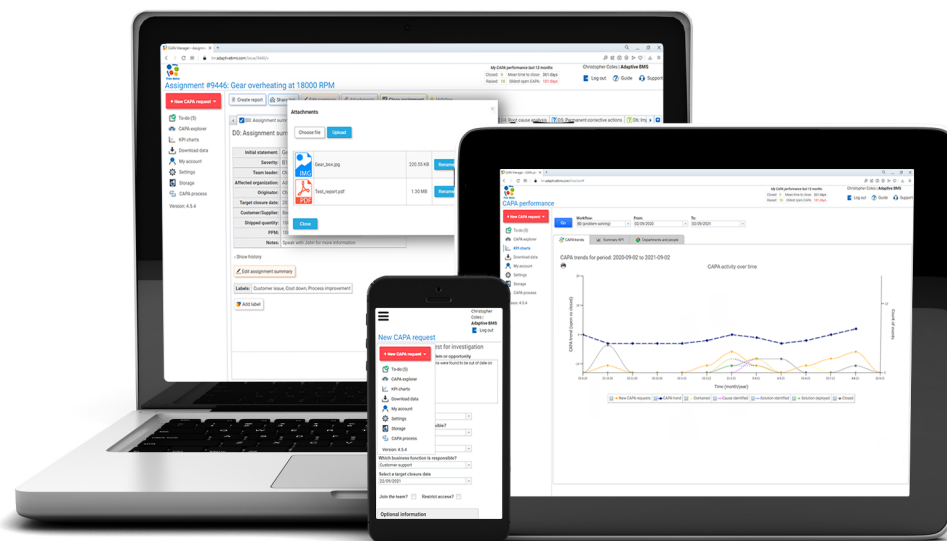


CAPA Manager User Guide

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A. Welcome to CAPA manager

A.1 Introduction

This guide provides basic instructions on how to use the CAPA manager software.

Most CAPA Manager questions should be answered in this User guide. If you're unable to find the answers to your questions, then please contact support-team@adaptivebms.com for more information.

A.2 Why use CAPA manager?

Adaptive CAPA Manager provides an electronic Corrective Action and Preventive Action (CAPA) solution for your business and supply chain. CAPA Manager software allows organisations and their teams to record, investigate, track and conclude improvement opportunities.

Typical applications include:

- Continuous Improvement management (CI)
- Corrective Action Reporting (CAR)
- Quality management
- Supplier quality management
- Audit action management
- Health, safety and environmental management (HSE)

CAPA Manager ensures that new improvement requests are assigned to the right person in your organization, stakeholders are kept informed of progress via auto e-mail updates. Adaptive CAPA Manager is intuitive to learn, easy to use and compliant. The system should help your business to quickly gain the competitive edge by allowing your teams to improve rapidly.

A.3 CAPA Manager features

- Compliant for ISO 9001, ISO 14001, OHSAS 18001, AS9100, ISO 9001, TS 16949 and QSR 820
- Multiple workflows: 8D, A3, DMAIC, PDCA, 8 Step, Audits, HSE investigations
- Instant Corrective Action Reports (CARs)
- Automatically allocate CAPA responsibility
- Automatic email notification
- Classify and prioritize issues
- Improvement statistics and data download
- Root cause toolkit - 6M (Ishikawa) and 5 Why
- Attach files to CAPA assignments
- Mobile device compatible
- Data download option
- Advanced CAPA labeling features
- CAPA follow-up verification function
- More...

B. Getting started

B.1 How to request an Adaptive CAPA Manager account?

Creating a CAPA manager account is quick and straightforward. You can sign up on our website [here](#). Enter your name, email and organisation, then click '**Create my CAPA manager account**'. This will give you instant access to a free demo account.

To request a fully functioning CAPA Manager account with more users and features, head to our pricing page [here](#).

Upon creating your new CAPA Manager account, you will be emailed your credentials and a link to the login page.

B.2 Log in to CAPA Manager

Upon creating your CAPA Manager account, you will have been emailed your account credentials and a link to the log in page. Navigate to the CAPA Manager log in page, enter your credentials and click the 'Log in' button.

Note: You will automatically be logged out after 60 minutes of inactivity.

Note: We recommend bookmarking the login page to save time when accessing CAPA Manager in the future.

Note: You may be asked for a secret code when you log in for the first time. This code will be sent to your registered email address automatically.

Email

email@address.com

Password

.....

Log in

B.3 Raise a new CAPA request (case, opportunity, audit action)

To request a new CAPA click the **'New CAPA request'** button in the left sidebar.

New CAPA request ▼

Note: The 'New CAPA request' button will automatically choose the default workflow as defined in the Setting menu. Choose alternative workflows by using the click-spot on the right-hand side of the button.

The New CAPA request page will be displayed. Fill in the prompted information as required:

Raise a new CAPA request for investigation

Enter a description of the problem or opportunity

1

2 Select workflow
8D (problem solving)

3 Which organization is responsible?
WillSpace

4 Select a priority
B2-8D: Minor build or customer issue, Cost dow

5 Which business function is responsible?
Logistics and stores

6 Select a target closure date
25/01/2023

Join the team? ☐ Restrict access? ☐

Request CAPA

Abandon changes

Optional information

Customer

Product

Shipped quantity

Quantity defective

Attachment
Choose File No file chosen

General notes
These notes will not be included in any report

7

1. Enter a description of the problem or opportunity

Briefly describe the opportunity or problem. Be clear, concise and descriptive.

2. Select a workflow

This cell will pre-populate to the default workflow as defined in settings. Choose a different workflow if this is needed.

3. Select a priority

Select the appropriate severity rating for the CAPA assignment. This rating may be used to help prioritize open CAPA assignments and requests.

4. Which organization is responsible?

Select the organization to be assigned the CAPA request.

Note: Linked organisations need to be set up by an administrator of your account.

5. Which business function or department is responsible?

Select the business function to be assigned the CAPA request.

