**Enablon Training by Function** 

# TIER O COPACKER SITES & BU QUALITY



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\*Click on the icon to be redirected to this page

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Chapter 1

# INTRODUCTION TO ENABLON

#### External Sites & BU Quality 1 INTRODUCTION TO ENABLON





#### **ABOUT ENABLON**

Enablon is a web-based tool used by Mondelez for managing Audits and Action Plans, streamlining the tracking of compliance and the execution of corrective and preventive actions (CAPA). The platform provides tools to organize, monitor, and validate activities related to risk management, regulatory compliance, and continuous improvement, ensuring that processes align with the Corporate Quality Audit Policy



#### **Target**

- Manage Mondelēz quality auditing process;
- Record and track Audit and Action Plans until completion;
- Ensure Root Cause Analysis and Efficiency Verification;
- Manage sites and auditors' non-availabilities



#### **Benefits**

- Ensures compliance with Quality Policy requirements;
- Maintains global consistency in auditing processes;
- Reduces manual workload by replacing (partially or completely, depending on the process) Excel and other offline solutions;
- Provides automated email notifications and reminders for auditors and auditees;
- Allows uploading Excel templates to auto-populate audit questionnaires in the system;
- Enables direct linking of CAPAs to audit findings;
- Automates the CAPA approval process;
- Facilitates tracking, reporting, and task completion to prevent recurring issues.

Chapter 2

# ENABLON MODULES, ROLES & PERMISSIONS

## 2 ENABLON MODULES, ROLES & PERMISSIONS







**ACTION PLAN ROLES & PERMISSION** 

Enablon's platform features two key modules: Audit and Action Plan, each offering tools to organize, monitor, and validate related activities, ensuring that processes align with the Corporate Quality Audit Policy. By integrating these modules, Mondelez can efficiently track progress, maintain consistency across sites, and improve decision-making through centralized data management



#### **Audit Module**

- The Audit Module provides complete management of the audit lifecycle, covering planning, execution, and reporting;
- It enables users to create and schedule assessments and self-assessments, handle non-availabilities, document and monitor findings, as well as generate reports automatically through Power BI integration;
- This module ensures a structured process to maintain compliance with internal policies and regulatory requirements;
- It streamlines the audit workflow with features such as automated reminders, notifications, and integrated tracking of all audit activities.



#### **Action Plan Module**

- The Action Plan Module is designed to streamline the follow-up process for audit findings and other identified issues;
- It allows users to efficiently create, assign, and monitor CAPAs, ensuring that each action is directly linked to specific audit findings;
- The module tracks progress, automates the approval process, and provides automated reminders to the responsible parties;
- This ensures all actions are completed and properly documented to maintain accountability and prevent recurring issues.

## 2 ENABLON MODULES, ROLES & PERMISSIONS







Roles and permissions define the levels of access and control users have within the system. Each role is assigned specific permissions that determine what actions a user can perform within each stage of the module workflow, such as viewing, editing, submitting, or approving content. This structure ensures that users have the appropriate access based on their responsibilities, maintaining both security and efficient workflow management



#### Action Plan Module – Permissions by Role

Enablon Role	MDLZ Role -	Action Plan Stages					
Enabion Role	IVIDLZ ROIE -	Draft	Validation	Do Action	Verification of Effectiveness	Closed or Archived	
Contributor	Plant Employee	Edit	View Only	Edit – if assigned	View Only	View Only	
Verifier	BU Quality Director	Edit	Edit	View Only	View Only	View Only	
Verifier	Anyone assigned as 'Verifier' in the Action Plan	Edit	View Only	Edit – if assigned	Edit – if assigned	View Only	
Auditor	Lead Audito	Edit	Edit	View only	View only	View only	

## 2 ENABLON MODULES, ROLES & PERMISSIONS







### ACTION PLAN ROLES & PERMISSIONS



#### Action Plan Module – Actions by Role

Enablon Role	MDLZ Role	Actions
Contributor	Plant Employee	<ul> <li>In the 'Draft' stage:</li> <li>Create and update an Action Plan Draft</li> <li>Submit the Action Plan for validation</li> <li>In the 'Do Action' stage, only for the Action Plans where assigned as owner or team member:</li> <li>Document actions progress and completion</li> <li>Submit the Action Plan for validation (IM) or verification of effectiveness (EM)</li> </ul>
Verifier	BU Quality Director	In the 'Verification (BU Quality Director)' stage:  Review the Action Plan  Approve, reject or discard the Action Plan Draft
Verifier	Anyone assigned as 'Verifier' in the Action Plan	In the 'Verification of Effectiveness' stage, only for the Action Plans where assigned as verifier:  • Document actions effectiveness over time  • Archive or reject the Action Plan
Auditor	Lead Auditor	In the 'Verification (Lead Auditor)' stage:  Review the Action Plan  Approve, reject or discard the Action Plan Draft

Chapter 3

# BASIC ENABLON NAVIGATION



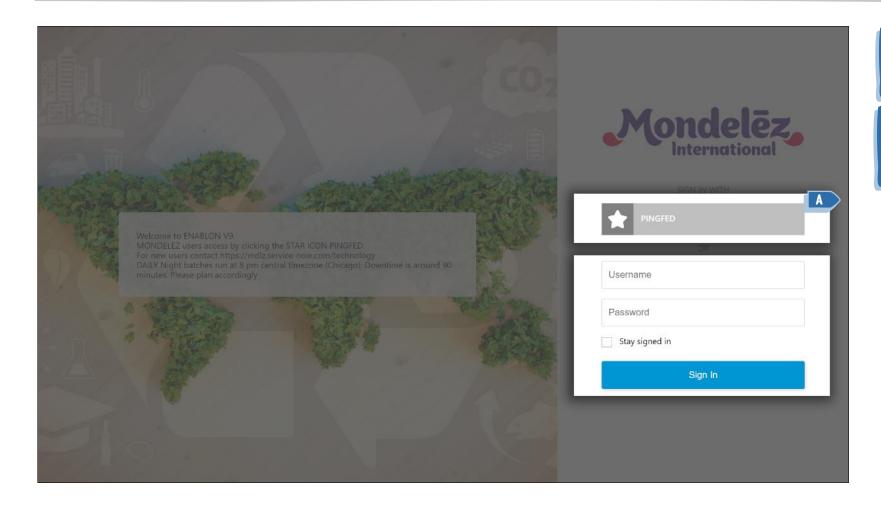






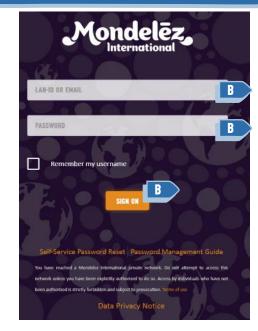


Enablon link: <a href="https://mondelez-az.us.enablon.io/mdlz/">https://mondelez-az.us.enablon.io/mdlz/</a>



Click on **'PINGFED'** to login using your MDLZ credentials

Enter your BP Account (with the @mdlzpartner.com domain), password and press Sign On.



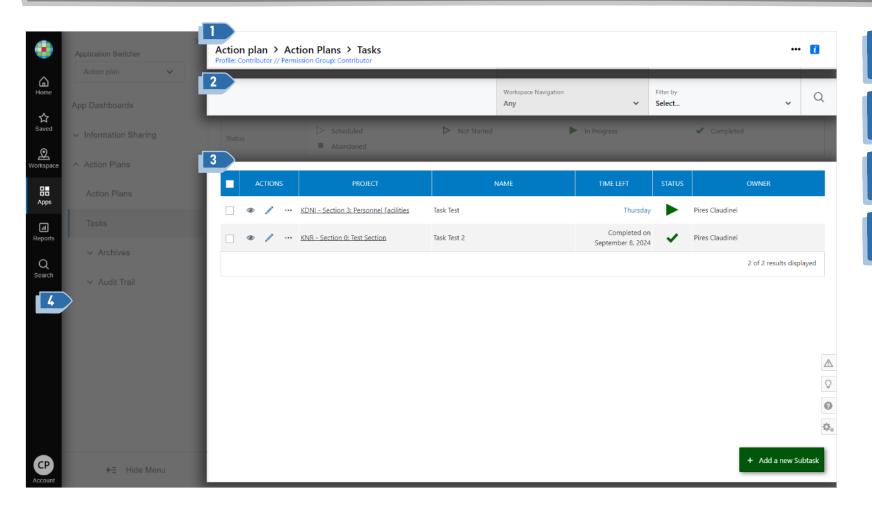








Every Enablon page includes four key components in its interface to streamline navigation throughout the platform efficiently



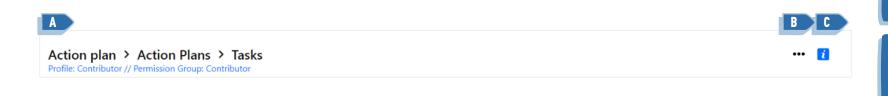
- 1 HEADER

  2 GLOBAL FILTER BAR
- 3 WORKSPACE
- 4 MAIN MENU





The Header is a banner located at the top of the interface that indicates your current location within the site and provides access to the More Options menu and the Information panel

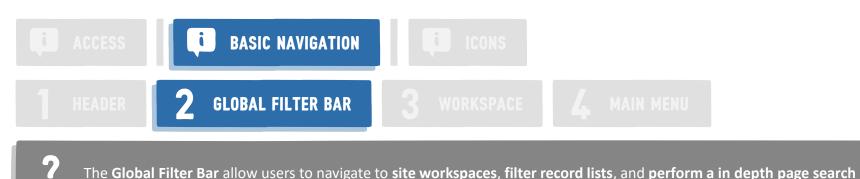


Display of your current location within the site. For users with multi-profile accounts, it also displays the current role (permission group) in use

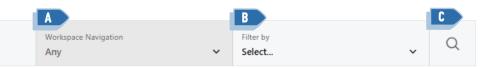
Allows the user to add the currently displayed page to favorites, change its display mode, export, and import information

Gives **general information** about the currently displayed page





The Cloud I made and the decision of the management of the construction of the constru



When a list of records is displayed, users can filter the list based on one or multiple

Enables users to navigate to local site

can filter the list based on one or multiple general criteria. The 'Filter By...' option will only appear if the records have criteria that can be filtered

Allows users to perform a detailed search

of records on the current page based on multiple criteria. This is different to the 'Global Search' option available from the Main Menu

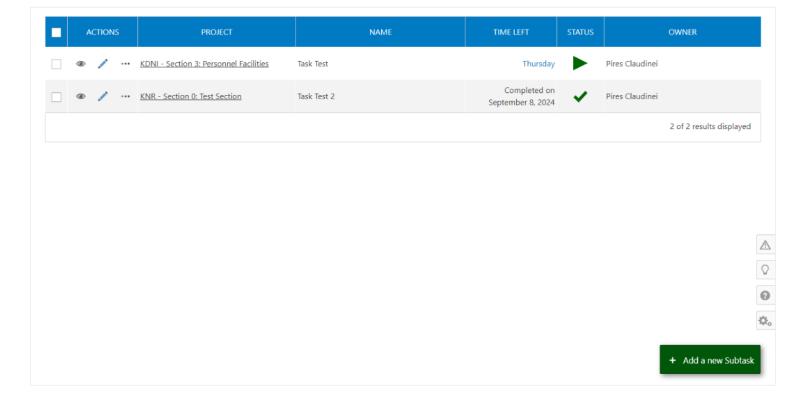
workspaces

The Global Filter Bar is not available when viewing Dashboard Walls. Additionally, certain options may not be displayed on specific pages, depending on the context or the type of content being accessed



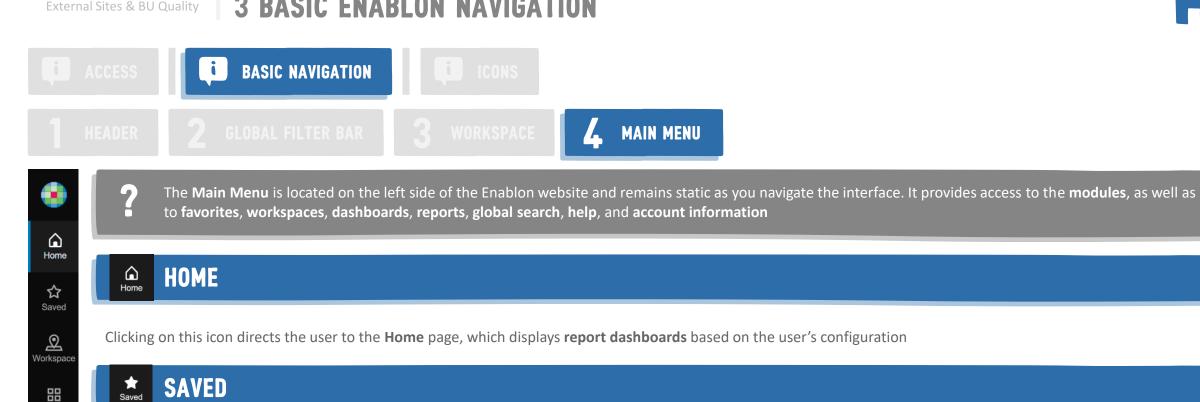


The Workspace is the area of the page that displays its content. If there are too many results, they will not be displayed; the user should filter them using the Global Filter Bar



Scroll vertically and horizontally on the page to view all its contents

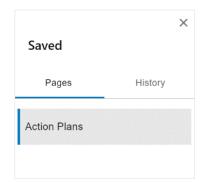




Clicking on this icon directs the user to the **Home** page, which displays **report dashboards** based on the user's configuration



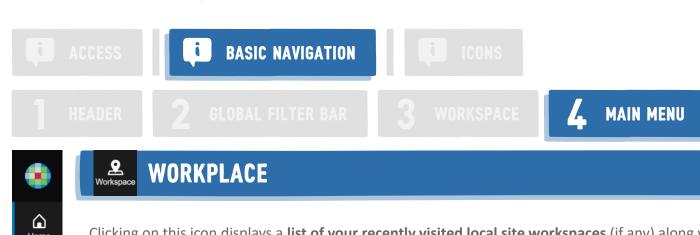
• Reports Clicking on this icon displays the user's favorites and recently visited pages. The Saved drawer includes two tabs:



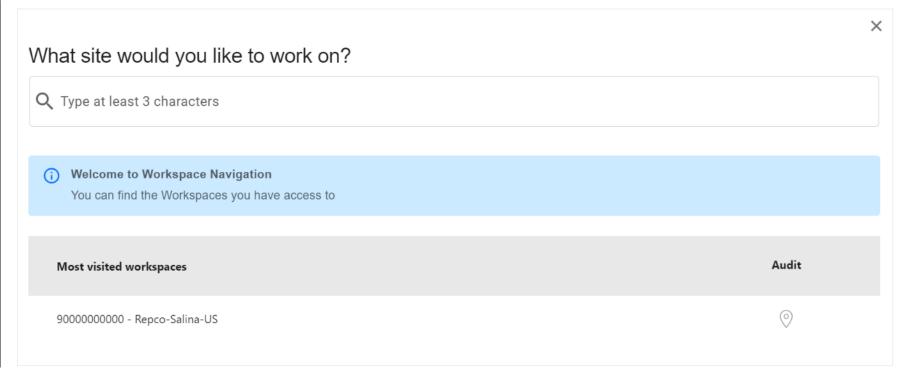
Pages – This tab displays a list of links to your favorite pages, which are bookmarked by selecting 'Add to Favorites' in the More Options menu. The list is shown in the order the pages were added, and you can remove favorites by hovering your mouse over them and clicking the X icon

History – This tab shows a list of all recently visited pages, with the most recent at the top. If you revisit a page already listed in the History tab, it will not be moved to the top





Clicking on this icon displays a list of your recently visited local site workspaces (if any) along with an option to search for a specific local site





公

Saved

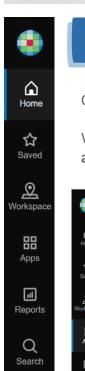
Q Workspace

믦

Reports



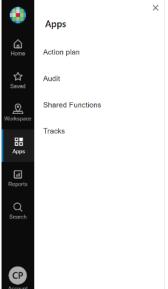


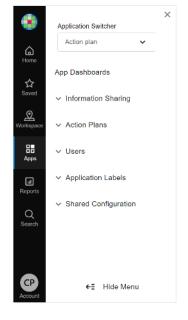




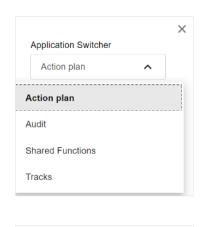
Clicking on this icon opens a list of the modules

When you select a specific module (Action Plan in this example), a **menu** appears beneath the module's name. **This menu includes the relevant sections and pages** associated with the selected module





Features of the Apps drawer include:



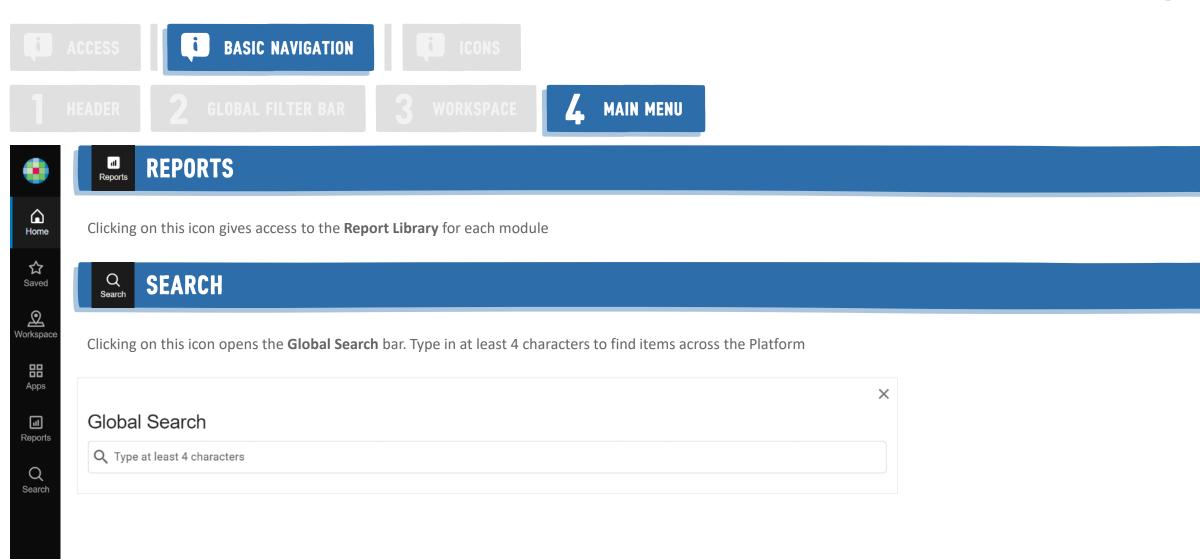
An **Application Switcher dropdown list** at the top of the Apps drawer. This enables users to navigate between Enablon applications/modules

The ability to

←≡ Hide Menu bottom of th

The ability to pin/hide the menu by clicking on 'Hide Menu' in bottom of the **Apps drawer** 





☆

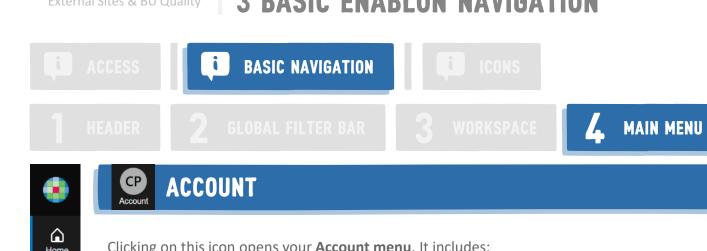
Workspace

믦

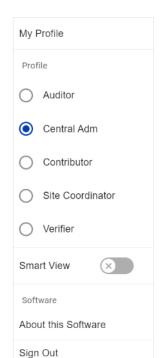
ⅎ Reports

#### **3 BASIC ENABLON NAVIGATION**





Clicking on this icon opens your **Account menu**. It includes:



My Profile – Links to your My Profile page, where you can view and edit your login information and other account details

Profile – Allows users with a multi-profile account to view the profile they are currently using and easily switch between profiles

Smart View (off/on) - Enables you to toggle Smart View on or off. When activated, it displays a dashboard with a list of smart cards upon opening an application, instead of the default dashboard showing reports

**About this Software** – Displays the current version of the site

Sign Out – Logs you out entirely from the Enablon platform, closing the current application and any other Enablon applications you have open











This list includes some of the most used icons for navigation



Eye Icon (View Details)



Pen Icon (Edit)



**Cloud with Down Arrow Icon** (Export)



Cloud with Up Arrow Icon (Import)



Magnifying Glass Icon (Select Values for field)



Calendar Icon (Select date)



**Approved Icon** 



Paper Clip Icon (Upload a new file to field attachments)

Chapter 4

# USEFUL ENABLON FEATURES



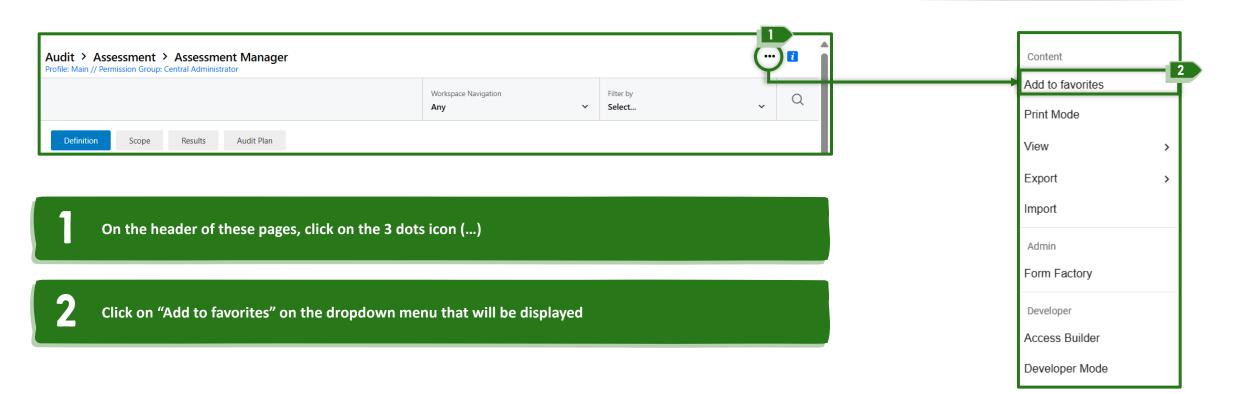




It's useful for plants to save the Assessment Results and Action Plans pages to their favorites for quick access, avoiding the need to follow all the steps to get to them



To add these page to your favorites:

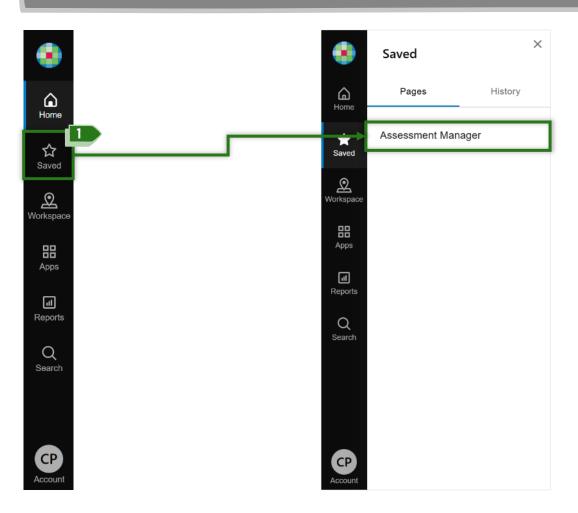












Click on "Saved" on the Main Menu located on the left side of the website. There, your favorite pages will be displayed

#### **4 USEFUL ENABLON FEATURES**

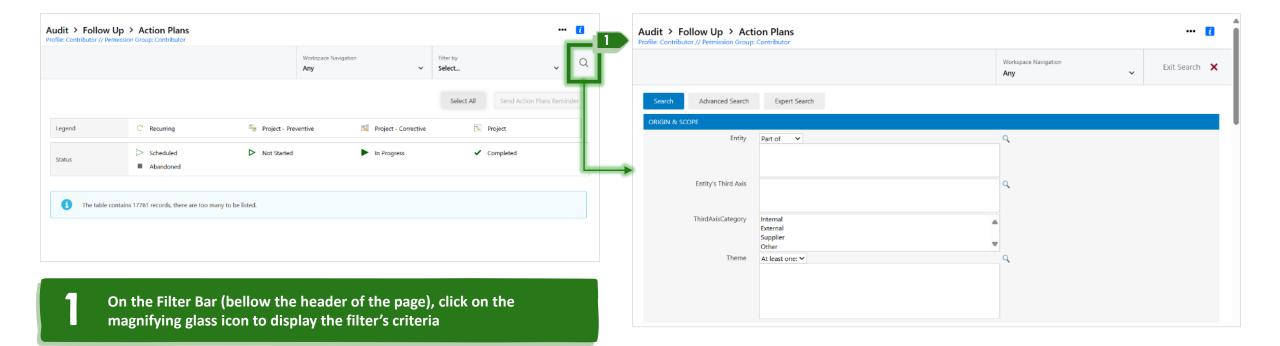






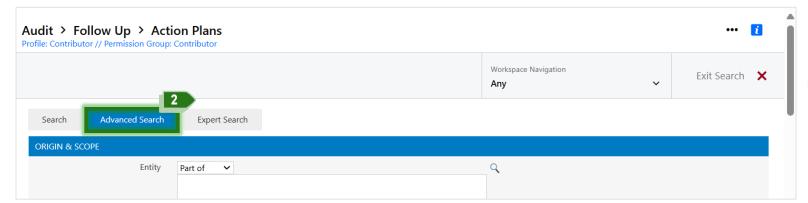


As explained in Chapter 3, the filter bar allows users to perform a **detailed search of records** on the current page **based on multiple criteria**. This is different to the 'Global Search' option available from the Main Menu – it will only filter the results displayed on the given page, not across the whole website. **To exemplify this feature, you will learn how to filter Action Plans by Assessment** 

