QIT Quality Management System

CAPA & SCAR Modules

Operating Manual

Web Edition

Version 2017

Content:

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.

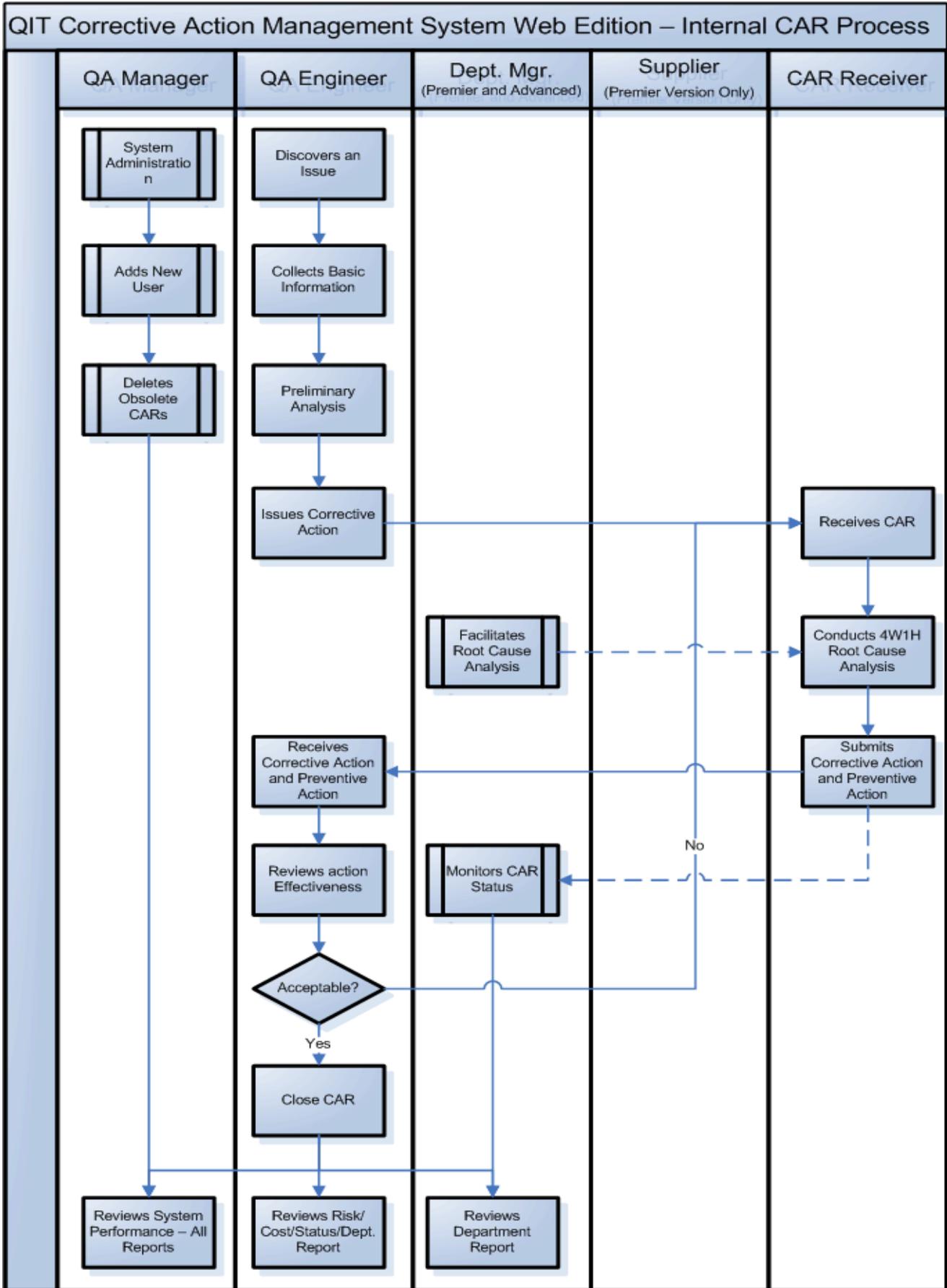**Open** – A newly issued CAPA without any root cause analysis

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

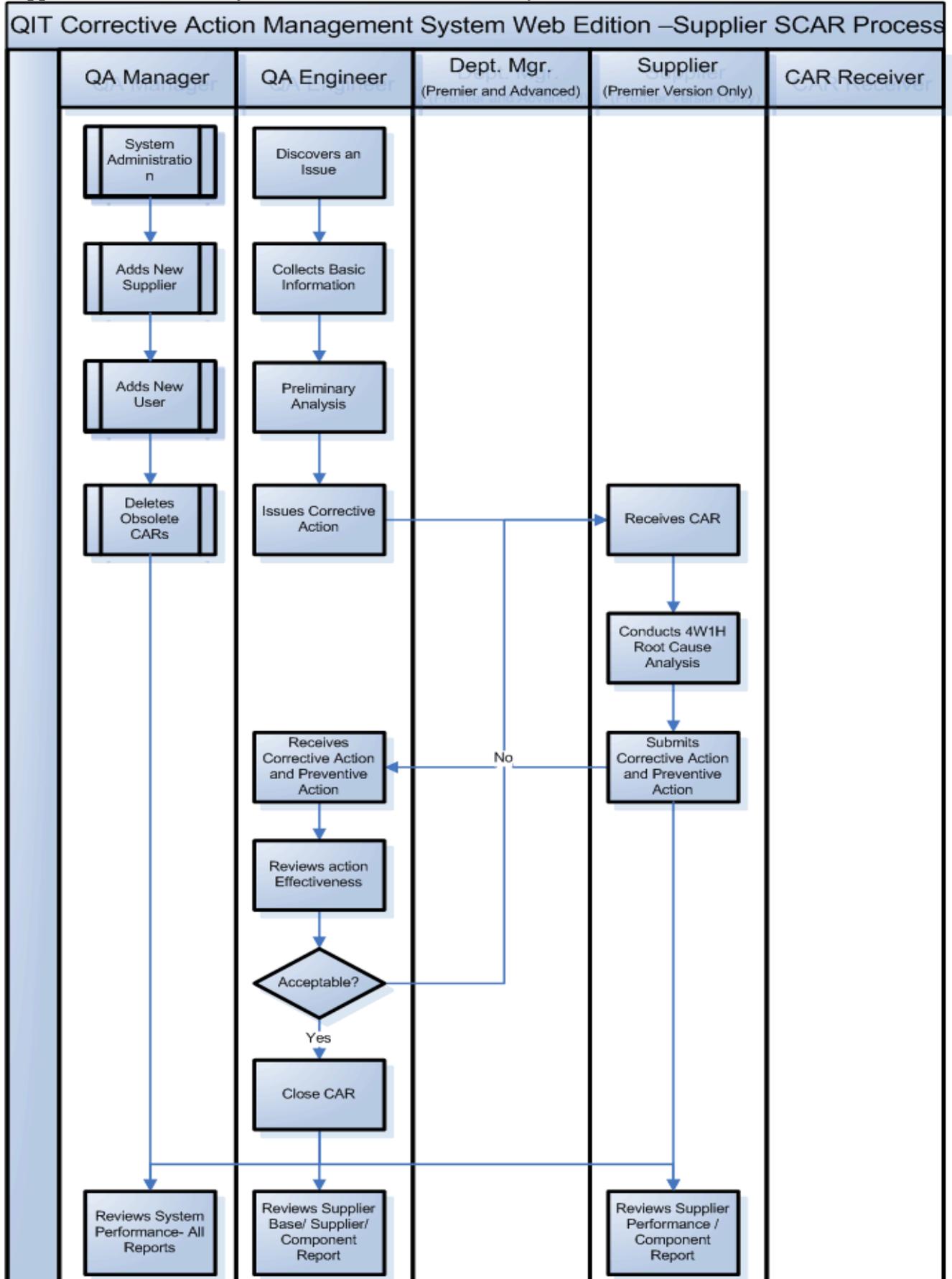**Verification** – CAPA needs to be reviewed and verified