6. Select a target closure date

Select the target closure date for the CAPA assignment.

7. Attaching files and optional data fields

Supporting images and documents may be added when raising a new CAPA assignment. Additional data may also be added if needed.

The screenshot displays two side-by-side form sections. The left section, titled 'Optional information', contains five input fields: 'Auditor', 'Auditors reference', 'Audit standard', 'Clause and text', and an 'Attachment' section with a 'Choose file' button and the text 'No file chosen'. The right section, titled 'General notes', has a sub-header 'These notes will not be included in any report' and a large, empty text area for notes.

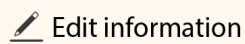
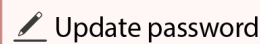
Click the **'Request CAPA'** button to record and assign the CAPA request, or the **'Cancel and return to previous page'** button to abandon the changes.

Request CAPA

C. People and users

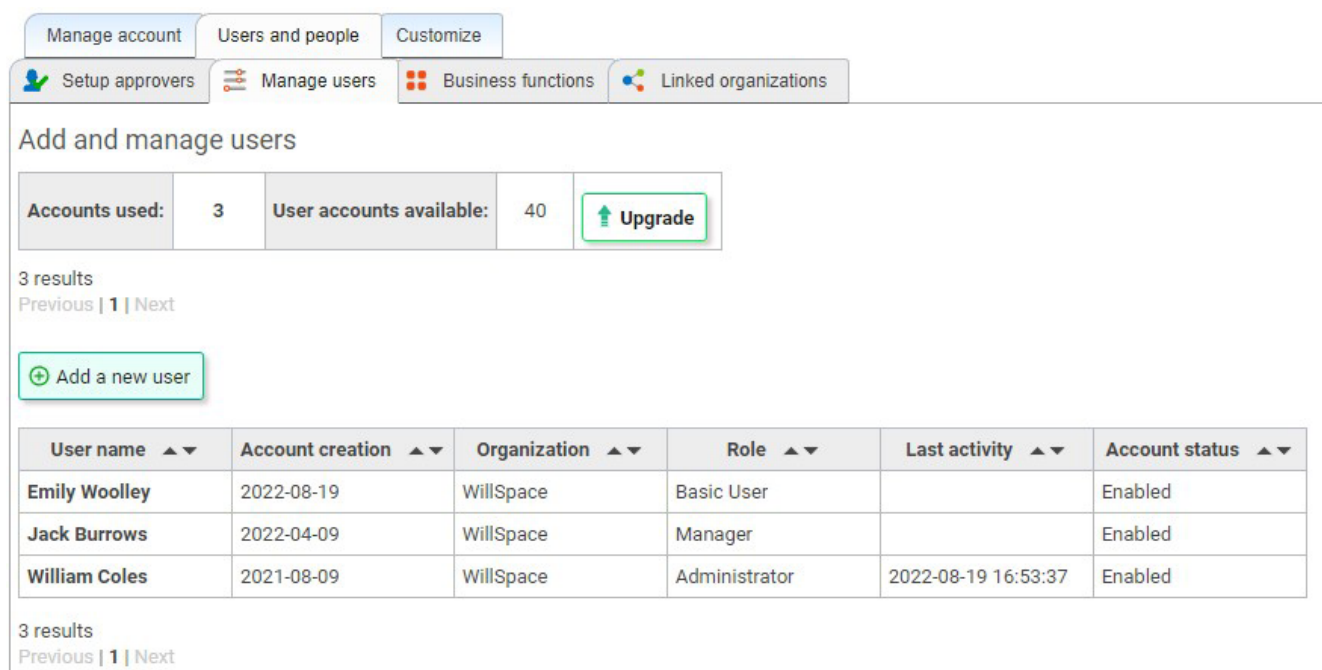
C.1 Updating your account details

You can change your Account details in the 'My account' section in the left sidebar. Here you can update your password and edit personal information.

C.2 Adding new users

Using the left navigation bar, go to '**Settings**', '**Users and people**', then '**Manage users**'. Here you can view all currently defined users connected to your organization and add new ones. The number of user accounts you have used and are available can also be viewed here.



User name ▲▼	Account creation ▲▼	Organization ▲▼	Role ▲▼	Last activity ▲▼	Account status ▲▼
Emily Woolley	2022-08-19	WillSpace	Basic User		Enabled
Jack Burrows	2022-04-09	WillSpace	Manager		Enabled
William Coles	2021-08-09	WillSpace	Administrator	2022-08-19 16:53:37	Enabled

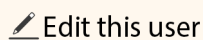
C.2.1 Adding a user to your organization

Click on the '**Add a new user**' button. Enter the full name and email address for the new account, then select '**Create new user account**'. You will be taken back to the '**Manage users**' page, where you should now be able to see the new user.

Tip: Upgrade to a premium account to add more users!

C.2.2 Edit or disable a user

To edit a users details, click on the user's name whilst on the **Manage users tab**, then select **'Edit this user'**. On this page, you can add or edit details as desired. Click **'Save changes'** to update or **'Leave without changes'** to abandon.



Note: Here, you can also disable the user if required. This action can be reversed.

C.2.3 Account types and user roles

Users must be allocated an account type when first created. This can be done by using the **'Account type'** drop-down selection whilst on the **edit user account details** page. Click **'Save changes'** to keep selection.