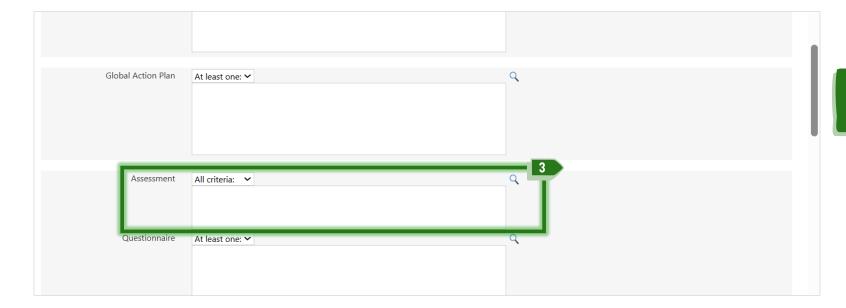








Click on Advanced Search to expand the filters criteria

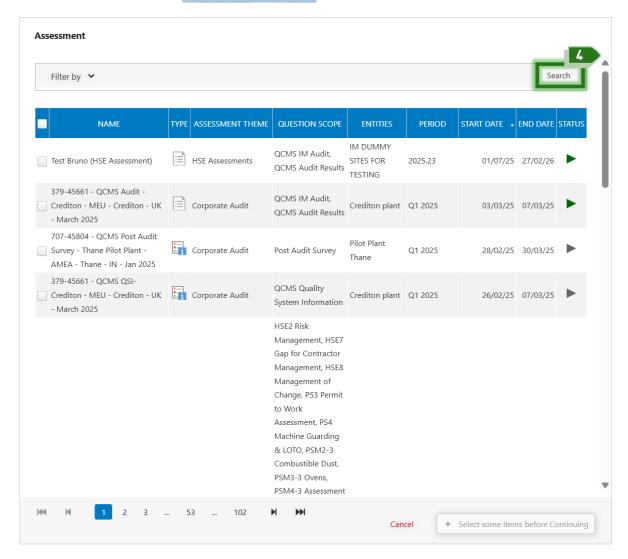


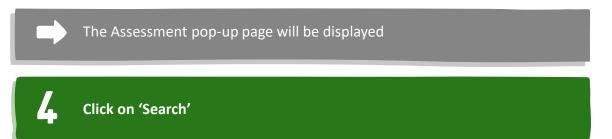
Scroll down to 'Assessment', then click on the magnifying glass icon







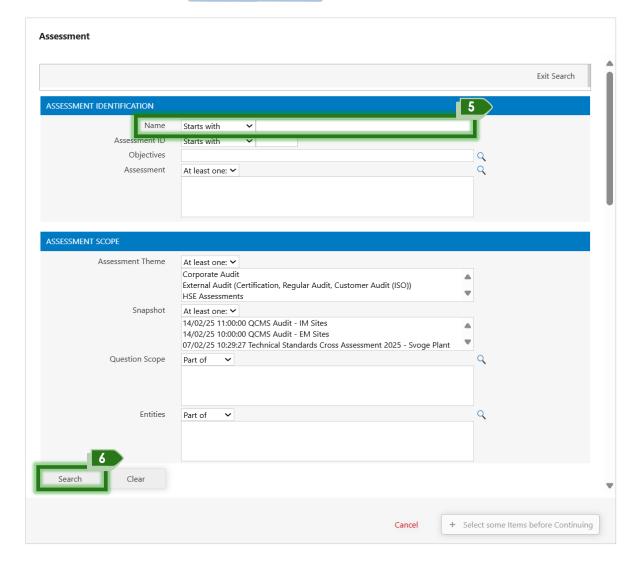












5 Enter the Assessment Name on the 'Name' field. When you don't have the exact name for the Assessment, you can change the option from "Starts with" to "Contains" and enter the Plant Name Starts with ASSESSMENT IDENTIFICATION **∨** Curitiba Name Contains Starts with Contains Does not contain Equal to Click on 'Search' to display the filter results

#### Internal Sites & BU Quality

## 4 USEFUL ENABLON FEATURES







NAME	TYPE	ASSESSMENT THEME	QUESTION SCOPE	ENTITIES	PERIOD	START DATE .	END DATE	STATUS
E Audit - Dummy - Jan - USA -December		Corporate Audit	SQE Audit, SQE Audit Results	SUPPLIER DUMMY SITES FOR TESTING - TIER 1	Q4 2024	13/12/24	14/12/24	~
MS Audit - Dummy - Jan - USA -December		Corporate Audit	QCMS IM Audit, QCMS Audit Results	EM DUMMY SITES FOR TESTING	Q4 2024	26/11/24	29/11/24	<b>~</b>
andards Cross 2024 - BIMO Plant		HSE Assessments	Management, HSE6 Emergency Management, HSE7 Gap for Contractor Management, HSE8 Management of Change, PS3 Permit to Work Assessment, PS4 Machine Guarding & LOTO, PS8 Pedestrian Safety, PSM2-3 Combustible Dust, PSM3-3 Ovens, PSM4-3 Assessment Anhydrous Ammonia Safety,		2024	11/11/24	02/12/24	·



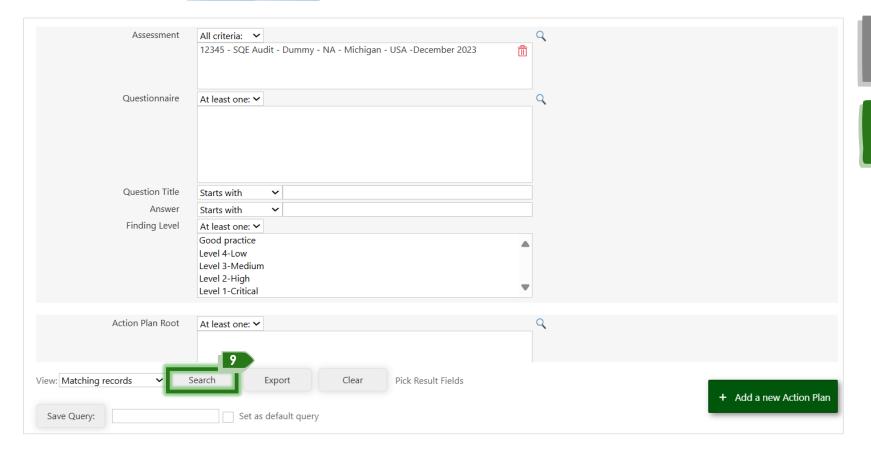
Select the desired assessment by marking the checkbox

Click on "+ Add the 1 Select Item"









- The selected Assessment will then be displayed in the "Assessment" field
- Click on "Search" to apply the filter criteria

### Chapter 5

# QUALITY SYSTEM INFORMATION

Chapter 5.1

# **PROCESS OVERVIEW**

## **5.1 PROCESS OVERVIEW**







Plant receives an email notification on the launch date

Plant fill out and submit the questionnaires

- \*Click on the chapter name to be redirected to it
- \*Click on the 📫 icon to be redirected to the table of contents

Chapter 5.2

# DOCUMENTING QSI FILLING OUT QSI QUESTIONNAIRES

5.2.1 <u>ACCESSING A QSI QUESTIONNAIRE</u>

5.2.2 FILLING OUT A QSI QUESTIONNAIRE

5 Quality System Information

#### 5.2.1 ACCESSING A QSI QUESTIONNAIRE





OR

GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'





QUESTIONNAIRE



An email notification will be received by the Quality Manager/CAPA Coordinator on the self assessment start date

Self-Assessment Notification Teste - IM Self Assessment is scheduled to start today: 30/05/24



noreply@enablonsaas.app

To • Araujo, Bruno Machado

(i) You forwarded this message on 04/06/2024 15:50.

If there are problems with how this message is displayed, click here to view it in a web browser.

#### This Message Is From an External Sender

Do not click links or open attachments if the message is unexpected or looks suspicious.

--- The following message has been generated automatically ---

Self-Assessment Notification Teste - IM Self Assessment is scheduled to start today, 30/05/24. Please take the necessary actions.

Item Reference:

- Assessment Manager [ehs]

Notification Teste - IM Self Assessment: https://mondelez-prjdev.ps.enablon.io/ehs/?u=/acs/Cmp&Usr RoleSet=14697&rid=1764

**Click on the link**. It directly redirects you to the **assessment page**. Then follow steps 3 and 4 to access the **questionnaire page** 

#### **5.2.1 ACCESSING A QSI QUESTIONNAIRE**





GO TO 'ASSESSMENT RESULTS'

SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'

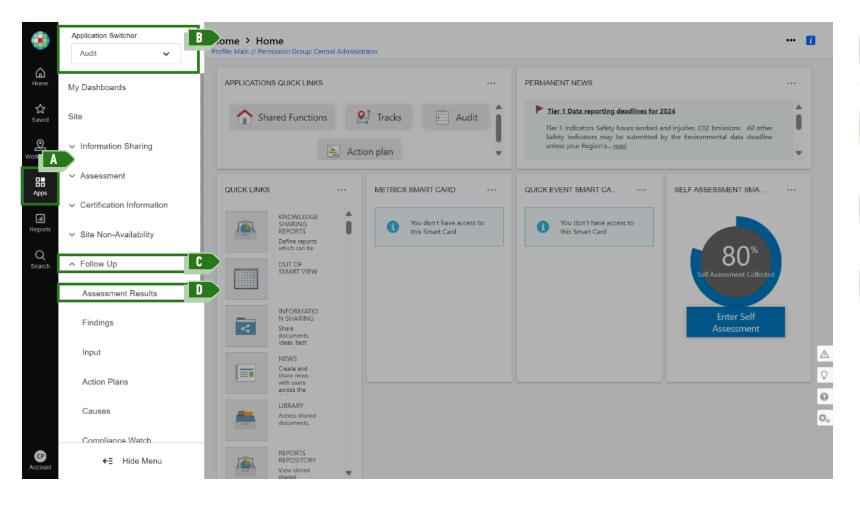
SELECT THE DESIREI QUESTIONNAIRE



QUESTIONNAIRE



On the **Enablon home page** 



Click on 'Apps'

On 'Apps' or 'Application Switcher', select 'Audit'

Click on 'Follow Up'

Click on 'Assessment Results'

#### **5.2.1 ACCESSING A QSI QUESTIONNAIRE**





GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'

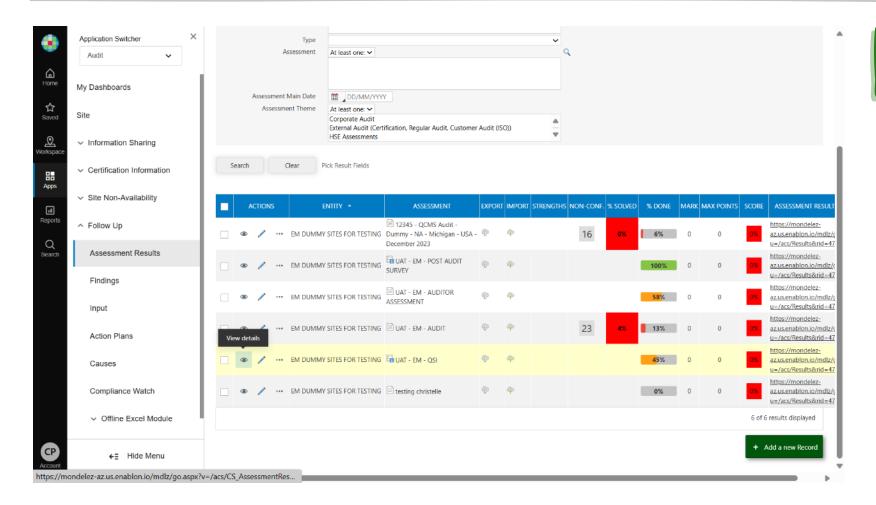
SELECT THE DESIRER
QUESTIONNAIRE



QUESTIONNAIRE



The Assessment Results page will be displayed. It contains all assessments related to the user





Click on the **eye icon** to select the desired **assessment** 

#### 5.2.1 ACCESSING A QSI QUESTIONNAIRE





GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRE

3 GO TO 'QUESTIONNAIRES'

SELECT THE DESIRED
QUESTIONNAIRE

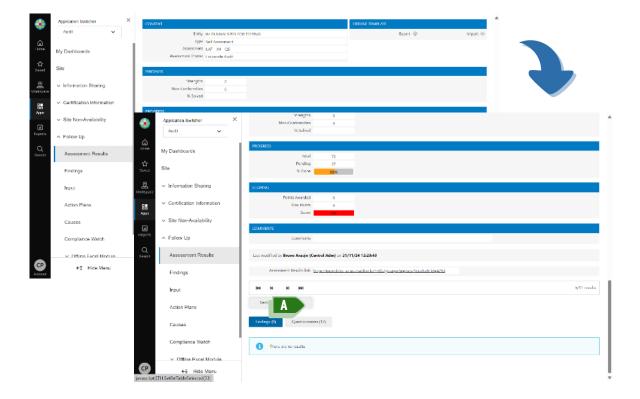


QUESTIONNAIRE PAGE



A page with general information about the selected assessment will be displayed

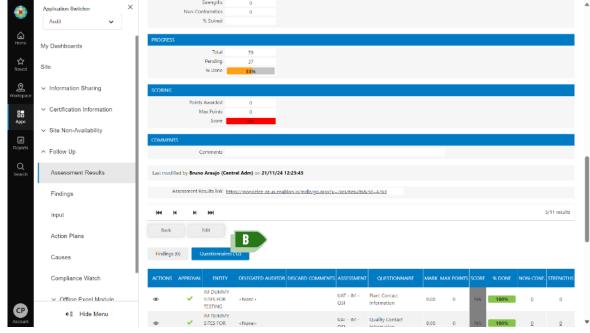
Scroll down to 'Findings'



Click on 'Questionnaires'

Findings (1)

Questionnaires (99)



#### 5.2.1 ACCESSING A QSI QUESTIONNAIRE





EMAIL NOTIFICATION 0R

GO TO 'ASSESSMEN'
RESULTS'

SELECT THE DESIRED
ASSESSMENT

GO TO 'QUESTIONNAIRES'

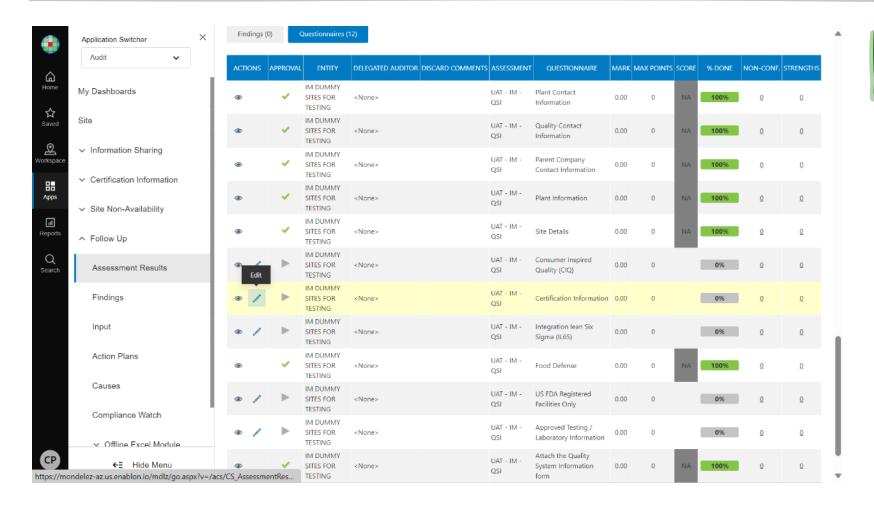
SELECT THE DESIRED QUESTIONNAIRE



QUESTIONNAIRE



A list of all the questionnaires related to the assessment will be displayed





Click on the **pen icon** to answer the desired questionnaire

#### 5.2.2 FILLING OUT A QSI QUESTIONNAIRE





GO TO 'ASSESSMEN RESULTS'

SELECT THE DESIREI
ASSESSMENT

GO TO 'QUESTIONNAIRES'

SELECT THE DESIRE QUESTIONNAIRE



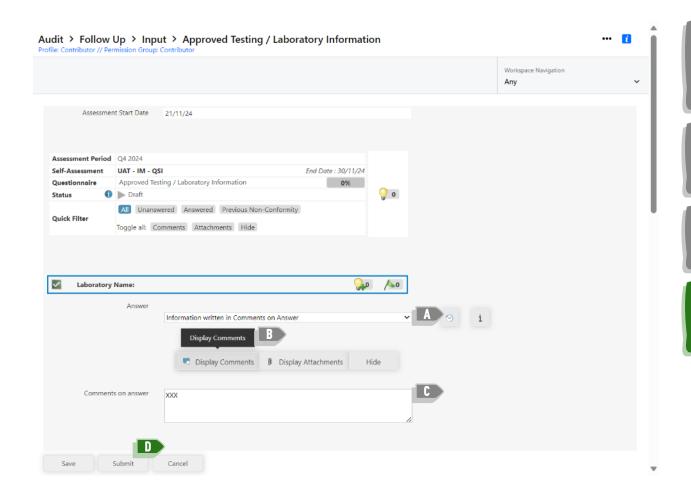
QUESTIONNAIRE PAGE

**HOW TO ANSWER THE QUESTIONNAIRES** 

HOW TO ANSWER THE LAST QUESTIONNAIRE (ATTACH QSI FORM)



DEADLINES



<u>Answer</u> – Select 'Information written in Comments on Answer' or one of the options available (depending on the question)

<u>Display Comments</u> - Click on 'Display Comments' to make the 'Comments on Answer' field visible

**Comments on Answer** – Answer the question in this field

Submit – Click on 'Submit' after answering all questions of the questionnaire

#### 5.2.2 FILLING OUT A QSI QUESTIONNAIRE





GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIREI
ASSESSMENT

GO TO 'QUESTIONNAIRES'

SELECT THE DESIRE QUESTIONNAIRE

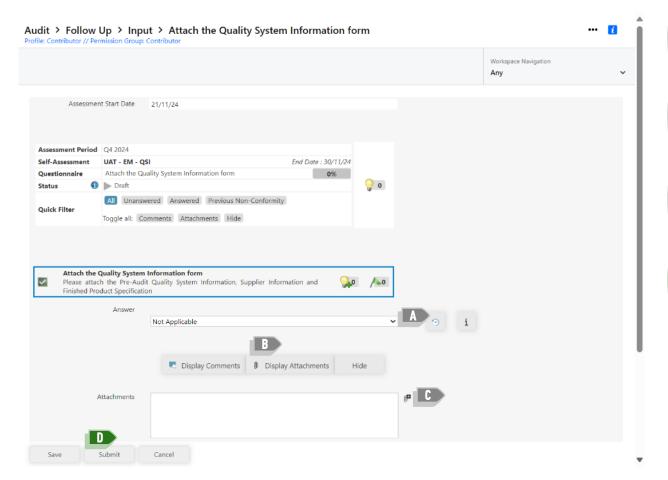


QUESTIONNAIRE PAGE

HOW TO ANSWER THE QUESTIONNAIRES

## HOW TO ANSWER THE LAST QUESTIONNAIRE (ATTACH QSI FORM)





Answer – Select 'Not Applicable'

Display Attachments - Click on 'Display Comments' to make the 'Attachments' field visible

Attachments – Click on the paper clip icon to attach the QSI Excel form and all materials requested in the notification email

Submit – Click on 'Submit' after attaching all required files

5 Quality System Information

#### 5.2.2 FILLING OUT A QSI QUESTIONNAIRE





OR

GO TO 'ASSESSMENT RESULTS' SELECT THE DESIREI
ASSESSMENT

GO TO QUESTIONNAIRES

4 SELECT THE DESIRED QUESTIONNAIRE



HOW TO ANSWER THE QUESTIONNAIRES

HOW TO ANSWER THE LAST QUESTIONNAIRE (ATTACH QSI FORM)





**Quality System Information Deadlines in Enablon** 

Start Date Submission Limit Date End Date

18 days before the audit start date

11 days before the audit start date

1 day after the audit end date

Chapter 6

# **ACTION PLANS**

Chapter 6.1

## **PROCESS OVERVIEW**

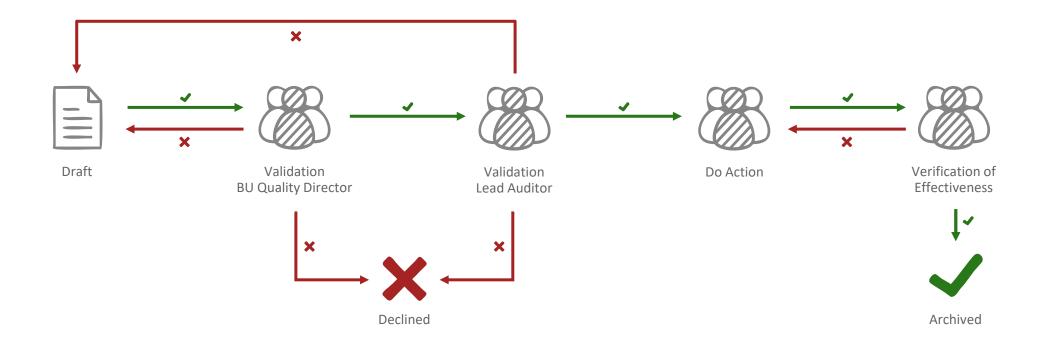
#### **6.1 PROCESS OVERVIEW**











## 6.1 PROCESS OVERVIEW









Draft	Validation (BU Quality Director)	<b>Validation</b> (Lead Auditor)	Do Action	Verification of Effectiveness
Stage Chapter 6.2	Stage Chapter 6.4		Stage Chapter 6.5	Stage Chapter 6.6
Stage Owner	Stage Owner	Stage Owner	Stage Owner	Stage Owner
Draft raiser & assigned Action Plan owner	BU Quality Director	Lead Auditor responsible for the Assessment used to create the Action Plan Draft	Assigned Action Plan owner & team members	Assigned verifier
Stage Actions	Stage Actions	Stage Actions	Stage Actions	Stage Actions
Create or update the Action Plan Draft	<ul> <li>Review the Action Plan Draft</li> </ul>	<ul> <li>Review the Action Plan Draft</li> </ul>	<ul> <li>Document actions progress and completion</li> </ul>	<ul> <li>Document actions effectiveness over time</li> </ul>
Submit the Action Plan     Draft for validation	Approve, reject or discard the Action Plan Draft	Approve, reject or discard the Action Plan Draft	<ul> <li>Add evidences, update status and insert comments to the Action Plan</li> <li>Submit the Action Plan for</li> </ul>	<ul> <li>Add evidences and insert comments to the Action Plan</li> <li>Archive or reject the Action Plan</li> </ul>
			<ul> <li>Submit the Action Plan for verification of effectiveness</li> </ul>	

#### **6.1 PROCESS OVERVIEW**





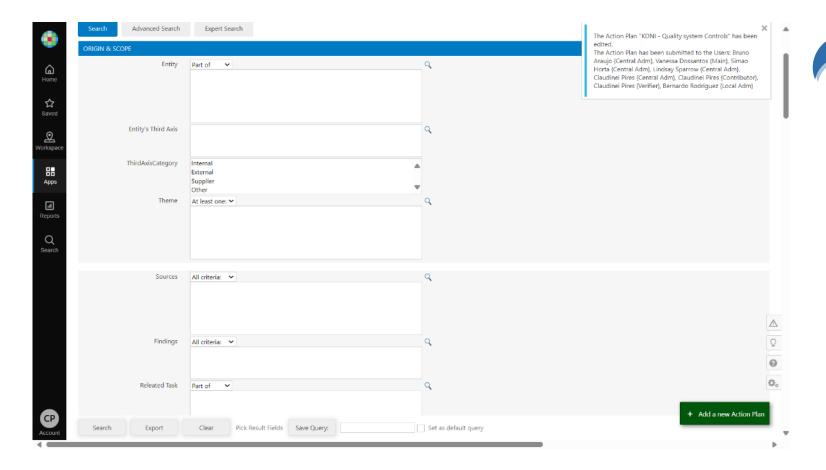
PROCESS WORKFLOW ABOUT STAGES





**EMAIL NOTIFICATIONS** 

An email notification is sent to the stage owner(s) every time the Action Plan moves to a new stage, whether it's due to submission, approval, or rejection. When the notification is triggered, a message will appear in the top-right corner of the screen confirming the action





