Content:

Introduction
Add a New CAR
Modify A CAR
Enter Root Cause and Corrective Action
Supplier Login
Review and Verification
System Configuration and Maintenance
Installation and System Configuration

Introduction

How to use this guide:

This User’s guide will guide the user through step-by-step processes with illustrations of how to use the program, generate reports and conduct routine maintenance.

How does the program process a CAR?

In a CAR System, there are three main stages:

Preliminary Analysis Stage - In this phase, the CAR Issuer will collect the basic information and enter the preliminary analysis and a suggested action to the CAR Receiver. Example: User wants QIT Consulting to implement a corrective action. User will collect the defect description and tell QIT their analysis of why they think there is a defect. User also needs to tell QIT what their suggested actions are – What the user wants QIT to do.

Real Root Cause Analysis and Action Implementation Stage - Example: QIT receives a CAR. QIT will conduct a root cause analysis and then implement corrective actions.

Verification of Actions and Results Stage - User will fill-in and review comments. Then user will verify the action results. If everything is ok, user will close the CAR.

Basic Definitions:

Preliminary Root Cause - First, the CAR Issuer needs to collect basic information and formulate a preliminary analysis of the issue in order to provide the correct information to a CAR Receiver. The preliminary root cause is the upfront analysis results from the CAR Issuers. CAR Receivers need to conduct further in-depth analysis and submit the real root cause in the Feedback Section of the program.

The Action Plan – Are suggestions from the CAR Issuers. The CAR Receivers need to conduct the real root cause analysis to define the proper corrective actions.

Response Due Date – It is the key to verify and monitor a CAR’s status whether pending or overdue. By default, the Response Due Date = Issued Date + 30 days.
**Action Completion Date** – It is the date that the CAR Receiver actually implements the CAR. Program doesn’t use it in status calculation.

**Action Close Date** – It is the date that the CAR Issuer actually closed the CAR. If it is filled in the program will automatically change the status to Closed.

**Response Time** = First root cause analysis submission date – Issue Date

**CAR Status**

System uses Response Due Date and Action Close Date to calculate Status.

System will first use the Action Close Date in the Review Section (the date the Issuer actually closed the CAR) as a trigger to verify if the CAR is closed or not. If the date has been filled in, the status shows Closed.

**Open** – A newly issued CAPA without any root cause analysis

**Pending** – CAPA has root cause analysis but pending for action completion

**Verification** – CAPA needs to be reviewed and verified

**Closed** - CAPA has completed verification.

**Overdue** – Unclosed CAPA and Response Due Date < Today
Internal CAR Process:

QIT Corrective Action Management System Web Edition – Internal CAR Process

QA Manager
- System Administration
  - Adds New User
  - Deletes Obsolete CARs

QA Engineer
- Discovers an Issue
- Collects Basic Information
- Preliminary Analysis
- Issues Corrective Action
  - Receives Corrective Action and Preventive Action
    - Reviews action Effectiveness
      - Acceptable?
        - Yes: Close CAR
        - No: Reviews System Performance – All Reports

Dept. Mgr. (Premier and Advanced)
- Facilitates Root Cause Analysis
- Monitors CAR Status
  - Reviews Risk/Cost/Status/Dept. Report

Supplier (Premier Version Only)
- Conducts 4W1H Root Cause Analysis
- Submits Corrective Action and Preventive Action
  - Reviews Department Report

CAR Receiver
- Receives CAR

Page 4 of 32
Supplier SCAR Process (for Premier Version Users Only):

<table>
<thead>
<tr>
<th>QA Manager</th>
<th>QA Engineer</th>
<th>Dept. Mgr. (Premier and Advanced)</th>
<th>Supplier (Premier Version Only)</th>
<th>CAR Receiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Administration</td>
<td>Discovers an Issue</td>
<td></td>
<td>Receives CAR</td>
<td></td>
</tr>
<tr>
<td>Adds New Supplier</td>
<td>Collects Basic Information</td>
<td></td>
<td>Conducts 4W1H Root Cause Analysis</td>
<td></td>
</tr>
<tr>
<td>Adds New User</td>
<td>Preliminary Analysis</td>
<td></td>
<td>Submits Corrective Action and Preventive Action</td>
<td></td>
</tr>
<tr>
<td>Deletes Obsolete CARs</td>
<td>Issues Corrective Action</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Close CAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reviews System Performance - All Reports</td>
<td>Reviews Supplier Base/ Supplier/ Component Report</td>
<td></td>
<td>Reviews Supplier Performance / Component Report</td>
<td></td>
</tr>
</tbody>
</table>
**Adding a New CAR**

1) Type in the **User Name**, **Password** and **Validation Code** on the right section to log into the system as internal user.

