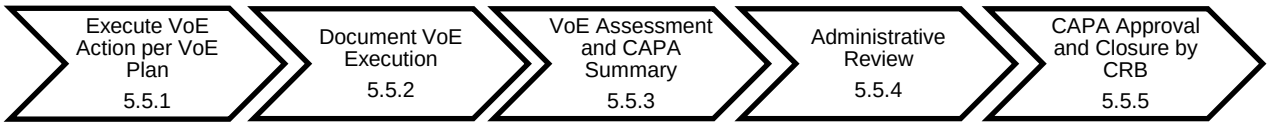
Attribute Field	Action and Field Description	Optional or Required
Implementation Summary	Summarize the steps taken to implement the assigned action per the CAPA Action Plan.	Required
Confirmation Completion	Was Confirmation task completed within Change Process? Confirmed. • **Yes** • **No**	Required
Confirmation Summary	Summarize the method for confirmation	Required (Reference)
Verification of Implementation (VoI) Completion	Was VoI task completed within Change Process? Confirmed. • **Yes** • **No**	Required
Verification of Implementation Summary:	Summarize the VOI associated with the implementation action.	Required (Reference)

Any Adverse Effects identified during VOI?	Based on the VoI Summary and Action task conclude if there were any adverse effect identified during, prior, or post implementation. Select: • **Yes** • **No**	Required
If Adverse Effects Identified CRB Notified?	Select: • **Yes** • **No**	Required-if Adverse effects identified
Was CAPA Action Plan revised?	Select: • **Yes** • **No**	Required-if Adverse effects identified
CAPA Action Plan Disposition	Document the CAPA Action Plan disposition if adverse effects are identified.	Required-if Adverse effects identified

5.4.3 CAPA Owner Routes the Completed Action Plan to the CRB for review and approval. CRB Shall review the record in accordance with Global CAPA Review Work Instruction.

5.5 Verification of Effectiveness and Closure of CAPA Record





5.5.1 Upon approval of CAPA implementation, the VoE Action Task Owner (CAPA Team Member) shall perform the VoE Action(s) per the instructions in the VoE Task (refer to Figure 15).

5.5.2 Example has been removed for company confidentiality.

5.5.3 CAPA Team Member shall complete the attribute fields in Figure 15 per Table 11 for Verification of Effectiveness Tasks.

Figure 15: VoE Task/Action Attribute Fields

Example has been removed for company confidentiality.

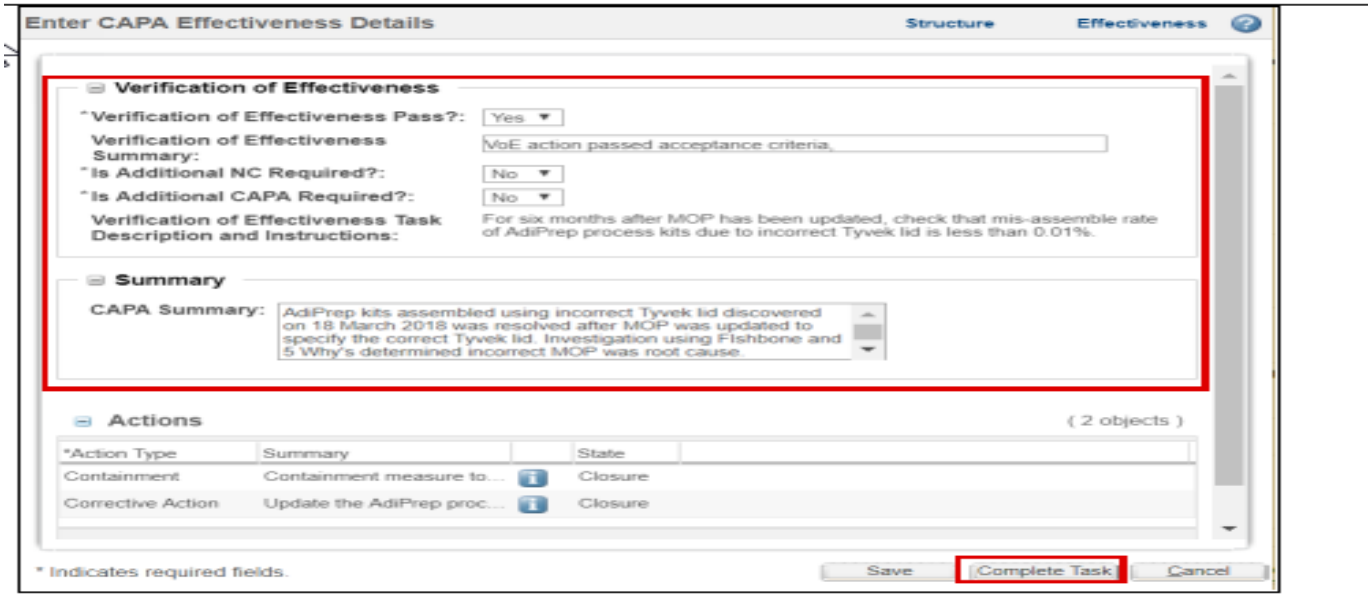
Table 11: VoE Task Attribute Field description

