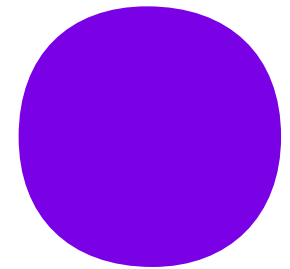


sanofi

01

Creation of Quality Attribute(QA) Template



Creation of QA Template

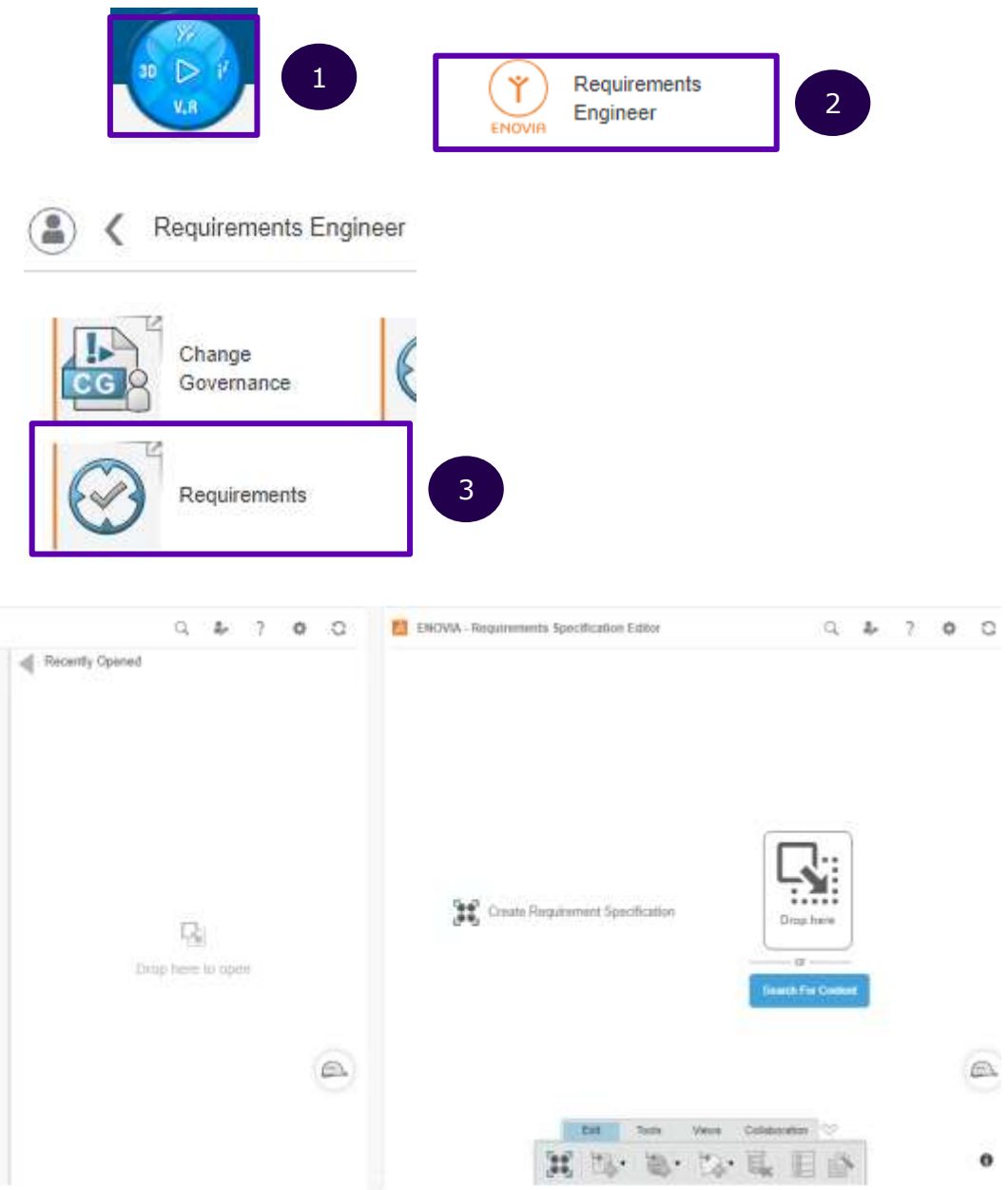
Internal

Open the Requirement Structure Editor

To create a QA Template, we will use the Requirement Structure Editor app.

1. Click on 3D Compass.
2. Then, Click on 'Requirement Engineer' under 'My Roles'.
3. Click on 'Requirements' app.
4. Requirements app is opened. Requirement Structure Editor on the left and Requirements Specification Editor on the right.

4



Creation of a Requirement Specification

To create a "Requirement Specification" (QA Template Header) object and to attach "Chapter".

1. Under Requirements Structure Editor app, Click on 'Create Requirement Specification' under 'Start a New Activity'.
2. The object will appear with a default name. (which could be edited , For this use case it is named as "QA_Microbial_Template")
3. Requirement Specification named as "QA_Microbial_Template" is created and displayed under Requirements Structure Editor.
4. To edit the name after it has been created, Double click on the object to rename it

1

Start a New Activity

Create Requirement

Create Requirement Specification

Create Requirement Specification

Create Specification Folder

2

Create Requirement Specification

Create

Classifications

Title *

Requirement Specification00000111

Credentials *

TechTransfer • Leader

Show more

Create

Create another

Cancel

3

ENOVIA - Requirements Structure Editor

Quality Attribute Template 1

Title	Revision	Type	Refined Into	Covers
QA_Microbial_Template 1	1	Requirement ...		

4

ENOVIA - Requirements Structure Editor

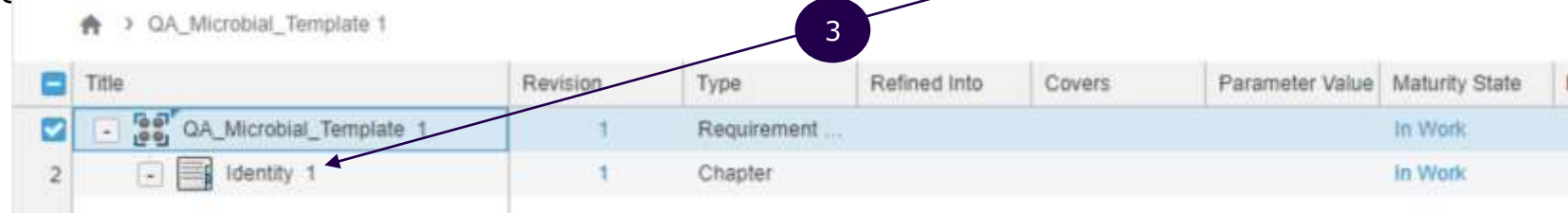
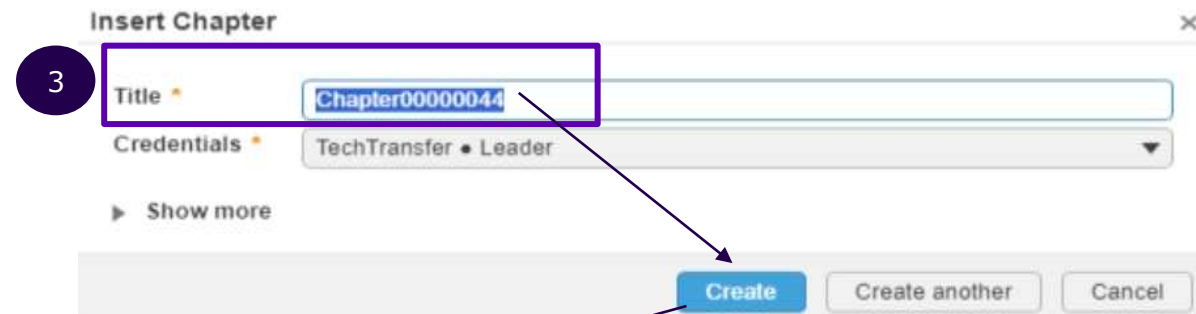
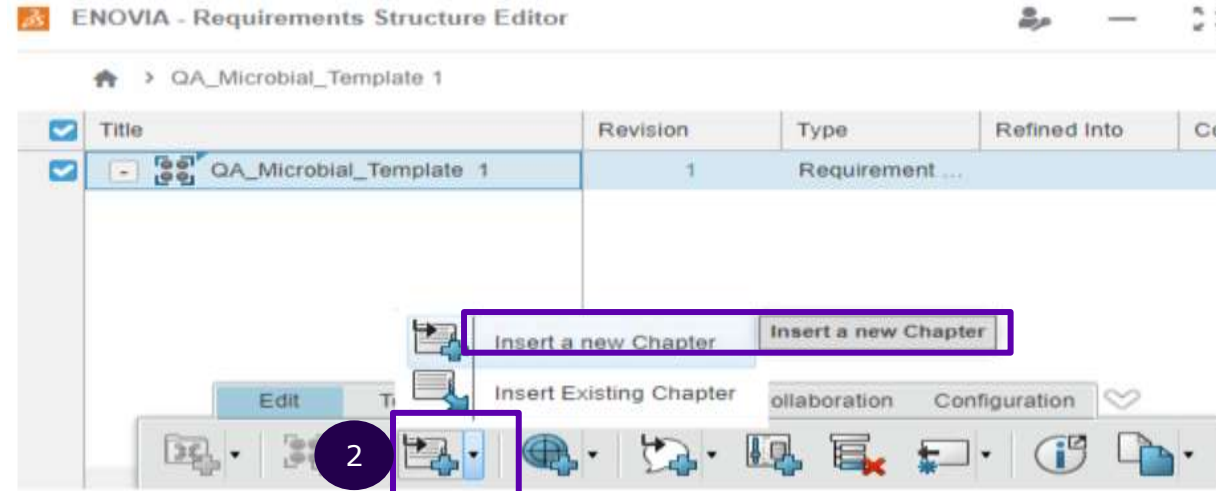
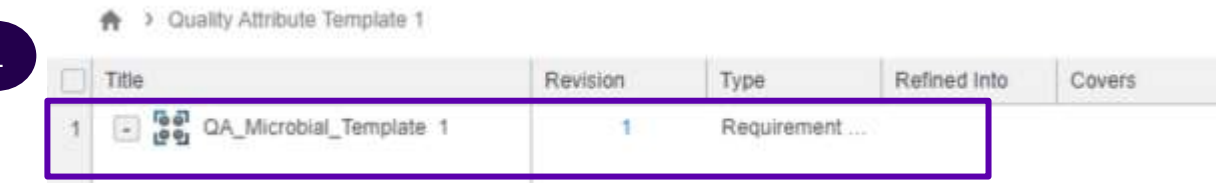
QA_Microbial_Template 1

Title	Revision	Type	Refined Into	Covers
QA_Microbial_Template	1	Requirement ...		