The Action Plan "KDNI - Quality system Controls" has been

The Action Plan has been submitted to the Users: Bruno Araujo (Central Adm), Vanessa Dossantos (Main), Simao Horta (Central Adm), Lindsay Sparrow (Central Adm), Claudinei Pires (Central Adm), Claudinei Pires (Contributor), Claudinei Pires (Verifier), Bernardo Rodriguez (Local Adm)

- \*Click on the chapter name to be redirected to it
- \*Click on the 📫 icon to be redirected to the table of contents

#### Chapter 6.2

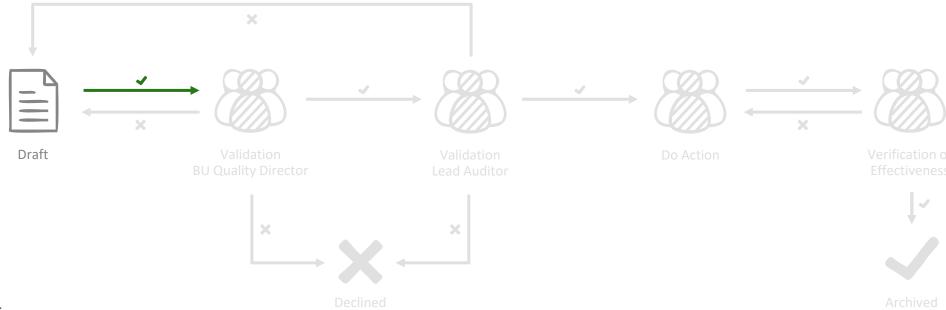
## **DRAFT**

- 6.2.1 **STAGE OVERVIEW**
- 6.2.2 <u>CREATING AN ACTION PLAN DRAFT</u>
- 6.2.3 <u>ACCESSING AN ACTION PLAN</u>

## **6.2.1 STAGE OVERVIEW**







#### **Stage Owner**

Draft raiser & assigned Action Plan owner

#### **Stage Actions**

- Create the Action Plan Draft
- Submit the Action Plan Draft for validation



GO TO 'ASSESSMENT RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

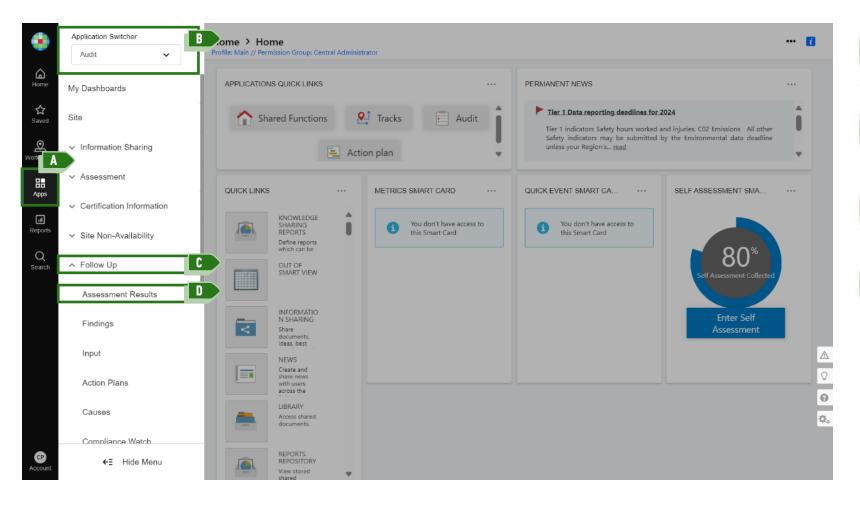
ADD AN ACTION PLAN TO THE DESIRED FINDING

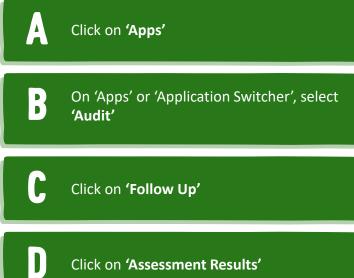


**ACTION PLANS POP-UP WINDOW** 



On the **Enablon home page** 







GO TO 'ASSESSMENT RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

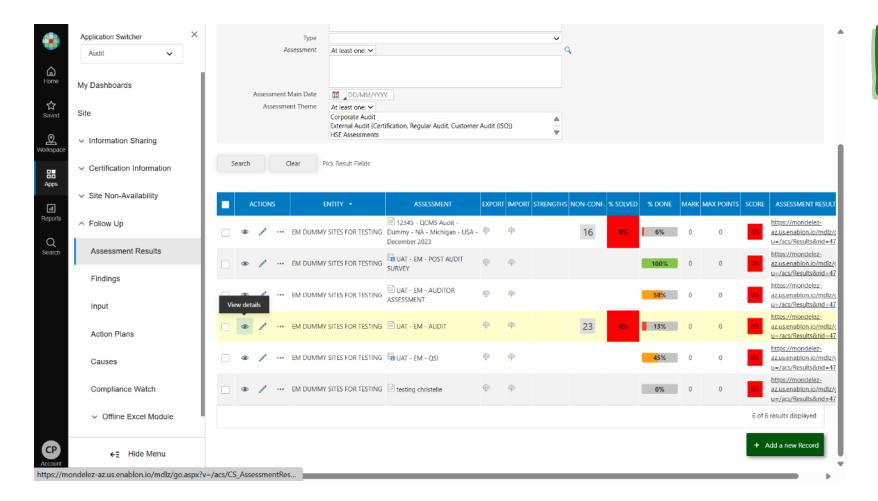
ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 



The Assessment Results page will be displayed. It contains all Assessment Results related to the user





Click on the **eye icon** to select the desired **Assessment Results** 



GO TO 'ASSESSMENT

2 SELECT THE DESIRED ASSESSMENT RESULTS

3 GO TO 'FINDINGS'

ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 



A page with general information about the selected Assessment Results will be displayed

Application Switcher	X CONTEXT OFFLINE TEMPLATE	
Audit 💙	Entity IM DUMMY SITES FOR TESTING Export   Type Audit  Assessment UAT - IM - AUDIT  Assessment Theme Corporate Audit	Import 🦚
Site	FINDINGS	
✓ Information Sharing	Strengths 0 Non-Conformities 17 96 Solved 636	
✓ Assessment	PROGRESS	
<ul> <li>Certification Information</li> </ul>	Total 326 Pending 297 % Done 8%	
<ul> <li>Site Non-Availability</li> <li>Follow Up</li> </ul>	SCORING	
Assessment Results	Points Awarded 0  Max Points 0  Score 036	
Findings	COMMENTS	
Input	Comments	
Action Plans	Cast modified by Bruno Araujo (Central Adm) on 11/12/24 12:32:21	
Causes	Assessment Results link https://mondelez-az.us.enablon.io/mdlz/go.aspx?u=/acs/Results&rid=4764	
<b>←</b> ≣ Hide Menu	Back Edit Delete	29/39 results

Scroll down to 'Findings'



GO TO 'ASSESSMENT RESULTS' 2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

ADD AN ACTION PLAN TO THE DESIRED FINDING



ACTION PLANS POP-UP WINDOW



A list of all the Findings associated with the selected Assessment Results will be displayed

Fi	indings	(23) Questionnaires (0)										
ACT	TIONS	QUESTION TITLE	ASSESSMENT	AUDIT THEME	ENTITY	REQUIREMENT	LEVEL	PERSON RESPONSIBLE	DESCRIPTION OF FINDING	ACTION DUE DATE	COMMENT ON FINDING CLOSURE	CAP
30	/	Section 1: General requirements	UAT - EM - AUDIT	Corporate Audit	EM DUMMY SITES FOR TESTING		Level 2- High		Test, test, test, Test, test, test, test, test, test	25/12/24	Add a new Action	on Pla
⊛	1	Section 2: Pneumatic Conveying Systems - Pressure Systems - Air Under Pressure (Compressed Air)	UAT - EM - AUDIT	Corporate Audit	EM DUMMY SITES FOR TESTING		Level 3- Medium			23/02/25		1
30	/	Section 4: Environmental Air	UAT - EM - AUDIT	Corporate Audit	EM DUMMY SITES FOR TESTING		Level 2- High			25/12/24		1 +
●	,	Section 5 : Special Gases (N2, CO2 and other gases)	UAT - EM - AUDIT	Corporate Audit	EM DUMMY SITES FOR TESTING		Level 1- Critical			02/12/24		2
<b>②</b>	/	Section 6: Water	UAT - EM - AUDIT	Corporate Audit	EM DUMMY SITES FOR TESTING		Level 4- Low			23/02/25		+
30	1	Section 7: Steam	UAT - EM - AUDIT	Corporate Audit	DUMMY SITES FOR TESTING		Level 2- High			25/12/24		+
3	1	Section 1: General Requirements	UAT - EM - AUDIT	Corporate Audit	EM DUMMY SITES FOR TESTING		Level 3- Medium		х	23/02/25		+
●	. /	Section 2: Determination of training needs for roles	UAT - EM -	Audit	DUMMY SITES		Level 3- Medium		х	23/02/25		+



Click on the plus sign icon to add a new Action Plan to the desired Finding. It's in the last column of this table, so if you are unable to see it, either zoom out or scroll to right



GO TO 'ASSESSMENT

2 SELECT THE DESIRED ASSESSMENT RESULTS

3 GO TO 'FINDING

4 ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 



ORIGIN & SCOPE

**PROBLEM** 

IMMEDIATE CORRECTION
PLANNED

MMEDIATE CORRECTION
ACTIONED

ROOT CAUSE

Although only mandatory fields (marked with \*) are required to submit an Action Plan Draft for validation, a well-structured document must be clear and comprehensive.

It is necessary to fill in all fields described in the following sections of this chapter to minimize the risk of rejection during validation stages. Once submitted, no further edits can be made unless the 'Draft' is rejected during validation stages



GO TO 'ASSESSMEN'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

4 ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 



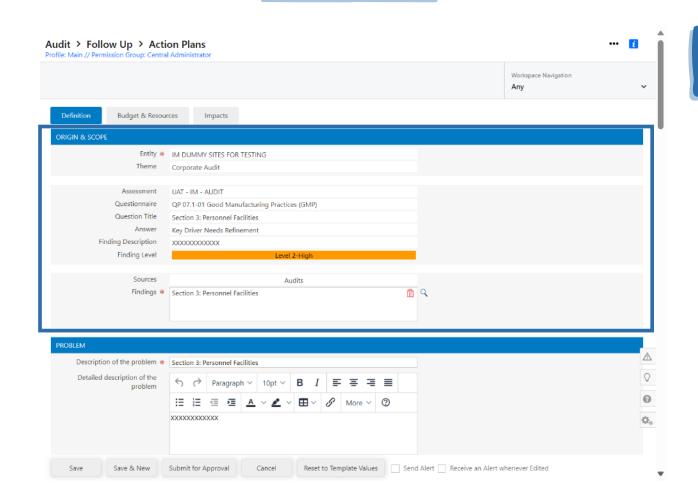
**ORIGIN & SCOPE** 

PROBLEM

MMEDIATE CORRECTION
PLANNED

MMEDIATE CORRECTION
ACTIONED

ROOT CAUSE



All fields in this section will be automatically filled with information from the Audit Module



GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 

REQUIRED FIELDS

ORIGIN & SCOPE

**PROBLEM** 

MMEDIATE CORRECTION
PLANNED

IMEDIATE CORRECTION

ACTIONED

**ROOT CAUSE** 

Answer Key D	Driver Needs Refinement	_
	00000000	
Finding Level	Level 2-High	
Sources	Audits	
Findings * Section	on 3: Personnel Facilities	- 1
		-1
		-1
PROBLEM		
Description of the problem * Section	on 3: Personnel Facilities	
Detailed description of the	Paragraph ∨ 10pt ∨ B I = = = ■	
problem		
≔		
XXXX	XXXXXXXXXXX	
	PRESS ALT+0 FOR HELP	
Origin of the problem * QCM	IS Audit	
Detailed origin of the problem		
Repeated problem ? No	v <b>E</b>	
Section Audited	v <b>F</b>	
Section Rating	v G	
Issue Rating	▼ <b>H</b>	$\triangle$
	_	0
IMMEDIATE CORRECTION - PLANNED		
Planned Actions 5	→ Paragraph ∨ 10pt ∨ B I 를 Ξ Ξ ≡ ■	○ ② ◆.
i≡	∃ Œ Œ A ∨ ∠ ∨ ⊞ ∨ 8 More ∨ ③	Ĉŧ₀
Save Save & New Submit	it for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited	•

<u>Description of the problem</u> - Automatically filled with information from the Audit Module

<u>Detailed description of the problem</u> - Automatically filled with information from the Audit Module

Origin of the problem - Select 'QCMS Audit'

Detailed origin of the problem - Include keywords that briefly identify the origin of the problem. Plants should use a common list of keywords to facilitate future searches

Repeated problem? - Select 'Yes' or 'No' to indicate whether this issue has occurred before



GO TO 'ASSESSMEN RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS

ADD AN ACTION PLAN TO THE DESIRED FINDING



REQUIRED FIELDS

ORIGIN & SCOPE

**PROBLEM** 

MMEDIATE CORRECTION
PLANNED

IMEDIATE CORRECTION
ACTIONED

ROOT CAUSE

Answer	Key Driver Needs Refinement	
Finding Description	xxxxxxxxxx	
Finding Level	Level 2-High	
Sources	Audits	
Findings *	Section 3: Personnel Facilities	
		_
PROBLEM		
Description of the problem *	Section 3: Personnel Facilities	
Detailed description of the problem	← → Paragraph × 10pt × B I = = = ■	
,	□ □ □ □ A ∨ ∠ ∨ □ ∨ Ø More ∨ ③	
	XXXXXXXXXXX	
	AND OUT OF THE PROPERTY OF THE	
	PRESS ALT+0 FOR HELP	
Origin of the problem *	QCMS Audit	
Detailed origin of the problem	D	
Repeated problem ?	No ▼ E	
Section Audited	▼ <b>F</b>	
Section Rating	▼ <b>G</b>	
Issue Rating	v H	$\triangle$
IMMEDIATE CORRECTION - PLANNED		V
Planned Actions	← ← Paragraph × 10pt × B I = = = =	<ul><li>○</li><li>②</li><li>◇</li><li>◇</li></ul>
		ďŁ.
	E E Œ Œ A ∨ ∠ ∨ ⊞ ∨ Ø More ∨ ③	
Save Save & New	Submit for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited	
Save or New	Submitted Approval Collect Meset to lettiplate values Sello Alert Necesse all Alert whethever collect	₩

Section Audited - Select the Audited Section

Section Rating - Select the Section Rating. It is set as the most critical finding rating among all findings from that section. The 'Section Ratings Table' contains general information about this topic

Issue Rating - Select the Issue Rating (same as Finding Rating). It is the 'Answer' field in the 'Origin & Scope' section. The 'Findings Ratings Table' contains general information about this topic

6.2 Draft

#### 6.2.2 CREATING AN ACTION PLAN DRAFT



GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS

4 ADD AN ACTION PLAN TO THE DESIRED FINDING





REQUIRED FIELDS

ORIGIN & SCOPE

PROBLEM

IMMEDIATE CORRECTION
PLANNED

MMEDIATE CORRECTION
ACTIONED

ROOT CAUSE



#### **Section Ratings Table**

Section Rating	Condition
Satisfactory	No Key Drivers, only Non-Conformity are allowed
Needs Refinement	At least one Key Driver Needs Refinement
Needs Improvement	At least one Key Drivers Needs Improvement
Repeat Needs Improvement	At least one Key Driver Repeat Needs Improvement

**Immediate Attention** 

At least one Key Driver Not Approval or Key Driver Immediate Attention



GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS

4 ADD AN ACTION PLAN TO THE DESIRED FINDING





REQUIRED FIELDS

ORIGIN & SCOPE

**PROBLEM** 

IMMEDIATE CORRECTION
PLANNED

MMEDIATE CORRECTION
ACTIONED

ROOT CAUSE /



#### **Findings Ratings Table**

Finding Rating	Initials	Level	Priority	Due Date
Key Driver Immediate Attention	KDIA	1 – Critical	1/A	30 Days
Key Driver Repeat Needs Improvement	KDRNI	1 – Critical	1/A	30 Days
Key Driver Needs Improvement	KDNI	1 – Critical	1/A	30 Days
Key Driver Needs Refinement	KDNR	2 – High	2/B	90 Days
Quality Chain Issue	QCI	2 – High	2/B	90 Days
Non-Conformity	NC	3 – Medium	3/C	90 Days
No Impact on Rating	NIR	4 – Low	4/D	90 Days
·				



GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

ADD AN ACTION PLAN TO
THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 



ORIGIN & SCOPE

ROBLEM

IMMEDIATE CORRECTION PLANNED

IMEDIATE CORRECTION
ACTIONED

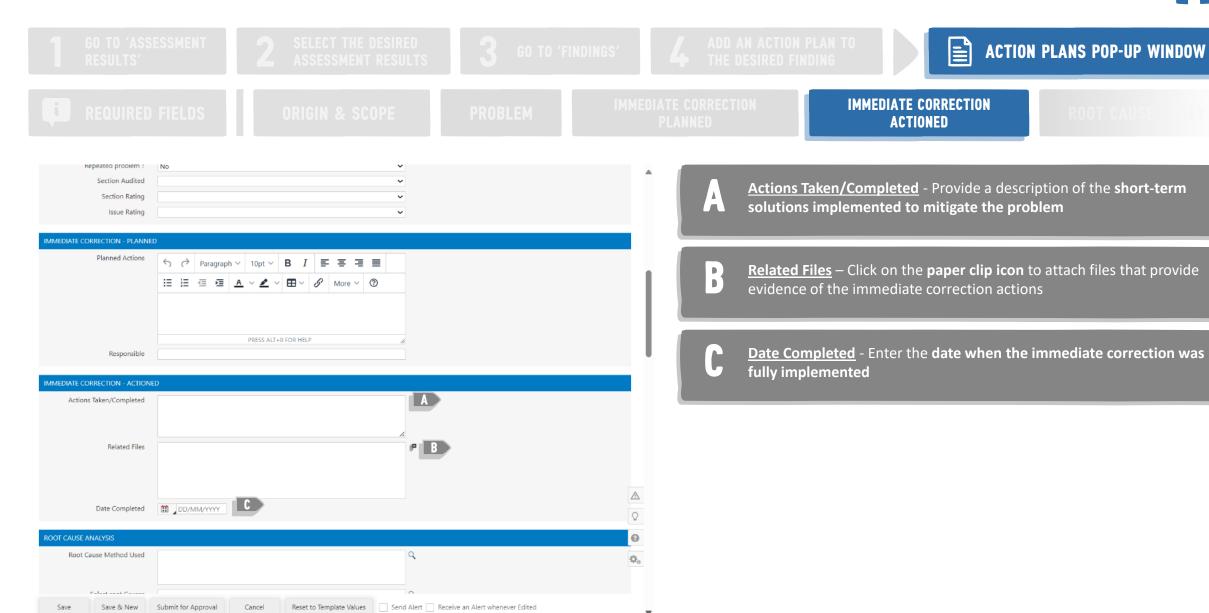
ROOT CAUSE

IMMEDIATE CORRECTION - PLANNED	
Planned Actions $\Leftrightarrow$ $\curvearrowright$ Paragraph $\lor$ 10pt $\lor$ B $I$ $\blacksquare$	
PRESS ALT+0 FOR HELP  Responsible	
IMMEDIATE CORRECTION - ACTIONED	
Actions Taken/Completed  Related Files	
Date Completed Doc/MM/YYYY	2
ROOT CAUSE ANALYSIS  Root Cause Method Used  Q	
Save Save & New Submit for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited	

<u>Planned Actions</u> - Provide a description of the **short-term solutions** planned to mitigate the problem

Responsible - Indicate the person or team responsible for implementing the immediate correction by entering their name(s). This is an open text field, so you can type in any name you want (the person does not need to have an Enablon account) It the finding is a QCI, you must also indicate the function of this person (Name/Function)

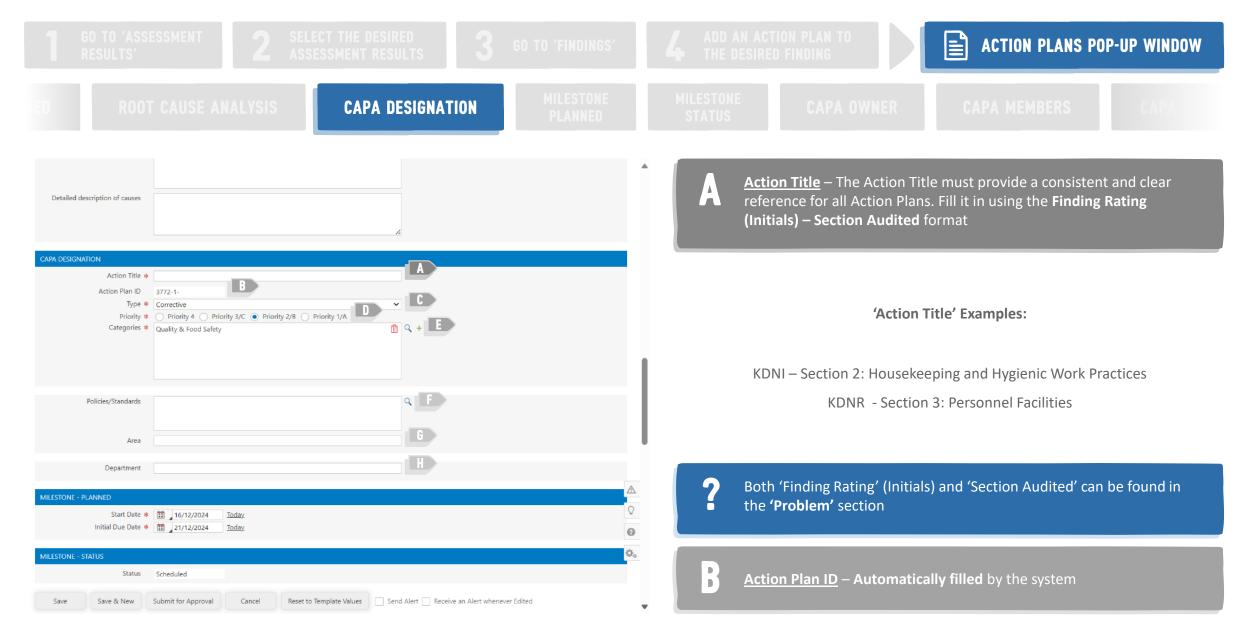




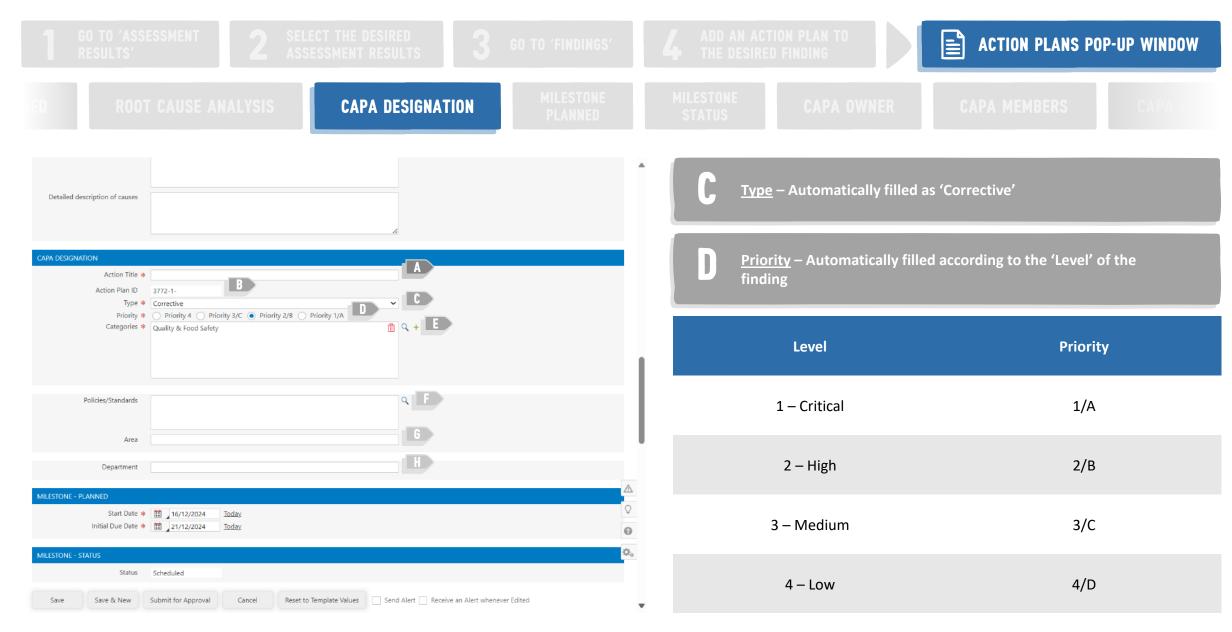


**ACTION PLANS POP-UP WINDOW ROOT CAUSE ANALYSIS** Root Cause Method Used – Click on the magnifying glass icon to Related Files select the **method used for root cause analysis**. Choose the appropriate technique from the options provided Date Completed 📋 DD/MM/YYYY OOT CAUSE ANALYSIS Q A Root Cause Method Used Select root Causes Root Cause Analysis Document(s) – Click on the paper clip icon to Root Cause Analysis Document(s) attach documents that supported the root cause analysis. Include reports, data sheets or any other file that detail the analysis conducted Detailed description of causes **Detailed description of causes** – Provide a comprehensive **description** CAPA DESIGNATION of the factors contributing to the issue. Include all relevant details Action Title \* that explain how and why the problem occurred Action Plan ID 3772-1-0 Priority \* Priority 4 Priority 3/C Priority 2/B Priority 1/A ₫Ę, m Q + Categories # Quality & Food Safety Save & New Submit for Approval Reset to Template Values Send Alert Receive an Alert whenever Edited