Attribute Field	Action and Field Description	Optional or Required
Verification of Effectiveness Task Details	Document the method and steps taken to execute the VoE task. Include the effectivity criteria.	Required
Verification of Effectiveness Results Overview	Document the result obtained after execution of the VoE method.	Required
Verification of Effectiveness Task Objective Evidence Attached?	Select: • **Yes** • **No**	Required
Verification of Effectiveness Task Pass?	Based on the result assess if the VoE passes or failed. Select: • **Yes** • **No**	Required

5.5.3.1 After completion of VoE Tasks, CAPA Team Members shall route the CAPA Record to the CAPA Owner.

5.5.4 The CAPA Owner shall complete the attribute fields in Figure 16 per Table 12.

Figure 16: CAPA Effectiveness Attribute Fields



Due to development timing limitations, "Is Additional NC Required?" and "Is

Table 12: CAPA Effectiveness Attribute Field description

Attribute Field	Action and Field Description	Optional or Required
Verification of Effectiveness Summary	Summarize the results of the VoE Actions performed and their results against the acceptance criterion.	Required
Verification of Effectiveness Pass?	Based on the results assess if the VoE passed or failed. Select: • **Yes** • **No**	Required
Is additional NC Required?	Select: • **Yes** • **No**	Required
Is additional CAPA Required?	Select: • **Yes** • **No**	Required
CAPA Summary	Document the CAPA summary per Step 5.5.5	Required

5.5.4.1 The CAPA Owner shall review the entire CAPA record and summarize the CAPA in the CAPA Summary Attribute Field in Figure 15. The CAPA summary shall include the following sections, if applicable:

5.5.4.1.1 Problem statement

5.5.4.1.2 Containment and corrections summary

5.5.4.1.3 Investigation summary

5.5.4.1.4 CAPA Action Plan overview

5.5.4.1.5 Implementation summary

5.5.4.1.6 Verification of Effectiveness summary

5.5.4.1.7 Objective evidence summary

5.5.5 The CAPA Owner shall route the CAPA to the CAPA Coordinator for administrative review in accordance with Global CAPA Review Work Instruction.

5.5.5.1 If the administrative review meets the requirement to progress forward to CRB per the Global CAPA Review Work Instruction, the CAPA Coordinator shall route the CAPA Record to the CRB for approval and closure.

5.5.6 Based on CRB review and CAPA Record disposition, per the Global CAPA Review Work Instruction, the CAPA Owner shall be required to perform the following actions only if CAPA closure is rejected by CRB:

5.5.6.1 If the CRB requests clarification of CAPA, provide the details requested and re-route CAPA.

5.5.6.2 If the CAPA Record per the Global CAPA Review Work Instruction

5.6 Revision and Due Date Extension Requests

5.6.1 If CAPA activities must be revised or cannot be completed by a defined due date, the CAPA Owner, with support from CAPA Investigator and CAPA Team members, shall complete the attribute fields in Figure 17 per Table 13.

