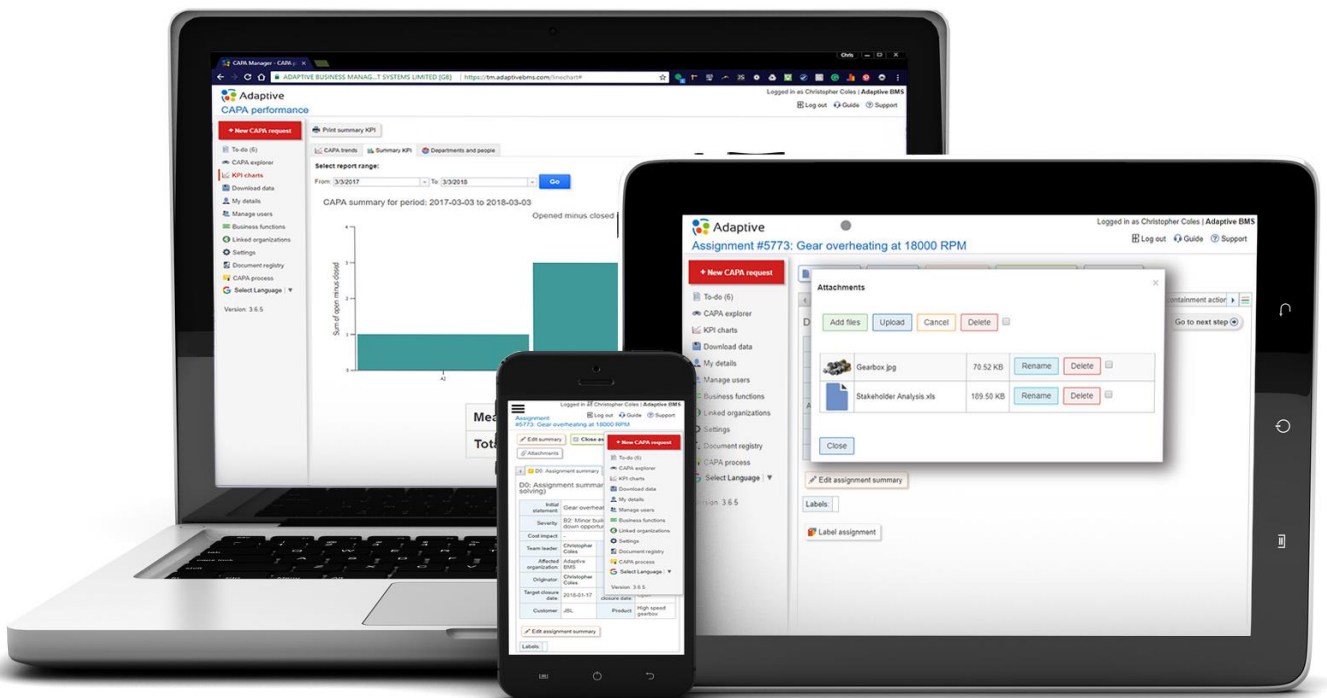




CAPA Manager User Guide



Contents

Contents

Contents	2
Introduction	3
CAPA Manager purpose	3
CAPA Manager features	4
Log in to CAPA Manager.....	5
Requesting a new CAPA (case, opportunity, audit action)	6
Selecting, searching and viewing CAPA assignments.....	7
Working with CAPA assignments.....	8
Workflow selection	9
Team roles and responsibilities	9
Labeling CAPA assignments	10
Action task list	10
Attachments (premium only)	10
Updating your details	11
Adding new users.....	11
Approve new CAPA assignments and closures	13
Notification E-mail function.....	14
Adding/changing a business function.....	15
Linking to other organizations.....	15
Severities and workflows.....	16
Auto reminder feature	16
User configurable fields	17
KPI charts	17
Producing a corrective action reports	17
Exporting data (premium only)	18
External documents registry	18
Link CAPA assignments	18
Language translator function	18
Restricting access to private assignments.....	19
Security information.....	19
System requirements.....	20
Tablets and handheld devices	20
Support.....	20
CAPA Manager workflows	1

Introduction

This guide provides users with simple instructions on how to use this CAPA and investigation management software.