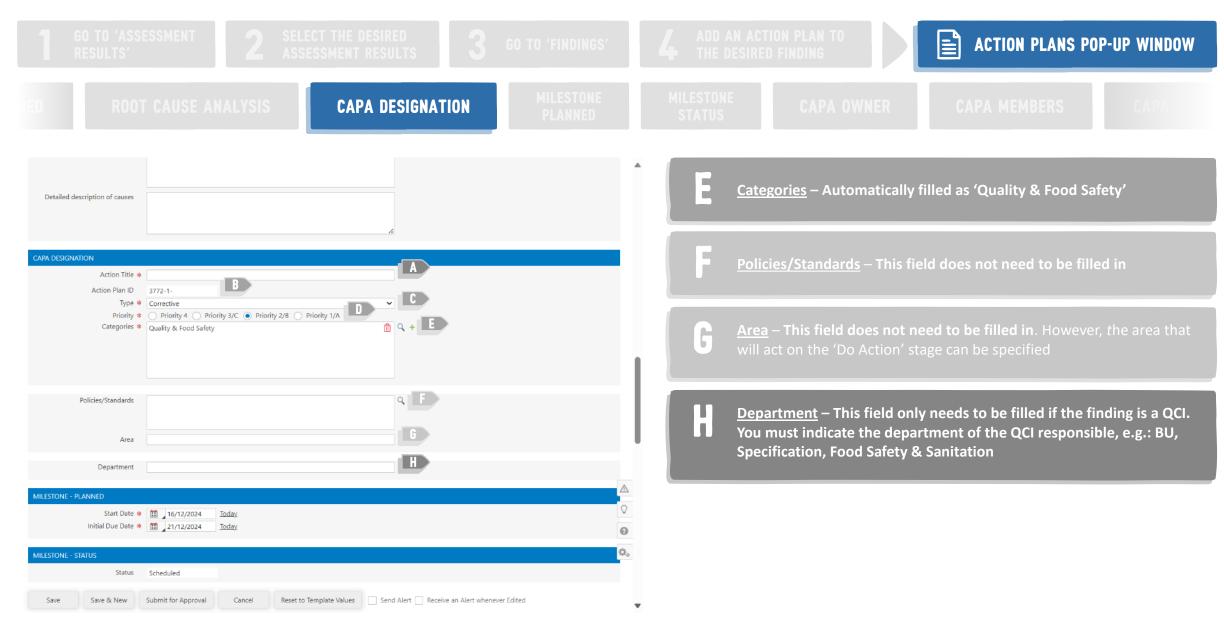














**ACTION PLANS POP-UP WINDOW** MILESTONE **PLANNED** Policies/Standards **Start Date – Automatically filled** by the system with the **date of the** 'Draft' creation. It can be modified if necessary Area Department B Initial Due Date – Automatically filled by the system according to the MILESTONE - PLANNED 'Priority' of the finding. It can be modified if necessary. If a change is Start Date \* 16/12/2024 Initial Due Date \* 📋 \_21/12/2024 needed, discuss the new date with the BU Quality team. Once the Action Plan Draft is submitted for approval, this date cannot be MILESTONE - STATUS updated without providing a detailed justification during the 'Do Status Scheduled Action' stage CAPA OWNER Owner \* Pires Claudinei i ii q APA MEMBERS i ₩Q Members Additional team members Active No CAPA - PLANNED Planned Action 

Reset to Template Values Send Alert Receive an Alert whenever Edited



GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

4 ADD AN ACTION PLAN TO THE DESIRED FINDING

ACTION PLANS POP-UP WINDOW

ROOT CAUSE ANALYSIS

CAPA DESIGNATION

MILESTONE PLANNED

MILESTONE Status

APA OWNER

APA MEMBERS

CADA

Policies/Standards	٩	
Area		
Department		
MILESTONE - PLANNED		
Start Date * Initial Due Date *	16/12/2024	
MILESTONE - STATUS		
Status	Scheduled	
CAPA OWNER		
Owner *	Pires Claudinei	
CAPA MEMBERS		
Members	i <b>≗</b> n Q	
		$\triangle$
Additional team members		0
Active	No	<ul><li>△</li><li>○</li><li>②</li></ul>
		Φ.
CAPA - PLANNED  Planned Action	←       →       Paragraph ×       10pt ×       B       I       ■       ■       ■       ■	74°0
Save & New	Submit for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited	•

Finding Rating - Priority	Due Date
KDIA - 1/A	30 Days
KDRNI - 1/A	30 Days
KDNI - 1/A	30 Days
KDNR - 2/B	90 Days
QCI - 2/B	90 Days
NC - 3/C	90 Days
NIR - 4/D	90 Days



**MILESTONE** Policies/Standards Area Department MILESTONE - PLANNED Start Date \* 16/12/2024 Initial Due Date \* 📋 \_21/12/2024 MILESTONE - STATUS A Status Scheduled Owner \* Pires Claudinei i ii q CAPA MEMBERS i ₩Q Members Additional team members Active No CAPA - PLANNED Planned Action Reset to Template Values Send Alert Receive an Alert whenever Edited Save & New Submit for Approval

**STATUS** 



ACTION PLANS POP-UP WINDOW

Status - Automatically filled as 'Scheduled'



Policies/Standards Area Department MILESTONE - PLANNED Start Date \* 16/12/2024 Initial Due Date \* 🛗 \_ 21/12/2024 MILESTONE - STATUS Status Scheduled i #Q A Owner \* Pires Claudinei CAPA MEMBERS i ₩Q Members Additional team members Active No CAPA - PLANNED Planned Action  $\hookrightarrow$  Paragraph  $\vee$  10pt  $\vee$  B I  $\equiv$   $\equiv$   $\equiv$ Reset to Template Values Send Alert Receive an Alert whenever Edited Submit for Approval

4 ADD AN ACTION PLAN TO THE DESIRED FINDING

**ACTION PLANS POP-UP WINDOW** 

MILESTONE STATUS

**CAPA OWNER** 

APA MEMBERS

CADA

Owner – Enter your Enablon account name. For Tier 0 Copackers, the Enablon Account Name is the name of the plant itself + 'EM BP Account'. Type in the first three letters and the name will automatically appear in a drop-down list



**ACTION PLANS POP-UP WINDOW CAPA MEMBERS** Policies/Standards Members – This will usually not be filled by Tier 0 Copackers, as you most likely have only one Enablon account, which is already Area indicated in the "Owner" field. However, if the owner will have collaborators with an Enablon account assisting in implementing the Department Action Plan, indicate them. MILESTONE - PLANNED Start Date \* 16/12/2024 Initial Due Date \* 📋 \_21/12/2024 Additional team members – Here you will indicate the name of the MILESTONE - STATUS Status Scheduled Action Plan owner and team members (who are responsible for it). This is an open text field, so there's no need for the person indicated CAPA OWNER here to have an Enablon account. This person will be responsible for Owner \* Pires Claudinei i ii q completing this Action Plan internally and sending the information for APA MEMBERS upload/update to the quality person/team who have access to i #4 A Members Enablon (they will upload the information to the system) Example: "Jane Sas, John Doff" Additional team members CAPA - PLANNED <u>Active</u> – Automatically filled as 'No' in the Draft Creation state

Reset to Template Values Send Alert Receive an Alert whenever Edited



GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 

CAPA - PLANNED

CAPA - ACTIONED

VERIFICATION OF EFFECTIVENESS
PLANNED

VERIFICATION OF EFFECTIVENESS

ACTIONED

SAVE & SUBMIT

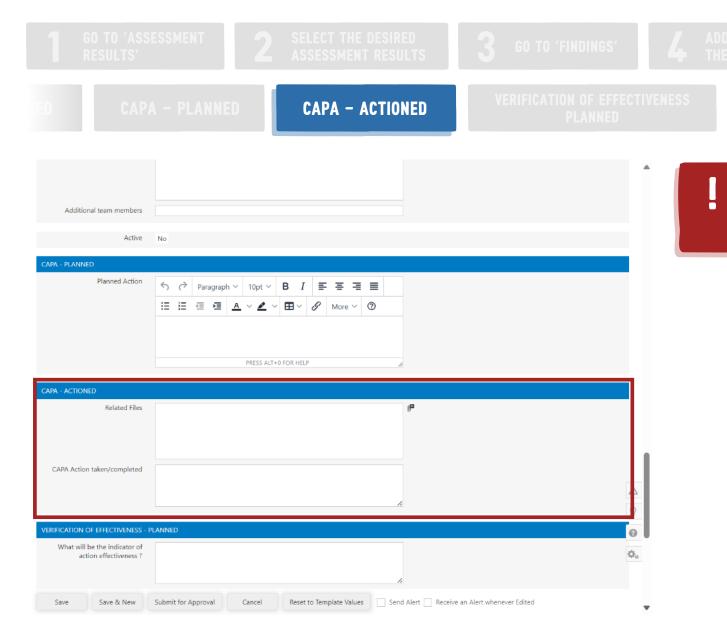
Additional team members	
Active	No
CAPA - PLANNED	
Planned Action	Solution Paragraph ✓ 10pt ✓ B I <td< td=""></td<>
	<i>y</i>
CAPA - ACTIONED  Related Files	ile
Nelateu Files	
CAPA Action taken/completed	
VERIFICATION OF EFFECTIVENESS - I	
What will be the indicator of action effectiveness ?	<b>♦</b>
Save & New	Submit for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited

<u>Planned Action</u> – Detail the corrective and preventive actions that will be implemented. Describe the proposed measures, specifying whether each action is intended to correct the current issue or prevent future occurrences.

Recommendation: specify the person or team (indicated in "additional team members") responsible for each action by the end of it. Example:

- "1. Implement new trainings to the quality personnel. Responsible: Jane Sas.
- 2. Review all standard procedures related to X. Responsible: John Doff."





VERIFICATION OF EFFECTIVENESS

ACTIONED

SAVE & SUBMIT

**ACTION PLANS POP-UP WINDOW** 

This section should not be filled out during the 'Draft' stage. It is filled out by the assigned CAPA owner/team during the 'Do Action' stage of the Action Plan

## 6.2.2 CREATING AN ACTION PLAN DRAFT



GO TO 'ASSESSMEN RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS'

4 ADD AN ACTION PLAN TO THE DESIRED FINDING



\_\_\_

CAPA - PLANNED

CAPA - ACTIONED

VERIFICATION OF EFFECTIVENESS PLANNED

/ERIFICATION OF EFFECTIVENESS

ACTIONED

SAVE & SUBMIT

CAPA Action taken/completed		•
VERIFICATION OF EFFECTIVENESS -	PLANNED	
What will be the indicator of action effectiveness ?	A	
Who is checking effectiveness?	ii Q B	
Verification Due Date	₩ JDD/MM/YYYY C	
VERIFICATION OF EFFECTIVENESS -	ACTIONED	
Effectiveness ?	v	
Comments about effectiveness		
Date Efficiency has been verified	□ DD/MM/YYYY	
Evidence of the Efficiency of the Action	g*	<ul><li>△</li><li>○</li><li>②</li></ul>
		0
Saving will start a new Audit Trail		Φo
* Required fields		
Save & New	Submit for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited	

What will be the indicator of action effectiveness? – Specify the metric or indicator that will be used to assess the effectiveness of the actions taken. Describe how this indicator will measure the success of the implemented measures.

<u>Mandatory</u>: specify the person responsible for each indicator by the end of it. The person checking the effectiveness of an action must be different than the person responsible for implementing the action

Who is checking effectiveness? – Enter your Enablon account name. For Tier 0 Copackers, the Enablon Account Name is the name of the plant itself + 'EM BP Account'. Type in the first three letters and the name will automatically appear in a drop-down list Exception: If the finding is a QCI, here you'll indicate the name of the region/BU Quality Leads.

6.2 Draft

#### 6.2.2 CREATING AN ACTION PLAN DRAFT



GO TO 'ASSESSMEN
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS

4 ADD AN ACTION PLAN TO THE DESIRED FINDING



**ACTION PLANS POP-UP WINDOW** 

ED (

PA - PLANNED

CAPA - ACTIONED

VERIFICATION OF EFFECTIVENESS PLANNED

VERIFICATION OF EFFECTIVENESS ACTIONED

**SAVE & SUBMIT** 

CAPA Action taken/completed		^
VERIFICATION OF EFFECTIVENESS -	PLANNED	
What will be the indicator of action effectiveness ?	A	
Who is checking effectiveness?	# Q B	
Verification Due Date	m Jod/MM/YYYY C	
VERIFICATION OF EFFECTIVENESS -	ACTIONED	
Effectiveness ?	v	
Comments about effectiveness		
Date Efficiency has been verified	□ JDD/MM/YYYY	
Evidence of the Efficiency of the Action	₽	<ul><li>△</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li><li>○</li>&lt;</ul>
		0
Saving will start a new Audit Trail		Ф
* Required fields		

Verification Due Date – Set the due date for verification. It is recommended to schedule the verification due date between 30 and 90 days after the initial due date specified in the 'Milestone' section. Important: Unless it is aligned with the BU Quality team, the Verification Due Date should not be longer than 6 months after the Audit End Date.

6.2 Draft

Saving will start a new Audit Trail

Save & New Submit for Approval

\* Required fields

## 6.2.2 CREATING AN ACTION PLAN DRAFT



**VERIFICATION OF EFFECTIVENESS ACTIONED** CAPA Action taken/completed stage of the Action Plan PERIFICATION OF EFFECTIVENESS - PLANNED What will be the indicator of action effectiveness HQ Who is checking effectiveness? Verification Due Date DD/MM/YYYY Effectiveness ? Comments about effectiveness □ DD/MM/YYYY Date Efficiency has been verified Evidence of the Efficiency of the

Reset to Template Values Send Alert Receive an Alert whenever Edited

**ACTION PLANS POP-UP WINDOW** 

This section should not be filled out during the 'Draft' stage. It is filled out by the assigned verifier during the 'Verification of Effectiveness' 6.2 Draft

#### 6.2.2 CREATING AN ACTION PLAN DRAFT



GO TO 'ASSESSMEN
RESULTS'

2 SELECT THE DESIRED ASSESSMENT RESULTS

**3** GO TO 'FINDINGS

ADD AN ACTION PLAN TO THE DESIRED FINDING



ED CAPA - P

CAPA - ACTIONED

VERIFICATION OF EFFECTIVENESS
PLANNED

/ERIFICATION OF EFFECTIVENESS
ACTIONED

**SAVE & SUBMIT** 

CAPA Action taken/completed		^
VERIFICATION OF EFFECTIVENESS -	PLANNED	
What will be the indicator of action effectiveness ?		
Who is checking effectiveness?	# Q	
Verification Due Date	■ JDD/MM/YYYY	
VERIFICATION OF EFFECTIVENESS -	ACTIONED	
Effectiveness ?	v	
Comments about effectiveness		
Date Efficiency has been verified	□ JDD/MM/YYYY	
Evidence of the Efficiency of the Action	₽ P	♠
		0
Saving will start a new Audit Trail		Ф.
Save Save & New	B Submit for Approval Cancel Reset to Template Values Send Alert Receive an Alert whenever Edited	I

Click on 'Save' if the 'Draft' stage is not yet completed and additional information is still needed or if tasks will be added. This will record the current progress of the Action Plan Draft and allow for further edits before submission. For information about tasks, refer to Chapter 6.3

Click on 'Submit for Approval' once all necessary fields have been filled. This will send the Action Plan for validation by the BU Quality Director. Ensure all information is accurate and comprehensive before submission





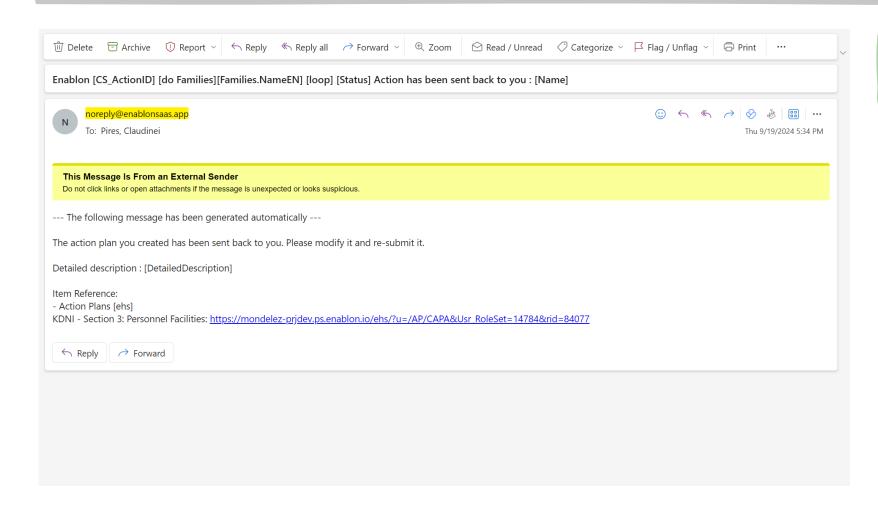
GO TO 'ACTION PL

**?** SELECT THE DESIRED ACTION PLAN





An email notification will be received by the Action Plan owner if the Action Plan is returned to the 'Draft' stage during the 'Validation' stages



Click on the link. It directly redirects you to the Action Plan





EMAIL NOTIFICATION

GO TO 'ACTION PLANS'

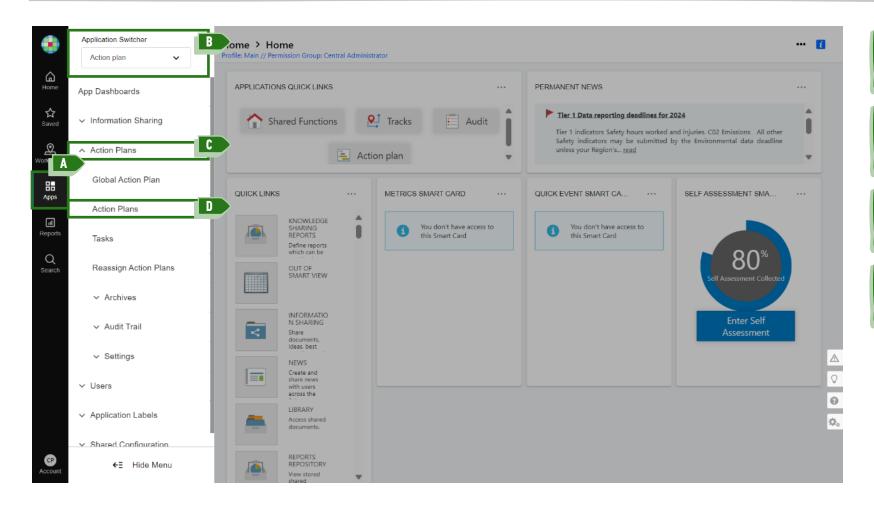
SELECT THE DESIRED ACTION PLAN



**ACTION PLAN** 



On the **Enablon home page** 









EMAIL NOTIFICATION

R

GO TO 'ACTION PLANS

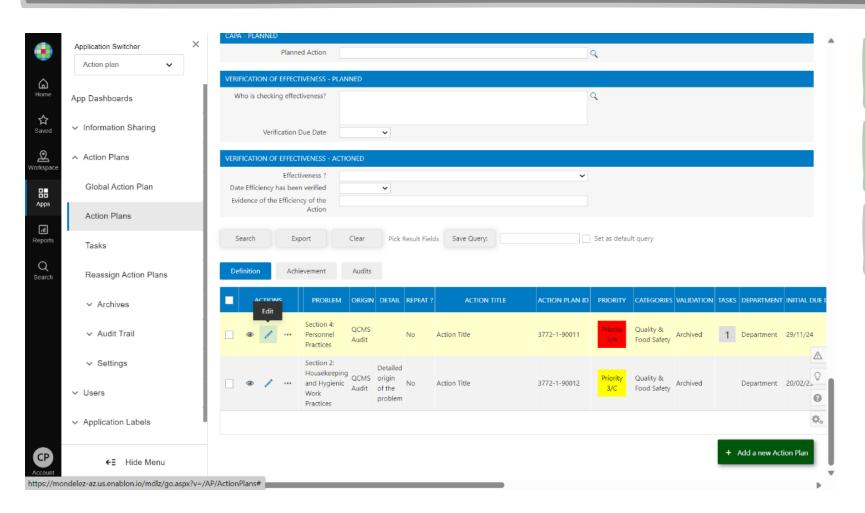
2 SELECT THE DESIRED ACTION PLAN

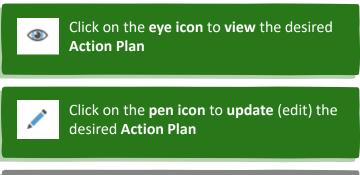


ACTION PLAN



The Action Plans page will be displayed. It contains a list of all the Action Plans related to the user





The 'Validation' column indicates the current stage of the Action Plan



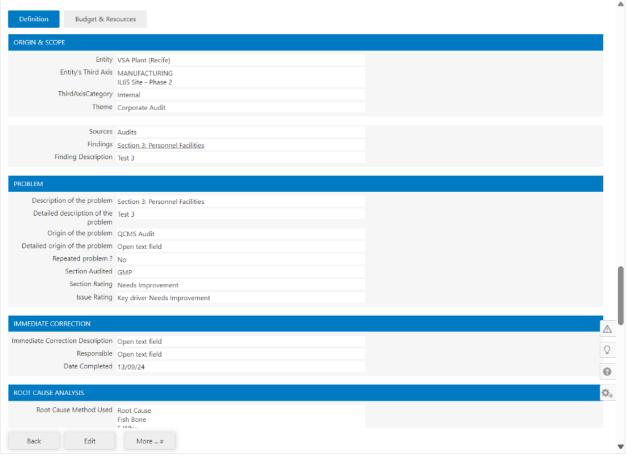




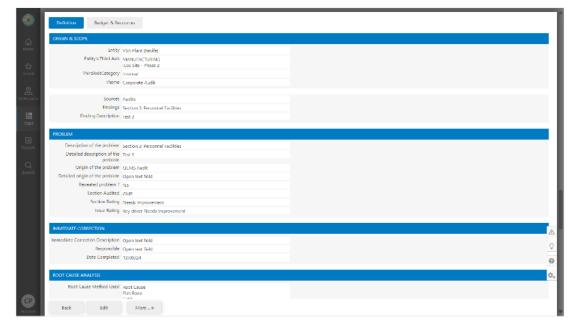
**ACTION PLAN** 



The Action Plan will be displayed







- \*Click on the chapter name to be redirected to it
- \*Click on the 🧻 icon to be redirected to the table of contents

Chapter 6.3

# **TASKS**

- 6.3.1 <u>ADDING TASKS TO AN ACTION PLAN</u>
- 6.3.2 **ACCESSING A TASK**
- 6.3.3 <u>DOCUMENTING A TASK'S PROGRESS AND COMPLETION</u>





GO TO 'ACTION PLANS'

**2** ADD A TASK TO THE DESIRED ACTION PLAN



Tasks are used to specify the actions each team member will participate in. When the Action Plan involves multiple actions and members, this approach enhances clarity and ensures everyone understands their responsibilities. This functionality will most likely not be used by Tier 0 Copackers, as the plant only has one Enablon account.