Figure 17: Initiate Extension or Revision Request and the Associated Attribute Fields

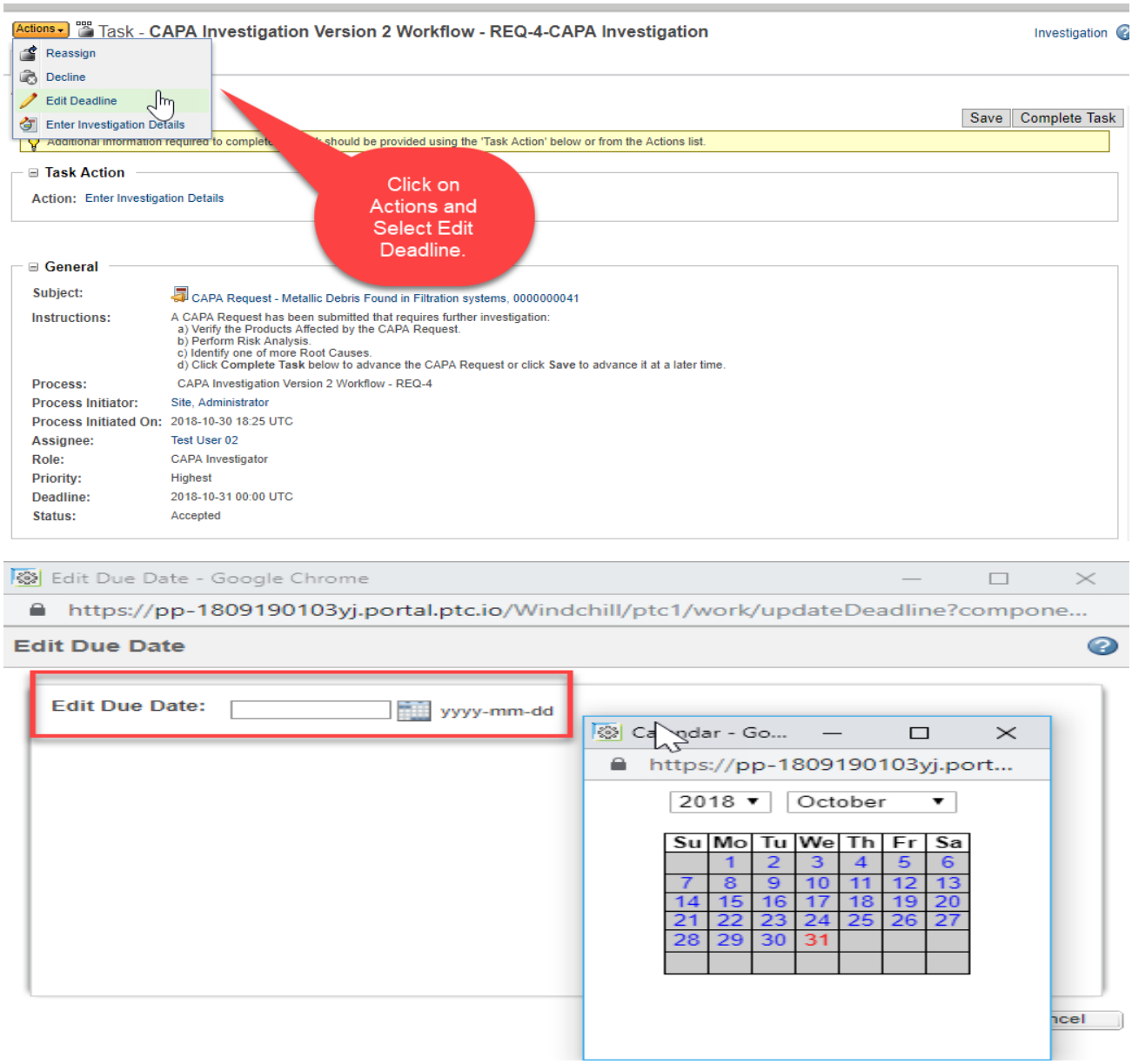


Table 13: Attribute Fields for CAPA Plan Revision or Due Date Extension

Attribute Field	Details	Optional or Required
Edit Due Date	Select the revised date, if applicable • Formatted DD/MMM/YYYY	Required
Summary	Document the summary of actions performed and completed to date	Required
Justification for Extension	Document the rationale for revision and / or extension	Required
Impact Assessment	Document the potential impact of revisions or due date extension to product, process(es) and Quality Management System (QMS) elements	Required
Risk Assessment	Document the potential risk of revisions or due date extension to product, process(es) and Quality Management System (QMS) elements	Required
Proposed Actions	Document the actions to be taken to mitigate impact and risk due to revision or due date extension. If no actions needed, document the rationale no additional actions.	Required
Submit to CRB	Submit the proposed request to the CRB for review and approval in accordance with the Global CAPA Review Work Instruction.	Required

6. REFERENCES

6.1 Internal References

6.1.1 Global Corrective Action and Preventive Action (CAPA) Management Procedure

6.1.2 Global Change Control Procedure

6.1.3 Global Field Action Procedure

6.1.4 Global SCAR Management Procedure

6.1.5 Product Identification and Traceability Procedure

6.1.6 Global Risk Management Procedure

6.1.7 Global Statistical Techniques Procedure

6.1.8 Global CAPA Review Work Instruction

6.1.9 Global Nonconformance Management Work Instruction

6.1.10 Global Root Cause Analysis Work Instruction

6.1.11 Global Definitions Glossary

6.1.12 Global Technology Work Instruction

6.1.13 Global Nonconformance Disposition and Bracketing Work Instruction

7. RECORDS

7.1 CAPA Record

8. APPLICABLE TERMS

8.1 The following terms, included in this document, are defined in the Global Definitions Glossary.

8.1.1 CAPA

8.1.2 CAPA Tier

8.1.3 Cause Code

8.1.4 Compliance Rating

8.1.5 Containment

8.1.6 Correction

8.1.7 Corrective Action

8.1.8 Failure Code

8.1.9 Field Action

8.1.10 Most probable cause