Account type

Basic user

▼

Basic user

Manager

Administrator

Save changes

Account type determines which CAPA Manager features are available to that user. The table below gives an overview of the differences between each option:

Function	Basic user	Manager	Administrator
Request CAPA:	✓	✓	✓
View CAPA assignment details:	<i>All CAPA's (not hidden)</i>	<i>Any</i>	<i>Any</i>
Edit CAPA assignment:	<i>As a team leader or member</i>	<i>Any</i>	<i>Any</i>
Edit problem statement:	<i>New CAPA only</i>	✓	✓
Delete a CAPA assignment:	-	-	✓
Setup users:	-	-	<i>Add/delete</i>
Setup business functions:	-	-	<i>Add/delete</i>
Settings menu:	-	-	<i>Full control</i>
Approve new assignments:	-	<i>If an approver</i>	✓
Approve assignment closure:	-	<i>If an approver</i>	✓
Download .csv:	<i>Requires activation</i>	<i>Requires activation</i>	<i>Always</i>

C.3 Team roles and responsibilities

Forming a team will help you complete CAPA assignments. Open the **'Form the team'** tab on the CAPA assignment and click the **'Manage team'** button. You can view all available users and select the users you would like to join the team. When finished, save changes to complete.

Tip: you can search for names using the search bar on the same page.

Tip: New team members will be notified by email.



C.3.1 Defining team roles

When adding users to the CAPA investigation team, you can define each person's role and responsibilities. To set a team member's role, Select the **'Edit role'** icon next to the team member's name on the **Form the team** investigation tab.

D1: Form the team - 8D (problem solving)

Team leader: William Coles

Tip: Change **Team Leader** under 'Edit summary'

No.	Name	Role	Edit role
#1	Jack Burrows	Subject matter expert	
#2	Emily Woolley	Six Sigma Black belt	

 Manage team

D. Working with CAPA investigations

D.1 CAPA Manager workflows

The CAPA manager workflow steps are displayed within each tab. The workflows run from left to right. The assignee or CAPA teams can enter data under each tab to complete the CAPA investigation.

D3: Interim containment actions - 8D (problem solving)

Interim containment action statement:	Local teams trained in the risk of cross contamination, 14th April 2022 All storage shelves checked to ensure products are segregated, 14th April 2022 All stock checked for contamination, 14th April 2022 Customer informed of issue, 15th April 2022
Containment status:	Local teams trained in the risk of cross contamination, 14th April 2022 All storage shelves checked to ensure products are segregated, 14th April 2022 All stock checked for contamination, 14th April 2022 Customer informed of issue, 15th April 2022
Author:	Christopher Coles
Target completion date:	2022-04-15
Date:	2022-04-13







[Edit containment actions](#)

Workflow Steps:

- ☒ D0: Summary and immediate actions
- ☒ D1: Form the team
- ☒ D2: Define the problem
- ☒ D3: Interim containment actions
- ☒ D4: Root causes
- ☒ D5: Plan permanent corrective actions
- ☒ D6: Implement permanent corrective actions
- ☒ D7: Prevent recurrence
- ☒ D8: Recognize the team
- ☐ Follow-up

D.1.1 Color coded steps

CAPA Manager Action: Incomplete steps display the '?' icon in their tab. The tab icon will change to a 'tick' when data has been added into a workflow stage. Closed CAPA's pending a follow up review will display a purple icon.

-  Amber: New CAPA task, gathering facts and data
-  Yellow: Issue contained. Initial action taken
-  Blue: Root cause analysis started
-  Green: Permanent actions being deployed
-  Gray: Closed
-  Purple: Closed, pending Follow-up inspection

D.1.2 Editing CAPA assignment stages

To add data to a step, click on its tab and select the edit icon:

Enter data as needed, then click the **'Save changes'** button to record your data.

Note: Changes to the D0 Tab are recorded to provide an auditable history.

D.1.3 Following CAPA assignments

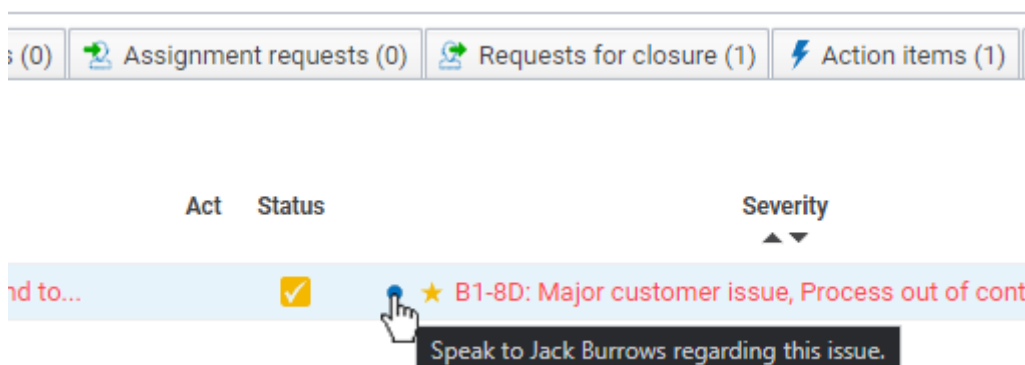
Following a CAPA allows you to identify investigations of particular interest to you. 'Followed' CAPAs will display the yellow 'following' icon in all list views. You will also receive email notifications when fundamental changes are made to these assignments.



You can follow a CAPA by selecting the grey **'Follow'** button towards the top of the page whilst viewing the CAPA assignment.

D.1.4 General notes

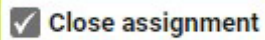
The General notes text box allows CAPA teams to keep casual notes to help with investigation activities. General notes are added and edited when raising a CAPA and in the Edit CAPA summary tab. The General Notes Icon will be displayed in all list views if notes have been added. To read these from a list view, simply hover your mouse pointer over the Blue dot icon.



Note: General notes will not be presented in the Final report. A history of general note changes is not maintained.

D1.5 Closing a CAPA assignment

Go to the CAPA assignment that you wish to close. At the top of the page, select the '**Close assignment**' button. A confirmation page will be displayed, where you'll also have the option to schedule a follow-up review. Click '**Yes**' to confirm the closure of the assignment.

A rectangular button with a thin green border and a light grey background. It contains a small black square icon with a white checkmark inside, followed by the text "Close assignment" in a bold, black, sans-serif font.

CAPA Manager Action: CAPA Manager will change the assignment status to closed (Grey), and the originator and team will receive an e-mail notification.