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

How to request an Adaptive CAPA Manager account?

To request a fully functioning CAPA Manager evaluation account, please click on the '[Create a CAPA Manager evaluation account](#)' link on the Adaptive homepage: adaptivebms.com

CAPA Manager purpose

Adaptive CAPA Manager provides an electronic Corrective Action and Preventive Action (CAPA) solution for your business and supply chain. The CAPA Manager software allows internal and external users to record, investigate, track and conclude improvement opportunities in your organization and supply chain. Typical applications include:

- Continual Improvement (CI) management
- Quality management
- Supplier quality management
- Audit action management
- Health, safety and environmental management (HSE)
- Team task management

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.

CAPA Manager features

- Compliant for ISO 9001, ISO 14001, OHSAS 18001, AS9100, ISO 9001, TS 16949 and QSR 820
- Multiple workflow options: 8D, A3, DMAIC, PDCA, 8 Step, HSE investigations
- Online Corrective Action Reports (CARs)
- Automatically allocate CAPA responsibility
- Automatic email notification
- Classify and prioritize issues
- Improvement statistics and data download
- Multilingual translator function
- 6M (Ishikawa) and 5 Why toolkit
- Attach files to CAPA assignments
- No software installs required
- Comprehensive user guide
- Mobile device compatible
- Data download option
- Advanced CAPA labeling features
- Lots more

Log in to CAPA Manager

Navigate to the CAPA Manager log in page using your Internet browser: <https://tm.adaptivebms.com/>

To enter the CAPA Manager system, type in your **User Email address** and **Password** as prompted on Log in screen. Then click the '**Log in**' button, you will then enter the CAPA Manager system.

Email

Password

[Lost password](#)

[Create a new account](#)

[Bookmark this page](#)

Requesting a new CAPA (case, opportunity, audit action)

+ New CAPA request ▾

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

Note: The 'New CAPA' 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 'New CAPA' button.

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

Enter a description of the problem or opportunity

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

Select workflow

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

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.

Note: CAPA assignees may change the severity once the CAPA request has been assigned to them.

Which organization is responsible?

Select the organization to be assigned the CAPA request.

Note: CAPA assignees may change the responsible **organization** once the CAPA request has been assigned to them.

Which business function or department is responsible?

Select the business function to be assigned the CAPA request.

Note: CAPA assignees (Team leaders) may change the responsible **Business function** once the request has been assigned to them.

Select a target closure date

Select the target closure date for the CAPA assignment.

Optional fields: Attaching files and optional data fields

Supporting images and documents may be added when raising a new CAPA assignment. Other data may also be added if needed; these data fields are displayed on the right of the Raise a new CAPA page.

Optional	
As originator:	<input checked="" type="checkbox"/>
Auditor	<input type="text" value="Christopher Coles"/>
Auditors reference	<input type="text" value="#005"/>
Attachment	<input type="text" value="D:\Christopher\Documen"/> <input type="button" value="Browse..."/>

Click the **'Request CAPA'** button to record and assign the CAPA request, or the **'Leave without saving'** link to abandon the changes.



Selecting, searching and viewing CAPA assignments

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

To-do page

Enter the **'To-do'** page by clicking on the link in the left-hand sidebar, select assignments that 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.