Closed- CAPA has completed verification.

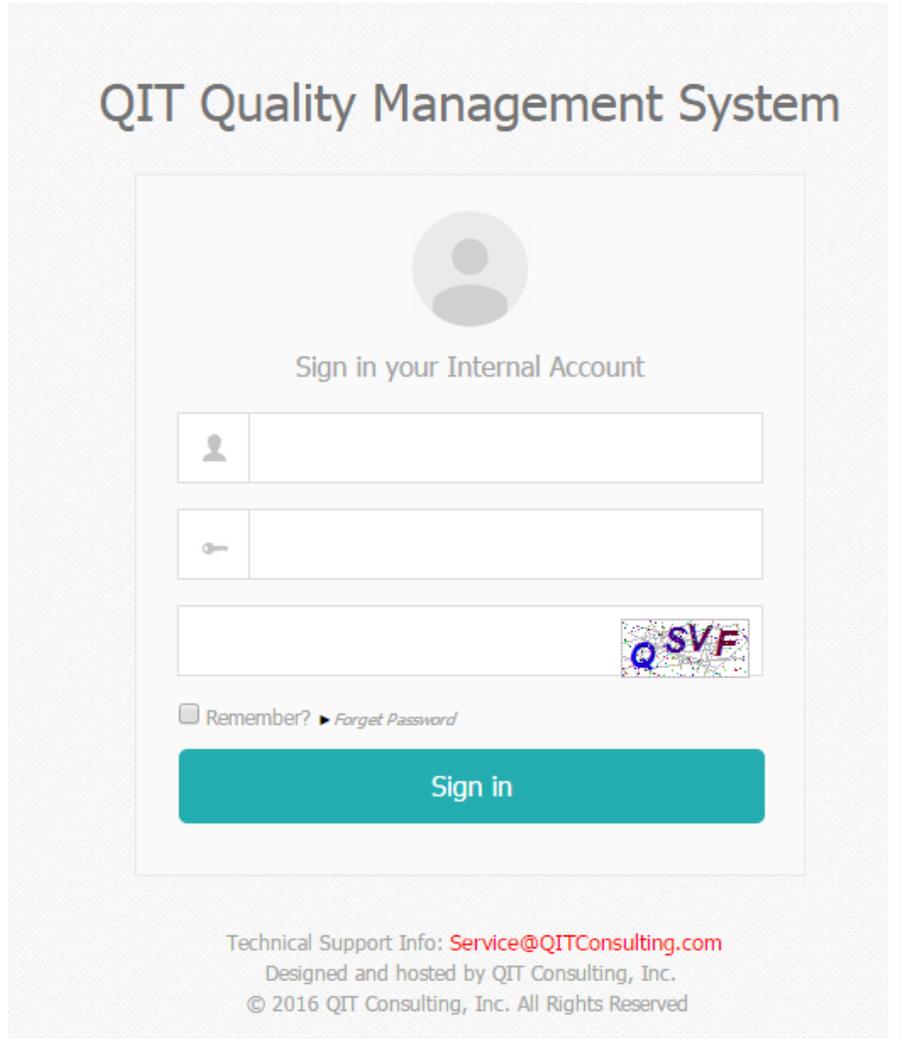**Overdue** – Unclosed CAPA and Response Due Date < Today

Internal CAR Process:

Supplier SCAR Process (for Premier Version Users Only):

QIT Corrective Action Management System Web Edition –Supplier SCAR Process

QA Manager	QA Engineer	Dept. Mgr. (Premier and Advanced)	Supplier (Premier Version Only)	CAR Receiver

- System Administration
- Discovers an Issue

- Adds New Supplier
- Collects Basic Information

- Adds New User
- Preliminary Analysis

- Deletes Obsolete CARs
- Issues Corrective Action → Receives CAR

Conducts 4W1H Root Cause Analysis

Receives Corrective Action and Preventive Action ← No ← Submits Corrective Action and Preventive Action

Reviews action Effectiveness

Acceptable?

No

Yes

Close CAR

- Reviews System Performance- All Reports
- Reviews Supplier Base/ Supplier/ Component Report
- Reviews Supplier Performance / Component Report

### *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.	QIT Quality Management System Sign in your Internal Account *(login form with username field, password field, validation code field showing "QSVF")* ☐ Remember? ▸ *Forget Password* **Sign in** Technical Support Info: Service@QITConsulting.com Designed and hosted by QIT Consulting, Inc. © 2016 QIT Consulting, Inc. All Rights Reserved
2) Click **CAPA tab** → **Initiate CAR** to start entering the basic CAR information.	Session Timeout: 59:53 Dashboard CAPA SCAR Reports Tools **CAPA** 🔴 **Initiate CAPA** 🔴 **Modify CAPA** ⸬ CAPA Initiators/Issuers. Issue a new CAPA to functional departments (e.g. Sales, Engineering or etc.) ⸬ CAPA Initiators/Issuers. Modify a CAPA. 🔴 **Review and Verification** 🔴 **Send Notification** ⸬ CAPA Initiators/Issuers. Review root cause analysis and corrective actions submitted by internal departments and verify the effectiveness of the corrective actions ⸬ QA Manager/System Admin. Send out a system wide message 🔴 **Reassign CAPA Owner** ⸬ Reassign CAPA Owner
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.	**Confirmation** Dear Administrator , Your data has been successfully submitted. Please select your next action. [Back] [Review CAPA Report] [Notify CAPA Owner]

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.*

Modify CAPA

Search

Year:	2014
CAPA Number:	