Creation of a chapter under Requirement specification

Create a Quality Attribute Category for Product Components

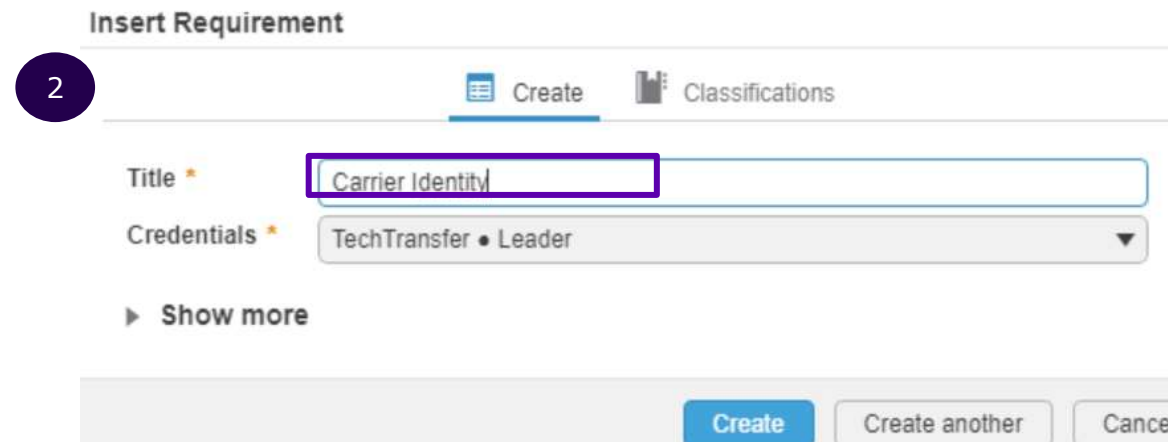
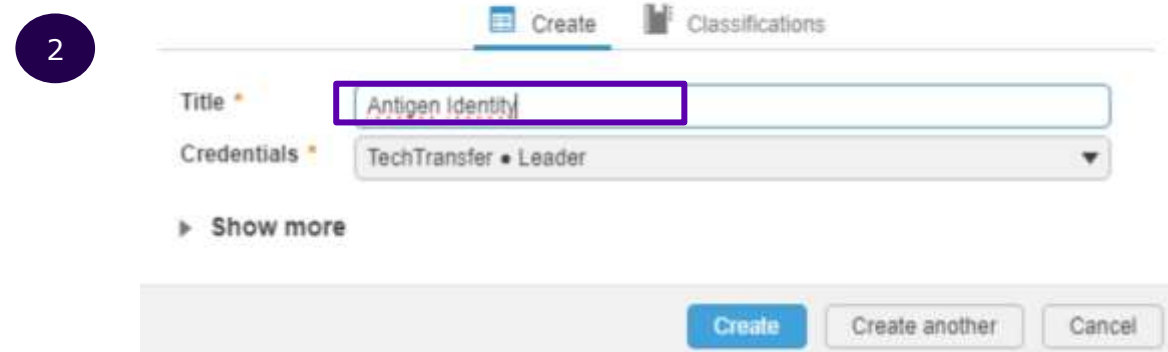
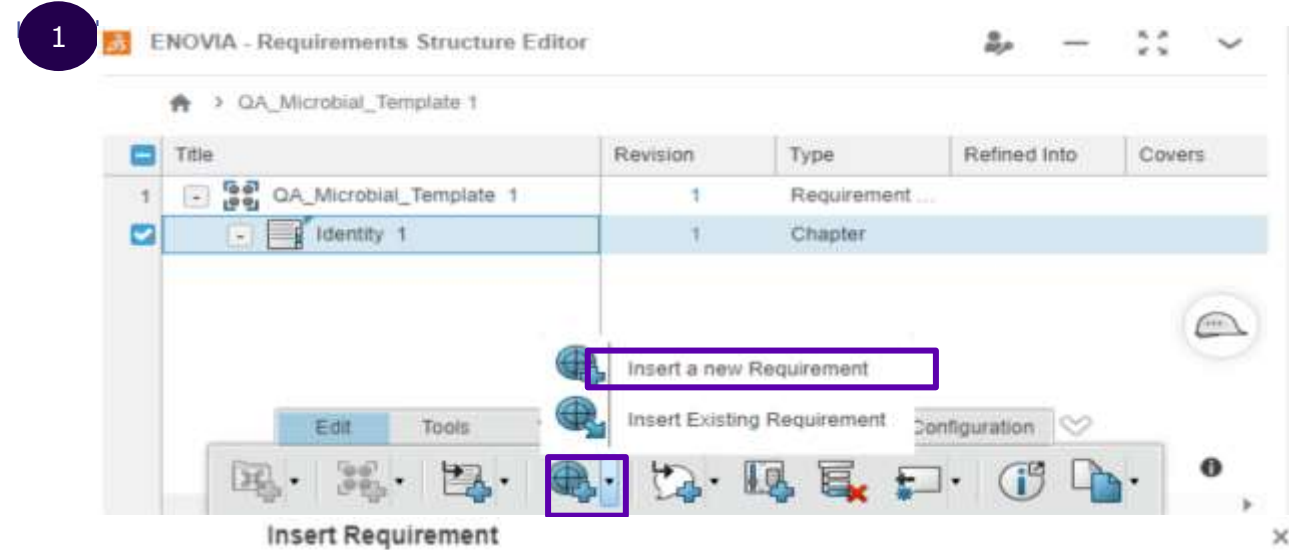
1. Under Requirements Structure Editor app, Select the "QA_Microbial_Template" created previously.
2. Click on 'Insert new chapter' icon and click on 'Insert a new chapter'.
3. New Chapter will be created with a default name which has been renamed as "Identity" and click on "Create". The newly created chapter will appear under QA_Microbial_Template.
4. User can create multiple QA category in the Template by following step 2 and 3.



Creation of a Requirement under Chapter

To create a "Quality Attribute" for a Quality Attribute category.

1. Under Requirements Structure Editor app, Click on previously created Chapter object 'Identity' and click on 'insert a new requirement'.
2. The object will appear with a default name. Click on 'Create' button. (which could be edited , For this use case the newly created requirement are named as "Antigen Identity")
3. Follow the Step 1 and 2 to create another Requirement (Example: "Carrier Identity").



Creation of a Requirement under a Chapter

The left screenshot shows the 'ENOVIA - Requirements Structure Editor' window. It displays a table with the following data:

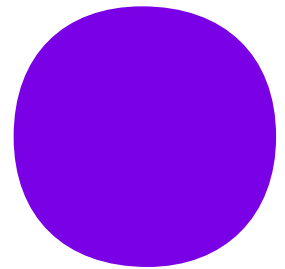
	Title	Revision	Type	Refined Into	Covers	Parameters
1	QA_Microbial_Template 1	1	Requirement ...			
2	Identity 1	1	Chapter			
3	Antigen Identity 1	1	Requirement	None	None	
4	Carrier Identity 1	1	Requirement	None	None	

The right screenshot shows the 'ENOVIA - Requirements Specification Editor - QA_Microbi...' window. It displays a tree view for 'QA_Microbial_Template 1' with the state 'In Work'. The tree structure is as follows:

- 1 - Identity
 - 1 - 1 Antigen Identity
 - NA
 - 1 - 2 Carrier Identity
 - NA

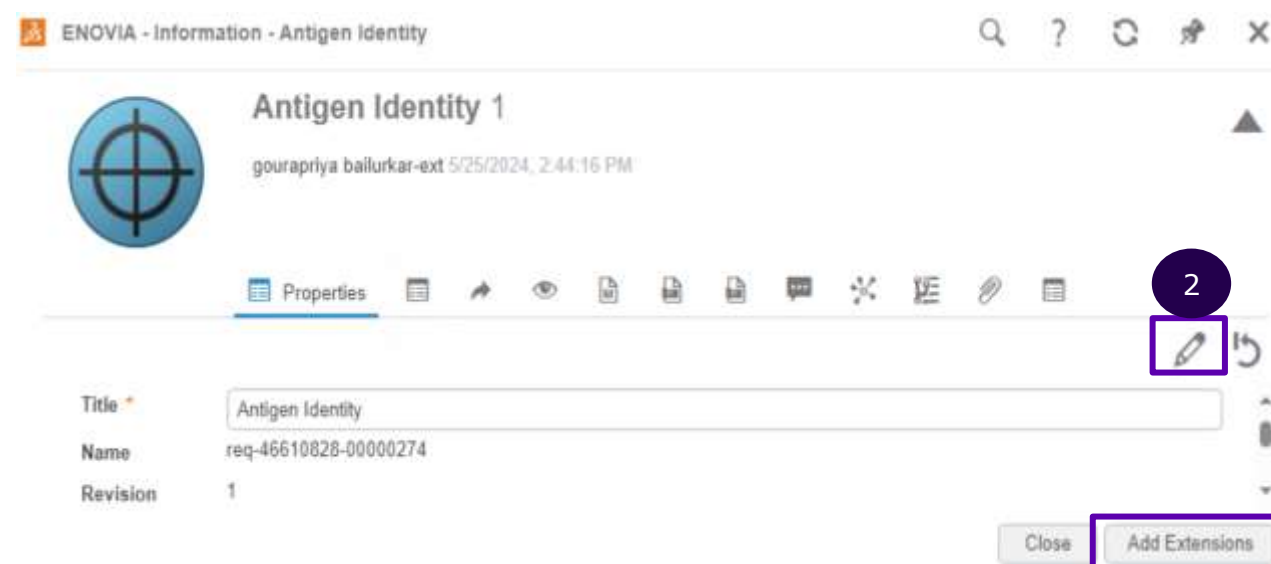
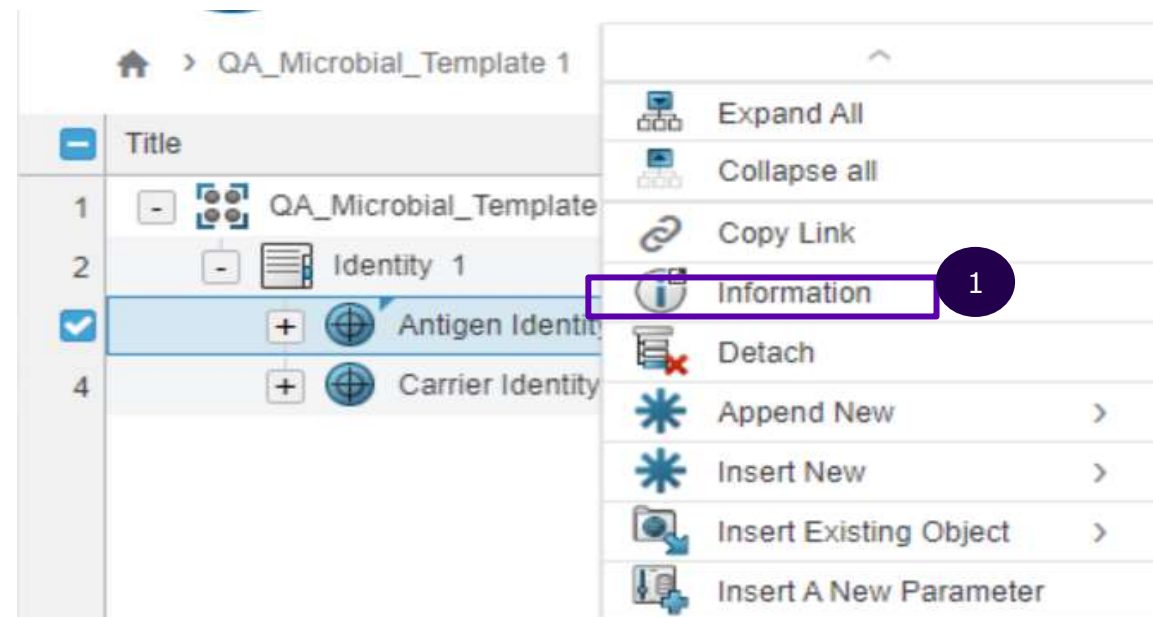
1. The newly generated Structure under the 'Requirement specification editor' it is illustrated in the above Fig.
2. NOTE: When creating the template, on the "Requirement Specification Editor" under the Requirements('Antigen Identity' and 'Carrier Identity' in the above image), created under 'Identity', must be filled with 'NA'. (It could be done by double clicking on the free space)

02 Adding Extensions & Attachments to a “Quality Attribute”



Adding Extensions and selecting attribute values from the pick list

1. Right click on the requirement object "Antigen Identity" and selecting Information from the list the properties page can be accessed.
2. And by clicking the Edit icon on the properties page and click on Add extensions
3. By selecting the Quality Attributes (from the pick list) the corresponding extension for the attributes could be added.