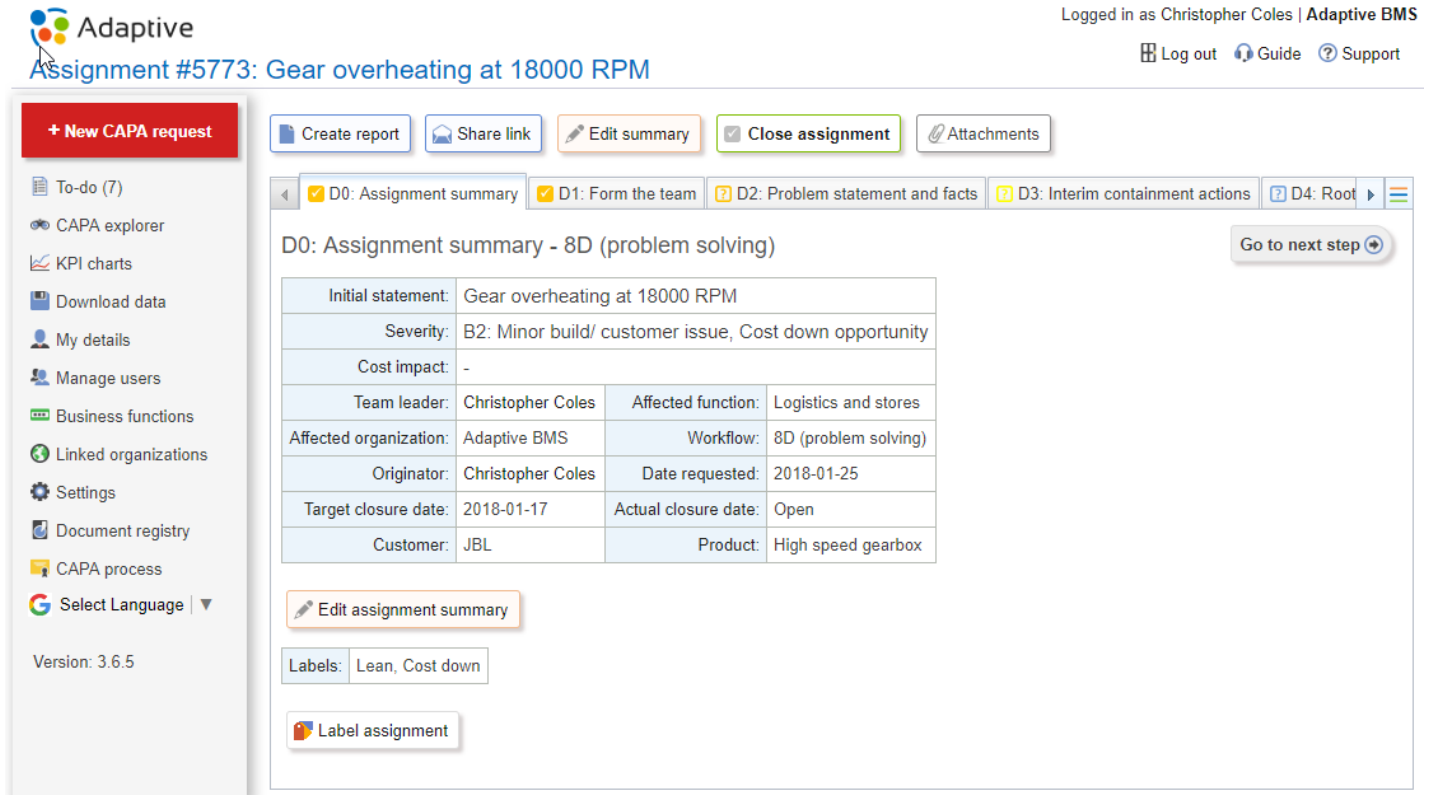
CAPA explorer page

In the left sidebar select the **'CAPA explorer'** link. All CAPA assignments will be displayed.

Use the filters to navigate the assignments, click on **'apply filter'** to activate your selection. Select and click on the assignment that you want to view.

Working with CAPA assignments

Each stage of the CAPA workflow is displayed under a tab. The workflows run from left to right. The assignee or CAPA teams can enter data under each tab to complete the CAPA:



Adaptive
Assignment #5773: Gear overheating at 18000 RPM

Logged in as Christopher Coles | Adaptive BMS
Log out Guide Support

+ New CAPA request

Create report Share link Edit summary Close assignment Attachments

D0: Assignment summary D1: Form the team D2: Problem statement and facts D3: Interim containment actions D4: Root