However, the material is available in case BU Quality request the addition of tasks to any Action Plan

Ideally, tasks should be added in the 'Draft' stage. However, they can be added between the 'Draft' and 'Do Action' stages. Be aware of the Action Plan's due date when creating a new task, as their results must be documented by the Action Plan owner in the 'Do Action' stage





GO TO 'ACTION PLANS'

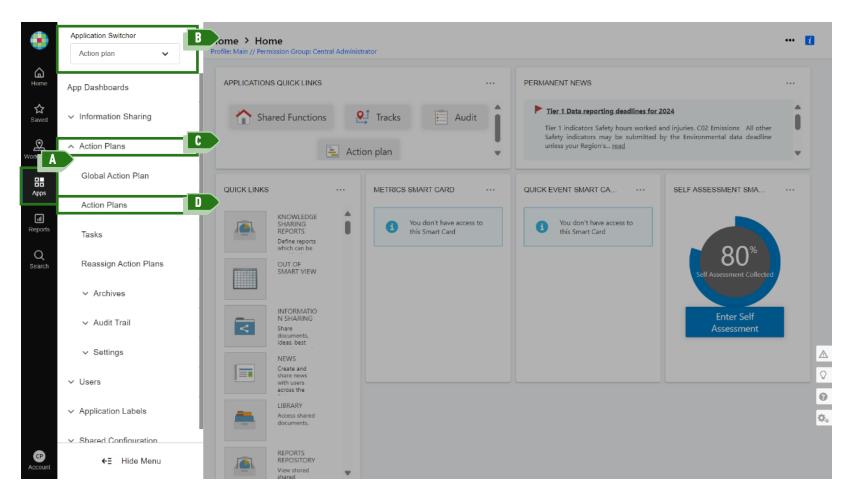
**7** ADD A TASK TO THE DESIRED ACTION PLAN



TASKS POP-UP WINDOW



On the **Enablon home page** 









GO TO 'ACTION PLANS'

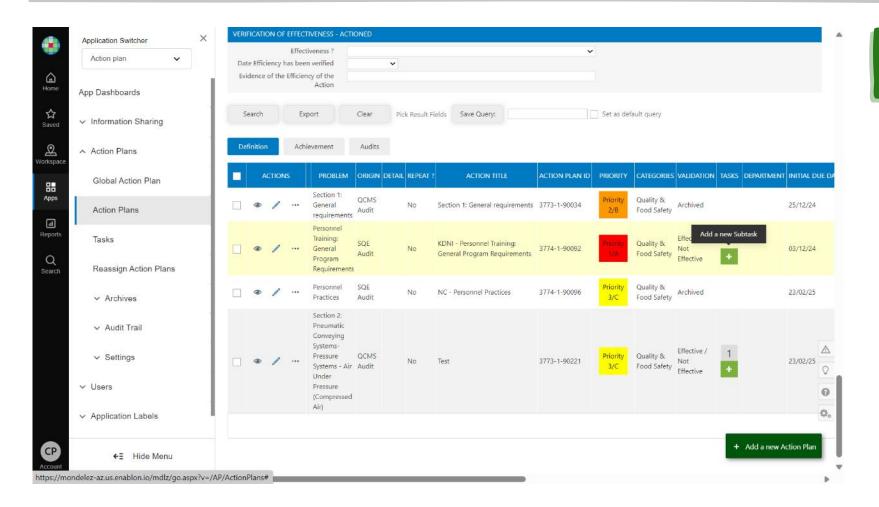
2 ADD A TASK TO THE DESIRED ACTION PLAN



TASKS POP-UP WINDOW



The Action Plans page will be displayed. It contains a list of all the Action Plans related to the user







ABOUT TASK

GO TO 'ACTION PLANS'

**2** ADD A TASK TO THE DESIRED ACTION PLAN



TASKS POP-UP WINDOW



SOURCE

**IDENTIFICATION** 

SCOPE

CLASSIFICATION

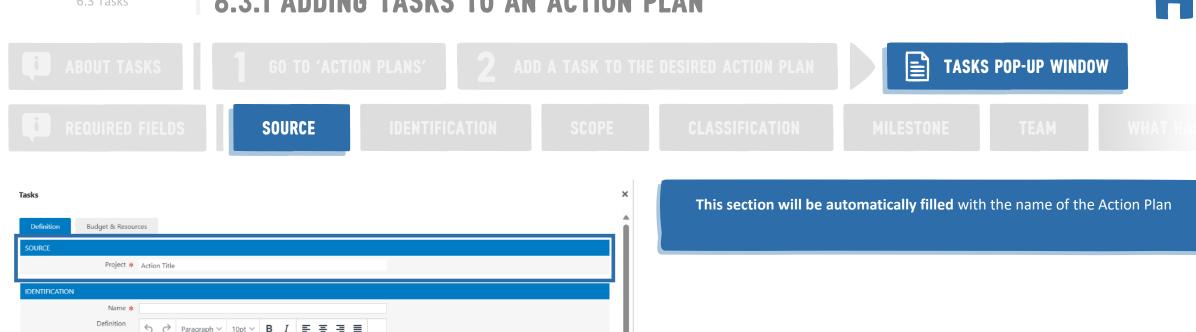
MILESTONE

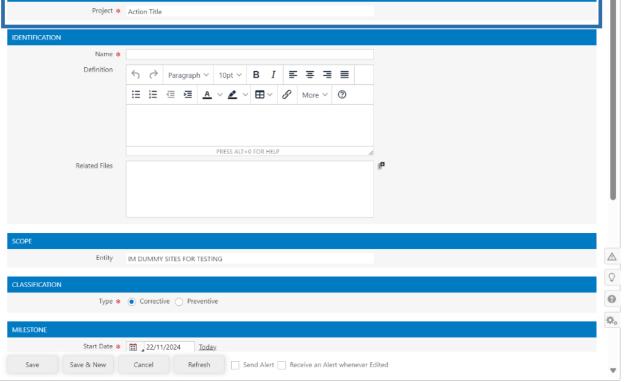
TEAM

WHAT HAS

Although only mandatory fields (marked with \*) are required to add a task to an Action Plan, a well-structured document must be clear and comprehensive. <u>It is necessary</u> to fill in all fields described in the following sections of this chapter to ensure the assigned team fully understands their responsibilities and the task's scope







Type \* O Corrective Preventive

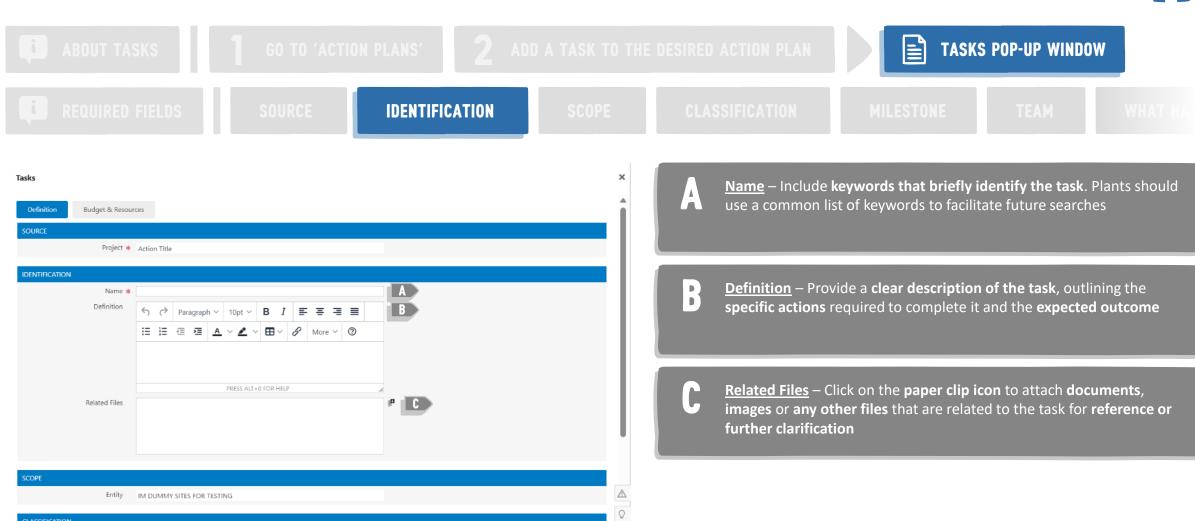
Send Alert Receive an Alert whenever Edited

Start Date \* 22/11/2024

MILESTONE

#### 6.3.1 ADDING TASKS TO AN ACTION PLAN





0

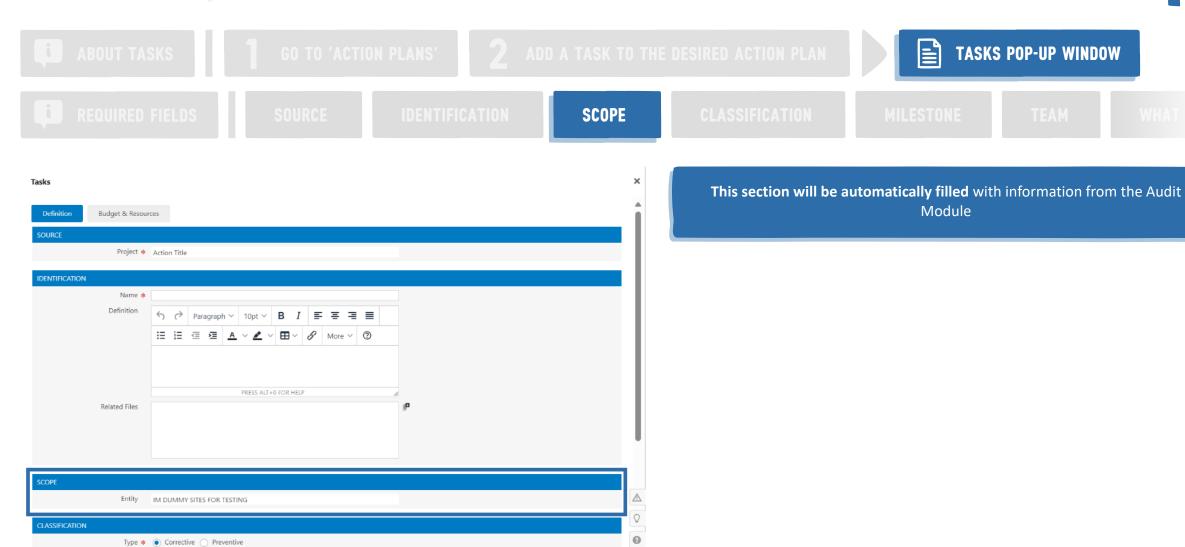
MILESTONE

Start Date \* 22/11/2024

Send Alert Receive an Alert whenever Edited

## 6.3.1 ADDING TASKS TO AN ACTION PLAN





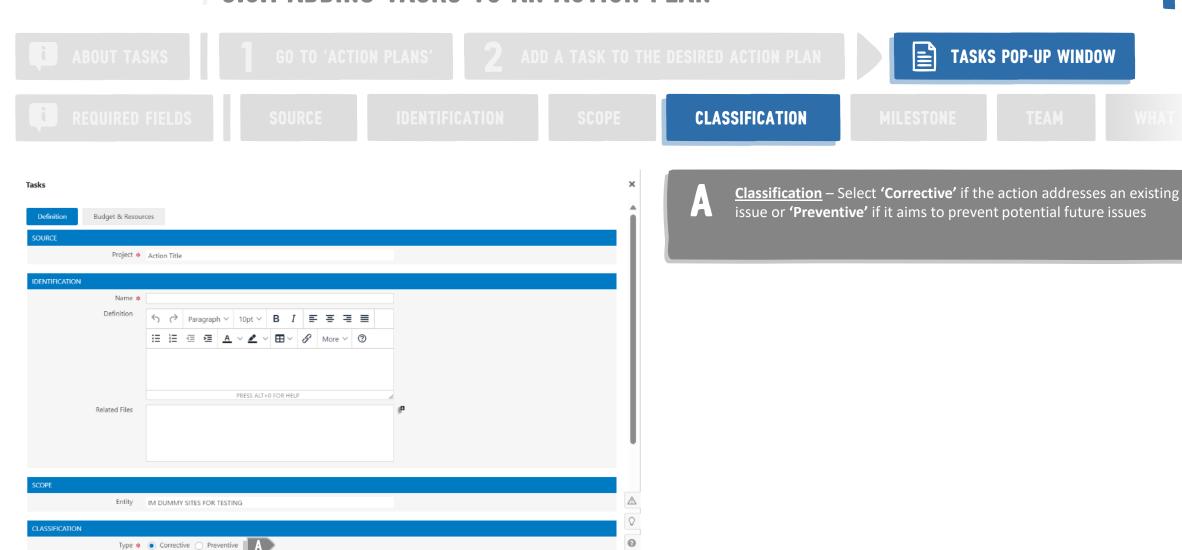
MILESTONE

Start Date \* 22/11/2024

Send Alert Receive an Alert whenever Edited

#### 6.3.1 ADDING TASKS TO AN ACTION PLAN





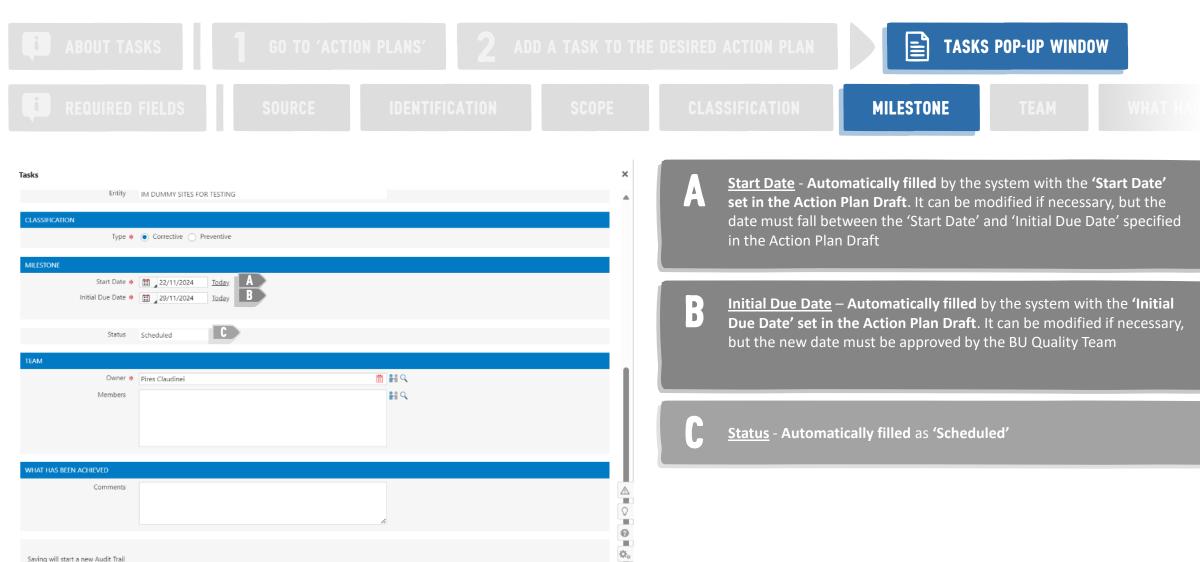
Required fields

Save & New

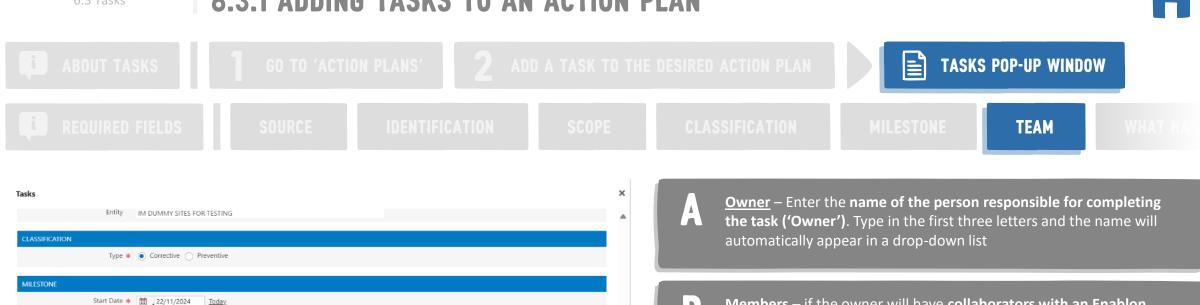
#### 6.3.1 ADDING TASKS TO AN ACTION PLAN

Send Alert Receive an Alert whenever Edited









Initial Due Date \* 29/11/2024 Status Scheduled m HQ A Owner \* Pires Claudinei HQ B Members WHAT HAS BEEN ACHIEVED Comments Saving will start a new Audit Trail \* Required fields Save & New Send Alert Receive an Alert whenever Edited

Members – if the owner will have collaborators with an Enablon account assisting in implementing the task, indicate them. Type in the first three letters and the name will automatically appear in a dropdown list





GO TO 'ACTION PLANS'

2 ADD A TASK TO THE DESIRED ACTION PLAN



TASKS POP-UP WINDOW



#### WHAT HAS BEEN ACHIEVED

SAVE

Tasks	×	
Entity	IM DUMMY SITES FOR TESTING	
CLASSIFICATION		
	Corrective    Preventive	
71		
MILESTONE		
Start Date *	(ii) _22/11/2024 Today.	
Initial Due Date 🕸	29/11/2024 <u>Ioday.</u>	
Status	Scheduled	
TEAM		
	Pires Claudinei iii 🕌 🔍	
Members	Pires Claudinei	
Wellibers	H ×	
WHAT HAS BEEN ACHIEVED		
Comments		
Saving will start a new Audit Trail		j.
* Required fields		
Save & New	Cancel Refresh Send Alert Receive an Alert whenever Edited	

This section should not be filled during this stage. It is filled out by the assigned task owner after actions have been taken to complete the task





ABOUT TASKS GO TO 'ACTION PLANS'

2 ADD A TASK TO THE DESIRED ACTION PLAN

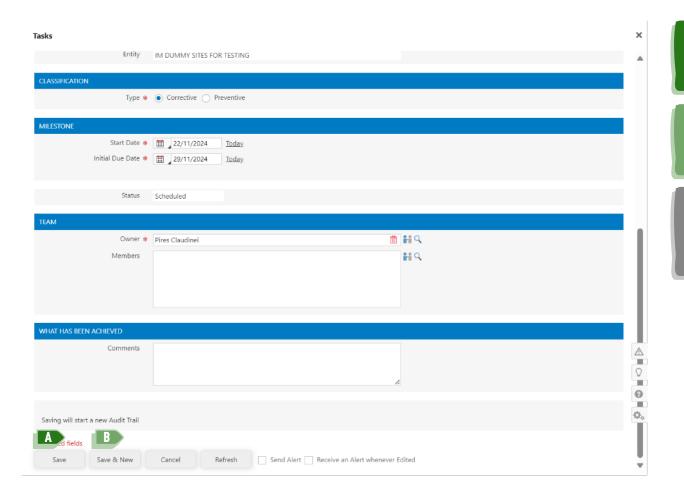


TASKS POP-UP WINDOW



WHAT HAS BEEN ACHIEVED

SAVE



Click on 'Save' once all necessary fields have been filled. This will send the task to the assigned task owner

Click on 'Save & New' to send the task to the assigned task owner and start a new task

If you click on 'Save' or 'Save & New', a message will appear at the top right of the screen indicating that an email notification has been sent to the task owner





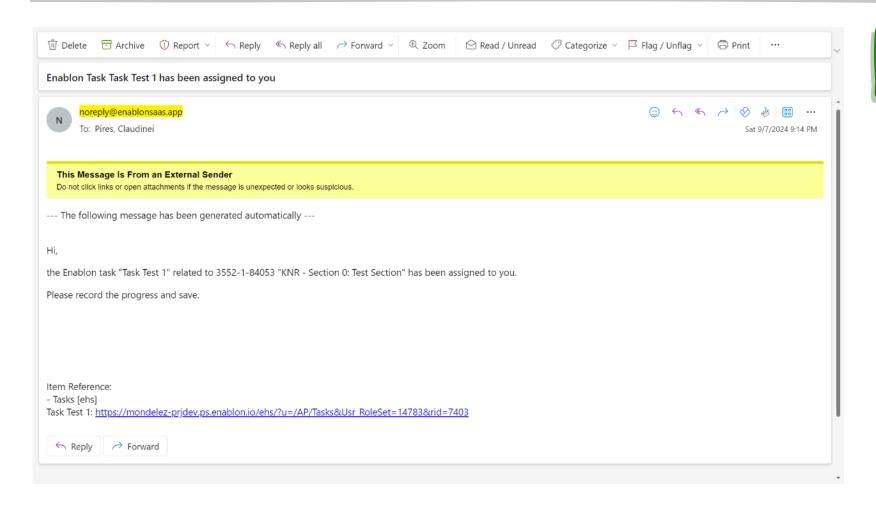
GO TO 'TASKS

SELECT THE DESIRED TASK





An email notification will be received by the assigned task owner after it is created



Click on the link. It directly redirects you to the task





EMAIL NOTIFICATION

GO TO 'TASKS'

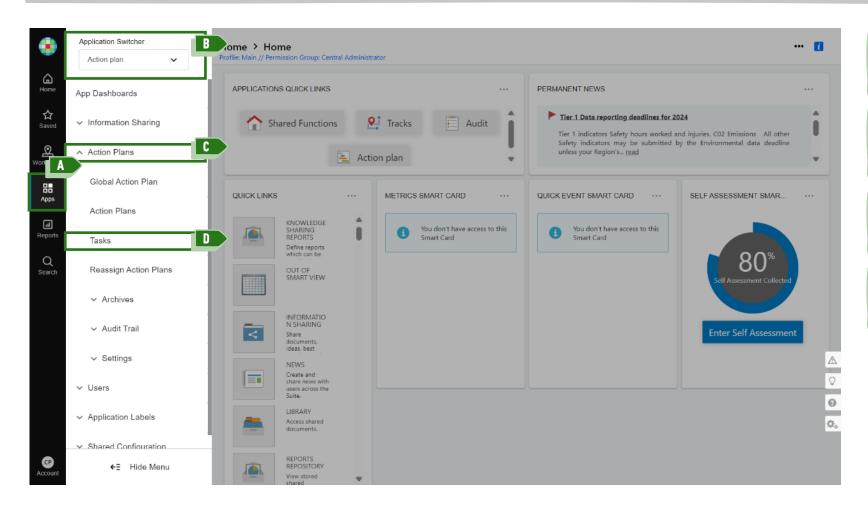
SELECT THE DESIRED TASK

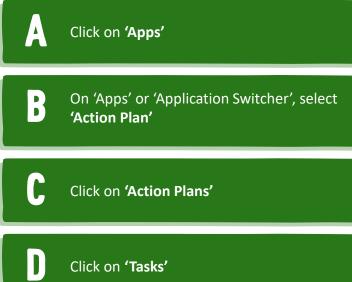


ASK



On the **Enablon home page** 









EMAIL NOTIFICATION

R

GO TO 'TASKS

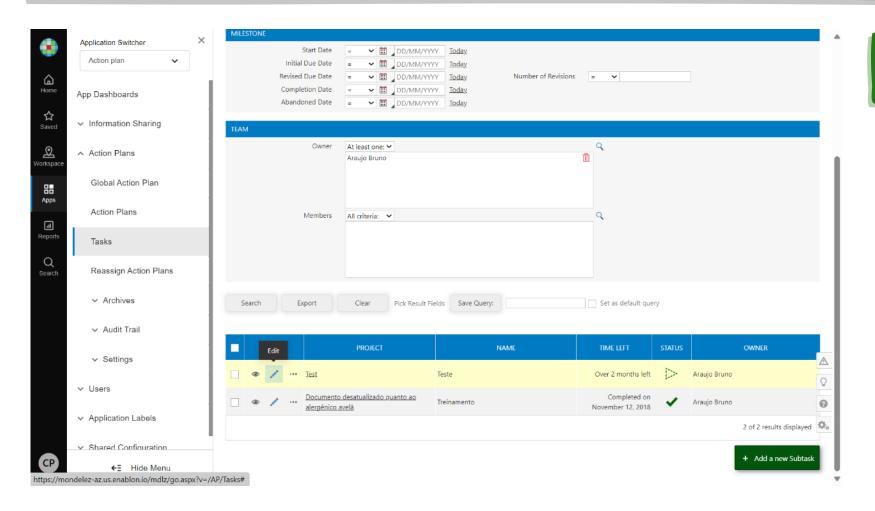
2 SELECT THE DESIRED TASK



TASK



The Tasks page will be displayed. It contains a list of all the tasks related to the user