2) Click **CAPA tab → Initiate CAR** to start entering the basic CAR information.

3) Enter the required information accordingly.

4) After entering all information,
click “Submit” to add the new CAR to the database.

Use **Save and Complete Later** function to save the form without submitting.

5) After submitting the data, the system will notify the User that the data has been submitted successfully.

6) Click “**Notify CAPA Owner**” to send a notification email to the CAR Representative who is responsible for this CAR.

7) System will use the User’s default email program e.g. Outlook to send the email.

Note: if system has been configured sending email through system, email form will be shown instead.

Go to **Tools  Auto-warning Setting** to change the email setting.
Modifying a CAR

1) Click “Modify CAR” and then Click the CAR Number.

Use Select Column to select different fields to show on the grid.

2) Modify the appropriate CAR information.

3) After modifying the CAR information, click “Submit” to add the changes to the database

Use Save and Complete Later function to save the form without submitting.

4) After submitting the data, the system will notify the User that data
has been successfully submitted.

5) Click “Notify CAPA Owner” to send a notification email to the CAR Representative who is responsible for this CAR.

6) System will use User’s default email program e.g. Outlook to send the email.

Note: if system has been configured sending email through system, email form will be shown instead.
**Entering a Root Cause and Corrective Action (CAR Receiver)**

1) After receiving the notification email from the Issuer, the CAR Representative needs to log into the system.

2) Click **“Root Cause Analysis”** on the menu tab to start entering the Root Cause Analysis and Corrective Action information.

   Click the CAR number to start the root cause analysis and enter corrective action.

   Click **“Print”** button to print out a hardcopy of the CAR form.

3) The CAPA Owner selects the CAR that was assigned to him/her.

   *Note: Different “User Roles” will have different user interfaces and*
4) Click “Add New Root Cause” to add any new Root Cause Analysis.

5) Follow the instructions to fill in the new Root Cause Analysis and Corrective Action info.

   Use Assign Task function to assign detailed containment action

   Use CA 5-Why and PA 5-Why to assign detailed corrective action and preventive action

   **Note:** To see the details of the defect description, check “Show CAR Info” on the Hide Reference option.

6) After all information has been added, click “Submit” to add the information to database.

   Click Project Team Discussion to add/review comments
After submitting the data, User can select the “Notify CAPA Issuer” option to email the information to the CAR Issuer.

Note: if system has been configured sending email through system, email form will be shown instead.
## Supplier Login

1. After receiving the notification email from the Issuer, the Supplier needs to log into the system.

Supplier needs to log in to the system from the left section

<table>
<thead>
<tr>
<th>QIT Quality Management System</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Sign in" /></td>
</tr>
</tbody>
</table>

2) Click **Root Cause Analysis** function and then select the SCAR that was assigned

<table>
<thead>
<tr>
<th>SCAR</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Root Cause Analysis" /></td>
</tr>
</tbody>
</table>

3) Click the CAR number to start the root cause analysis and enter the corrective action.

Click **Print** button to print out a hardcopy of the CAR form

*Note: Different “User Roles” will have different user interfaces and
access to the system.

Use **Select Column** to select different fields to show on the grid.

4) Click “**Add New Root Cause**” to add any new Root Cause Analysis.

5) Follow the instructions to fill in the new Root Cause Analysis and Corrective Action info.

   **Note:** To see the details of the defect description, check “**Show CAR Info**” on the Hide Reference option.

6) After all information has been added, click “**Submit**” to add the information to database.

   Click **Project Team Discussion** to add/review comments

   Use **Save and Complete Later** function to save the form without submitting.
7) After submitting the data, User can select the **Notify SCAR Issuer** option to email the information to the CAR Issuer.
**Retrieve and Complete Action Item**

1) After receiving a notification email from a CAR Representative, the Action Owner will log into the system.

2) Click Retrieve and Complete Action Item

Click **CAPA Number** and then click **Retrieve and Complete Action Item**

Note: Only CAPAs that have been assigned detailed containment actions in **Assign Task** function and CA and PA that assigned 5-
Why/detailed CA and PA in 5-Why section will be shown on this list.

CAPAs without detailed actions will be shown on **Review and Verification** function.

Click **Assign Task** button to fill in containment action completion date

Click **CA 5-Why** to fill in CA completion date

Click **PA 5-why** to fill in PA completion date

Click **Submit**

Click **Submit** again on the main page to submit all actions
**Review and Verification**

1) After receiving a notification email from a CAR Representative, the CAR Issuer will log into the system.
2) Click SCAR tab and then click Review and Verification.

3) Select the “Action Priority” from the list.