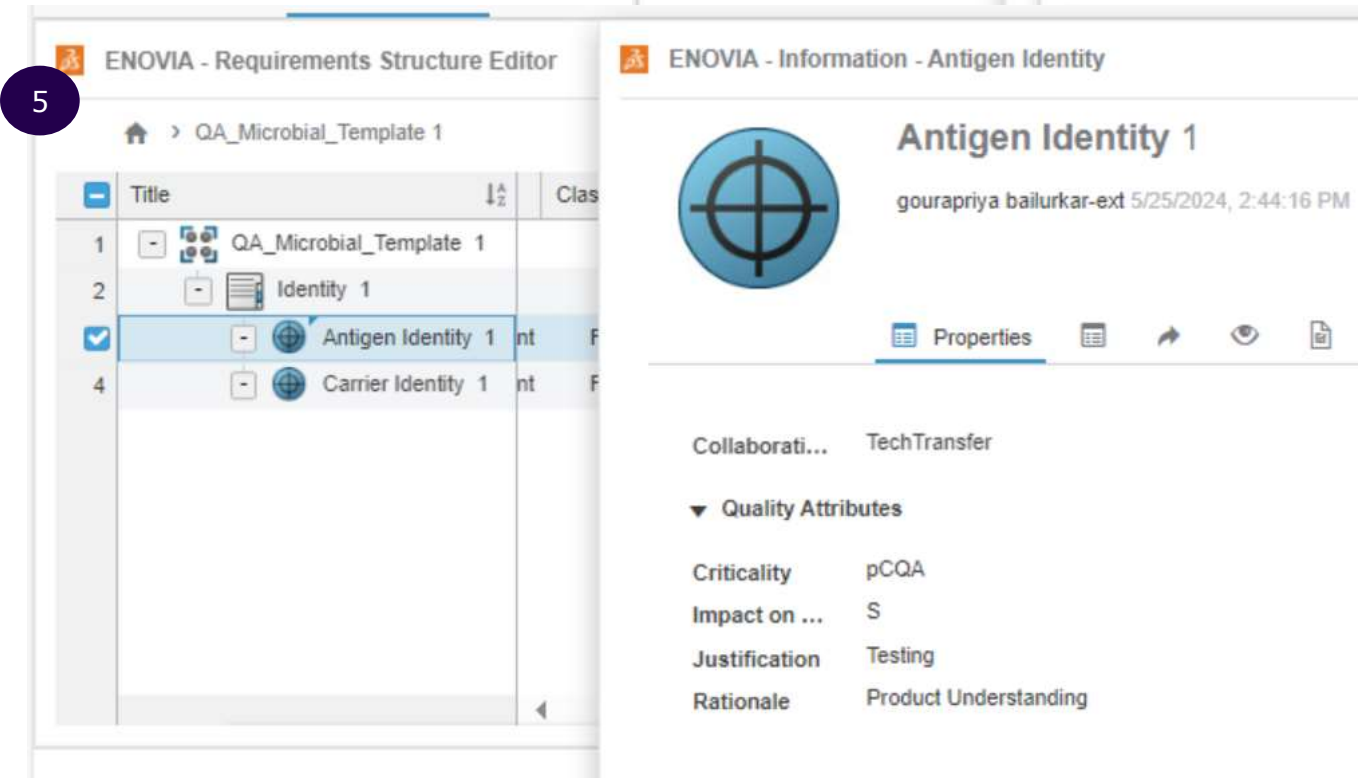
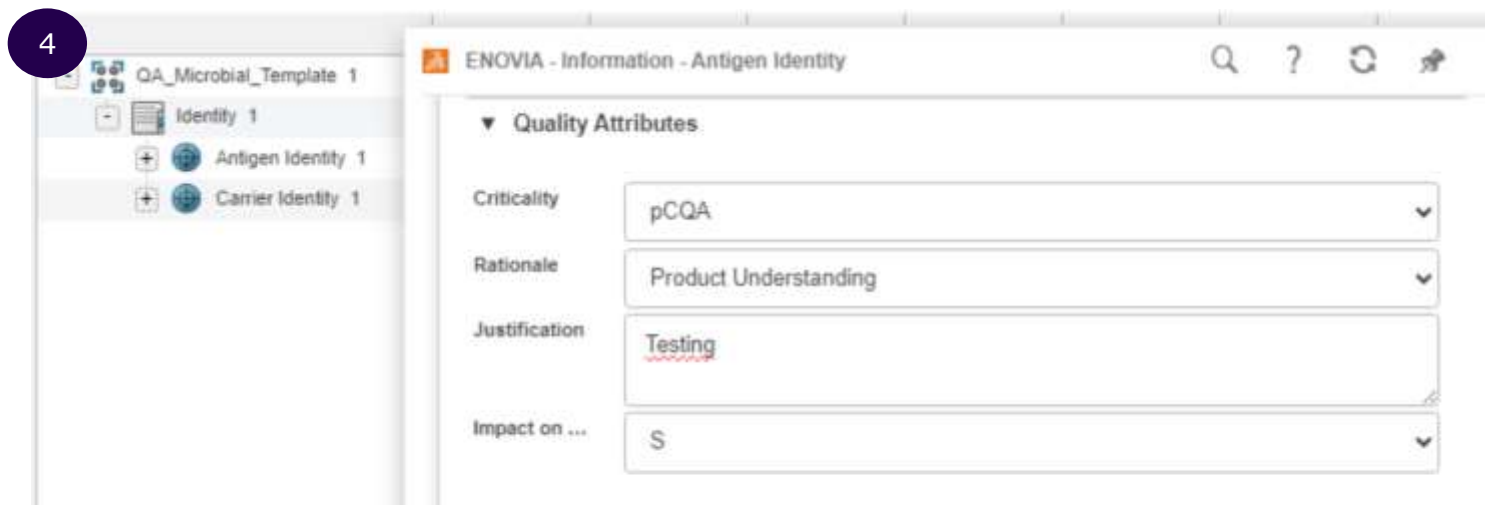
3



Adding Extensions and selecting attribute values from the pick list

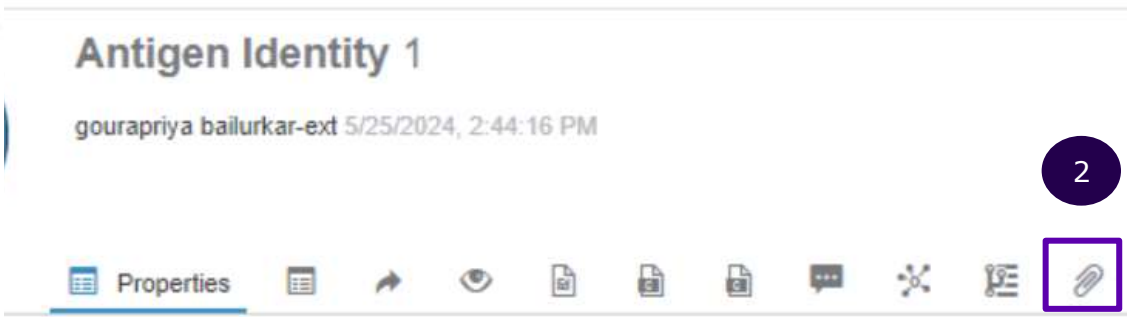
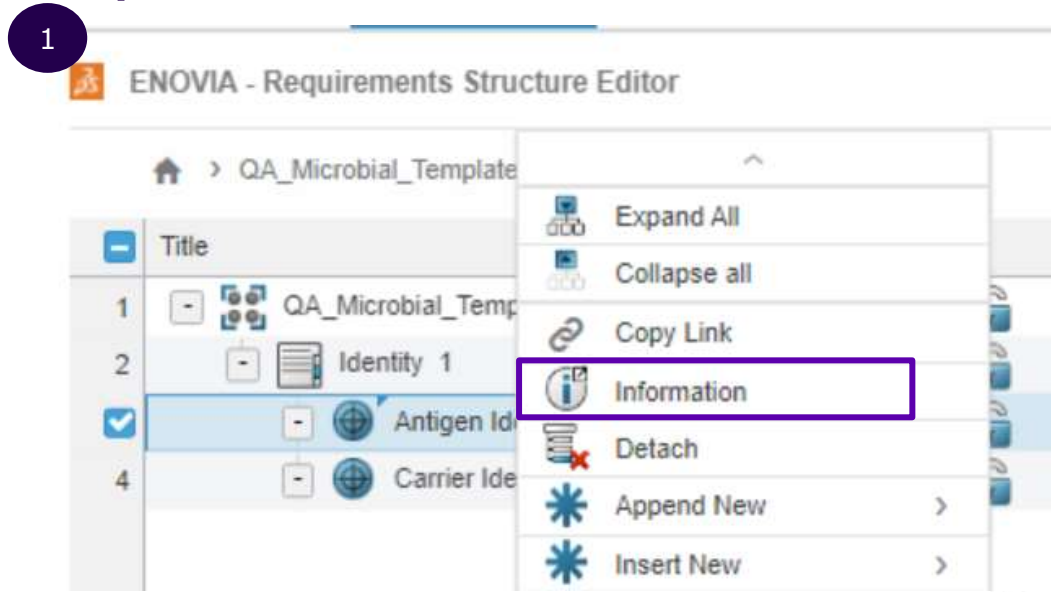
4. By selecting the attribute values from the drop down list the Antigen Identity can be filled and completed by clicking on ok.