Search

Select Columns

	CAPA Number	Case Number	Product/Process	Issuer	Issue Date	Due Date	CA Owner	Region	Status	Current Control	Attachment	Print
	CAR-14-0017	441		Administrator	04/01/2014	05/01/2014	qawen	UK	Open	0	No Attachment	
	CAR-14-0015	45		Administrator	03/12/2014	03/19/2014	qawen	USA	Overdue 5		No Attachment	
	CAR-14-0014	45		Administrator	03/12/2014	03/19/2014	qawen	USA	Overdue 5		No Attachment	
	CAR-14-0013			Administrator	03/05/2014	04/05/2014	qawen	UK	Open	0	No Attachment	
	CAR-14-0012	45		Administrator	03/03/2014	04/03/2014	qawen	UK	Open	7	No Attachment	
	CAR-14-0011	44		Administrator	02/28/2014	03/28/2014	otwen	USA	Overdue 4		Attachment	
	CAR-14-0010	45		Administrator	02/28/2014	03/28/2014	qawen	UK	Overdue 4		Attachment	
	CAR-14-0008	55		Administrator	02/26/2014	03/26/2014	qawen	USA	Overdue 0		No Attachment	
	CAR-14-0006	test		Administrator	02/14/2014	03/14/2014	qawen	USA	Overdue 0		No Attachment	
	CAR-14-0005	55		Administrator	01/19/2014	02/19/2014	qawen	USA	Overdue 8		No Attachment	
	CAR-14-0001	441		Administrator	01/08/2014	02/08/2014	qawen	USA	Overdue 0		No Attachment	

Page: 1   Total Record:11

Back

Modify CAPA

Search

Year:	2014
CAPA Number:	

Search

Add or remove columns

☑ Product/Process	☑ Due Date	☑ Status	☐ Occurrence	☐ Other Cost
☑ Issuer	☑ CA Owner	☐ Severity	☐ Unit Cost	☐ Cost
☑ Issue Date	☑ Region	☐ Defective Qty	☑ Current Control	☐ Submit Status

Select All   Done

	CAPA Number	Case Number	Product/Process	Issuer	Issue Date	Due Date	CA Owner	Region	Status	Current Control	Attachment	Print
	CAR-14-0017	441		Administrator	04/01/2014	05/01/2014	qawen	UK	Open	0	Attachment	
	CAR-14-0015	45		Administrator	03/12/2014	03/19/2014	qawen	USA	Overdue 5		Attachment	
	CAR-14-0014	45		Administrator	03/12/2014	03/19/2014	qawen	USA	Overdue 5		Attachment	
	CAR-14-0013			Administrator	03/05/2014	04/05/2014	qawen	UK	Open	0	Attachment	
	CAR-14-0012	45		Administrator	03/03/2014	04/03/2014	qawen	UK	Open	7	Attachment	
	CAR-14-0011	44		Administrator	02/28/2014	03/28/2014	otwen	USA	Overdue 4		Attachment	
	CAR-14-0010	45		Administrator	02/28/2014	03/28/2014	qawen	UK	Overdue 4		Attachment	
	CAR-14-0008	55		Administrator	02/26/2014	03/26/2014	qawen	USA	Overdue 0		Attachment	
	CAR-14-0006	test		Administrator	02/14/2014	03/14/2014	qawen	USA	Overdue 0		Attachment	
	CAR-14-0005	55		Administrator	01/19/2014	02/19/2014	qawen	USA	Overdue 8		Attachment	
	CAR-14-0001	441		Administrator	01/08/2014	02/08/2014	qawen	USA	Overdue 0		Attachment	

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.

Preliminary Analysis and Action Plan

Basic CAPA Info

CAPA Number:	CAR-14-0017	Product/Process:	441
CAPA Issuer:	Administrator	Product Name:	kk
CAPA Region:	UK	CAPA Issue Date:	04/01/2014
Location:	CT Facility	CAPA Category:	Critical
CAPA Type:	Internal audit	Audit #:	
Case Number:			

Possible Root Cause and Corrective Action Plan– Qualitative Analysis

Defect Description (5000 characters limit):
test

Possible root cause, if known (1000 characters limit):
sdf

Recommended Containment Action (1000 characters limit):
sdf

Recommended corrective action
sdf

4) After submitting the data, the system will notify the User that data

has been successfully submitted.

Confirmation

Dear Administrator ,
Your data has been successfully submitted. Please select your next action.

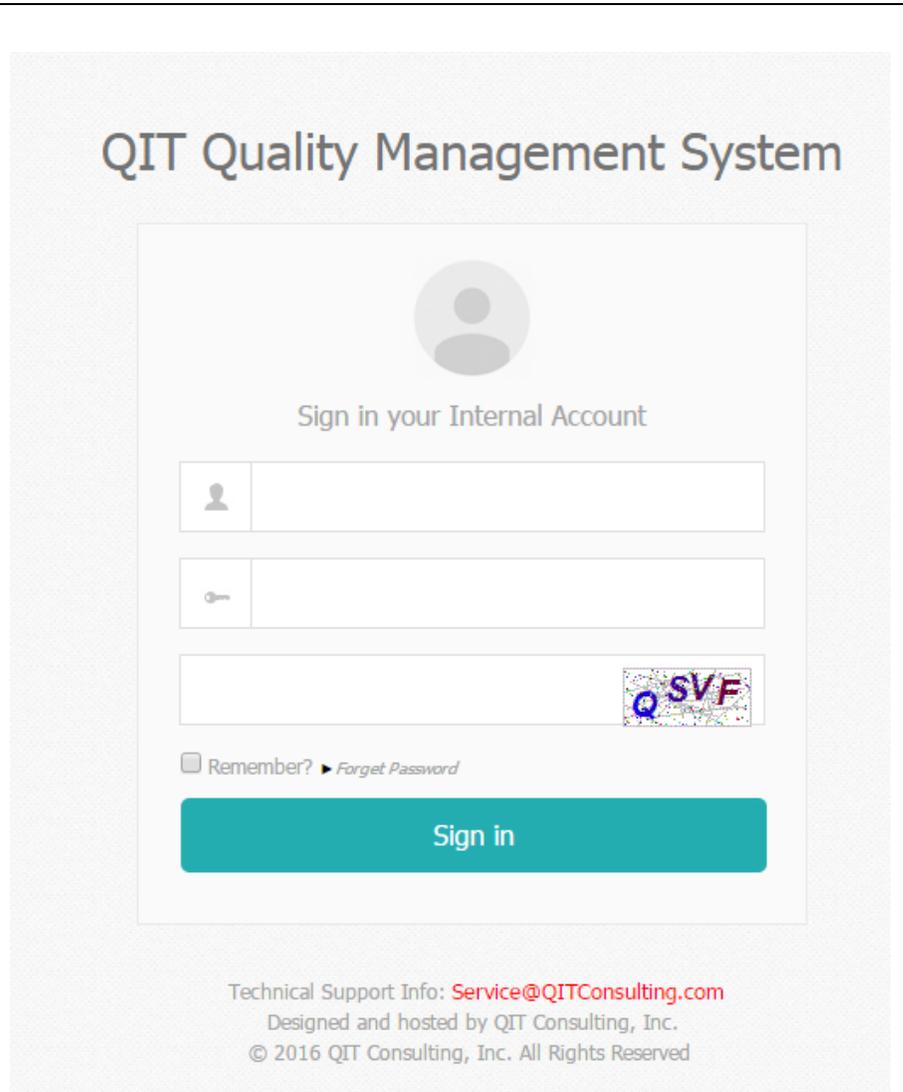| Back | Review CAPA Report | Notify CAPA Owner |