D.2 Selecting, Searching and viewing CAPA assignments

There are two methods of accessing current CAPA assignments; these are described below:

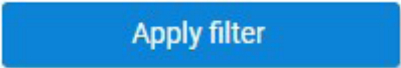
D.2.1 To-do page

The **To-do** page is accessible via the left-hand sidebar. Here, you can select assignments you have raised or have been assigned by clicking on either the **My CAPA assignments** or **My CAPA requests** tabs.

Select and click on the CAPA assignment that you want to view.

D.2.2 CAPA explorer page

CAPA explorer can also be found in the left sidebar. All CAPA assignments will be displayed here. Use the filters to navigate the assignments, and click '**Apply filter**' to activate your selection. From here, you can select the assignment that you want to view.




Apply filter

Note: CAPA explorer reports can be produced by clicking the '**Print report**' button

D.3 Labeling CAPA assignments

CAPA assignments can be associated with editable labels to help future searching and analysis. On the Summary and immediate actions page, click '**Add label**' and select the labels that apply to the assignment.



Add label

Note: Labels can be defined via the **customize** tab in settings. Unique labels are defined for each workflow.

D.4 Action items

CAPA Manager provides a simple task list for use within CAPA assignments. The Action items task list can be activated by clicking on the '**Action items**' button in any CAPA assignment:

Assignment #11213: Batch #2345 of the assembly 23-4532-23 Valve v

My CAPA performance last 12 months
 Closed: 3 Mean time to close: 140 days
 Raised: 12 Oldest open CAPA: 387 days

Christopher Coles | Adaptive BMS
 Log out Guide Support

Action items for assignment: #11213

No.	Action detail	Responsible	Time	Target date	Complete?	Edit	Delete
1	Check local training register to ensure cross-contamination risk is covered.	Jane Walters	n/a	2022-04-13	✓		
2	Set Maximum SAP stock limit for the Valve build area	John Smith	10 days remaining	2022-09-15	No		

The task list applies to the entire CAPA assignment and is not stage-specific. The following functions are provided:

- Add a new action
- Assign a target date
- Complete an action
- Edit an action
- Delete an action

Only assignment owners, team members, and administrators can interact with the task list.

D.5 Attachments (Premium accounts only)



Attach supporting files to CAPA assignments using the file attachment feature. Supporting documents like images, documents and drawings can be attached to a CAPA assignment when creating a new CAPA or editing.

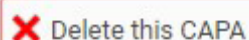
- Each uploaded file is limited to a maximum size of 1Mb
- Your organization will have a predefined amount of file storage assigned to it
- Contact our support team to understand or change these limits

Tip: Reduce file size and delete unneeded attachments to maximize storage space!

D.6 Deleting CAPA assignments (Premium accounts only)

Administrators are offered a '**Delete CAPA**' feature found at the bottom of the **Edit assignment summary** screen. When this button is activated, all CAPA details and history are removed from the system. An email is sent to all other system admins and the CAPA owner, informing them that the CAPA has been deleted, who deleted it and the initial problem statement text.

Note: Deleted CAPA assignments cannot be recovered.


 A rectangular button with a red border and a red 'X' icon followed by the text 'Delete this CAPA'.

D.7 Restricting access to private assignments

It is possible to restrict who can see the details of any assignment. Only the assignment team can see the assignment details when this feature is enabled.


 The text 'Restrict access?' followed by a checked checkbox.

When raising a new assignment, private assignments can be enabled by selecting 'Restrict access'. Once raised, only the team leader can switch this function on or off by editing the assignment summary.

The table below shows who can see restricted CAPA data and who cannot.

Restricted CAPA data visible to:						
Private CAPA status	Assignment leader	Assignment team	Administrator	Requestor	Manager	Other users
List view: Not in the team	Yes	Yes	Yes, without detail	Yes, without detail	No	No
List view: In team	Yes	Yes	Yes	Yes	Yes	Yes
See text detail	Yes	Yes	No	No	No	No
Change team leader	Yes	No	Yes	No	Yes	No
Interact with attachments	Yes	Yes	Can delete, not open	No	No	No
Assignment/Closure approval requests	Only if a nominated approver.	Only if a nominated approver.	No detail, can select leader, or approve closure	No	No detail, can select leader, or approve closure	No
Turn off Privacy	Yes	No	No	No	No	No

E. Notifications

E.1 Auto reminder features

CAPA Manager includes a powerful notification engine. The application will automatically send an email to key stakeholders and users under certain conditions:

E.1.1 Approaching reminder notifications

Team leaders can be automatically reminded via email if they have open assignments approaching their due dates.

This feature can be enabled and set up via the **Settings** menu. Go to **Organization** or **General settings**, then find the **Notification emails** tab on the **Edit details** page.

E.1.2 Overdue reminder

Team leaders can be automatically reminded that they have open assignments that are past their due dates. This feature can also be switched on via the Notification emails tab.

Note: Notifications are controlled under the **General settings** tab in the **Settings** screen.

Change settings

CAPA approvals Default settings Organization details Notification emails Purchasing contact

Reminders are sent for overdue assignments

☐ Never.

☒ At the start of each week.

☐ At the start of each month.

☐ At the start of each quarter.

Reminder notifications are sent before target closure date


☐ Off

☐ 1 Day

☒ 5 Days

☐ 10 Days

Save changes

 **Go back**

E.2 Standard notifications

Aswell as reminder features, CAPA manager notifies users with the standard messages described below:

All users

- Initial account login credentials
- Login security code for two-step authentication (enabled in settings)
- Password reset link

Team leader (CAPA owner)

- When a new CAPA request is assigned to them
- If a CAPA is approaching the scheduled closure date (Settings> Manage account> Account settings)
- If a CAPA is late for closure (Settings> Manage account> Account settings)

Originator (The user who initially raised the CAPA)

- When a CAPA, raised by them has been closed

Team members (The CAPA team)

- Team members will be informed when they are added to a CAPA team
- When a CAPA assignment they are involved with is closed

Approvers

- Approvers are informed when a new CAPA request requires approval

Note: Approvers are defined under **settings**.