D0: Assignment summary - 8D (problem solving) Go to next step

Initial statement:	Gear overheating at 18000 RPM		
Severity:	B2: Minor build/ customer issue, Cost down opportunity		
Cost impact:	-		
Team leader:	Christopher Coles	Affected function:	Logistics and stores
Affected organization:	Adaptive BMS	Workflow:	8D (problem solving)
Originator:	Christopher Coles	Date requested:	2018-01-25
Target closure date:	2018-01-17	Actual closure date:	Open
Customer:	JBL	Product:	High speed gearbox

Edit assignment summary

Labels: Lean, Cost down

Label assignment

Version: 3.6.5

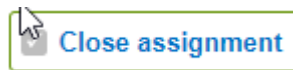
Editing a CAPA assignment element

To add data to stage, click on its tab and then select the edit icon: 

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

CAPA Manager Action: CAPA Manager will change the tab icon to a 'tick icon' when data has been entered into a workflow stage.

Closing a CAPA assignment




In the CAPA assignment that you wish to close. At the top of the page select the Close this assignment link. A confirmation box will be displayed. Click OK to close the assignment.

CAPA Manager Action: CAPA Manager will change assignment status to closed (White). An e-mail notification will be sent to the originator and team.

Workflow selection

CAPA Manager provides multiple workflows for users to follow during the CAPA investigation (see Workflow selection). Each workflow is broken down into individual improvement steps or stages.

Note: The use of all workflow elements is not mandatory within the system. Stages can be omitted depending on CAPA requirement. Uncompleted stages display the ‘?’ Icon in their tab. Completed icons will display a ‘tick’ icon: 

Setting your organization's default workflow

Your organization preferred workflow can be selected by any CAPA manager administrator via the **settings menu**. Setting the default workflow does not prevent alternative workflow from being selected by the team.

Selecting a workflow

The most suitable workflow can be chosen by editing the first tab in any CAPA assignment. A drop-down menu displays the available workflow options. Workflow can be changed at any time regardless of assignment status in accordance with the team’s needs.



Team roles and responsibilities


When adding the CAPA investigation team each person's role and responsibilities can also be defined. Just click the edit symbol next to the team member's name in the 'Form the team' investigation tab.

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

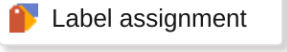
Team leader: Christopher Coles

Tip: To change the Team Leader, edit the settings in the first tab.

No.	Name	Role	Edit role
#1	Bob Hope	Subject matter expert	
#2	Adaptive Developer	Six Sigma Black belt	

 Manage team

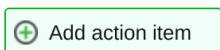
Labeling CAPA assignments





CAPA assignments can be associated with editable  labels to help future searching and analysis. Just select the labels that apply to the assignment.

Note: Labels are defined in the **Settings** page. Unique labels are defined for each workflow.

Action task list

CAPA Manager provides a simple action (task) list for use within CAPA assignments. The 'Add action' button will appear depending on the workflow selected:



No.	Action detail	Who	Target date	Complete?	Edit
5	Update the packaging document 345-456 to include the diffuser	Bob	2016-06-14	Yes	 
6	Train out new packaging procedure with packing team	John Hope	2016-06-24	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.


Attachments (premium only)

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

Updating your details

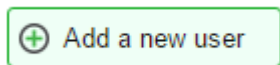
Go to the **My details** page. Here you  can change your password and personal information.

Adding new users

Using the left navigation bar, click '**Settings**', then '**Manage users**'. The **All users** page will be displayed. You will be presented with a table of currently defined users connected to your organization.

Add a user to your organization

Click on the Add a new user button. Enter the full name and email address for the new account.



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

Edit or disable a User

Click on the user's name in the **Manage users** screen. The edit user screen will be displayed.

Click '**Save changes**' to record or your browser back button to abandon the changes.

User Roles

Users must be allocated a role type when they are first created. Role type determines which CAPA Manager features are available to that user.