Click on the **pen icon** to **update** (edit) the desired **task** 





**EMAIL NOTIFICATION** 

GO TO

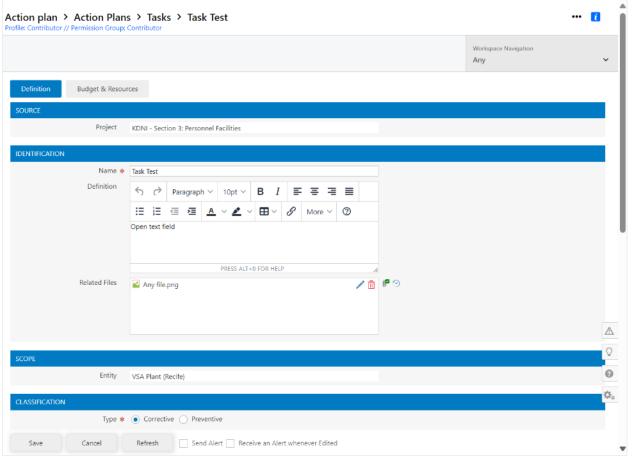
2 SELECT THE DESIRED TASK



TASK



The task will be displayed





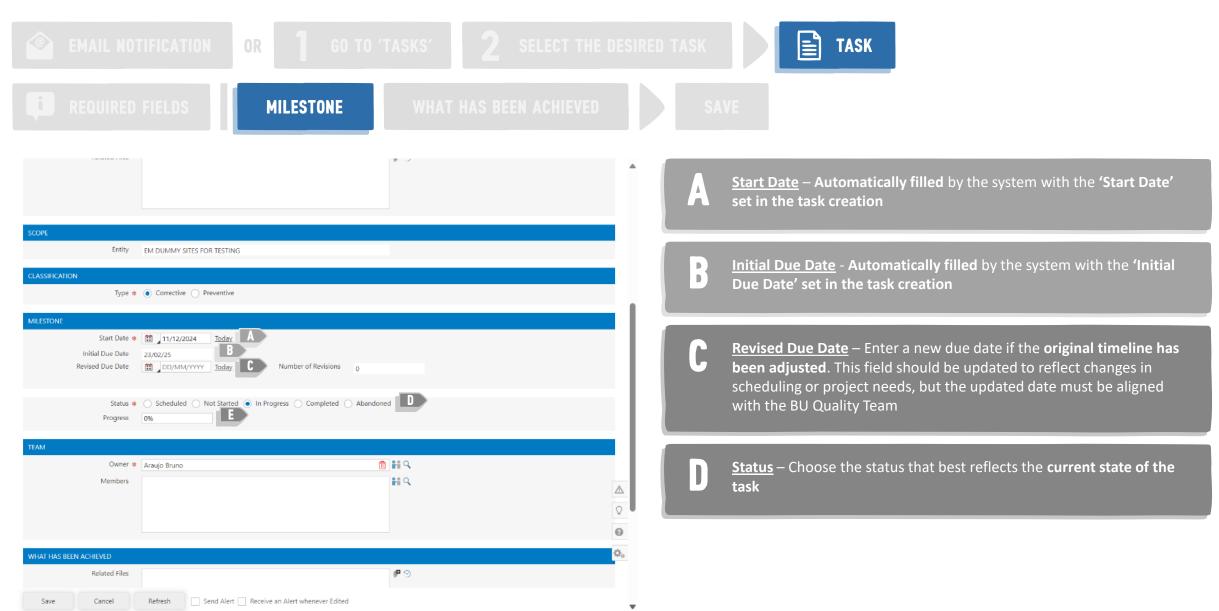
•	Detailion Budget & Resources	
	SOUNCE	
Home	Project KONI - Section & Personnel facilities	
☆ Sized	DENTHICATION	
_	Name Task Fest Definition Open text field	
<u> </u>	Related Files Any Illa.pag	
Workspace	■ supunday	
88	scopt	
Apps	Fettly VSA_Plant_Recited	
1		
Reports	G ASSIDATION	
_	Type Corrective	
Q Search	MIESTONE	
	Start Date: 19/09/24	
_	initial Due Date: 26/09/24	
	Revised Due Date Number of Revisions g	
	Time left Tomorrow	
	Status in Progress	
	Progress 30%	
		∇
	IDM .	Θ
	Owner Pires Claudinei Members	ψ.
	nterioris	3/10
	WHAT HAS REIN ACHEVED	
<b>@</b>	Back Edit Odete More #	
Account		





- Although only mandatory fields (marked with \* ) are required to send an updated task to the Action Plan owner, a well-structured document must be clear and comprehensive. It is necessary to fill in all fields described in the following sections of this chapter to ensure the Action Plan owner has all the necessary information on what was done to properly document the actions taken during the 'Do Action' stage
- Most fields will be automatically filled with the information provided during the task creation. Only the 'Milestone' and 'What has been achieved' sections should be modified. Complete any missing fields or update them with the most current information, ensuring accuracy and completeness





Cancel

Send Alert Receive an Alert whenever Edited

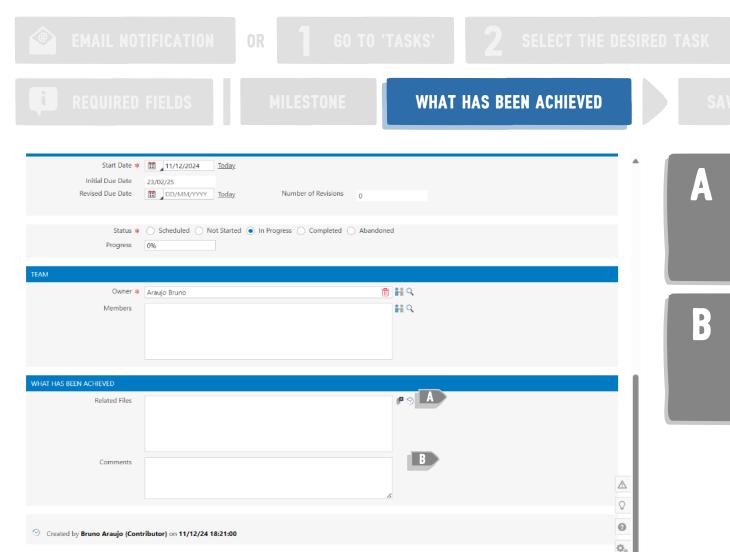




Required fields

#### 6.3.3 DOCUMENTING TASKS PROGRESS AND COMPLETION





Send Alert Receive an Alert whenever Edited

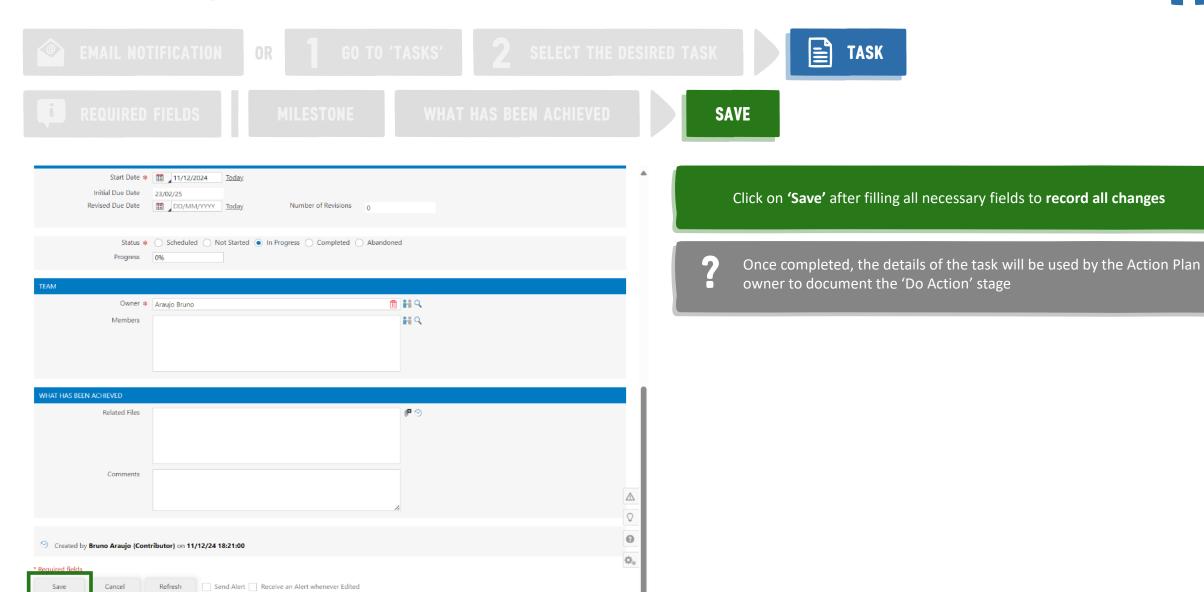


Related Files – Click on the paper clip icon to attach documents, images or any other files that document the achievements or progress made on the task. These files should provide evidence or further detail about the outcomes and support the verification of the task's effectiveness

<u>Comments</u> – Provide a summary of the results and accomplishments for this task. Include any relevant details about the actions completed, challenges faced or differences from the initial expectations. If the initial due date was changed, detail the reasons for this adjustment

₩





- \*Click on the chapter name to be redirected to it
- \*Click on the 📫 icon to be redirected to the table of contents

Chapter 6.4

# VALIDATION (BU QUALITY DIRECTOR)

6.4.1 **STAGE OVERVIEW** 

6.4.2 SINGLE VALIDATION

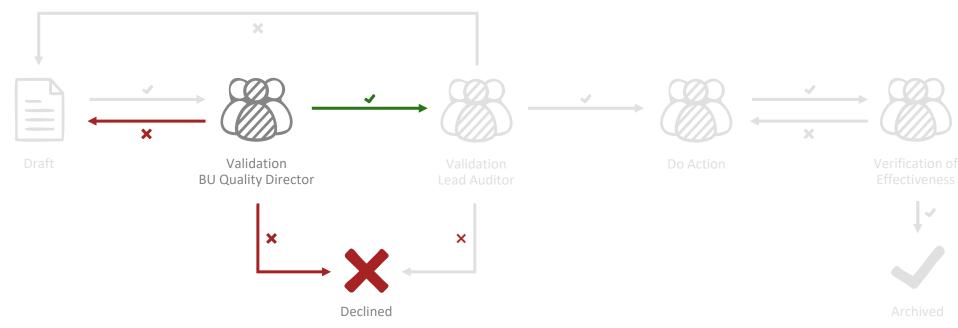
6.4.3 **BULK VALIDATION** 

# **6.5.1 STAGE OVERVIEW**









#### **Stage Owner**

**BU Quality Director** 

#### **Stage Actions**

- Review the Action Plan Draft
- Approve, reject or discard the Action Plan Draft

#### 6.5.1 STAGE OVERVIEW







- **Edits to the Action Plan should not be made during the 'Validation' stages**. If any changes are necessary, they should be addressed to the Action Plan owner after validation feedback is provided
- Although only mandatory fields (marked with \* ) are required to submit an Action Plan Draft for validation, a well-structured document must be clear and comprehensive. The validator should rely on their judgment to determine which fields are necessary fields at this stage
- Ensure that all sections have been thoroughly reviewed before approving, rejecting, or discarding the Action Plan Draft. It is essential that all necessary fields are correctly filled and accurately reflect the intended information

#### 6.5.2 SINGLE VALIDATION





OF

GO TO 'ACTION PLANS

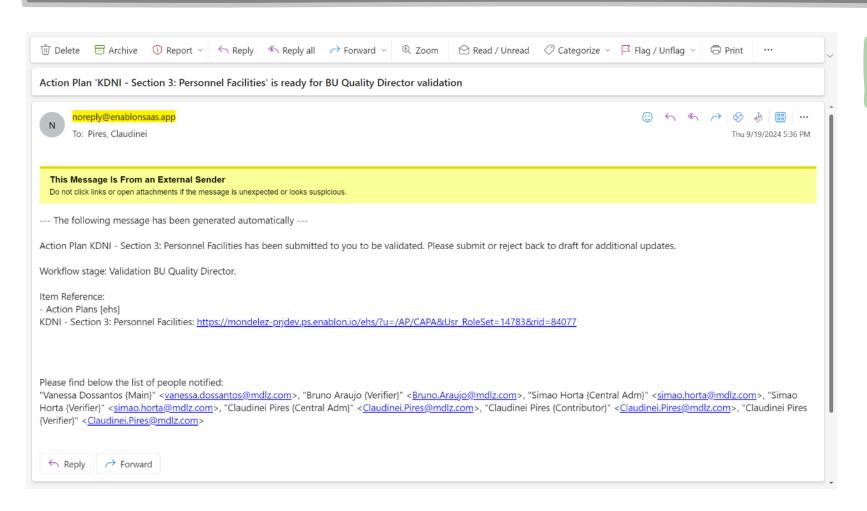
**SELECT THE DESIRED ACTION PLAN** 



ACTION PLAN



An email notification will be received by the BU Quality Director when an Action Plan Draft is submitted to 'Validation (BU Quality Director)'



Click on the link. It directly redirects you to the Action Plan

#### 6.5.2 SINGLE VALIDATION





EMAIL NOTIFICATION

GO TO 'ACTION PLANS'

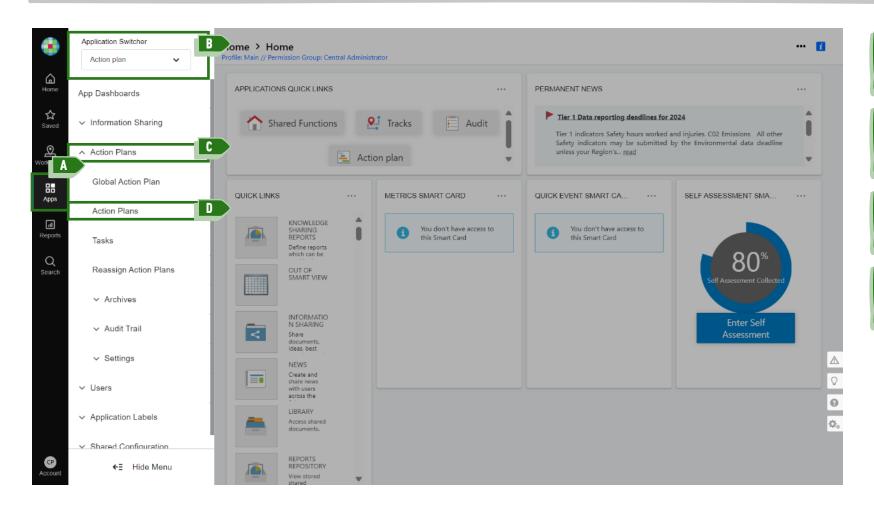
2 SELECT THE DESIRED ACTION PLAN



CTION PLAN



On the **Enablon Home page** 



Click on 'Apps'

On 'Apps' or 'Application Switcher', select 'Action Plan'

Click on 'Action Plans'

Click on 'Action Plans'

#### 6.5.2 SINGLE VALIDATION





**EMAIL NOTIFICATION** 

GO TO 'ACTION

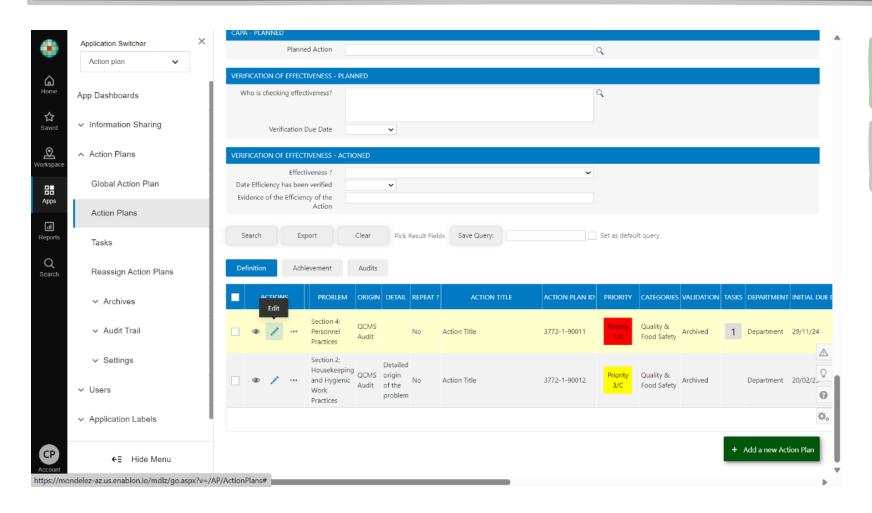
2 SELECT THE DESIRED ACTION PLAN

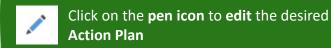


ACTION PLAN



The Action Plans page will be displayed. It contains a list of all the Action Plans related to the user





The 'Validation' column indicates the current stage of the Action Plan

#### **6.5.2 SINGLE VALIDATION**





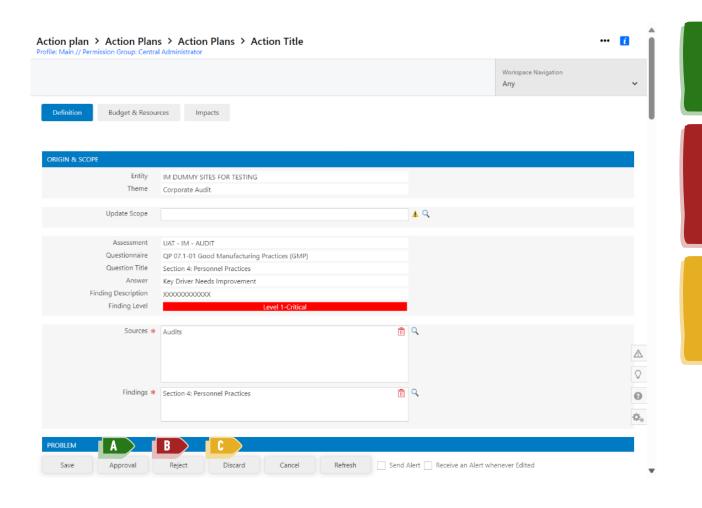
EMAIL NOTIFICATION

GO TO 'ACTION PLANS

**2** SELECT THE DESIRED ACTION PLAN



#### APPROVE, REJECT OR DISCARD



If all necessary fields are filled and the Action Plan is clear and wellstructured, click on 'Approval' to send the Action Plan Draft to the 'Do Action' stage

If necessary fields are not filled or if the Action Plan is unclear or poorly structured, click on 'Reject' to send the Action Plan Draft back to the 'Draft' stage for revision. Comments specifying what the revision should focus on are mandatory

If the Action Plan is no longer applicable or if the issue has been resolved through other means, click on 'Discard' to terminate the Action Plan process. Comments explaining the reasons for this decision are optional

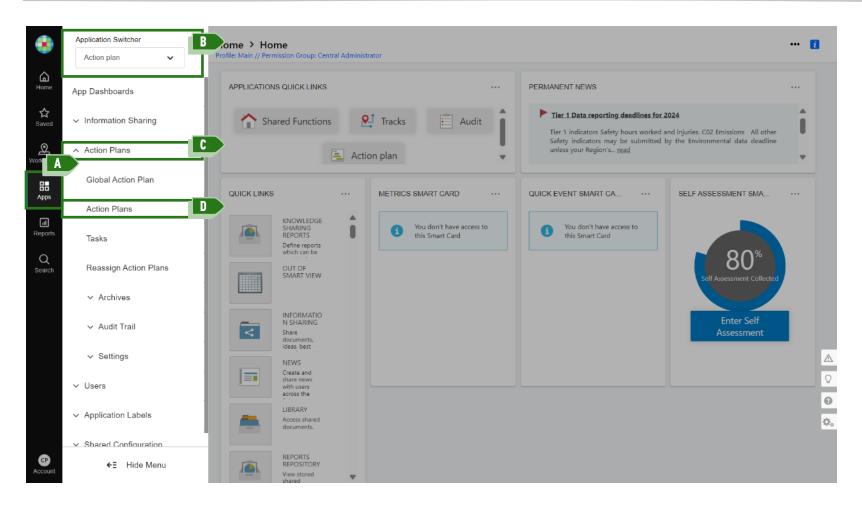


GO TO 'ACTION PLANS'





On the **Enablon Home page** 







GO TO 'ACTION PLANS'



The Action Plans page will be displayed. It contains a list of all the Action Plans related to the user. Each column in this list represents a field of the Action Plan ERIFICATION OF EFFECT VENESS - ACTIONED Definition Achievement **Audits** Date Efficiency has been Evidence of the Efficie Click on 'Audits' at the top of the table to see all ☆ Pick Result Fields Save Query: Set as default query Search Actions Plans fields displayed in table mode - this will facilitate the review process Q Achievement ENTITY ASSESSMENT QUESTIONNAIRE QUESTION TITLE ANSWER FINDING DESCRIPTION FINDING LEVEL PLANNED ACTIONS RESPONSIBLE DETAILED CAUSES ACTION TITLE ACTION PLAN After revision, select multiple Action Plans to IM approve, reject, or discard in bulk by checking DUMMY Section 4: Detailed UAT - IM -SITES 3772-1-90011 Personnel Needs XXXXXXXXXXXXXX Bruno Araújo description of Action Title the box in the rst column of the list AUDIT Manufacturing FOR Planned Actions TESTING QP 07.1-01 Section 2: DUMMY Detailed Housekeeping XXXXXXXXXXXXX Planned Actions Responsible description of 3772-1-90012 Manufacturing and Hygienic FOR Practices (GMP) Work Practices TESTING You can filter the Action Plans displayed Personnel DUMMY by Assessment (click here) Training: Key Driver KDNI - Personnel Training: SUPPLIER -3774-1-90092 General FOR General Program Requirements Program TESTING Δ Requirements - TIER 1 SUPPLIER 0 6.1 - Good SITES Personnel Manufacturing Practices SUPPLIER test, test, Test, test, NC - Personnel Practices 3774-1-90096 FOR Conformity Medium test, Test, test, test Practices (GMP) TESTING ₽, - TIER 1 Send Alert Discard



GO TO 'ACTION PLANS'





IMPORTANT: All selected Action Plans must be in the same stage (Validation BU Quality Director) for bulk validation to function properly. The 'Validation' column indicates the current stage of the Action Plan. If you are not able to approve them all at once, this indicates that the selected Action Plans are in different stages. You must then filter the Validation column to show only the Action Plans in the "Validation BU Quality Director" stage:

Action plan > Action Plans > Ac Profile: Contributor // Permission Group: Contributor	tion Plans			<u>i</u>		
		Workspace Navigation Any	Filter by Select	· L	A	Click on th
CAPA DESIGNATION						
Priority Pric Categories All crite  B  Validation Valic Do A Effect	rith viith viith virth virth virth virth virth virth virth virty 4 Priority 3/C Priority 2/	/B  Priority 1/A	Q		В	Scroll dow Director" (
View: Matching records Search	Export Clear F	Pick Result Fields		+ Add a new Action Pla	C	Click on "S

Click on the magnifying glass icon bellow the header of the page

Scroll down to "Validation" and select "Validation BU Quality Director" (under the correct workflow)

Click on "Search" to apply the filtering criteria

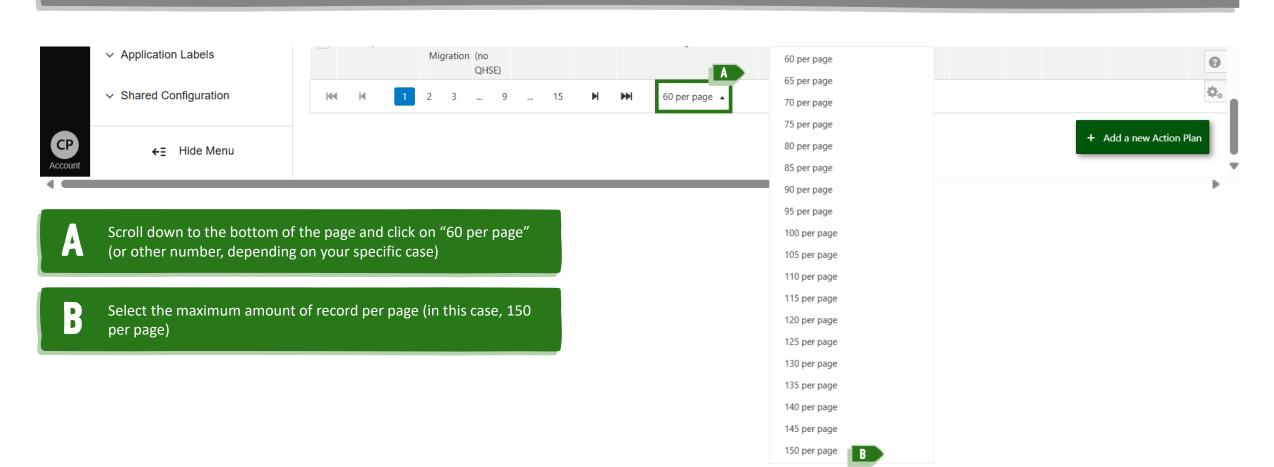


GO TO 'ACTION PLANS





IMPORTANT: If the Action Plans are being displayed in multiple pages, make sure to change the page view to the maximum amount per page. This way, you will be able to approve them all at once without having to be changing pages. To do this:



- \*Click on the chapter name to be redirected to it
- \*Click on the 📫 icon to be redirected to the table of contents

Chapter 6.5

### DO ACTION

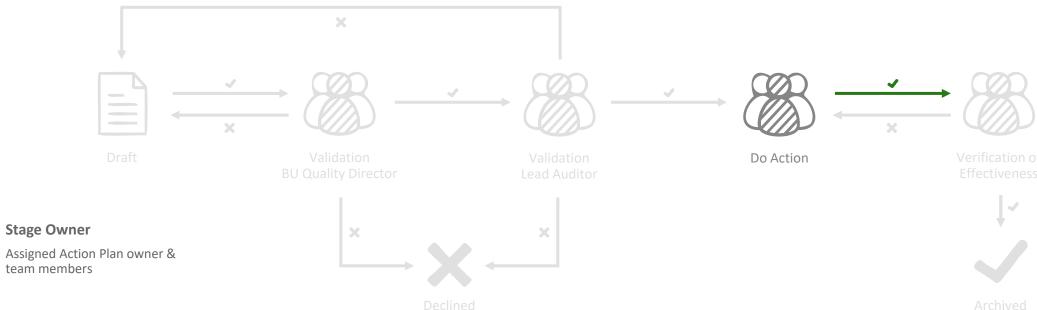
6.5.1 **STAGE OVERVIEW** 

6.5.2 <u>DOCUMENTING DO ACTION PROGRESS AND COMPLETION</u>

#### **6.5.1 STAGE OVERVIEW**







#### **Stage Actions**

- Document actions progress and completion
- Add evidences, update status and insert comments to the Action Plan
- Submit the Action Plan for verification of effectiveness