Followers (When 'Follow' is selected in the CAPA)

- Followers are informed when key CAPA information has been changed.

Administrators

- All account administrators are notified when a CAPA is deleted

F. CAPA approvals

F.1 Approve new CAPA assignments and closures

Enforcing approval for CAPA requests before they are assigned or closed is made possible with CAPA manager. This function can be toggled under Approval policy within **Settings, Manage account, General settings**. When either feature is enabled, the nominated approver is responsible for allowing CAPA requests and assignments to move through the CAPA manager system.

The screenshot displays the 'Settings' page in CAPA Manager, with the 'General settings' tab selected. The 'Approval policy' section is highlighted with a blue border. It contains the following configuration options:

- Basic system logic:**
 - Organization-wide default Team leader for new tasks: William Coles
 - Default Workflow for new tasks: SD (problem solving)
 - CAPA numbering option:
 - ☐ Sequential (recommended)
 - ☒ Non-sequential (superseded)
- Approval policy:**
 - All users may close their CAPA assignments without approval:**
 - ☒ Yes: Any user may close a CAPA assigned to them.
 - ☐ No: CAPA assignments will be routed to an Approver or Administrator for final closure.
 - New CAPA requests are automatically assigned:**
 - ☒ Yes: New CAPA requests will be assigned based on the business function affected by the issue, or fall back to the organization-wide default (see below).
 - ☐ No: New CAPA requests will remain unassigned and will be routed to an Approver, Manager or Administrator for assignment.
 - Assignment target closure dates are updated automatically:**
 - ☐ Yes: CAPA assignment target closure dates are automatically updated as the task is progressed.
 - ☒ No: CAPA assignment target closure dates are always set manually.

Tip: When a new CAPA request is assigned to this organization, and if the auto-assignment feature is enabled by the organization's administrators, it will be automatically assigned to the default Team leader nominated below if either (1) no business function was selected for the assignment, or (2) no auto-assignee was set up for that business function. Of course, the CAPA assignment can be reassigned later if necessary.

- Notification policy:**
 - Reminders are sent for overdue assignments:**
 - ☒ Never.
 - ☐ At the start of each week.
 - ☐ At the start of each month.
 - ☐ At the start of each quarter.
 - Reminder notifications are sent before target closure date:**
 - ☒ Off
 - ☐ 1 Day
 - ☐ 5 Days
 - ☐ 10 Days

A 'Save changes' button is located at the bottom of the 'Approval policy' section.

F.1.1 Setup approvers

In **Settings** navigate to the **Setup approvers** tab under **Users and people**. Here, you can select company approvers from the list.

- Only Administrators and Managers can appoint an approver
- At least one approver must be defined for your organization

F.1.2 CAPA approvals

On the **To-do** page, approvers will be presented with the following tabs:

- Assignment requests
- Closure requests

A list of CAPA requests and assignments awaiting approval can be found under the **Assignment requests** and **Requests for closure** tabs.

F.1.3 Approve a new CAPA request

To assign a new CAPA request, click on it and select an assignee.

F.1.4 Approve the closure of a CAPA request

To approve an assignment for closure, open the assignment and select '**Close assignment**'.

F.2 Follow-up inspections

Follow-up inspections allow the CAPA Team to schedule a future review of corrective actions to check the effectiveness.

When a Follow-up inspection is scheduled, the CAPA can be closed but will retain the 'Pending Follow-up' status.

F.2.1 How to initiate a Follow-up inspection

Follow-up inspections are initiated by selecting the Follow-up inspection check box under the Corrective action tab or the Close CAPA dialogue box.

When activating a Follow-up inspection, you will be prompted to enter a target date and nominate an assessor. Also, a new Follow-up tab is displayed in the CAPA to collect Follow-up inspection status.

Note: When the CAPA is closed pending Follow-up, a notification email is sent to the nominated assessor. The Follow-up task will appear on their To-do list.

F.2.2 Approving a Follow-up inspection

Follow-up inspections are approved by entering data in the 'Follow-up' tab in the CAPA and checking the Approved box.