8.1.11 Nonconformance

8.1.12 Preventive Action

8.1.13 Primary Site

8.1.14 Process Issue

8.1.15 Product Issue

8.1.16 QMS Issue

8.1.17 Risk Region – Expected

8.1.18 Risk Region - Actual

8.1.19 Root Cause

8.1.20 Supplier Corrective Action Report

8.1.21 Verification of Implementation

8.1.22 Verification of Effectiveness

9. APPENDIX

9.1 Appendix A – No CAPA Action Plan Criteria

9.1.1 A CAPA Action Plan shall be required unless one or more of the follow criteria are met and objective evidence substantiating the criteria met is submitted to CRB for review:

- If issue was escalated to CAPA because of Field Action escalation and investigation finds that the Field Action is the only action required to address issue.
- Investigation findings cause risk rating of issue to be revised to a level that would not require CAPA escalation.

9.2 Appendix B – Corrective Acton / Preventive Action Categories

Category	Details
Error Proof	Description: • Action eliminates potential for error by making error occurrence physically unattainable. Examples of error proofing include, but are not limited to: • Architectural or physical manufacturing change • Engineering control • Removal of equipment or process step • Poke yoke fixtures, controls, or design
Error Prevention	Description: • Action prevents error occurrence by providing prompts through procedural or physical safeguards to trigger action. Examples of error prevention include, but are not limited to: • Procedural enhancements or modifications • Attention activators • Color-coding of components or similar visual aid
Detect and Recover	Description: • Action achieves the ability to undo error immediately with the use of prompts to trigger correction. Examples of detect and recover include, but are not limited to: • Alarms • Signs and notices • New or increased inspection

Category	Details
Duplication	Description: • Action achieves duplication or redundancy that cannot undo the error but allows the error to be identified during review. Examples of duplication include, but are not limited to: • Double checks or supervision • Communication or reminders • Training, as sole corrective and / or preventive action