The table below gives an overview of the differences between the available user roles:

Function	Basic user	Manager	Administrator
Request CAPA:	Yes	Yes	Yes
View CAPA assignment details:	All CAPA's (not hidden)	Any	Any
Edit CAPA assignments:	As a team leader or member	Any	Any
Edit problem statement:	New CAPA only	Yes	Yes
Setup users:	No	No	Add/delete
Setup business functions:	No	No	Add/delete
Settings menu:	No	No	Full control
Approve new assignments:	No	Yes	Yes
Approve assignment closure:	No	Yes	Yes

Approve new CAPA assignments and closures

It is possible to enforce approval for CAPA requests before they are assigned or closed. This function is controlled in the **Settings** page. When either feature is enabled, the nominated approver is responsible for allowing CAPA request and assignments to move through the CAPA manager system.

All users may close their CAPA assignments without administrator assistance

- Yes: Any user may close a CAPA assigned to them.
- No: Non-administrative users must ask an administrator to approve CAPA assignment 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. Assignment must be performed manually by an administrator.

Setup approvers

Under '**Settings**' choose the **Approver** tab. You can select company approvers from the list

- Only Administrators and Manager can select as an approver
- At least one approver must be defined for your organization

CAPA approvals

In 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 each tab.

The screenshot shows a navigation bar with five tabs: 'My CAPA assignments (6)', 'My CAPA requests (31)', 'Team memberships (2)', 'Assignment requests (16)', and 'Closure requests (0)'. Two green arrows point to the 'Assignment requests (16)' and 'Closure requests (0)' tabs. Below the tabs, the text '6 results. Previous | 1 | Next' is visible. At the bottom, a table header is shown with columns: ID, STATEMENT, STATUS, SEVERITY, ORGANIZATION, FUNCTION, LEADER, and CUSTOMER.

Approve a new CAPA request

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

Approve the closure of a CAPA request

To approve an assignment for closure, click on it and select '**Close this assignment**'.

Notification E-mail function

CAPA Manager will automatically send an email to key stakeholders as CAPA assignments are raised, progressed, updated and closed:

Team leader (assignment owner)

Will be informed of new CAPA requests assigned to them.

Originator

Originators will be informed when their CAPA request is closed.

Team members

Team members will be informed when they are added to a team or when an assignment they are involved with is closed.

CAPA request approvers (when enabled)

Approvers are informed when a new request requires approval.


Tip: In Microsoft® Outlook, notification e-mails can be added directly to your Outlook Tasks. Just drag the notification e-mail to the task list using your mouse.

Adding/changing a business function



Business functions are at the heart of CAPA Manager. CAPA Manager decides whom to assign investigations to base on the responsible business function chosen when raising a new CAPA request. Using the left navigation bar, click **Settings**, then **Business functions**. The Browse function screen will be displayed. You will be presented with a table of currently defined Business Functions and their relevant default team leaders.

Edit a business function

Click on the Business Function you want to edit. Further Business Function detail will be displayed. Click on the **'Edit details'**  icon to edit the name or default Team leader as required. Click **'Save changes'** to record or select your browser back button to abandon the changes.

Add a new business function

Click on the **'Add a new function'** link on the left. Enter the new Business Function name and its default assignee as required. Click the **'Save changes'** button to record, or the **'Leave without saving'** link to abandon the changes. **Tip:** Business functions cannot be deleted. If you want to remove a business function then simply rename it as 'N/A' or similar.

Linking to other organizations

Using the left navigation bar, click **'Settings'**, then click **'Linked organizations.'** The **'Manage organizations'** screen will be displayed. You will be presented with 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.

Add a new organization

Click on the **'Add a new linked organization'** link on the left. Enter the new Organizations name as required. Click the **'Save Changes'** icon to record, or **'Leave without saving'** to abandon the changes.
Severities and workflows

Severities and workflows

CAPA Manager come pre-equipped with powerful workflows. A complete list of the available work flows can be found at the end of this guide: See [CAPA Manager workflows](#)

Customize severity text

Severity text can be configured for each workflow. This allows audit workflows to use different severity text to problem-solving workflows. Administrators can edit the business severity rating text by clicking on the **Settings** menu in the left sidebar and selecting **Severities**.

Switch off unwanted workflows

Unwanted workflows can be disabled, so they are not available for the users to select. Administrators can disable workflows by clicking on the **Settings** menu in the left sidebar and selecting **Severities**.