5. Once the attributes are filled it will be reflected on the properties page.



Attachment of a document under the 'Requirement' (Antigen Identity)

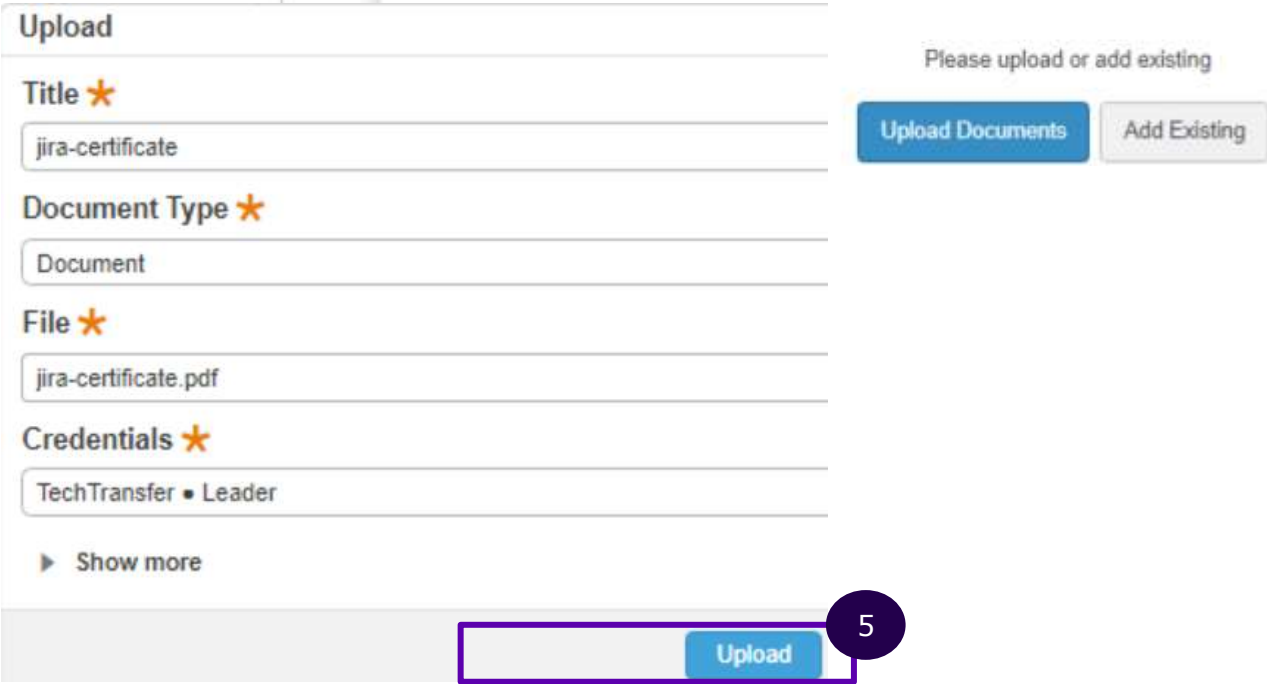
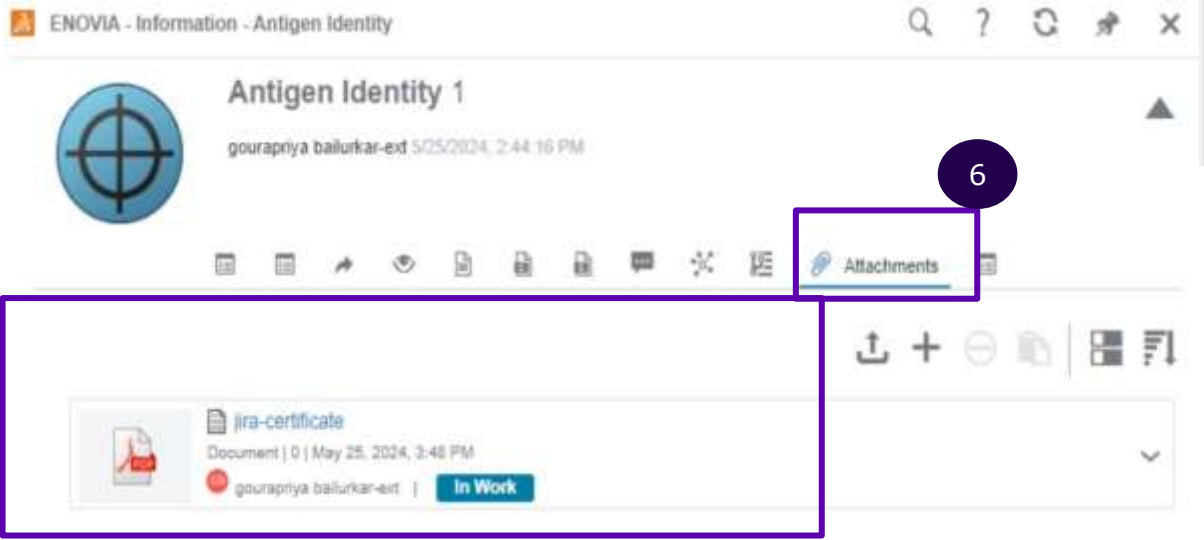
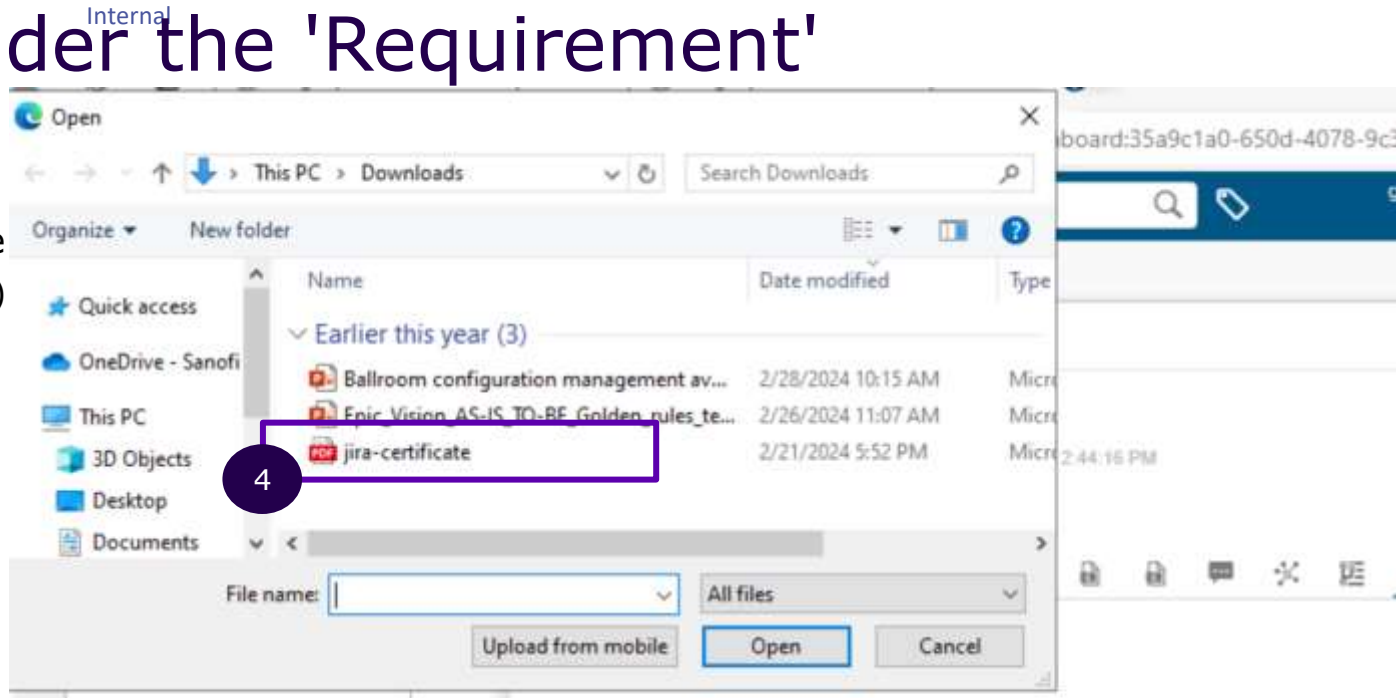
- 1. By doing a right click and selecting the information on the Antigen Identity and via attachment icon, the documents can be attached.
- 2. On the properties page of the Antigen Identity there is an attachment icon to perform attachment
- 3. By clicking on the attachment icon , It opens a window with access to upload the documents



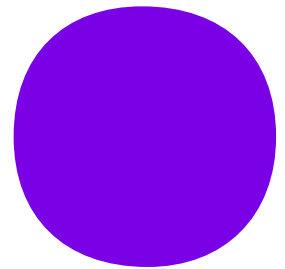
Requirement
Antigen Identity
req-46610828-00000274

Attachment of a document under the 'Requirement' (Antigen Identity)

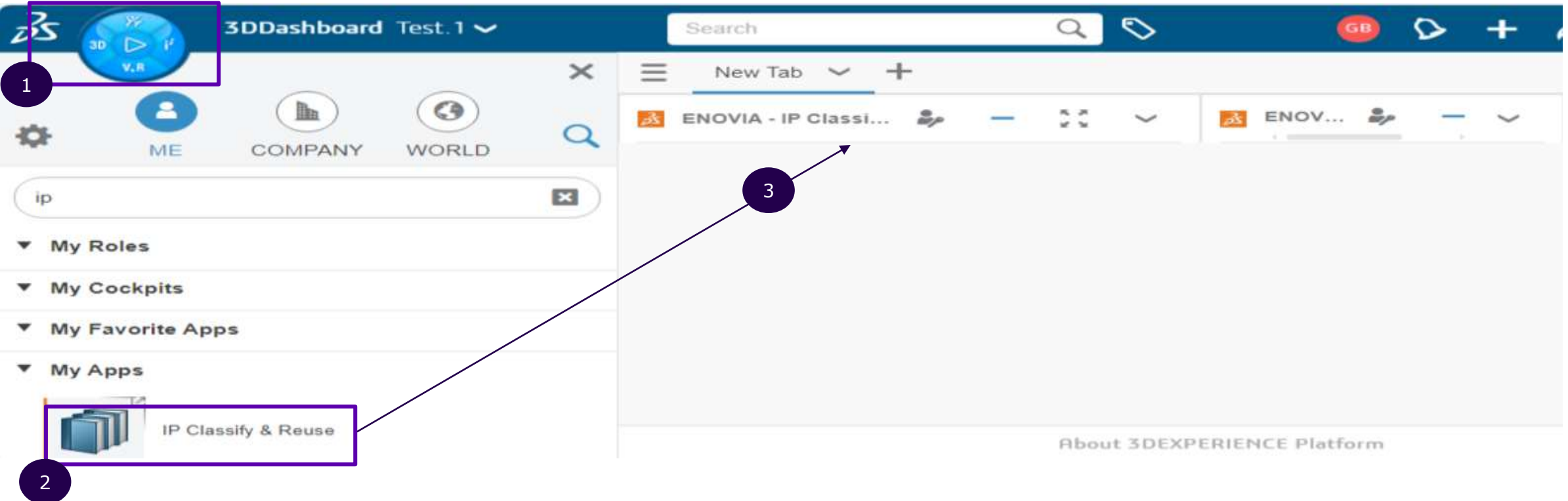
- 4. The document that must be attached can be selected from the user's document (or any specific space from the user's machine)
- 5. Once the document is selected, by clicking on 'upload' will attaches the document under the properties page.
- 6. The uploaded document will appear directly under the attachments Icon.