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.	**QIT Quality Management System** Sign in your Internal Account [username field] [password field] Q SVF ☐ Remember? ▶ *Forget Password* **Sign in** Technical Support Info: Service@QITConsulting.com Designed and hosted by QIT Consulting, Inc. © 2016 QIT Consulting, Inc. All Rights Reserved
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*	**Root Cause Analysis, Corrective Action and Preventive Action** **Search** Year: 2014 CAPA Number: [Search] [Select Columns] (table below)

Root Cause Analysis, Corrective Action and Preventive Action table:

CAPA Number	Product/Process	Issuer	Issue Date	Due Date	CA Owner	Status	Cost	Attachment	Print
CAR-14-0017	441	Administrator	04/01/2014	05/01/2014	qawen	Open	156.00	No Attachment	
CAR-14-0015	45	Administrator	03/12/2014	03/19/2014	qawen	Overdue	244.00	No Attachment	
CAR-14-0014	45	Administrator	03/12/2014	03/19/2014	qawen	Overdue	244.00	No Attachment	
CAR-14-0012	45	Administrator	03/03/2014	04/03/2014	qawen	Open	57.00	Attachment	
CAR-14-0011	44	Administrator	02/28/2014	03/28/2014	otwen	Overdue	552.00	Attachment	
CAR-14-0010	45	Administrator	02/28/2014	03/28/2014	qawen	Overdue	156.00	Attachment	
CAR-14-0008	55	Administrator	02/26/2014	03/26/2014	qawen	Overdue	0.00	No Attachment	
CAR-14-0006	test	Administrator	02/14/2014	03/14/2014	qawen	Overdue	0.00	No Attachment	
CAR-14-0005	55	Administrator	01/19/2014	02/19/2014	qawen	Overdue	552.00	No Attachment	
CAR-14-0001	441	Administrator	01/08/2014	02/08/2014	qawen	Overdue	1356.00	No Attachment	

Page: 1   Total Record:10

[Back]

access to the system.

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

Root Cause Analysis, Corrective Action and Preventive Action

Search

Year: 2014
CAPA Number:

Search

Add or remove columns

☑ Product/Process ☑ Due Date ☑ Status ☐ Occurrence ☐ Other Cost
☑ Issuer ☑ CA Owner ☐ Severity ☐ Unit Cost ☑ Cost
☑ Issue Date ☐ Region ☐ Defective Qty ☐ Current Control ☐ Submit Status

Select All   Done

	CAPA Number	Product/Process	Issuer	Issue Date	Due Date	CA Owner	Status	Cost	Attachment	Print
	CAR-14-0017	441	Administrator	04/01/2014	05/01/2014	qawen	Open	156.00	Attachment	📄
	CAR-14-0015	45	Administrator	03/12/2014	03/19/2014	qawen	Overdue	244.00	Attachment	📄
	CAR-14-0014	45	Administrator	03/12/2014	03/19/2014	qawen	Overdue	244.00	Attachment	📄
	CAR-14-0012	45	Administrator	03/03/2014	04/03/2014	qawen	Open	57.00	Attachment	📄
	CAR-14-0011	44	Administrator	02/28/2014	03/28/2014	otwen	Overdue	552.00	Attachment	📄
	CAR-14-0010	45	Administrator	02/28/2014	03/28/2014	qawen	Overdue	156.00	Attachment	📄
	CAR-14-0008	55	Administrator	02/26/2014	03/26/2014	qawen	Overdue	0.00	Attachment	📄
	CAR-14-0006	test	Administrator	02/14/2014	03/14/2014	qawen	Overdue	0.00	Attachment	📄
	CAR-14-0005	55	Administrator	01/19/2014	02/19/2014	qawen	Overdue	552.00	Attachment	📄
	CAR-14-0001	441	Administrator	01/08/2014	02/08/2014	qawen	Overdue	1356.00	Attachment	📄

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

Root Cause Analysis, Corrective and Preventive Action

Add New Root Cause

No data found

Back

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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.*

CAPA Feedback

Hide CAPA Details

Basic CAPA Info				
	CAPA Number:	CAR-14-0017	Product/Process:	441
	Location:	CT Facility	Product Name:	kk
	CAPA Issue Date:	04/01/2014	CAPA Issuer:	Administrator
	CAPA Type:	Internal audit	CAPA Region:	UK
	CAPA Category:	Critical	Audit #:	

Preliminary Root Cause and Action Plan		
	Defect Description (5000 characters limit):	test
	Preliminary root cause, if known:	sdf
	Recommended Containment Action (1000 characters limit):	sdf
	Recommended corrective action:	sdf
	Possible Failure Mode:	Assay out of Control

CA Representative	CA Owner:	qawen	Response Due Date:	05/01/2014

Risk Analysis	Severity:	N/A	Occurrence:	N/A
	Current Control:	N/A	RPN #/Risk:	N/A

Quality Cost	Defective Qty:	12	Unit Cost:	12.00
	Other Cost:	12.00	Total Cost:	156.00

Forming a Team:	

Actual Containment Action:	

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

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

Preventive Action:	
	Preventive Action: [ ]
	[PA Action]
	Preventive Action Completion Date: [_____] [📅]
FMEA	FMEA/Control Plan Responsible:(2000 character limit) [ ]
	FMEA Due Date: [_____] [📅] FMEA Completion Date: [_____] [📅]
	FMEA First Fill out Date: [_____] [📅] FMEA Last Modification Date: [_____] [📅]
Lessons Learned	Lessons Learned from the problem:(2000 character limit) [ ]
Attachment:(Max file size 10Mb)	1: [ ] [Browse...] Description: [ ]
	2: [ ] [Browse...] Description: [ ]
	3: [ ] [Browse...] Description: [ ]
	4: [ ] [Browse...] Description: [ ]
	5: [ ] [Browse...] Description: [ ]
	More
	[Submit] [Save and Complete Later] [Back] ⌃Project Team Discussion **0 Comment(s)**