Account settings Account limits My organization Define labels Define severities Configurable fields

Severities and workflows

Customize severity text and hide workflows below:

▼ 8D (problem solving) workflow severities

Hide this workflow:

Severity description	Creation date	Modify
A1: Safety critical, Legislative Non-compliance, Accident	2012-11-02	Edit
A2: Non safety critical component failure, No build condition	2012-11-02	Edit
B1: Major customer issue, Process out of control	2011-11-19	Edit
B2: Minor build/ customer issue, Cost down opportunity	2011-11-19	Edit
C: Nice to do, process assembly improvement, EH&S observation	2011-11-19	Edit
D: BOM amendment	2012-11-02	Edit

Auto reminder feature

Team leaders can be automatically reminded that they have open assignments that are past their due date. Reminder intervals can be set via the **Settings** menu.

User configurable fields

Administrators can configure some data fields to match the organization's particular needs. Click on the **Settings** menu in the left sidebar, then select the **Configure fields** tab to set the field name and field tooltip.

Account settings Account limits My organization Define labels Define severities **Configurable fields**

Custom fields

Customize the name and tool tip of the optional data fields by selecting 'Edit' below:

Configurable field name	Configurable hover tip	Modify
Customer	Customer id code	Edit
Product	Product id code	Edit

Tip: Changes to configurable fields will be instantly visible in all CAPA assignments.

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

KPI charts

Using the left navigation bar, click **KPI charts**. A full range of graphical views and reports are available. Select the type of graph or report you require from the list.

Adaptive CAPA performance

Logged in as Christopher Coles | Adaptive BMS
Log out Guide Support

New CAPA request Print line chart

To-do (4) CAPA explorer **KPI charts** Download data My details Manage users Business functions Linked organizations Settings Document registry CAPA process Select Language

Version: 3.5.0

CAPA trends Summary KPI Departments and people

Select report range:
From: 3/20/2016 To: 3/20/2017 Go

CAPA trends for period: 2016-03-20 to 2017-03-20

CAPA activity over time


Legend: New CAPA requests, CAPA trend, Contained, Cause identified, Solution identified, Solution deployed, Closed

Producing a corrective action reports

Select the first tab of any CAPA assignment. Selecting the **'Create report'** will bring up the 8D report page.

The report can be saved or printed via your web-browser.

Exporting data (premium only)

A copy of your organization's CAPA database can be  exported in .csv format for analysis using third-party software packages. The data download function is available to administrators only and can be found in the left-hand sidebar.

External documents registry

Linking to external supporting documents

Link to any supporting documents or images by adding the relevant URLs to your text. CAPA Manager will automatically create the links when the text is saved.

Connecting to your company document registry


Open your own document registry by clicking on the link in the left navigation bar. This connection can be configured to the URL location of your choice in the settings menu.

The default setting is Google Drive; this feature also works great with Dropbox, Skydrive, SharePoint or your local network locations.

Link CAPA assignments

Link to other CAPA assignments by typing the text '**Task #ID number.**'


Language translator function

Select Language 

Powered by  Google™ Translate

All CAPA Manager pages provide a translator function. The translator selection window is located in the top left of the sidebar on all pages. Just select your desired language in the pull-down box, all translatable text will be displayed in the chosen language.

Restricting access to private assignments

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

Private assignments can be enabled by selecting 'Restrict access' when raising a new assignment or under the D0 tab. **Restrict access?**

Security information

Communication between your browser and the CAPA Manager server is via industry standard 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 so 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, either 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.

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.






Tablets and handheld devices

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

Support

If you experience difficulties, please contact support@adaptivebms.com describing the issue encountered and the browser version you are using, and we'll aim to resolve the problem as fast as we can.

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	Pre-diagnostic (initial top-level data gathering)	DEFINE: Describe customer, process & expected output	PLAN: Establish objectives and plan changes	PLAN: Define current condition	Description of incident	Evidence and clause	Description of incident
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	IMPROVE: Describe the 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