03 Attaching QA Templates to a product family under Library



Accessing Library and attaching the newly created template



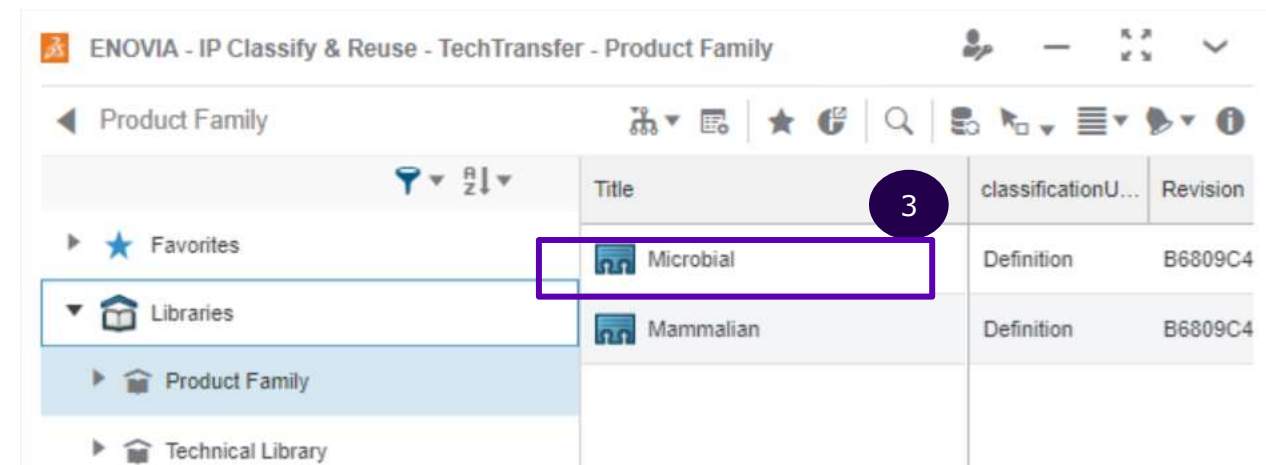
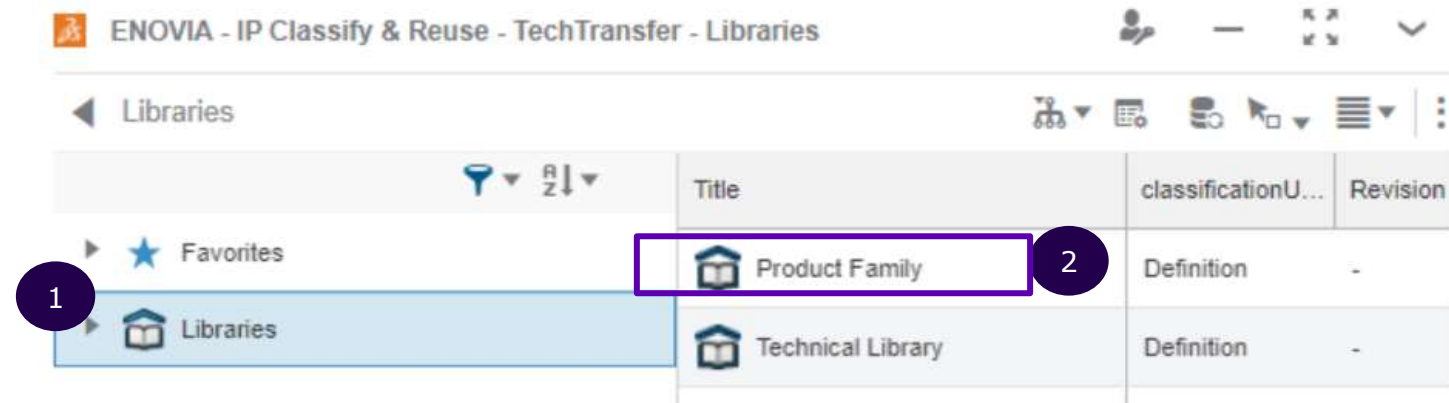
1. Click on 3D compass.
2. Search for IP classify & Reuse
3. Drag and Drop the 'IP classify & Reuse' widget to the 'Dashboard'
4. The widget will be appearing under the 'Dashboard' as shown in the above fig (3)

Accessing Library and attaching the newly created template

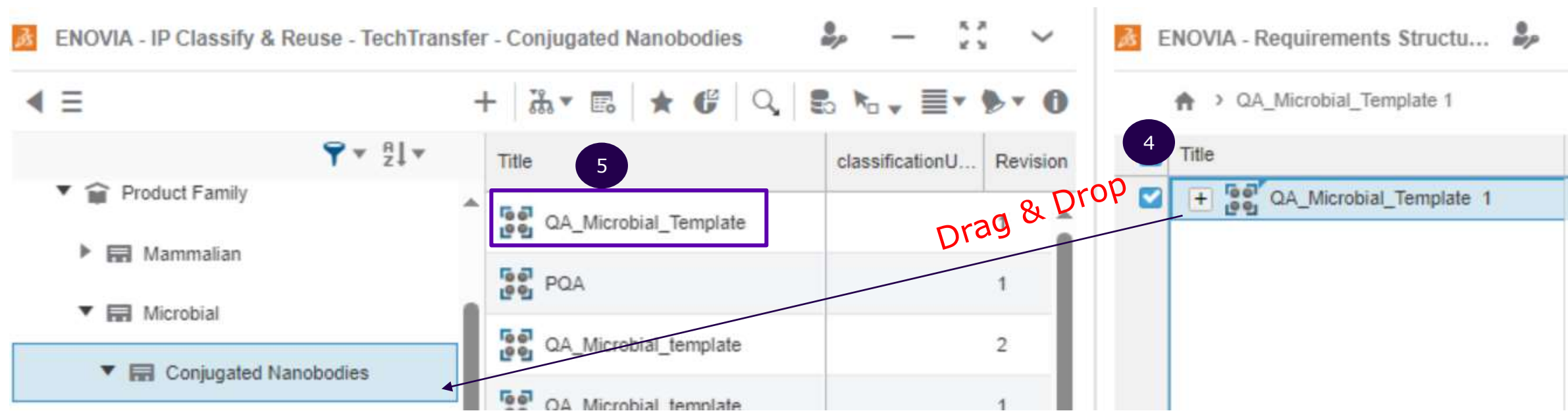
1. Click on Libraries.

2. And Click on 'Product Family', Which opens the contents associated with the product Family

3. Then click on the Microbial

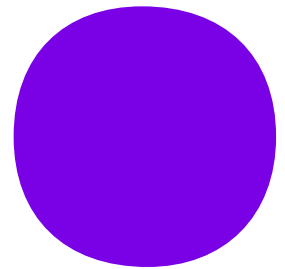


Accessing Library and attaching the newly created template



- 4. The Created 'QA_Attribute_Template'. Is drag and dropped from the 'Requirement structure Editor' widget to the Conjugated Nanobodies (Which is a subfamily of Microbial).
- 5.And the added template will reflect under the structure as in the above Fig (5).

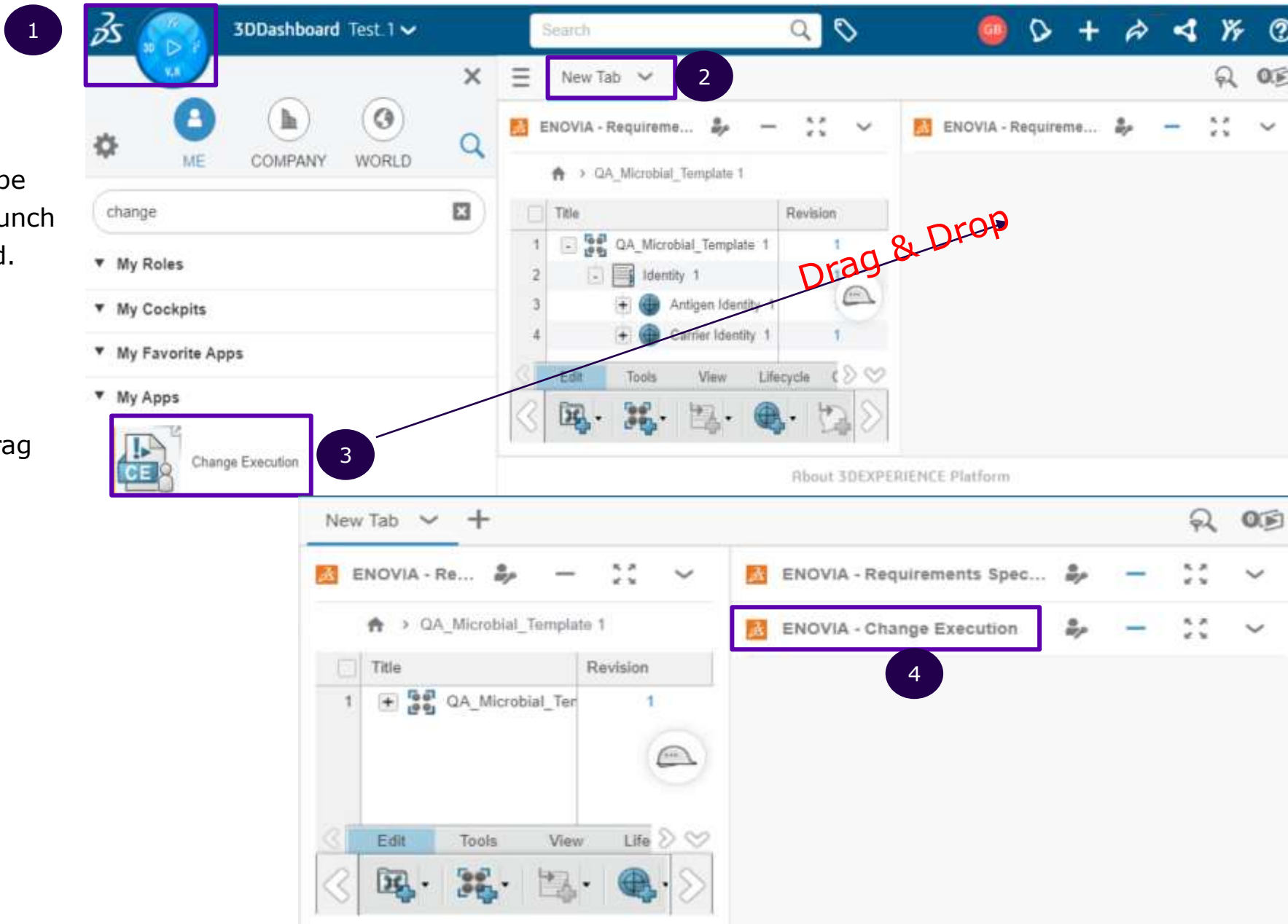
04 'Release' of Quality Attribute Template



Access of 'Change Execution' Widget for the 'Release' of attribute

To 'Release' the created template it could be done via 'Change Execution Widget', To launch the widget the following steps are followed.

1. Through the 3DCompass the Widget 'Change Execution' could be searched.
2. And The 'Change Execution' could be drag and dropped to the 'dashboard' (In this example scenario it will be 'New Tab').
3. Once the widget is synchronized it will appear in the dashboard automatically as shown in the Fig4.