6.5 Do Action

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION





G

GO TO 'ACTION PLANS

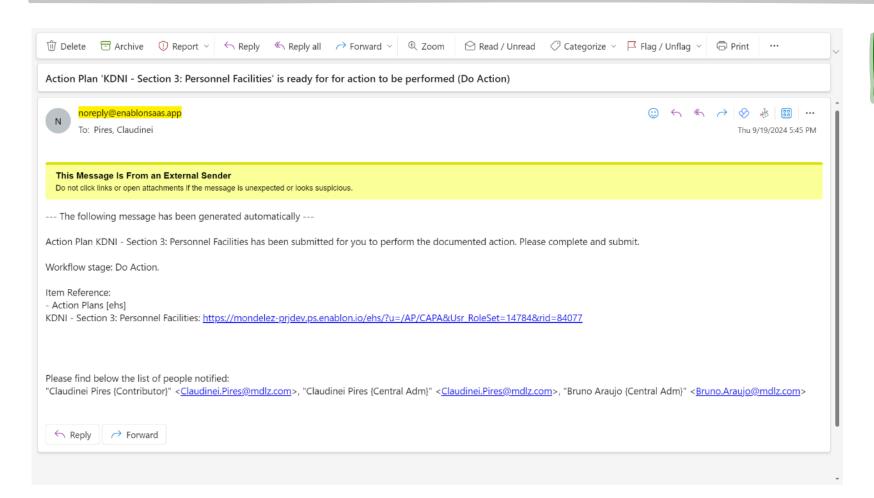
SELECT THE DESIRED ACTION PLAN



ACTION PLAN



An email notification will be received by the Action Plan owner and team when an Action Plan Draft is approved for 'Do Action'



Click on the link. It directly redirects you to the Action Plan

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION





**EMAIL NOTIFICATION** 

GO TO 'ACTION PLANS'

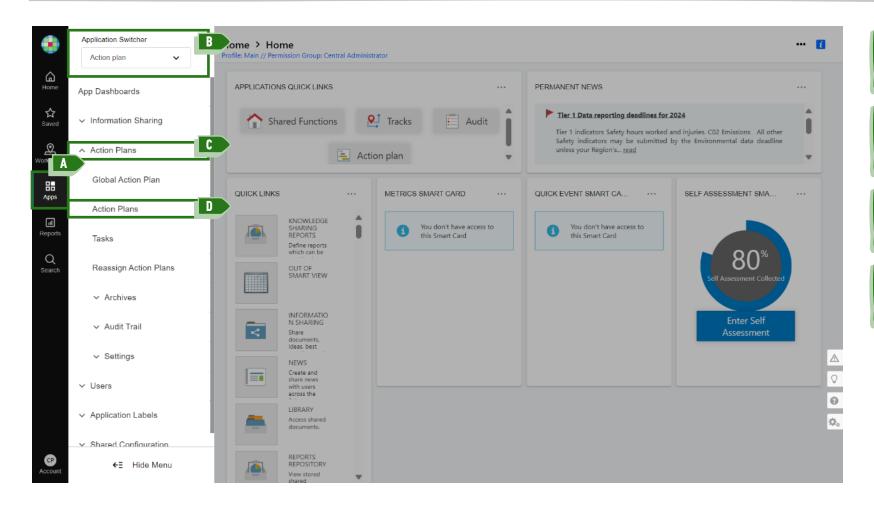
2 SELECT THE DESIRED ACTION PLAN

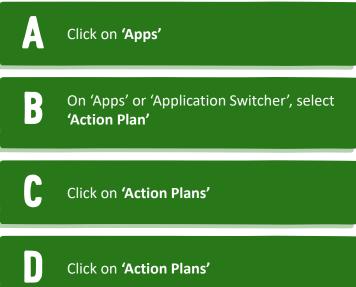


**ACTION PLAN** 



On the **Enablon Home page** 





6.5 Do Action

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION



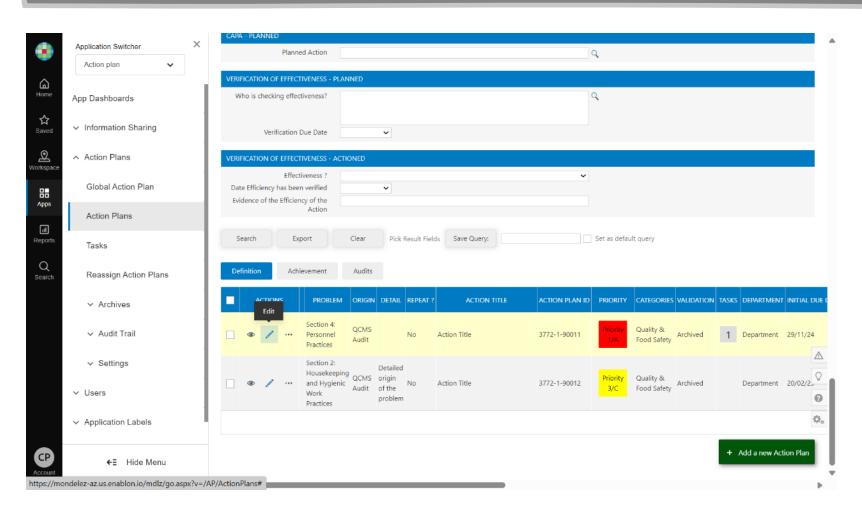


**SELECT THE DESIRED ACTION PLAN** 





The Action Plans page will be displayed. It contains a list of all the Action Plans related to the user





The 'Validation' column indicates the current stage of the Action Plan

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION





**EMAIL NOTIFICATION** 

GO TO 'ACTION PLAN

2 SELECT THE DESIRED ACTION PLAN





MILESTONE - PLANNED

**MILESTONE - STATUS** 

CAPA - ACTIONED

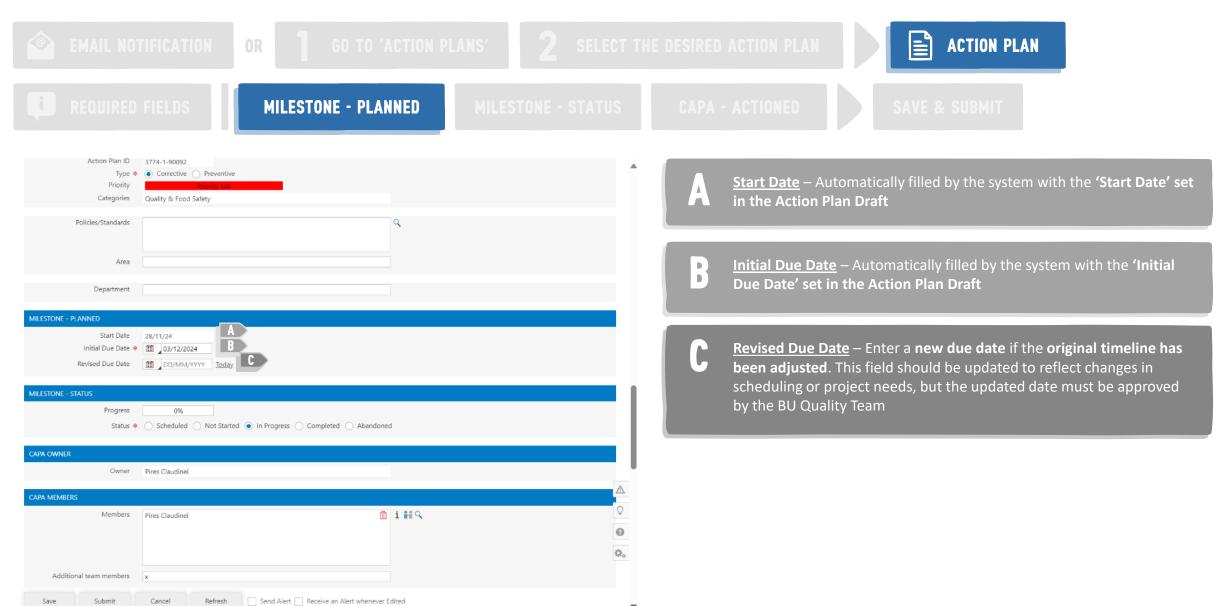
SAVE & SUBMIT

Although only mandatory fields (marked with \*) are required to submit an Action Plan for validation, a well-structured document must be clear and comprehensive. It is necessary to fill in all fields described in the following sections of this chapter to prevent the Action Plan from being rejected during the validation and verification of effectiveness stages. Once submitted, no further edits can be made unless the Action Plan is rejected

Most fields will be automatically filled with the information provided during the 'Draft' stage. Only the 'Milestone – Planned', 'Milestone – Status' and 'CAPA - Actioned' sections should be edited to update the 'Do Action' status, add comments, and attach evidence of the effectiveness and completion of the actions taken

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION





Refresh Send Alert Receive an Alert whenever Edited

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION





What will be the indicator of action effectiveness?

Who is checking effectiveness?

IFICATION OF EFFECTIVENESS - ACTIONED

Bruno Araujo (CAPA Verifier) Simao Horta (CAPA Verifier)

Claudinei Pires (CAPA Verifier)

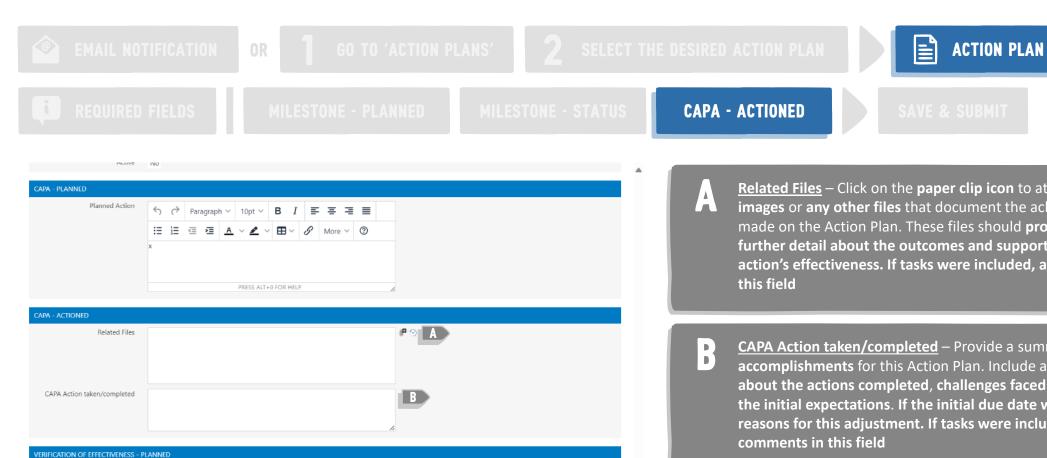
Verification Due Date DD/MM/YYYY

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION

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Send Alert Receive an Alert whenever Edited

Related Files – Click on the paper clip icon to attach documents, **images** or **any other files** that document the achievements or progress made on the Action Plan. These files should provide evidence or further detail about the outcomes and support the verification of the action's effectiveness. If tasks were included, attach all task files in

**CAPA Action taken/completed** – Provide a summary of the **results** and accomplishments for this Action Plan. Include any relevant details about the actions completed, challenges faced or differences from the initial expectations. If the initial due date was changed, detail the reasons for this adjustment. If tasks were included, list all task

CAPA Action taken/completed

Who is checking effectiveness?

What will be the indicator of action effectiveness?

Bruno Araujo (CAPA Verifier) Simao Horta (CAPA Verifier)

Claudinei Pires (CAPA Verifier)

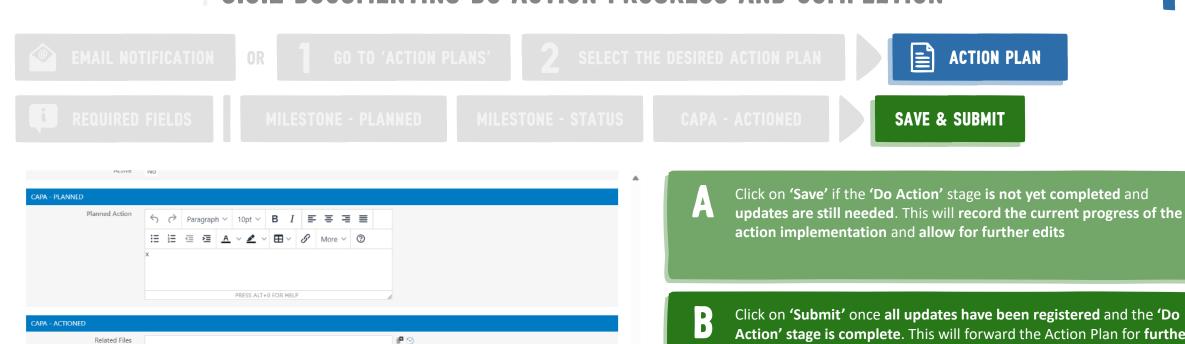
Verification Due Date DD/MM/YYYY

#### 6.5.2 DOCUMENTING DO ACTION PROGRESS AND COMPLETION

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Send Alert Receive an Alert whenever Edited

Click on 'Submit' once all updates have been registered and the 'Do Action' stage is complete. This will forward the Action Plan for further review and approval. Ensure all information is accurate and comprehensive before submission, as the Action Plan will no longer be editable after this action

- \*Click on the chapter name to be redirected to it
- \*Click on the 📫 icon to be redirected to the table of contents

Chapter 6.6

# VERIFICATION OF EFFECTIVENESS

6.6.1 **STAGE OVERVIEW** 

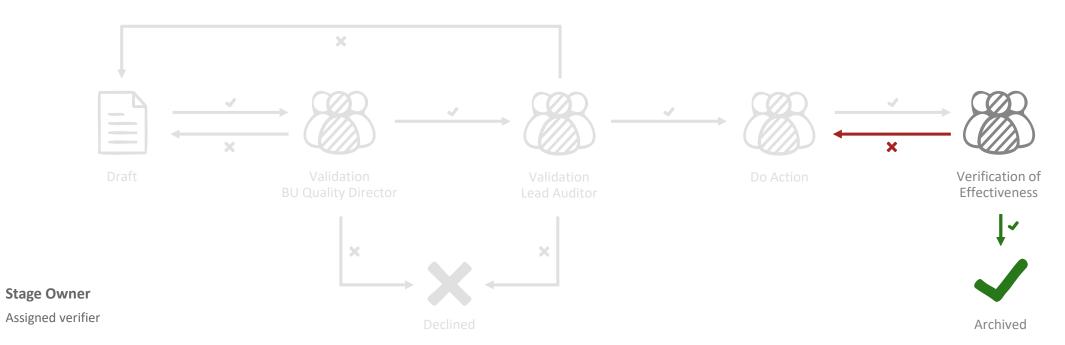
6.6.2 <u>DOCUMENTING VERIFICATION OF EFFECTIVENESS PROGRESS AND COMPLETION</u>

#### 6.6 Verification of Effectiveness 6.6.1 STAGE OVERVIEW









#### **Stage Actions**

- Document actions effectiveness over time
- Add evidences and insert comments to the Action Plan
- Archive or reject the Action Plan

#### 6.6 Verification of Effectiveness 6.6.1 STAGE OVERVIEW







- Verification of Effectiveness is not simply confirmation that the action was completed, but rather an assessment of whether the action taken successfully addressed the root cause of the issue. This step ensures that the corrective and preventive measures implemented have resolved the problem and prevented recurrence, demonstrating true effectiveness beyond just immediate corrections
- Having a due date for verification between 30 to 90 days allows for a thorough assessment of the action's effectiveness over time. This period is crucial for observing whether the corrective and preventive measures truly address the root cause and prevent recurrence. Immediate task completion does not always indicate long-term success, so this time frame ensures that the action's impact is sustainable and effective, rather than just a quick fix. Continuous monitoring during this period helps confirm that the issue has been fully resolved

#### 6.6 Verification of Effectiveness 6.6.2 DOCUMENTING VERIFICATION OF EFFECTIVENESS PROGRESS AND COMPLETION

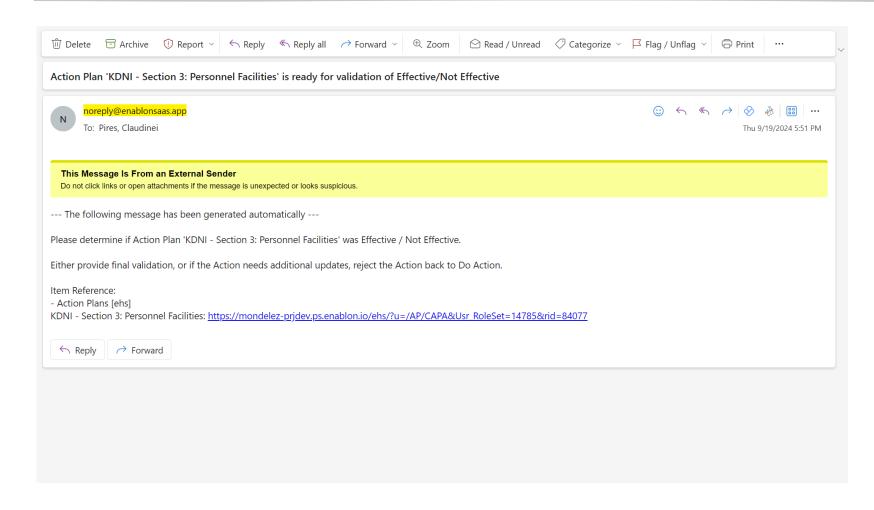








An email notification will be received by the assigned verifier when an Action Plan is submitted for 'Verification of Effectiveness'



Click on the link. It directly redirects you to the **Action Plan** 





EMAIL NOTIFICATION

GO TO 'ACTION PLANS'

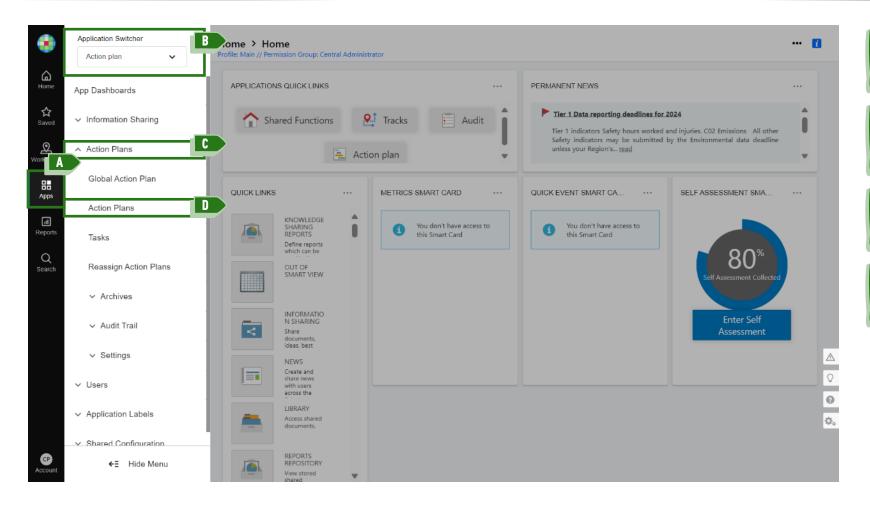
SELECT THE DESIRED ACTION PLAN



ACTION PLAN



On the **Enablon Home page** 









**EMAIL NOTIFICATION** 

DR

GO TO 'ACTION PLANS

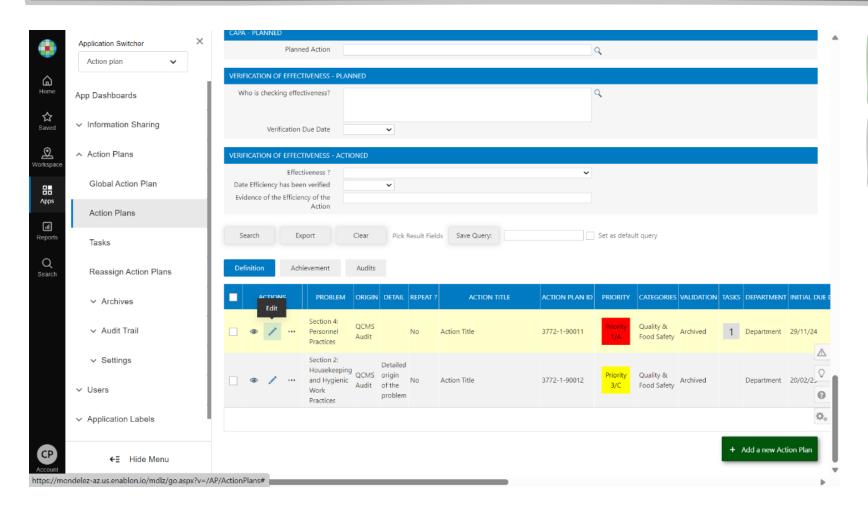
2 SELECT THE DESIRED ACTION PLAN



**ACTION PLAN** 



The Action Plans page will be displayed. It contains a list of all the Action Plans related to the user





The 'Validation' column indicates the current stage of the Action Plan





EMAIL NOTIFICATION

OR

GO TO 'ACTION PLANS

**SELECT THE DESIRED ACTION PLAN** 



**ACTION PLAN** 



VERIFICATION OF EFFECTIVENESS – ACTIONED



APPROVE



Only the 'Verification of Effectiveness - Actioned' section should be modified during this stage. All fields in this section should be filled in before approving or rejecting an Action Plan





**EMAIL NOTIFICATION** 

R

GO TO 'ACTION PLANS

**?** SELECT THE DESIRED ACTION PLAN



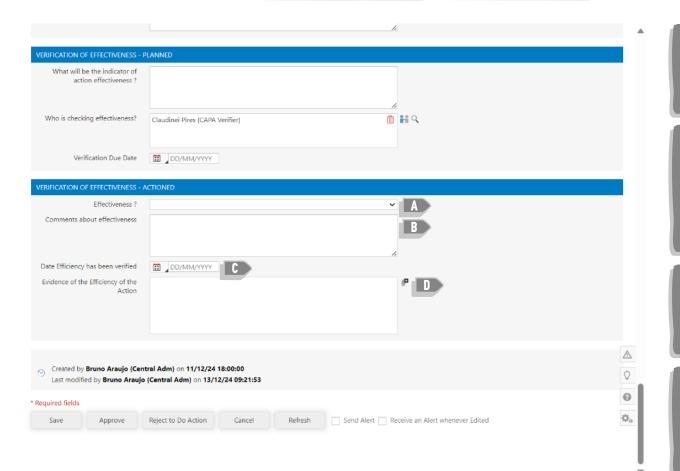
**ACTION PLAN** 



REQUIRED FIELDS

**VERIFICATION OF EFFECTIVENESS - ACTIONED** 

**APPROVE** 



<u>Effectiveness</u> – This field should be filled after monitoring the action's effectiveness over time. Select 'Yes' or 'No' to indicate if the actions taken were effective in resolving the issue

Comments about effectiveness – This field should be filled while monitoring the action's effectiveness over time. Provide detailed comments on the effectiveness of the actions taken. Include observations, outcomes and any other relevant feedback that helps assess the success of the measures implemented

Date Efficiency has been verified — This field should be filled after monitoring the action's effectiveness over time. Enter the date when the efficiency of the actions was verified

Evidence of the Efficiency of the Action — This field should be filled while monitoring the action's effectiveness over time. Click on the paper clip icon to attach documents, images or any other files that provide evidence of the action's efficiency





**EMAIL NOTIFICATION** 

R

GO TO 'ACTION PLANS

2 SELECT THE DESIRED ACTION PLAN



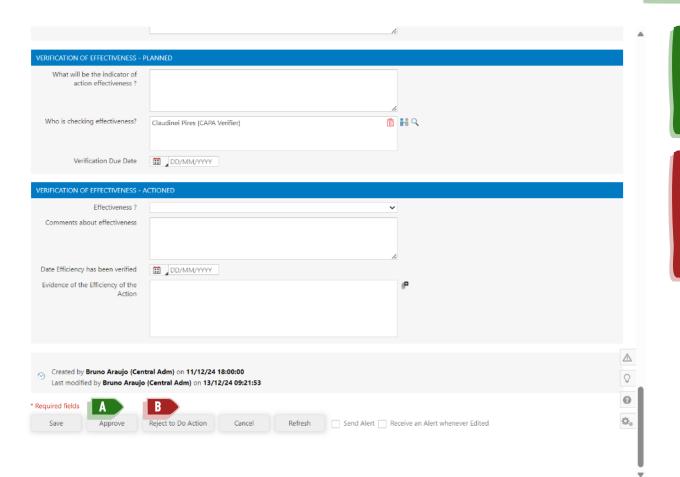
**ACTION PLAN** 



REQUIRED FIELDS

VERIFICATION OF EFFECTIVENESS - ACTIONED

**APPROVE** 



If the effectiveness of the action is deemed sufficient based on the indicators used and ongoing analysis over time, click on 'Approve' to confirm the Action Plan's success, complete the verification process and archive the Action Plan

If the effectiveness of the action is deemed insufficient based on the indicators used and ongoing analysis over time, click on 'Reject to Do Action' to send the Action Plan back to the 'Do Action' stage for revision. Comments specifying what the revision should focus on are mandatory

Chapter 7

# POST AUDIT SURVEY

Chapter 7.1

## **PROCESS OVERVIEW**

#### 7.1 PROCESS OVERVIEW







Scheduler creates the Post Audit Survey Self-Assessment Plant fill out the questionnaires

- \*Click on the chapter name to be redirected to it
- \*Click on the 📫 icon to be redirected to the table of contents

Chapter 7.2

# ANSWERING A POST AUDIT SURVEY – FILLING OUT POST AUDIT SURVEY QUESTIONNAIRES

7.2.1 <u>ACCESSING A POST AUDIT SURVEY QUESTIONNAIRE</u>

7.2.2 FILLING OUT A POST AUDIT SURVEY QUESTIONNAIRE

#### 7.2.1 ACCESSING A POST AUDIT SURVEY QUESTIONNAIRE





OF

GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'





QUESTIONNAIRE



An email notification will be received by the Quality Manager/CAPA Coordinator on the self assessment start date

Self-Assessment Notification Teste - IM Self Assessment is scheduled to start today: 30/05/24



noreply@enablonsaas.app

To Araujo, Bruno Machado

i You forwarded this message on 04/06/2024 15:50.
If there are problems with how this message is displayed, click here to view it in a web browser.