- Needs Attention CAR’s – All overdue CAR’s
- Pending for Action CAR’s – All CAR’s without a root cause and corrective action.
- Pending for Review CAR’s – All CAR’s that have root cause and corrective action but are waiting for reviews.

User can select to see All CAPA or My CAPA to narrow the list.

4) Click on the CAR Number you want to review.

5) Review the root cause and the actions.

6) Enter comments.

Note: If the action is acceptable, enter the “Action Close Date” to close this action.

7) After entering all the required information, click “Submit” to submit the data to the database.

Fill in CAPA Watch fields to add
the CAPA to Watch List for long-term effective monitoring.

8) If all root causes and corrective actions are closed, the system will automatically close the CAR.
**System Configuration and Maintenance**

**Add or Delete a Department**

1) Click “Setting” tab and then click “Dropdown Field Management” → Department to add/modify department settings.

*Note: Only the Quality Manager has authorization to change system settings.*

*Note: Before deleting a Department please ensure all CAR’s and all Users’ settings under this Department have been deleted. Once the Department is deleted, all information related to this department will be erased.*

---

**Manage Part and Process**

1) Click “Setting → Dropdown Field Management → Product”

Use **Upload** function to upload part/process from Excel

Click **Template** to download template file.
### Add or Delete a User

1) Click “Setting → System Configuration → User Account”

Note: Before deleting a User Account, please ensure that all CAR’s assigned to this user have been deleted. Once the user account is deleted, all information related to this user will be erased.

Note: For new users, the default password is the user’s email address.

### Manage Group

Click 1) Click “Setting → Dropdown Field Management → Group”

Click 1) Click “Setting → Dropdown Field Management → Group Member”

### Manage Failure Mode

1) Click “Setting → Dropdown Field Management → Failure Mode” to add/modify Failure Mode settings.

Note: Before deleting a Failure Mode, please ensure all CAR’s this
**Failure Mode has been deleted.**
Once the Failure Mode is deleted, all information related to this user will be erased.

*Note: The modifications of a Failure Mode will only take effect on CAR’s added after changes and all previous CAR’s will keep the old setting.*
**Delete or Re-Open a CAR**

1) Click “Setting ➔ System Configuration ➔ Manage CAR”

   to delete or reopen a CAR.

Note: Delete CAR’s with caution. If a CAR is deleted, all the data in the reports will be changed.

Use the “Re-open CAR” only when the issue or the incident is still open. If it is in the case of a failure mode happening again, consider it a new incident and issue a new CAR.

**Manage Supplier**

1) Click “Setting ➔ Dropdown Field Management ➔ Manage Supplier” to add/modify Supplier settings.

Note: Before deleting a Supplier, please ensure all CAR’s this supplier has been deleted.

2) Click “1) Setting ➔ Dropdown Field Management ➔ Manage Supplier Account” to add the supplier account. The default password is the supplier’s contact email address.

**Manage Supplier Account**

1) Click “Setting ➔ Dropdown Field Management ➔ Supplier Account”

   to add/modify users’ information.

Note: Before deleting a Supplier Account, please ensure all CAR’s to this supplier account has been deleted.
### Supplier Listing

<table>
<thead>
<tr>
<th>Supplier No.</th>
<th>Supplier Name</th>
<th>Contact Name</th>
<th>Email</th>
<th>Home Page</th>
<th>Modify</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Supplier 1</td>
<td>John Doe</td>
<td><a href="mailto:doejohn123@gmail.com">doejohn123@gmail.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>Supplier 2</td>
<td>Jane Smith</td>
<td><a href="mailto:smithjane123@gmail.com">smithjane123@gmail.com</a></td>
<td>2022</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT123</td>
<td>Supplier 3</td>
<td>Bob Brown</td>
<td><a href="mailto:brownbob123@gmail.com">brownbob123@gmail.com</a></td>
<td><a href="http://www.sup.com">http://www.sup.com</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Page 1, Total Records 11
Auto-warning Settings

1) Click Setting Email Setting

Auto-warning Settings to modify auto-warning email setups.

Note: by default the system will use QIT’s SMPT server to send emails. User can always change it to a preferred SMTP server.

User can also setup

1) When to send and who to receive coming due warning email
2) Who to receive overdue email
3) Using System to send email
4) Using Outlook to send email
5) Password to close CAPA
6) Default email messages

Use Auto-warning Email function to set up default email messages.

Use Auto Email Configuration to set up default email messages.

Online User Control

User can review user information on

1) Click Tools System Configuration Online User Control

Click Logout to manually log out user.

Note: Use this function to close user’s connection, when a user’
| account is blocked due to abnormal logout. |   |