G. Reports and data export

G.1 Producing a corrective action report

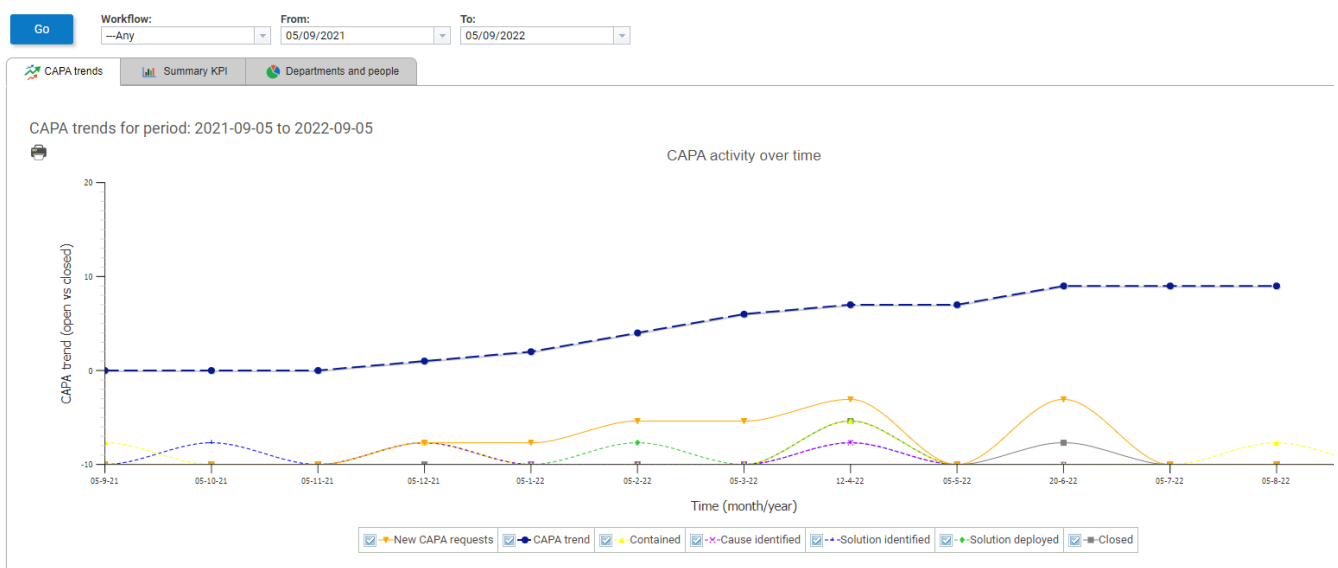


Selecting the '**Create report**' in any CAPA assignment will bring up the 8D report page. The report can be saved or printed via your web browser. A corrective action report can also be generated directly from any list view by clicking on the **CAPA report** icon next to the CAPA assignment name.

Note: 5Why and 6M tools will not be displayed in the report if they contain no data.

G.2 KPI charts

Use the left navigation bar to view your KPI charts. A full range of graphical views and reports are available. Select the type of graph or report you require using the tabs and dropdown selections.



G.3 Exporting data for analysis (Premium only)

The data download tool can export a copy of your organization's CAPA database in .csv format for analysis using third-party software packages. This function is always available to administrators and can be granted to any user under the Edit user page.

You can generate a filtered report directly from the CAPA explorer page found in the left-hand sidebar.

H. Setting up and configuration

H.1 Editing severities and workflows

CAPA Manager comes pre-equipped with powerful workflows. You can find a complete list of the available workflows at the end of this guide on the CAPA Manager workflows page.

H.1.1 Customize severity text

Severity text can be configured for each workflow. Doing so allows audit workflows to use different severity text for problem-solving workflows. Administrators can edit the business severity rating text on the **'Define severities'** tab via the **'Settings'** menu.

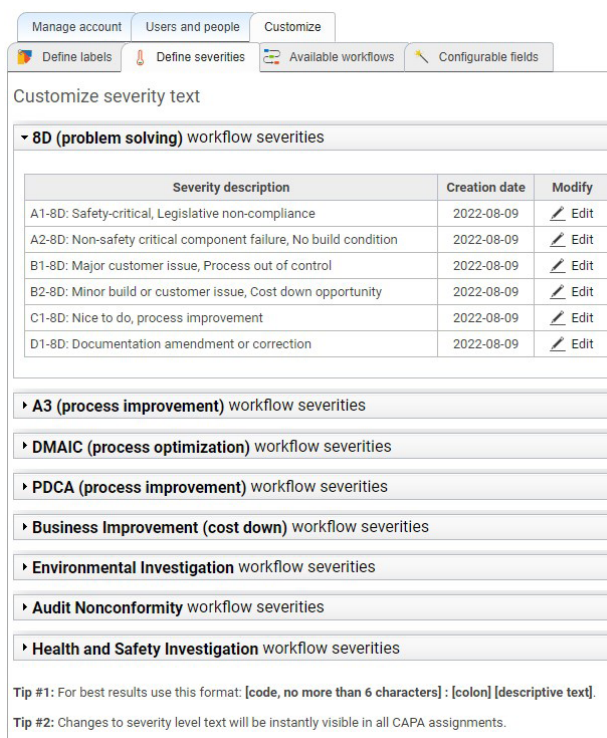
Tip: For the best results, use this text format:

[code, 6 characters] : [colon] [descriptive text].

Note: Pre-defined severity text can be found on the **'CAPA Manager default Severity levels'** page at the end of this user guide.

H.1.2 Switch off unwanted workflows

It is possible to disable unwanted workflows, so they are not available for the users to select. Administrators can disable workflows on the **'Define severities'** tab in **Settings**.



The screenshot shows the 'Define severities' tab in the CAPA Manager settings. The interface includes tabs for 'Manage account', 'Users and people', and 'Customize'. Under 'Customize', there are sub-tabs: 'Define labels', 'Define severities' (active), 'Available workflows', and 'Configurable fields'. The main heading is 'Customize severity text'. Below it, a section titled '8D (problem solving) workflow severities' contains a table with severity descriptions, creation dates, and edit links. Other workflow categories are listed below the table, each with a dropdown arrow.

Severity description	Creation date	Modify
A1-8D: Safety-critical, Legislative non-compliance	2022-08-09	Edit
A2-8D: Non-safety critical component failure, No build condition	2022-08-09	Edit
B1-8D: Major customer issue, Process out of control	2022-08-09	Edit
B2-8D: Minor build or customer issue, Cost down opportunity	2022-08-09	Edit
C1-8D: Nice to do, process improvement	2022-08-09	Edit
D1-8D: Documentation amendment or correction	2022-08-09	Edit

Below the table, the following workflow categories are listed with expandable arrows:

- A3 (process improvement) workflow severities
- DMAIC (process optimization) workflow severities
- PDCA (process improvement) workflow severities
- Business Improvement (cost down) workflow severities
- Environmental Investigation workflow severities
- Audit Nonconformity workflow severities
- Health and Safety Investigation workflow severities

Tip #1: For best results use this format: [code, no more than 6 characters] : [colon] [descriptive text].

Tip #2: Changes to severity level text will be instantly visible in all CAPA assignments.

H.2 Adding/changing a business function

Business functions are at the heart of CAPA Manager. CAPA Manager decides whom to assign investigations based on the responsible business function chosen when raising a new CAPA request. To Browse and add functions, Go to **Settings**, then to the **Business functions** tab. A table of currently defined Business Functions and their relevant default team leaders will be displayed.