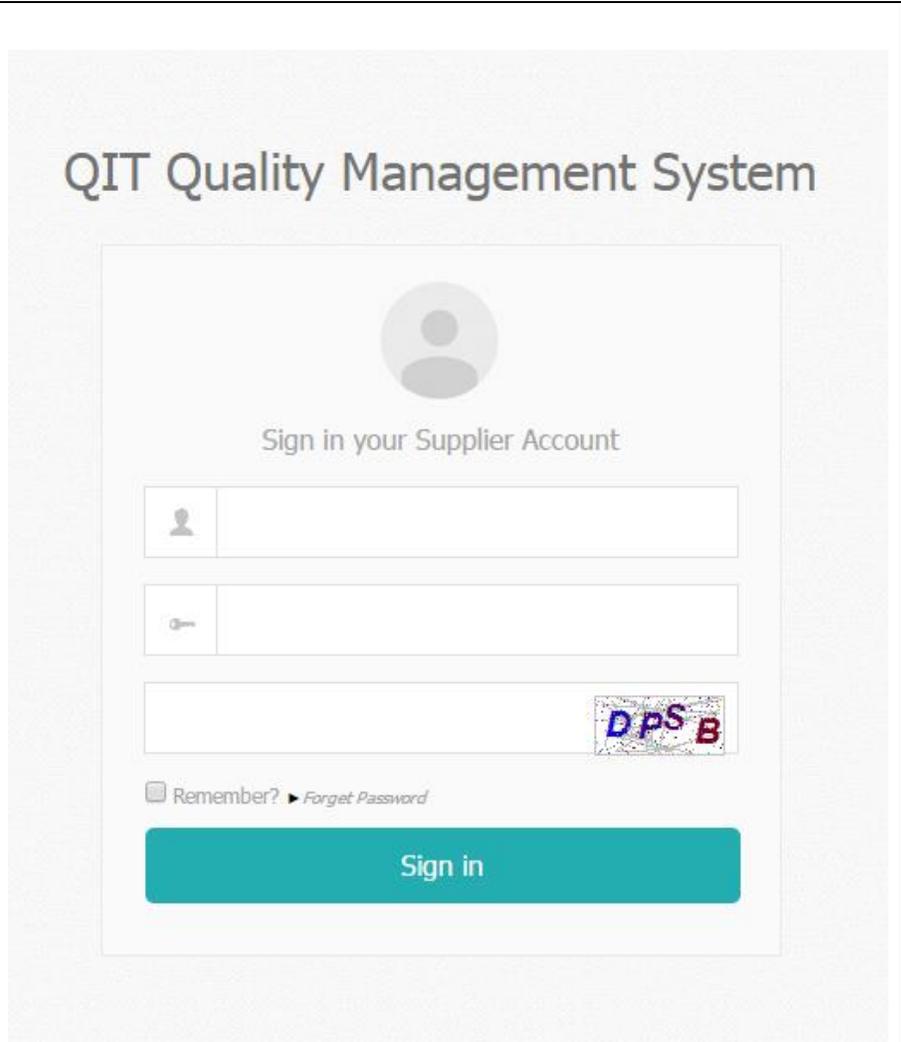|	
7) After submitting the data, User can select the "**Notify CAPA Issuer**" option to email the information to the CAR Issuer. Note: if system has been configured sending email through system, email form will be shown instead.	**Confirmation** Dear Administrator , Your data has been successfully submitted. Please select your next action. [Back] [Review CAPA Report] [Notify CAPA Issuer]

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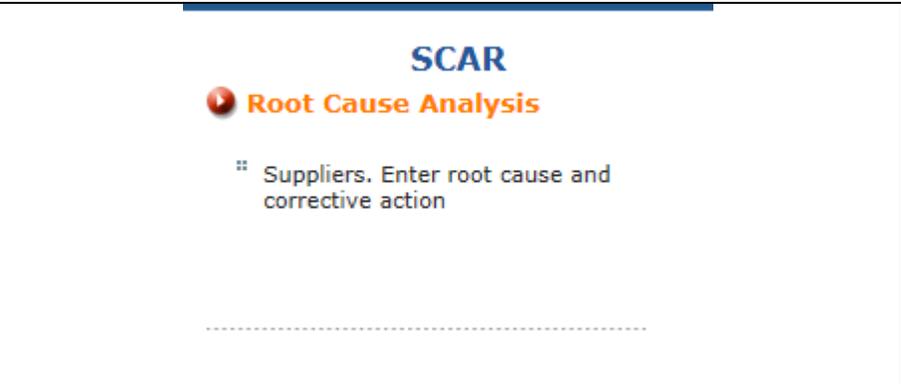
### *Supplier Login* 1. After receiving the notification email from the Issuer, the Supplier needs to log into the system. Supplier needs to log in to the system from the left section	QIT Quality Management System Sign in your Supplier Account DPS B ☐ Remember? ▸ *Forget Password* Sign in
2) Click **Root Cause Analysis** function and then select the SCAR that was assigned	**SCAR** 🔴 **Root Cause Analysis** ▪ Suppliers. Enter root cause and corrective action
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*	