#### This Message Is From an External Sender

Do not click links or open attachments if the message is unexpected or looks suspicious.

--- The following message has been generated automatically ---

Self-Assessment Notification Teste - IM Self Assessment is scheduled to start today, 30/05/24. Please take the necessary actions.

Item Reference:

- Assessment Manager [ehs]

Notification Teste - IM Self Assessment: <a href="https://mondelez-prjdev.ps.enablon.io/ehs/?u=/acs/Cmp&Usr">https://mondelez-prjdev.ps.enablon.io/ehs/?u=/acs/Cmp&Usr</a> RoleSet=14697&rid=1764

**Click on the link**. It directly redirects you to the **assessment page**. Then follow steps 3 and 4 to access the **questionnaire page** 

#### 7.2.1 ACCESSING A POST AUDIT SURVEY QUESTIONNAIRE





GO TO 'ASSESSMENT RESULTS'

SELECT THE DESIRED
ASSESSMENT

GO TO 'QUESTIONNAIRES'

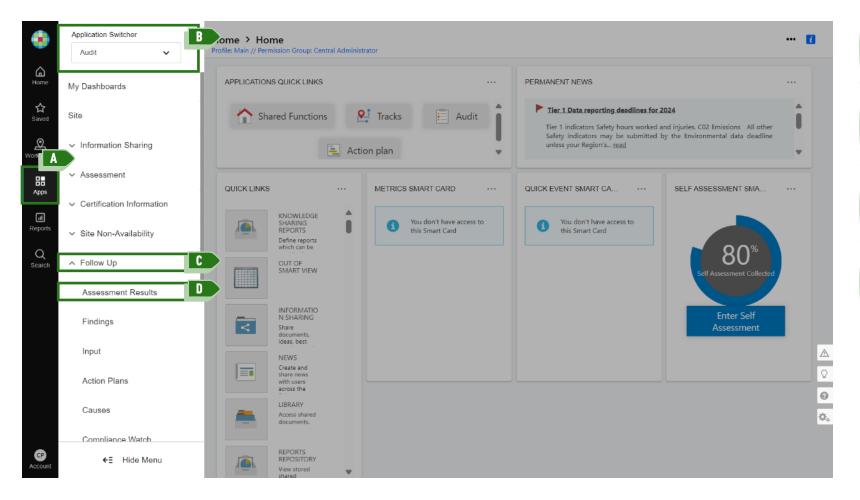
SELECT THE DESIRED QUESTIONNAIRE

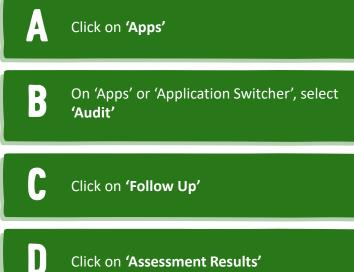


QUESTIONNAIRE



On the **Enablon home page** 





#### 7.2.1 ACCESSING A POST AUDIT SURVEY QUESTIONNAIRE





R GO TO 'ASSESSMEN RESULTS'

2 SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'

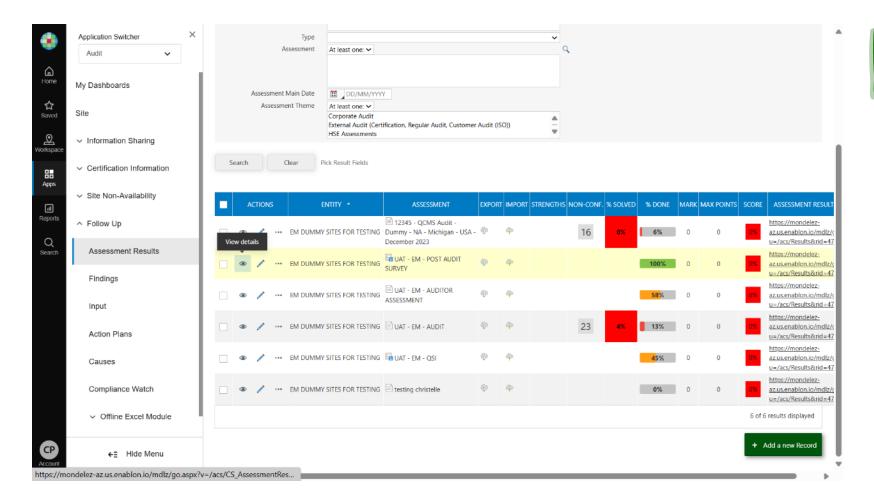
SELECT THE DESIRED QUESTIONNAIRE



QUESTIONNAIRE PAGE



The Assessment Results page will be displayed. It contains all assessments related to the user





Click on the **eye icon** to select the desired **assessment** 

#### 7.2.1 ACCESSING A POST AUDIT SURVEY QUESTIONNAIRE





TION

GO TO 'ASSESSMEN'
RESULTS'

2 SELECT THE DESIRE ASSESSMENT

GO TO 'QUESTIONNAIRES'

SELECT THE DESIRE QUESTIONNAIRE

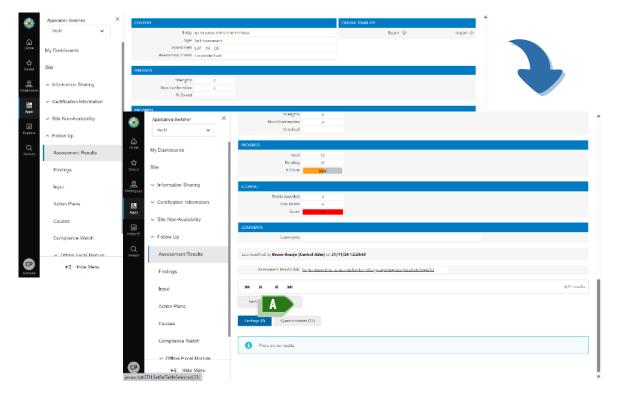


QUESTIONNAIRE PAGE



A page with general information about the selected assessment will be displayed

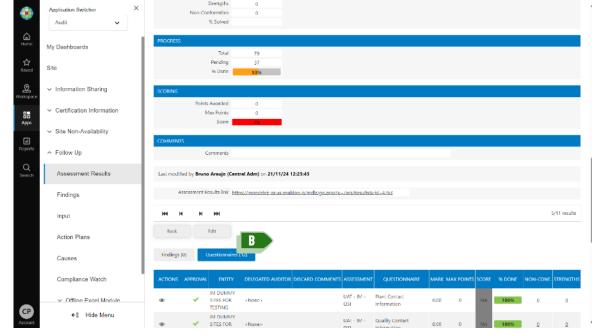
Scroll down to 'Findings'



Click on 'Questionnaires'

Findings (1)

Questionnaires (99)



#### 7.2.1 ACCESSING A POST AUDIT SURVEY QUESTIONNAIRE





GO TO 'ASSESSMI RESULTS' 2 SELECT THE DESIRED
ASSESSMENT

GO TO QUESTIONNAIRES

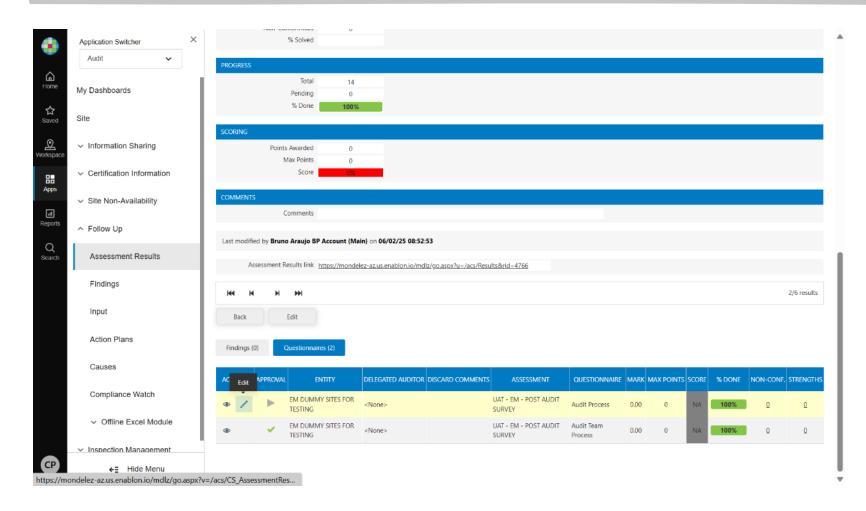
SELECT THE DESIRED QUESTIONNAIRE



QUESTIONNAIRE PAGE



A list of all the questionnaires related to the assessment will be displayed





Click on the **pen icon** to answer the desired questionnaire

#### 7.2.2 FILLING OUT A POST AUDIT SURVEY QUESTIONNAIRE





OF

GO TO 'ASSESSMEN'
RESULTS'

SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'

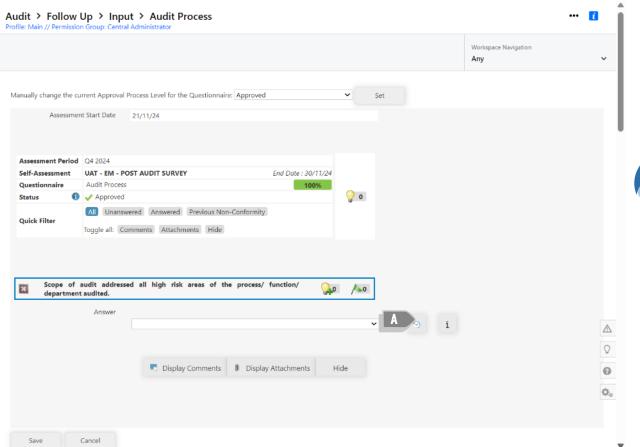






#### **HOW TO ANSWER THE QUESTIONNAIRES**





<u>Answer</u> – Select between one of the available options the answer to the given question



Strongly Agree

Agree

Disagree

#### 7.2.2 FILLING OUT A POST AUDIT SURVEY QUESTIONNAIRE





OR

GO TO 'ASSESSMEN'
RESULTS'

SELECT THE DESIRED ASSESSMENT

GO TO 'QUESTIONNAIRES'

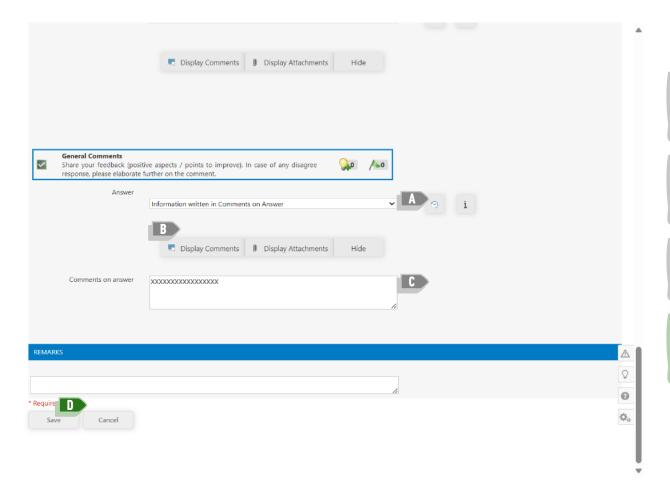
SELECT THE DESIRE QUESTIONNAIRE



QUESTIONNAIRE PAGE

#### **HOW TO ANSWER THE QUESTIONNAIRES**





For 'General Comments' questions:

<u>Answer</u> – Select 'Information written in Comments on Answer'

<u>Display Comments</u> - Click on 'Display Comments' to make the 'Comments on Answer' field visible

<u>Comments on Answer</u> – Answer the question in this field

Save – Click on 'Save' after answering all questions of the questionnaire

#### 7.2.2 FILLING OUT A POST AUDIT SURVEY QUESTIONNAIRE





OR

GO TO 'ASSESSMEN'
RESULTS'

SELECT THE DESIRED
ASSESSMENT

GO TO QUESTIONNAIRES

SELECT THE DESIRED QUESTIONNAIRE



**HOW TO ANSWER THE QUESTIONNAIRES** 





#### Post Audit Survey Deadlines in Enablon

Start Date	Submission Limit Date	End Date
30 days after the audit end date	45 days after the audit end date	60 days after the audit end date

### Chapter 7

## SITE NON-AVAILABILITY



GO TO 'SITE NON-AVAILABILITY'

**?** CREATE THE SITE NON-AVAILABILITY REQUEST



SITE NON-AVAILABILITY REQUEST PAGE



On the **Enablon home page** 







GO TO 'SITE NON-AVAILABILITY'

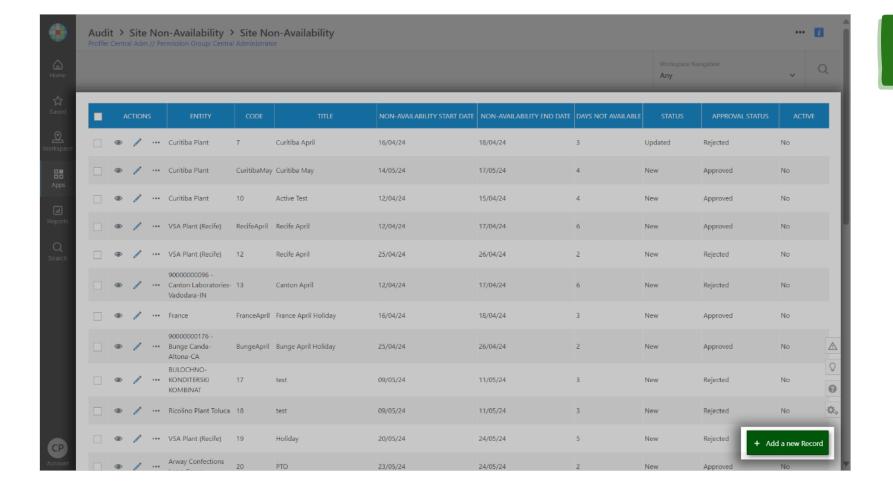
**?** CREATE THE SITE NON-AVAILABILITY REQUEST



SITE NON-AVAILABILITY REQUEST PAGE



A list with all the site non-availability requests will be displayed



Click on '+ Add a new Record' to create the site non-availability request

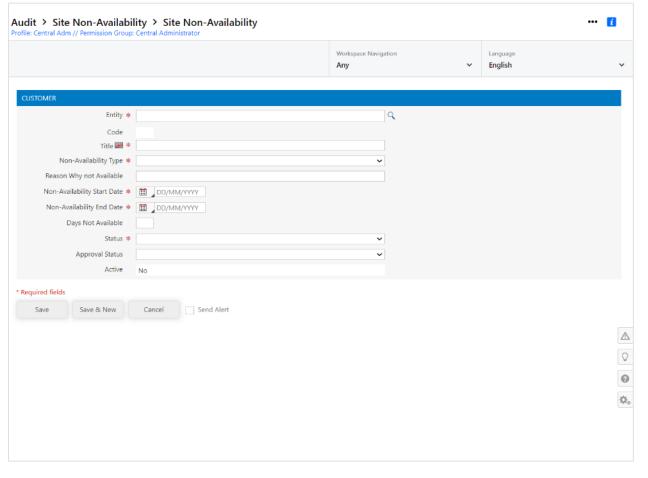




SITE NON-AVAILABILITY REQUEST PAGE



The site non-availability request page will be displayed





•	Audit > Site Non-Availab Profile: Central Adm // Permission Group	ility > Site Non-Availability pr Central Administrator	🗓
Home		Workspace Nerspriam  Any  ✓ English	~
☆ Samed	CLISTOMER		
	Entity #	Q.	
Workspace:	Code		
	Title 🚟 *		
88	Non-Availability Type *	v	
Apps	Reason Why not Available		
rii Reports	Non-Availability Start Date *	-	
Reports	Non-Availability End Date *  Days Not Available	■ JDD/MM/YYYY	
0	Status #	<b>v</b>	
Q Search	Approval Status	v	
		No.	
		No.	
	* Required fields		
	Save Save & New	Cancel Send Alert	
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			<ul><li>△</li><li>○</li><li>◆</li></ul>
			4.0
Arzeitti			



GO TO 'SITE NON-AVAILABILITY'

**?** CREATE THE SITE NON-AVAILABILITY REQUEST



#### SITE NON-AVAILABILITY REQUEST PAGE



#### ACCEPTABLE REASONS FOR SITE NON-AVAILABILITY

CUSTOMER

SAVE

Classification	Acceptable	Unacceptable	
	Quality Manager on vacation (annual leave/s)	Plant Manager on vacation / offsite	
Absence of Quality Manager and Plant Manager	Quality Manager on short sick leave (notify to Auditing team on a timely manner)	Long term absence >3 months: - Quality Manager on long sick leave - Plant Manager and Quality Manager transition - Quality Manager maternity/paternity leave	
	Deceased member of plant management (such as Plant Director, Quality Manager)		
Plants closure/ not operating	Public holiday when site is not operating	Week before or after holidays	
	Plant Closure Announcement		
	Natural / Environmental disaster (such as flooding, earthquake, tsunami, hurricane etc.)		
Activities impacting full production run	Preventive maintenance and/or sanitation impacting a significant number of MDLZ production lines (>50%) or key areas of the factory affecting CCPs (Case Dependent)	Preventive maintenance/sanitation in a limited number of production lines (<50%) Project works ongoing (unless critical process steps affected: CCPs). e.g. installation of new line / parts of the line / plant trials with R&D on site	
	Ongoing Special Situation (Case Dependent)		
	School Holidays (1-2 weeks max) — only if staff availability is significantly impacted making not possible to support the QCMS Audit	School Holidays without a significant impact in audit involved staff availability	
Plant planned activities	Audits, assessment and activities which involved large team and/or external party and are promptly notified (3 months in advanced) e.g.	Requesting for periods of time longer than 1 month at a time in anticipation of audits and none confirmed date. e.g.  Unannounced GFSI audits	
	<ul> <li>GFSI audits and/or regulatory audits, SMETA, HSE audit, Legal Compliance</li> <li>IL6S Phase Assessment (thorough assessment that lasts 1 week)</li> <li>HACCP validation / Sanitation Review</li> <li>Manufacturing Standards kick-off week</li> <li>Internal Control Audit</li> </ul>	Audit within the local team and/ or non-food safety and quality related: - Financial audits - Site Internal Audits	
	Quality Round Table (QRT) Meetings, trainings or equivalent- which are <u>only</u> held 2 to 3 times per year and/or are promptly notified (3 months in advanced) Eg; QSE training, Loss analysis meeting (with external resources on site), QA celebrations, Community Meetings	Production peak season SAP installation/ IQS or other system installations (not impacting production running) IL6S projects that can last for months	
	Scheduled visit of Company Executive	Routine BU/Region meetings Team building meetings, trainings, workshops that were not promptly notified (3 months in advanced)	



GO TO 'SITE NON-AVAILABILITY'

**?** CREATE THE SITE NON-AVAILABILITY REQUEST



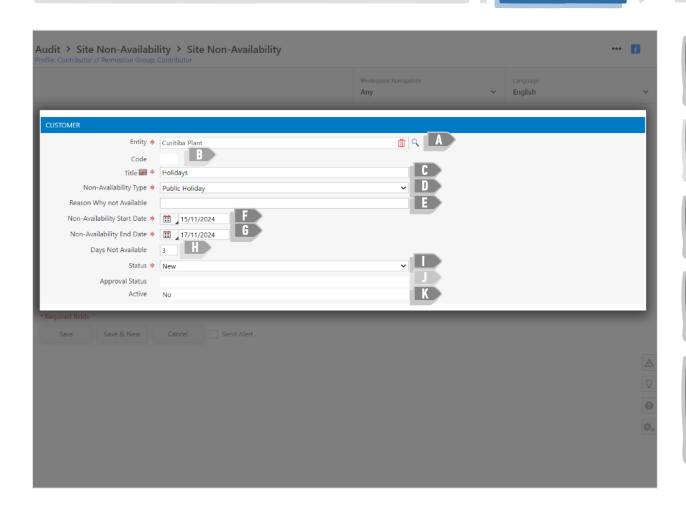
SITE NON-AVAILABILITY REQUEST PAGE



ACCEPTABLE REASONS FOR SITE NON-AVAILABILITY

**CUSTOMER** 

SAVE



Entity – Type in the plant name or select it from a list by clicking on the magnifying glass icon

<u>Code</u> – **Automatically filled** by the system

<u>Title</u> – Type in a **short description** for the Site Non-Availability

Non-Availability Type – Select the non-availability type from the available options in the choice list

Reason Why not Available – Provide a clear description of the reasons for non-availability. Share comments or justifications that explain the situation in detail, including any relevant context or contributing factors



GO TO 'SITE NON-AVAILABILITY'

**?** CREATE THE SITE NON-AVAILABILITY REQUEST



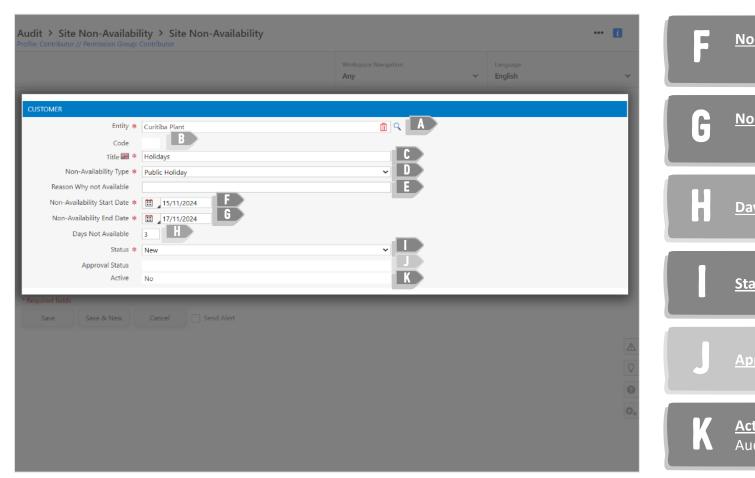
SITE NON-AVAILABILITY REQUEST PAGE



ACCEPTABLE REASONS FOR SITE NON-AVAILABILITY

**CUSTOMER** 

SAVE



Non-Availability Start Date – Fill in the non-availability start date Non-Availability End Date – Fill in the non-availability end date <u>Days Not Available</u> – Automatically filled by the system Status - Select between 'New', 'Updated' or 'Cancelled' Active – Will display 'No' until approval is granted by Mondelez Quality Auditing



GO TO 'SITE NON-AVAILABILITY'

**?** CREATE THE SITE NON-AVAILABILITY REQUEST



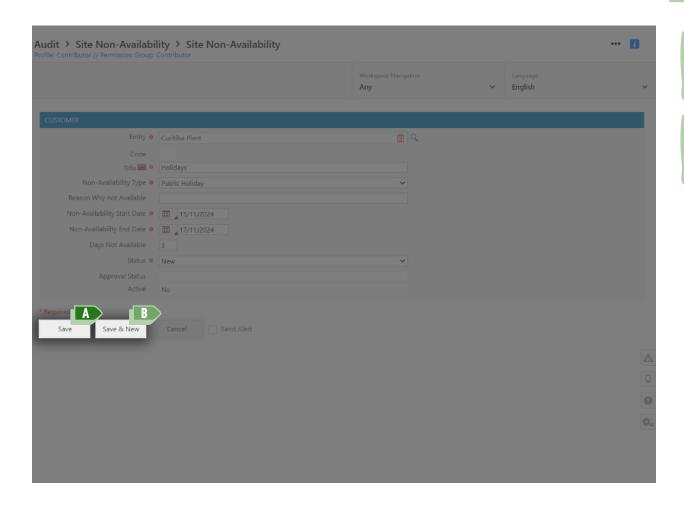
SITE NON-AVAILABILITY REQUEST PAGE



ACCEPTABLE REASONS FOR SITE NON-AVAILABILITY

CUSTOMER





Click on 'Save' once all required fields have been filled. This will send the site non-availability request for approval

Click on 'Save & New' to send the site non-availability request for approval and create a new request