H.2.1 Edit a business function

Select the Business Function you want to edit or to see further details about that function. Click on the **'Edit details'** button to edit the name or default Team leader as required. Click **'Save changes'** to record or select **'Cancel changes'** to return to the previous page.

H.2.2 Add a new business function

Click on the **'Add a new business function'** button, enter the new Business Function name and select its default assignee as required. Click the **'Save changes'** button to record or the 'Cancel and return to previous page' button to abandon the changes.

Tip: Business functions cannot be deleted. If you want to remove a business function, you will need to rename it as 'N/A' or similar.

H.3 User configurable fields

Administrators can configure some data fields to match the organization's particular needs. Go to the **settings** menu via the left sidebar > **Customize**, then select the **Configure fields** tab to set the field name and field tooltip using the **'Edit'** buttons.

Note: User-defined fields are not available for the audit workflows. Compliant fields are already pre-defined for these.

H.4 Security policy setup

CAPA Manager user access can be configured to meet your organization's security policy. Administrators can access these options under **Settings > Manage account > Security Policy**.

Account security rules

Enable math recapture:	<input checked="" type="checkbox"/>
Password Expiry(days):	365 ▾
Enforce special rules:	<input checked="" type="checkbox"/>
Enable two-step authentication:	<input checked="" type="checkbox"/>

H.4.1 Password strength minimum requirement

As a minimum, all CAPA Manager user passwords must be at least eight characters long. They must contain one uppercase, one lowercase, and one numeric character.

H.4.2 Enforce password special rules (recommended)

Special rules can be enabled to ensure all passwords contain at least one special character (£&# etc.) and cannot have three consecutive characters (111, bbb etc.) When switched off, only the minimum requirements apply.

H.4.3 Password expiry option (recommended)

Password time limits can be set to suit your needs. If this feature is enabled, users will be forced to update their passwords at the interval required by your organization. Expiry notifications will begin seven days before password deletion.

If a user's password expires before they can update their details, they should use the reset password link on the Log in page to generate a new password. When set to none, the same password can be kept indefinitely.

H.4.4 Failed attempt banning options

CAPA Manager only tolerates three failed login attempts. After three failed attempts, CAPA Manager will take action to prevent a possible security risk by either:

- Banning the user account for 24Hrs.
- Offer a math recapture dialogue.

An account administrator can set the above security logic.

Un-banning a user account

Account administrators can unban users anytime by editing their user details and selecting the **'Reset security'** button. This button resets the failed login attempts counter for that user.



H.4.5 Two-step authentication (recommended)

When enabled, this feature will track the IP address and location of all users. If the user changes physical location, a verification email will be sent to their email address. The email will contain a secret code which must be entered to gain access to the system. When switched off, the user's physical location is not tracked.

H.5 Linking to other organizations

Via the left navigation bar, head to **Settings > Users and people > Linked organizations**. The **'Linked organizations'** tab will present a table of currently defined linked organizations.

You can raise and allocate CAPA assignments to linked organizations and track progress. CAPA assignments that have been passed on to another organization may be viewed by the initiator. Only teams within the organization can update and progress CAPA requests assigned to them.

H.5.1 Add a new organization

Click the **'Create a linked account'** button and enter the new Organizations name and other information as required. When finished, click the **'Create linked demo account'** button to save changes or **'Abandon changes'**.

I. Additional features

I.1 Language translation

CAPA Manager has been designed to be compatible with your favourite browser translator.

I.2 Tablets and handheld devices

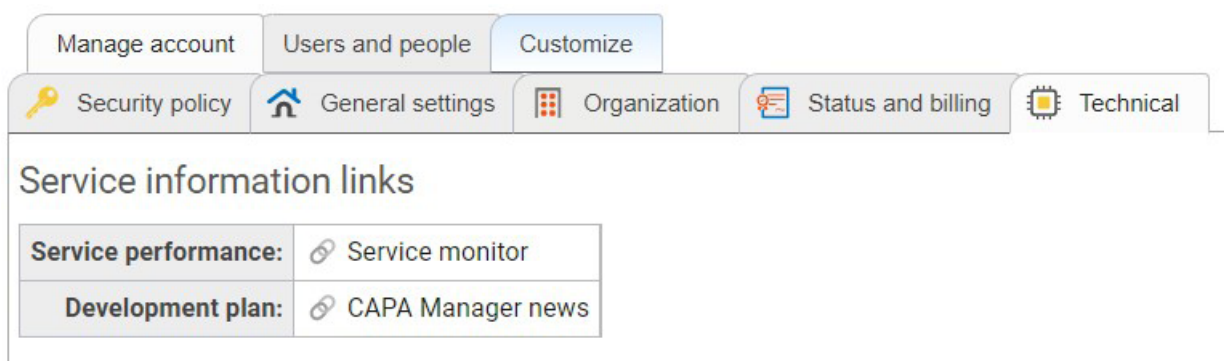
CAPA Manager works excellent on most Tablet PCs and other handheld devices. This enables users to record opportunities for improvement and progress issues whilst on the move.

I.3 Support and help

If you experience difficulties, don't hesitate to contact support@adaptivebms.com describing the issue encountered and the browser version you are using. We'll aim to resolve the problem as fast as we can.

I.4 System status and development news

System status history, technical bulletins and CAPA Manager Development news can all be easily found via: **Settings > Manage account > Technical**



I.5 Security information

Your browser and the CAPA Manager server communicate via premium HTTPS (Hypertext Transport Protocol Secure). This provides security against eavesdropping and 'man-in-the-middle' tampering with data. Individual user accounts are password protected, and failed attempt banning is also incorporated into this system.

Users must follow secure and sensible password policies. The CAPA Manager software does not enforce any particular password policy since different Organizations have different (and mutually incompatible) standards. However, the following points may serve as a broad guideline:

- Passwords should be of sufficient complexity, changed regularly and never revealed to a third party, deliberately or inadvertently - not even to employees or representatives of Adaptive Business Management Systems Ltd. We will not, under any circumstances, ask users to reveal their passwords to us.
- User accounts should never be shared by two or more people.
- Users should change their passwords immediately if they suspect that the secrecy of their current ones may have been compromised.