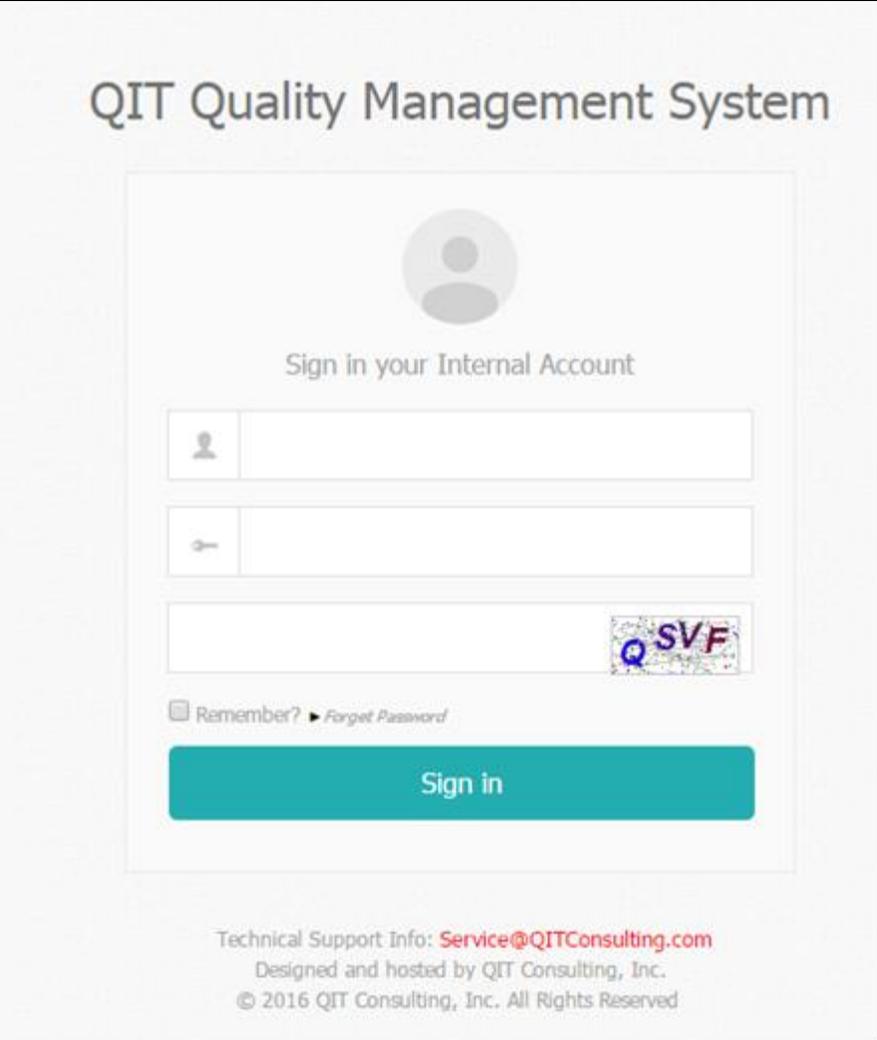|	
access to the system. *Use **Select Column** to select different fields to show on the grid.*	**Root Cause Analysis, Corrective Action and Preventive Action** Search Year: 2014 SCAR Number: ____ Search Select Columns SCAR Number / Issue Date / Due Date / Issuer / Supplier Name / CA Owner / Defective Qty / Status / Attachment / Print SCAR-14-0005 03/03/2014 04/03/2014 Administrator 1 1 1 Open Attachment SCAR-14-0004 02/28/2014 03/28/2014 Administrator 1 1 0 Overdue Attachment Page: 1 Total Record:2 Back
4) Click "**Add New Root Cause**" to add any new Root Cause Analysis.	**Root Cause Analysis, Corrective and Preventive Action** Add New Root Cause No data found Back Send email to service@qitconsulting.com with questions or comments about this website. Copyright © 2014 QIT Consulting, Inc.
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.*	**SCAR Feedback** Show SCAR Details **Actual Containment Action:** — Actual Containment Action: [ ] Containment Action Date: [ ] **Root Cause Analysis** — Who is involved with the problem? [ ] * When did the problem occur? [ ] * Where did the problem occur? [ ] * How did the problem occur? [ ] * Why did the problem occur? (root cause summary) [Please see 5-Why analysis] * 5-Why Analysis Primary Failure Mode: [Assay out of Control] **Corrective Action:** — Corrective Action: [Please see 5-Why analysis] Corrective Action Completion Date: [ ] * First Affected Lot Number: [ ] **Preventive Action:** — Preventive Action: [ ]
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.	**Preventive Action:** — Preventive Action: [ ] Preventive Action Completion Date: [ ] **FMEA** — FMEA/Control Plan Responsible:(2000 character limit) [ ] FMEA Due Date: [ ] FMEA Completion Date: [ ] FMEA First Fill out Date: [ ] FMEA Last Modification Date: [ ] **Lessons Learned** — Lessons Learned from the problem:(2000 character limit) [ ] **Attachment:(Max file size 10Mb)** — Initiating Book3.xlsx Failure rate data 0.0084M 03/03/2014 Delete 1: [ ] Browse... Description: [ ] 2: [ ] Browse... Description: [ ] 3: [ ] Browse... Description: [ ] 4: [ ] Browse... Description: [ ] 5: [ ] Browse... Description: [ ] More Submit Save and Complete Later Back Project Team Discussion 0 Comment(s)

7) After submitting the data, User can select the "**Notify SCAR Issuer**" option to email the information to the CAR Issuer.	**Confirmation** Dear 1 , Your data has been successfully submitted. Please select your next action. [Back] [Review SCAR Report] [Notify SCAR Issuer]

### *Retrieve and Complete Action Item* 1) After receiving a notification email from a CAR Representative, the Action Owner will log into the system.	**QIT Quality Management System** Sign in your Internal Account [user field] [password field] [captcha: QSVF] ☐ Remember? ▸ *Forget Password* **Sign in** Technical Support Info: Service@QITConsulting.com Designed and hosted by QIT Consulting, Inc. © 2016 QIT Consulting, Inc. All Rights Reserved
2) **Click Retrieve and Complete Action Item**	🔴 **Retrieve and Complete Action Item** " Action Owner retrieves action items and then fills in Completion Date and Self-assessment
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-	**Retrieve and Complete Action Item** **Search** Year: 2014 CAPA Number: [ ] [Search] [Select Columns] Table: CAPA Number / Product/Process / Issuer / Issue Date / Due Date / CA Owner / Region / Status / Attachment / Print CAR-14-0015 / 45 / Administrator / 03/12/2014 / 03/19/2014 / qawen / USA / Overdue / No Attachment / 📄 Page: 1 Total Record:1 [Back]