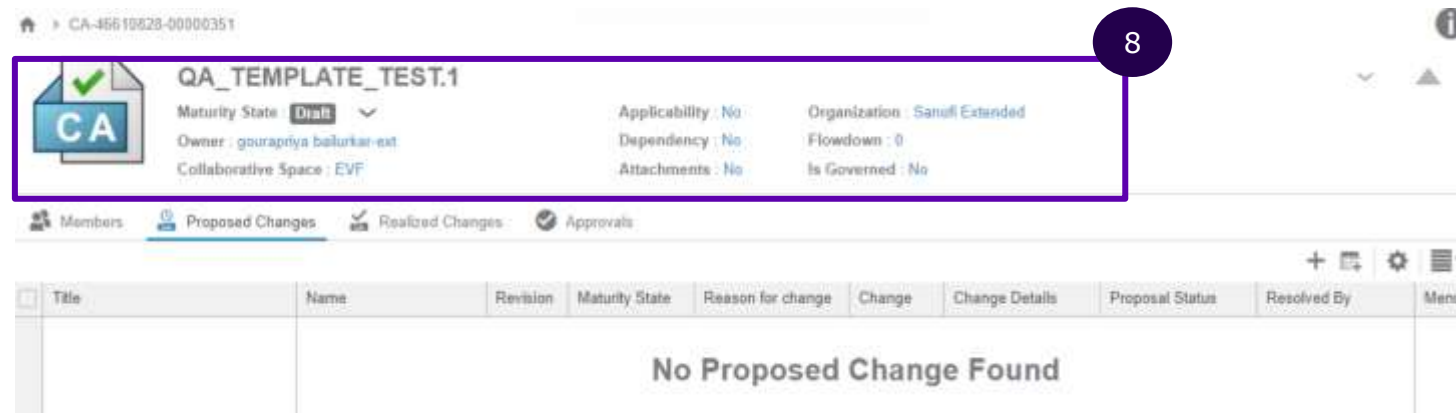


Access of 'Change Execution' Widget for the 'Release' of attribute

5. From Change the execution widget, create a 'New Change Action'.

6. create a New change action with title name 'QA_TEMPLATE_TEST.1'.

7. By clicking on create a New Change action has been created as shown in the fig(8).



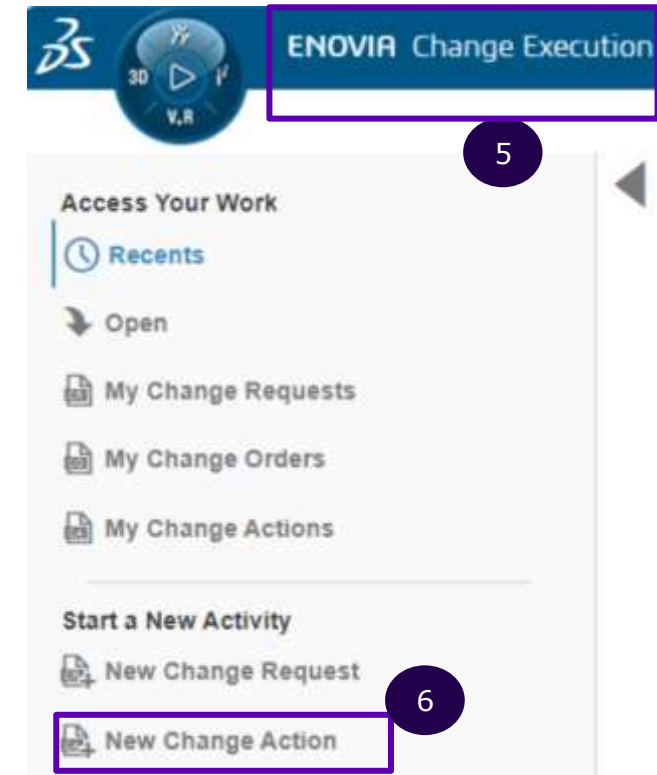
CA-46619828-00000351

QA_TEMPLATE_TEST.1

Maturity State: **Draft** | Applicability: No | Organization: Sanofi Extended
 Owner: gourapriya balurkar-ext | Dependency: No | Flowdown: 0
 Collaborative Space: EVF | Attachments: No | Is Governed: No

Members | Proposed Changes | Realized Changes | Approvals

Title	Name	Revision	Maturity State	Reason for change	Change	Change Details	Proposal Status	Resolved By	Menu
No Proposed Change Found									



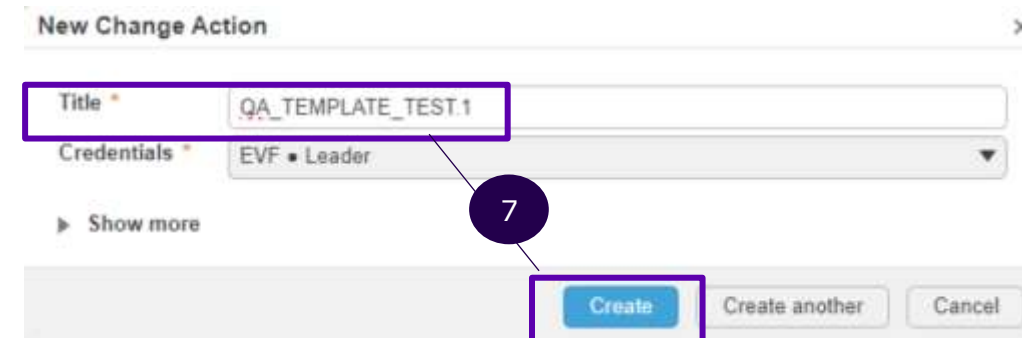
ENOVIA Change Execution

Access Your Work

- Recents
- Open
- My Change Requests
- My Change Orders
- My Change Actions

Start a New Activity

- New Change Request
- New Change Action**



New Change Action

Title: QA_TEMPLATE_TEST.1

Credentials: EVF • Leader

Show more

Create Create another Cancel

Access of 'Change Execution' Widget for the 'Release' of attribute

The screenshot displays two side-by-side windows from the ENOVIA software. The left window, titled 'ENOVIA - Requirements Structure Editor', shows a tree view of requirements. A purple box highlights a section containing 'QA_Microbial_Template: 1' (Requirement), 'Identity: 1' (Chapter), 'Antigen Identity: 1' (Requirement), and 'Carrier Identity: 1' (Requirement). A red circle with the number '9' is positioned above this box. The right window, titled 'ENOVIA - Requirements Specification Editor - QA_Microbial_Template', shows details for 'QA_TEMPLATE_TEST.1'. Below the details, a tab labeled 'Proposed Changes' is highlighted with a purple box. A red arrow points from the highlighted requirements in the left window to the 'Proposed Changes' tab in the right window. The text 'Drag & Drop' is written in red across the arrow. The bottom of the right window shows a table with the message 'No Proposed Change Found'.

Title	Revision	Type	Refined Into	Covers
QA_Microbial_Template: 1	1	Requirement		
Identity: 1	1	Chapter		
Antigen Identity: 1	1	Requirement	None	None
Carrier Identity: 1	1	Requirement	None	None

Title	Name	Revision	Maturity State	Reason for ch...	Change	Change Details	Pl	Menu
No Proposed Change Found								

9. Select all the elements and place it under the 'proposed changes' of the 'Change Execution' of the Widget via 'drag & drop'.

Access of 'Change Execution' Widget for the 'Release' of attribute

10. The attached attribute element 'QA_TEMPLATE_TEST.1' will be reflecting under 'Change Action',.

11. The owner of the Change Action will be seen in the below list

CA-46610828-00000343



Release_QATemplate

Maturity State : **Draft** ▼

Owner : gourapriya bailurkar-ext

Collaborative Space : EVF


Members Proposed Changes Realized Changes

11

	Title	Name	Revision
<input type="checkbox"/>	 Carrier Identity	req-46610828-000002...	1
2	 Identity	chp-46610828-000000...	1
3	 Antigen Identity	req-46610828-000002...	1
4	 QA_Microbial_template	rsp-46610828-000001...	1

12

CA-46610828-00000343



Release_QATemplate


Maturity State : **Draft** ▼

Owner : gourapriya bailurkar-ext

Collaborative Space : EVF

Members Proposed Changes Realized Changes Approvals

Applicability : No Organization : Sanofi Extended
Dependency : No Flowdown : 0
Attachments : No Is Governed : No