Unfortunately, Adaptive Business Management Systems Ltd. cannot accept responsibility for any loss or alteration of information or any breach of privacy caused by an intruder successfully 'cracking' a user's password. Please see our Security statement, which can be downloaded from our web page for more information about security: <https://www.adaptivebms.com/>.

If you require alternative security arrangements, please get in touch with our support team, who will be happy to provide what you need.

I.6 System requirements






Compatible Browsers:

- AOL®
- Google Chrome™
- Firefox®
- Internet Explorer®
- Konqueror®
- Mozilla®
- Netscape
- Opera browser©
- Safari®
- Any other standards-compliant browser

Note: Older, non-compliant browsers may not display CAPA Manager pages correctly or may not fully support some of the system's functionality. If you experience problems, ensure that:

- You are using the latest version of your browser software
- You have JavaScript enabled

I.7 CAPA Manager Workflows

8D (Problem-solving)	Business improvement (Cost down)	DMAIC (Process optimization)	PDCA (Process improvement)	A3-PDCA (Process improvement)	H&S Investigation	Audit Non- conformity	Environmental incident
D0: Assignment summary	Assignment summary	DEFINE: Problem statement	PLAN: Opportunity summary	PLAN: Project title	Incident description	Non-conformance statement	Brief incident description
D1: Form the team	Identify support team	DEFINE: Form the team	PLAN: Form the team	PLAN: Form the team	Investigating team	Responsibility	Investigating team
D2: Describe the problem PPM: Calculator	Pre-diagnostic (initial top-level data gathering)	DEFINE: Describe customer, process & expected output PPM: Calculator	PLAN: Establish objectives and plan changes	PLAN: Define current condition PPM: Calculator	Description of incident Audit data	Evidence and clause Audit data	Description of incident Audit data
D3: Interim containment actions	Diagnostics (identify key measures)	MEASURE: Define measurement plan	DO: Make interim changes	PLAN: Define the goal	Remedial immediate actions	Immediate corrections	Remedial immediate actions
D4: Root cause analysis 	Analyze data (define current state)	ANALYZE: List analysis summary	DO: Define and deploy measures	PLAN: Root cause analysis 	Actual probable causes 	Root cause causes 	Actual probable causes 
D5: Permanent corrective actions	Design the 'To- be' model	IMPROVE: Define opportunities	CHECK: Analyze results	DO: Deploy countermeasures	Permanent corrective actions	Corrective action summary	Permanent corrective actions
D6: Implement and validate	Define rollout plan	Describe deployment plan	ACT: Identify further changes	CHECK: Effective confirmation	Deploy corrective actions	Corrective actions	Deploy corrective actions
D7: Prevent recurrence	Implement changes	CONTROL: Define ongoing measures	ACT: Further improvement plan	ACT: Follow-up actions	Detail procedure changes	Management system changes	Detail procedure changes
D8: Closure and team celebration	Analyze success and report	CONTROL: Update processes and report	ACT: Document changes and report	ACT: Document changes and report	Summarize and close investigation	Validation statement	Summarize and close investigation

I.8 CAPA Manager default severity levels

Note: All the pre-defined text below can be edited as needed within the settings menu.

8D (problem solving) workflow severities

- A1-8D: Safety-critical, Legislative non-compliance
- A2-8D: Non-safety critical component failure, No build condition
- B1-8D: Major customer issue, Process out of control
- B2-8D: Minor build or customer issue, Cost down opportunity
- C1-8D: Nice to do, process improvement
- D1-8D: Documentation amendment or correction

A3 (process improvement) workflow severities

- A1-A3: Safety-critical, Legislative non-compliance
- A2-A3: Non-safety critical component failure, No build condition
- B1-A3: Major customer issue, Process out of control
- B2-A3: Minor build or customer issue, Cost down opportunity
- C1-A3: Nice to do, process improvement
- D1-A3: Documentation amendment or correction

DMAIC (process optimization) workflow severities

- A1-DC: High impact - Significant safety improvements
- A2-DC: High impact - Significant bottom-line savings
- B1-DC: Major customer improvement, Cost reduction opportunity
- B2-DC: Minor customer improvement, Cost reduction opportunity
- C1-DC: Nice to do, process improvement
- D1-DC: Process amendment or correction

PDCA (process improvement) workflow severities

- A1-PA: Safety-critical, Legislative non-compliance
- A2-PA: Non-safety critical component failure, No build condition
- B1-PA: Major customer issue, Process out of control
- B2-PA: Minor build or customer issue, Cost down opportunity
- C1-PA: Nice to do, process improvement
- D1-PA: Documentation amendment or correction

Business Improvement (cost down) workflow severities

- A1-BI: Very-high impact - Significant potential savings
- A2-BI: High impact - High potential savings
- B1-BI: Major customer improvement, good ROI
- B2-BI: Minor customer improvement, minor savings
- C1-BI: Internal improvement, modest savings
- D1-BI: Savings not fully understood

Environmental Investigation workflow severities

- A1-Env: Very-high
- A2-Env: High
- B1-Env: Medium-high
- B2-Env: Medium
- C1-Env: Low
- D1-Env: Very-low

Audit Nonconformity workflow severities

- A1-Aud: Safety-related legislative non-compliance
- A2-Aud: Legislative non-compliance (not safety-critical)
- B1-Aud: Process out of control or broken
- B2-Aud: Minor process issue
- C1-Aud: Basic process improvement
- D1-Aud: Minor documentation amendment

Health and Safety Investigation workflow severities

- A1-HSE: Very-high
- A2-HSE: High
- B1-HSE: Medium-high
- B2-HSE: Medium
- C1-HSE: Low
- D1-HSE: Very-low