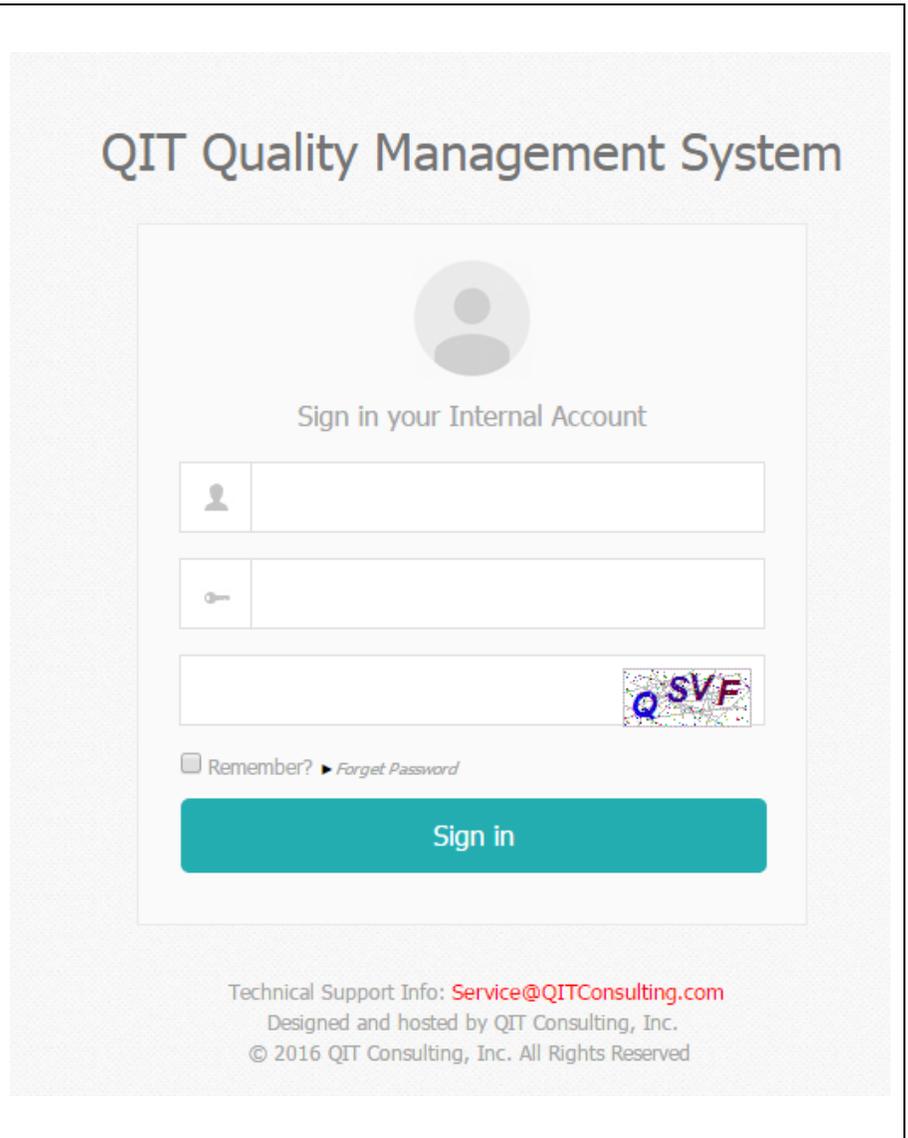|	
Why/detailed CA and PA in 5-Why section will be shown on this list. CAPAs without detailed actions will be shown on **Review and Verification** function.	**Retrieve and Complete Action Item** 	CA Completion Date	Corrective Action	Print
---	---	---
	Please see 5-Why analysis sfd	Retrieve and Complete Action Item	 Page: 1 Total Record:1 Back
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	**Actual Containment Action:** asdf afdasdf Containment Action Date: Assign Task — Assign Task — Total 1 action(s) **Root Cause Analysis** Who is involved with the problem? asdf When did the problem occur? adsf Where did the problem occur? adsf How did the problem occur? adf Why did the problem occur? (root cause summary) Please see 5-Why analysis adsf Primary Failure Mode: Assay out of Control **Corrective Action:** Please see 5-Why analysis sfd CA 5-why — Total 1 action(s) Corrective Action Completion Date: First Affected Lot Number: **Preventive Action:** sfsdf PA 5-why — Total 1 action(s) Preventive Action Completion Date:
Click **Submit**	**Assign Task** | Action	Department	Who	Target Date	Comp. Date	Self-assessment
---	---	---	---	---	---
sdfsdf	Customer Services	qawen	03/31/2014		
	Select	Select			
	Select	Select			
	Select	Select			
	Select	Select				 Submit Add Action
Click **Submit** again on the main page to submit all actions	**Lessons Learned** — Lessons Learned from the problem:(2000 character limit) **Attachment:(Max file size 10Mb)** 1: Browse... Description: 2: Browse... Description: 3: Browse... Description: 4: Browse... Description: 5: Browse... Description: More **Review and Verification** — Reviews/Comments and Verifications: Internal Comments (this field will be omitted from supplier report and CAPA report): Department: Reviewer: Action Close Date: Submit Back ⌃Project Team Discussion 0 Comment(s)

Review and Verification

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

QIT Quality Management System

Sign in your Internal Account

Remember? ▶ *Forget Password*

Sign in

Technical Support Info: Service@QITConsulting.com
Designed and hosted by QIT Consulting, Inc.
© 2016 QIT Consulting, Inc. All Rights Reserved

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.	**Attachment:(Max file size 10Mb)** Initiating Book3.xlsx Failure rate data 0.0084M 03/03/2014 Delete **Review and Verification** Reviews/Comments and Verifications: Internal Comments (this field will be omitted from supplier report and CAPA report): Department: Engineering Dept. Reviewer: Administrator Action Close Date: _____ **SCAR Watch List** Watch Reason: WatchDate: _____ Add to Watch List: ○ Yes ● No Submit Back ⇧Project Team Discussion **0 Comment(s)**
8) If all root causes and corrective actions are closed, the system will automatically close the CAR.	**Message from webpage** X ⚠ This corrective action is closed. CAR Number CAR-13-0005 is closed! OK
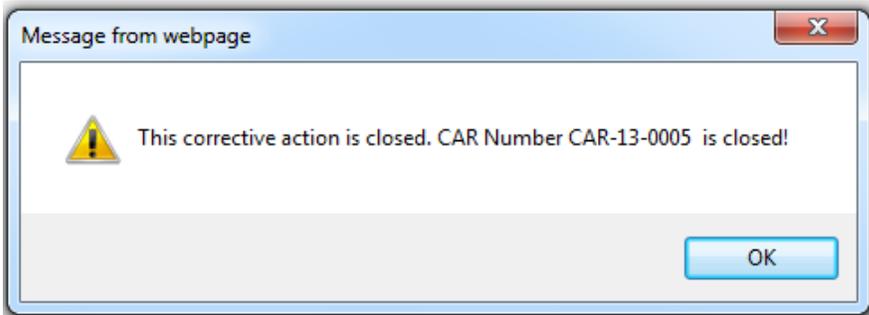
System Configuration and Maintenance

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.

Department

Department	Modify	Delete
Engineering Dept.		
Managed Services		
Human Resources		
Technology Solutions		
Marketing		
National IT		
Customer Services		
Sales		
Manufacturing		
Quality		

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Add   Back

Mange 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.

Product

Search

Product/Process: [ ]

Search

SKU	Product Number	Product Type	Product	Supplier Name	Modify	Delete
wen	123	wood	book	1		
tyygh	45565	air	fdgdg	flyangle		
asdf	asfd	earth	asdf	1		
adsf	afds	water	afa	1		
wen1	12311	wood	123	1		
6544	6544	wood	456	1		
asdas	asdasd	wood	asd	flyangle		
dd	44	wood	kk	1		
kk	45	wood	dd	1		
testSKU	55	wood	test	1		
dddd	441	wood	kk	1		
6	7	wood	7	1		
123	321	air	123	1		
test	test	wood	12	1		

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Add   Back   Upload Product Data: [ ] Browse...   Upload   Template

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.