8 gourapriya bailurkar-ext

Owner

Adding of Approver to 'Release' the template

13. Under the option 'Approval' the approver to release the template could be added.

14. From the picklist the assigned approver could be selected and added.

15. The Approver will be seen in the list along with the owner of the 'Change Action'.

ENOVIA - Change Execution

CA-46610828-00000343

Release_QATemplate

Maturity State: Draft

Owner: gourapriya bailurkar-ext

Collaborative Space: EVF

Applicability: No

Dependency: No

Attachments: No

Organization: Sanofi Extended

Flowdown: 0

Is Governed: No

Members

Proposed Changes

Realized Changes

Approvals

Assignee

Approver

Informed User

13

ENOVIA - Change Execution

CA-46610828-00000343

Release_QATemplate

Maturity State: Draft

Owner: gourapriya bailurkar-ext

Collaborative Space: EVF

Applicability: No

Dependency: No

Attachments: No

Organization: Sanofi Extended

Flowdown: 0

Is Governed: No

Members

Proposed Changes

Realized Changes

Approvals

GB

gourapriya bailurkar-ext

Owner

GN

Gayathri Naru-ext

Approver

15

ENOVIA - Change Execution

CA-46610828-00000343

Release_QATemplate

Maturity State: Draft

Owner: gourapriya bailurkar-ext

Collaborative Space: EVF

Applicability: No

Dependency: No

Attachments: No

Organization: Sanofi Extended

Flowdown: 0

Is Governed: No

Members

Proposed Changes

Realized Changes

Approvals

Assignee

Approver

Informed User

Gayathri Naru-ext

Rahul Ragulapally-ext

Vishal Bhosale

Priyanka Andhavarapu

Sowmya Keesari

Shweta Gupta-ext

Arbab Mukherjee

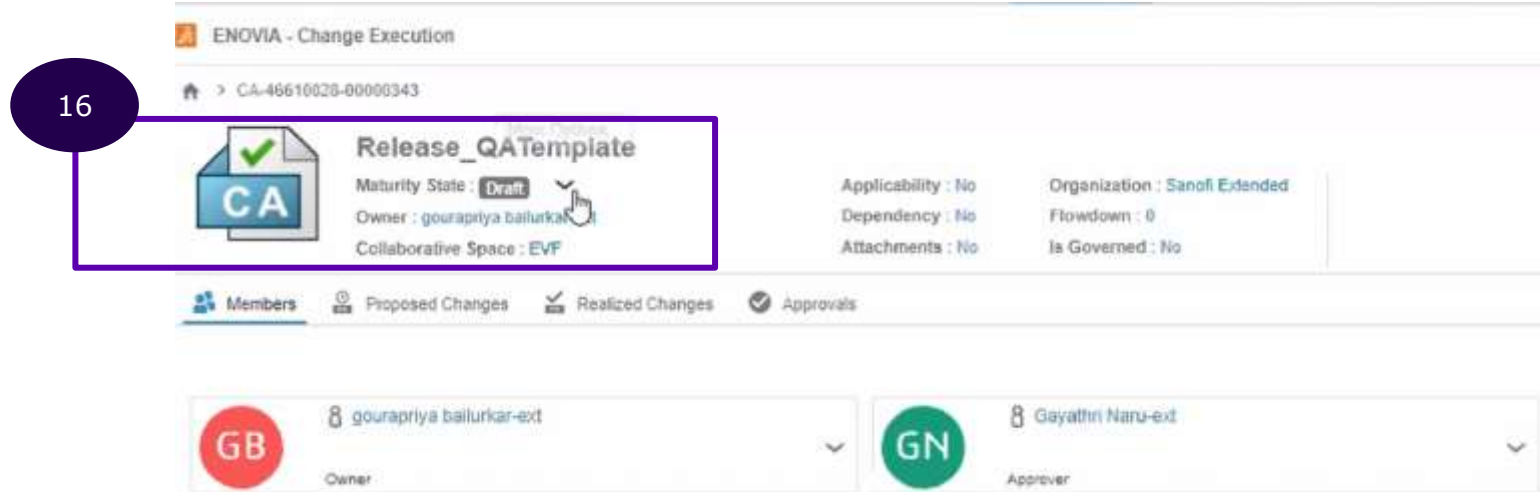
Madhusudhan Nayani

Shivani Munale-ext

14

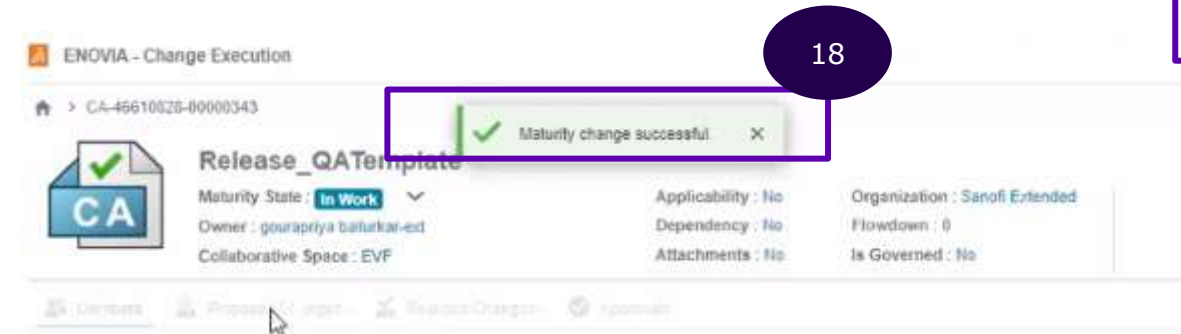
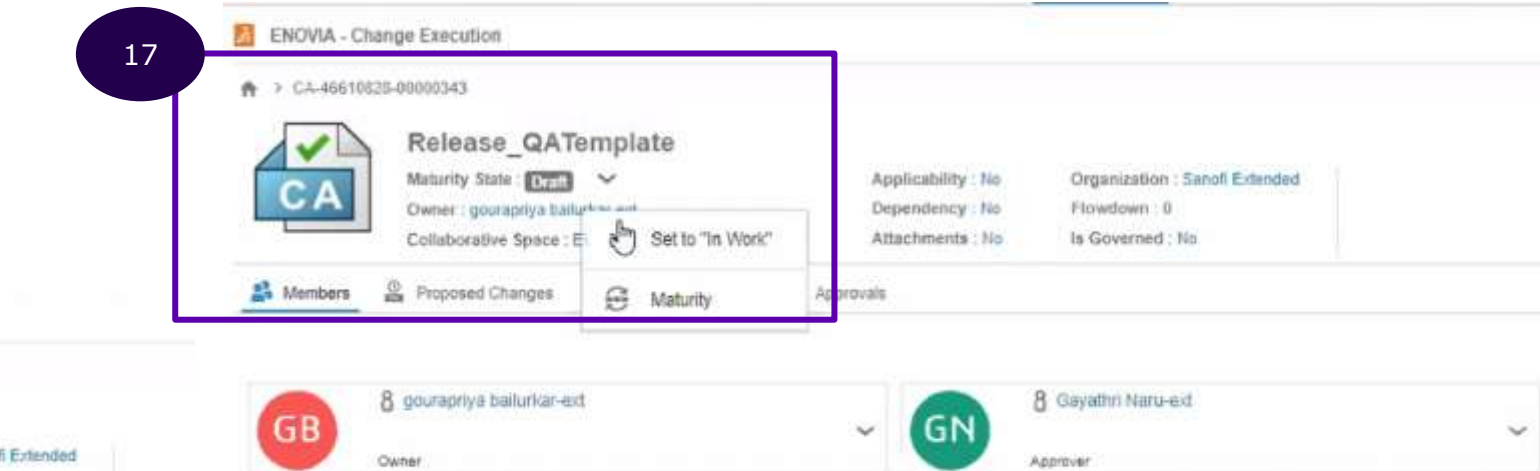
Change of Maturity state

16. The maturity state could be modified by clicking on the state.



17. The owner of the Change action will set the maturity from
DRAFT -> IN WORK -> APPROVAL.

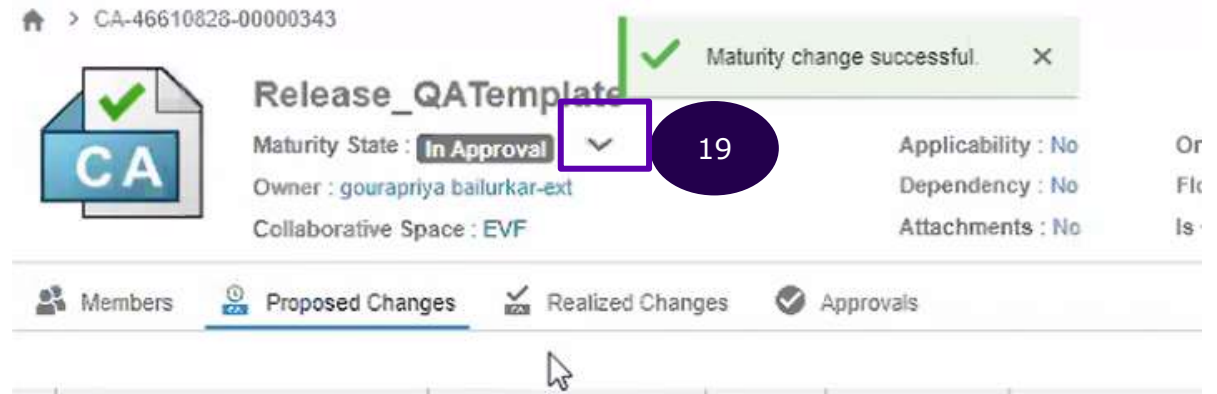
18. After change of status a confirmation message will be displayed, And will be sent to the approver



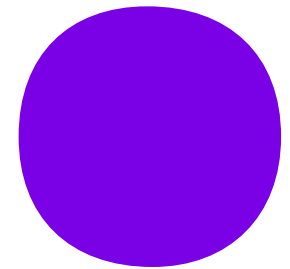
Change of Maturity state

19. The maturity of 'IN WORK' to 'IN APPROVAL' state has been changed by clicking on the small arrow next to the maturity state

After this step the Approver will get the notification alert regarding the assigned approval state and he will take over the process as explained in the next section.



05 Assigned Approver Releases the QA attribute



Notification & Approval of the Assigned Team member

1.The assigned approval will receive a notification.

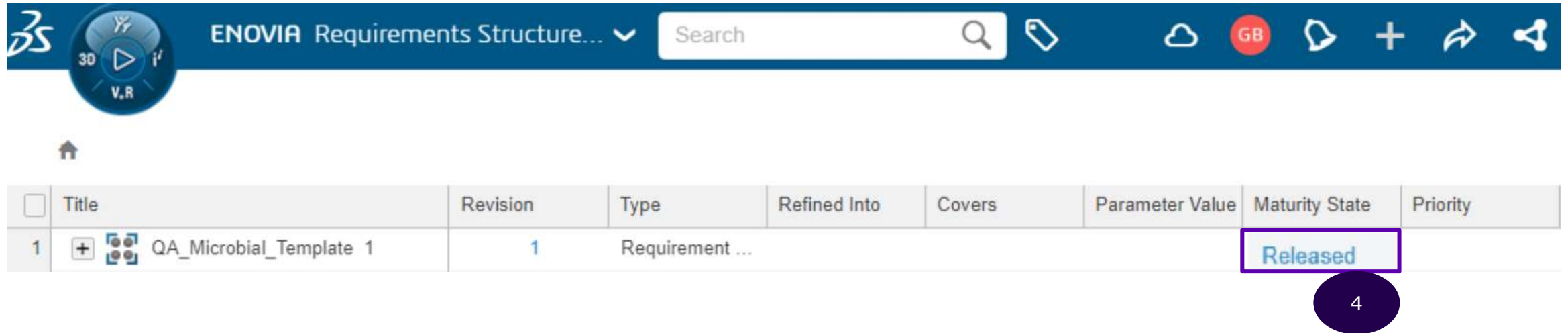
2.By clicking on the notification information the tool will takes directly to the approval page.

3.By clicking on the arrow and selecting approval with the comments the attribute will be 'Released'.



The image illustrates the notification and approval process in the ENOVIA software. It consists of three main components:

- Step 1:** A screenshot of the user interface showing the 'Notifications' icon in the top right corner, highlighted by a purple box and a circled '1'.
- Step 2:** A screenshot of the '3DNotification Center' window showing a notification from 'gourapriya bailurkar-ext' assigned a task: 'Approval task to review changes done on Change Action : CA-46610828-00000343, titled : Release_QATemplate on Change Action:Release_QATemplate(CA-46610828-00000343)'. This notification is highlighted by a purple box and a circled '2'.
- Step 3:** A screenshot of the 'Release_QA_Microbial_Templat' task card showing its maturity state as 'In Approval'. Below it, the 'Approval task to review changes' card is shown with a status of 'Awaiting Approval'. This card is highlighted by a purple box and a circled '3'.

Released Template

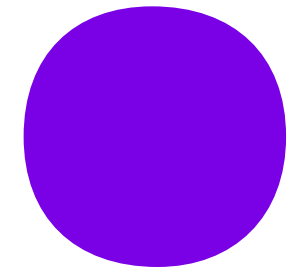


The screenshot shows the ENOVIA Requirements Structure interface. At the top, there is a blue header bar with the ENOVIA logo, a search bar, and various icons. Below the header, a table displays the requirements structure. The table has columns for Title, Revision, Type, Refined Into, Covers, Parameter Value, Maturity State, and Priority. A single row is visible, representing a requirement titled 'QA_Microbial_Template 1' with revision '1' and type 'Requirement ...'. The 'Maturity State' column for this row is highlighted with a purple box and contains the text 'Released'. A purple circle with the number '4' is positioned below the 'Released' text.

	Title	Revision	Type	Refined Into	Covers	Parameter Value	Maturity State	Priority
1	  QA_Microbial_Template 1	1	Requirement ...				Released	

1. When the created 'QA_Microbial_Template' is released the maturity status displays it .
2. Now the template is official, and it can be duplicated and adapted for future projects.