Internal User

Search

User Name: [   ]

[Search]

Department	User Name	Login Name	Email	Access Level	Status	Modify	Delete
Engineering Dept.	Simon	Simon	service@qitconsulting.com	Level I/QA Manager	Enable		✖
Engineering Dept.	abit	abit	service@qitconsulting.com	Level II/QA Engineer	Enable		✖
Engineering Dept.	L1	L1	service@qitconsulting.com	Level I/QA Manager	Enable		✖
Technology Solutions	sjf	sjf02	service@qitconsulting.com	Level I/QA Manager	Enable		✖
National IT	L3	L3	service@qitconsulting.com	Level III/QA Engineer 2	Enable		✖
Engineering Dept.	L4	L4	service@qitconsulting.com	Level IV/CAR Owner	Enable		✖
Marketing	Jonathan Zheng	JonathanZheng	service@qitconsulting.com	Level V/Department Manager	Enable		✖
Marketing	L4a	L4a	service@qitconsulting.com	Level IV/CAR Owner	Enable		✖
Technology Solutions	Song jf	jf	service@qitconsulting.com	Level V/Department Manager	Enable		✖
Human Resources	Simon Huang	SimonHuang	service@qitconsulting.com	Level V/Department Manager	Enable		✖
Human Resources	dd	dd	service@qitconsulting.com	Level I/QA Manager	Enable		✖
Human Resources	ww	ww	service@qitconsulting.com	Level III/QA Engineer 2	Enable		✖
Technology Solutions	ff	ff	service@qitconsulting.com	Level II/QA Engineer	Enable		✖
Engineering Dept.	lzy	lzy	service@qitconsulting.com	Level I/QA Manager	Enable		✖
Technology Solutions	L11	L11	service@qitconsulting.com	Level I/QA Manager	Enable		✖
Technology Solutions	L22	L22	service@qitconsulting.com	Level II/QA Engineer	Enable		✖
Technology Solutions	L22	L22	service@qitconsulting.com	Level II/QA Engineer	Enable		✖

Mange Group

Click 1) Click " **Setting → Dropdown Field Management → Group**

Click 1) Click " **Setting → Dropdown Field Management → Group Member**

Group Listing

Group	Group Description	Quantity	Modify	Delete
test1	1111	0		✖
bbbbb	a ya	3		✖
ccccc	a ya	1		✖
444	test	2		✖
teas	1234	8		✖
123	453453hjk	9		✖
hjk	dt	0		✖
admin1111	tat	8		✖
fghfgh	rtdg	1		✖
tteesstt	tttttt	6		✖
7	6666	3		✖
rewrew	fvgdfds	1		✖
SCAR Review Board		2		✖
12	Materials	0		✖

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Manage Failure Mode

1) Click1) 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.

Failure Mode

Failure Mode	Modify	Delete
Assay out of Control	📝	✖
Workmanship/Insufficient Training	📝	✖
Improper Procedure/Sequence	📝	✖
Inadequate Machine Setup	📝	✖
Equipment faulty	📝	✖
Material Defect- Incoming Material	📝	✖
Poor Product Design/Difficult to Make/	📝	✖
Transportation Damage	📝	✖
Dimensional OOT	📝	✖
SEA Defect	📝	✖

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Delete or Re-Open a CAR

1) Click 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 CAR

Search

| Year: | 2014 |
| CAPA Number: | |

[Search]   [Reopened CAR Summary]

	CAPA Number	Issuer	Issue Date	CAPA Status		Delete
	SCAR-14-0005	Administrator	03/03/2014	Pending		✖
	SCAR-14-0004	Administrator	02/28/2014	Overdue		✖
	SCAR-14-0003	Administrator	02/28/2014	Overdue		✖
	SCAR-14-0002	Administrator	02/28/2014	Overdue		✖
	SCAR-14-0001	Administrator	02/28/2014	Overdue		✖
	CAR-14-0017	Administrator	04/01/2014	Pending		✖
	CAR-14-0016	Administrator	03/31/2014	Closed On Time	Reopen	✖
	CAR-14-0015	Administrator	03/12/2014	Overdue		✖
	CAR-14-0014	Administrator	03/12/2014	Overdue		✖
	CAR-14-0013	Administrator	03/05/2014	Open		✖
	CAR-14-0012	Administrator	03/03/2014	Open		✖
	CAR-14-0011	Administrator	02/28/2014	Overdue		✖
	CAR-14-0010	Administrator	02/28/2014	Overdue		✖
	CAR-14-0008	Administrator	02/26/2014	Overdue		✖
	CAR-14-0007	Administrator	02/26/2014	Closed On Time	Reopen	✖
	CAR-14-0006	Administrator	02/14/2014	Overdue		✖

Manage Supplier

1) Click 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) Click " **Setting ➔ Dropdown Field Management ➔ Manage Supplier Account"** to add the supplier account. The default password is the supplier's contact email address.

Supplier Listing

Search

Supplier Name: [ ]

[Search]

Supplier No.	Supplier Name	Contact Name	Email	Home Page	Modify	Delete
1	1	1	wangyikang050601@163.com	1	📝	✖
2008	sun	shine	wangyikang050601@163.com	2222	📝	✖
CT0000	flyangle	sjf	wangyikang050601@163.com	http://www.baidu.com/	📝	✖
435	453		17j@qqsvc.fdg		📝	✖
QIT 123	QIT Consulting		service@qitconsulting.com		📝	✖

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Manage Supplier Account

1) 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.

Auto-warning Settings

1) Click 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

Auto-warning Setting

Auto-warning Setting
Email Setup:
Smtp Server: smtp.gmail.com
Smtp Server Port: 465
Account: qit.autowarning@gmail.com
Password: ••••••••
Email Priority: Low
Email Format: Html
Use SSL: ⦿ Yes ○ No
Send a testing message to: [Test Account Setting] Test

Email Recipient Setup:
Please check the name to enroll people who need to receive auto-warning email!

☐ 11111
☐ abit
☐ bryan
☐ dd
☐ ff
☐ kevin
☐ L1
☐ L11
☐ L22
☐ L22

☑ Send a warning email when the CAPA is due in the next 7 days.
  ☑ Send email to Issuer
  ☑ Send email to CAPA Owner
  ☐ Send email to the selected group
☑ Send a warning email ONLY when the CAPA is overdue.
  ☑ Send email to Issuer
  ☑ Send email to CAPA Owner
  ☐ Send email to the selected group
☐ Use system to send email .
☑ Use user's default email client e.g. Outlook to send email.
☑ Send a warning email when the Audit is due in the next 30 days.
☑ Send a warning email when the Audit is Overdue.

Save Settings	Load Default	Auto-warning Email	Auto Email Configure

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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'

Online User Control

Search
On-Line: On-Line
Login Name:
Search

	Login Name	User Name	Login Time	Access Level	Department	Email	Status	
👤	jim.smith	Administrator	04/03/2014	Administrator	Engineering Dept.	service@qitconsulting.com	On-Line	Logout

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account is blocked due to abnormal logout.	