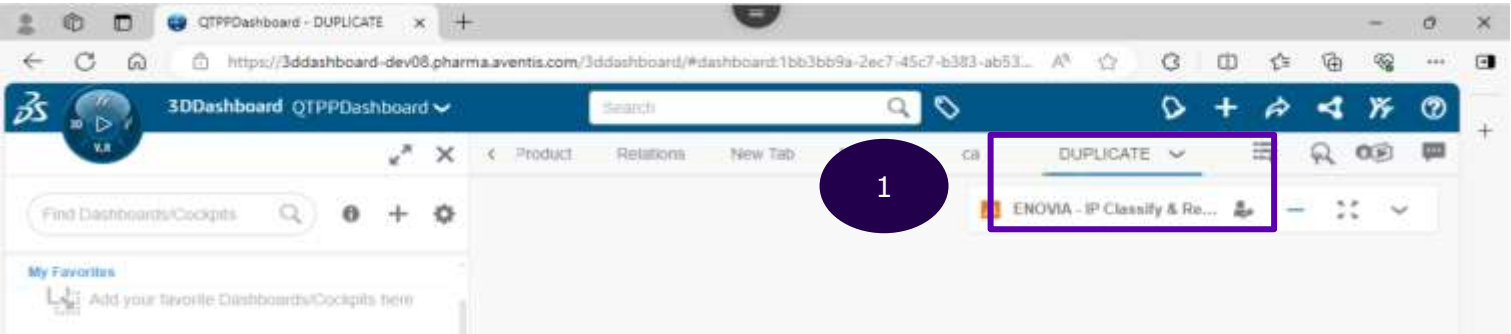
06 Creation of Product Specific Quality Attribute List



Creation of Product Specific Quality Attribute List

To create Product specific Quality Attribute List,

1. In Dashboard, Create a tab (DUPLICATE) and add IP Classify and Reuse app.
2. Go to the subclass under Product Family to open the Quality Attribute Template from which the Product specific Quality Attribute List will be created.(For Example let us take the QA Template from Slide 4 – QA_Microbial_Template)



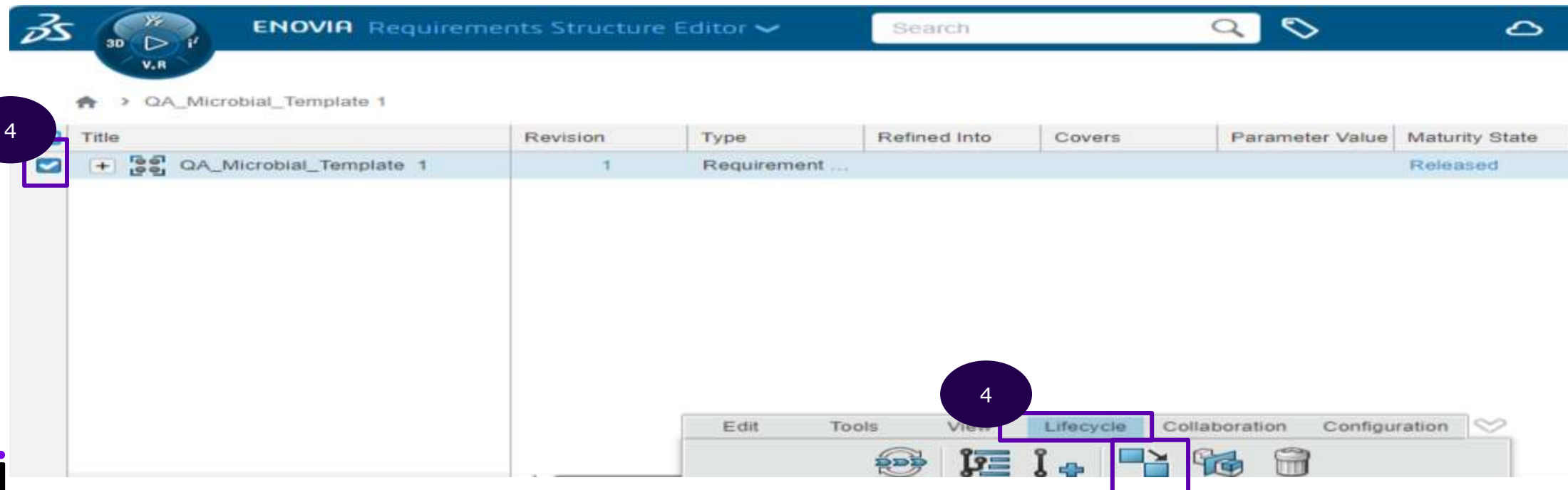
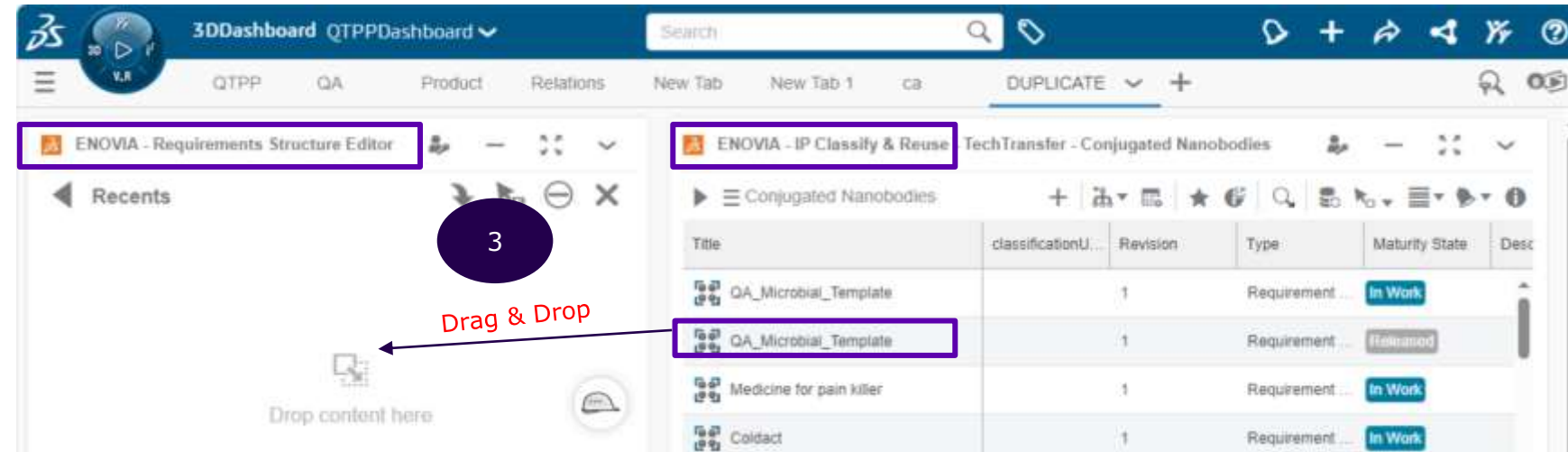
The screenshot shows the 3DEXPERIENCE | ENOVIA IP Classify & Reuse - Tech... interface. The left sidebar shows a tree view with 'Product Family' expanded, and 'Conjugated Nanobodies' selected. The main table lists various templates, with 'QA_Microbial_Template' highlighted by a red circle and the number 2.

Title	classificationU...	Revision	Type	Maturity State
QA_Microbial_Template		1	Requirement ...	Released
Medicine for pain killer		1	Requirement ...	In Work
Coldact		1	Requirement ...	In Work
Pain Killer 123Sk check		1	Requirement ...	In Work
Pain Relief		1	Requirement ...	In Work
Testing Template_KK		1	Requirement ...	In Work
Testing Template_KK		1	Requirement ...	Released

Creation of Product Specific Quality Attribute List

3. Add Requirements app. In the same tab then Drag and Drop the QA Template from Step 2.(IP classify & reuse -> requirement structure editor).

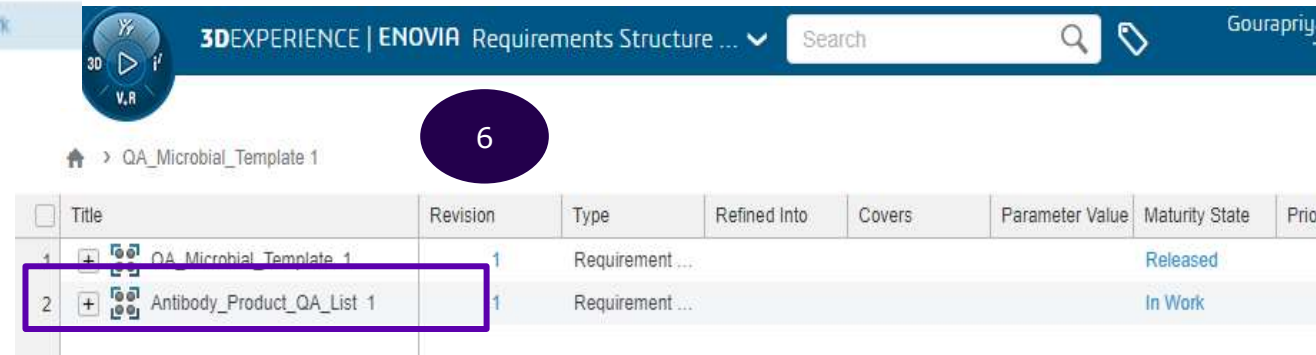
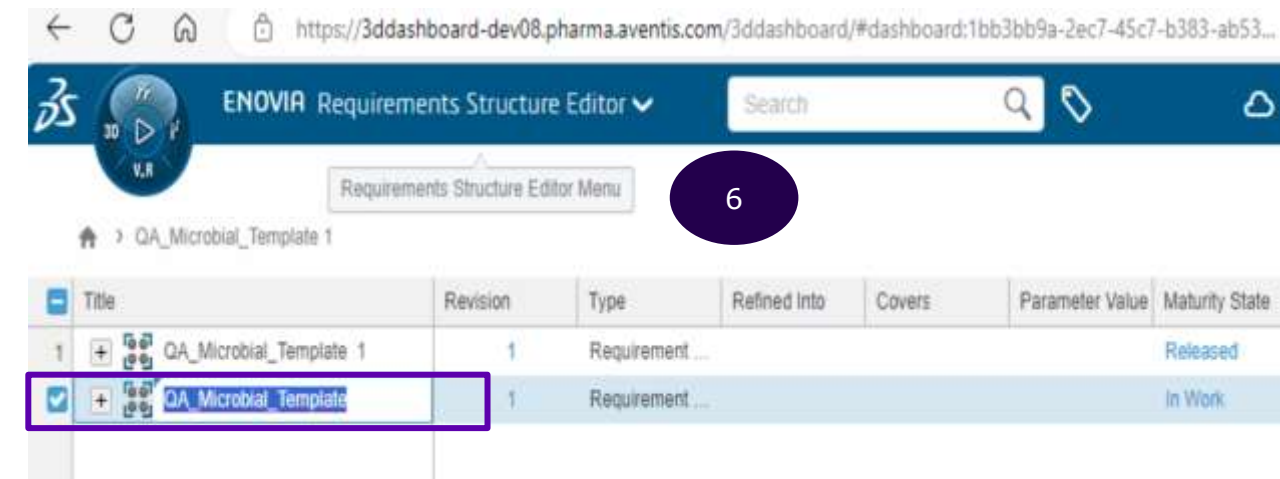
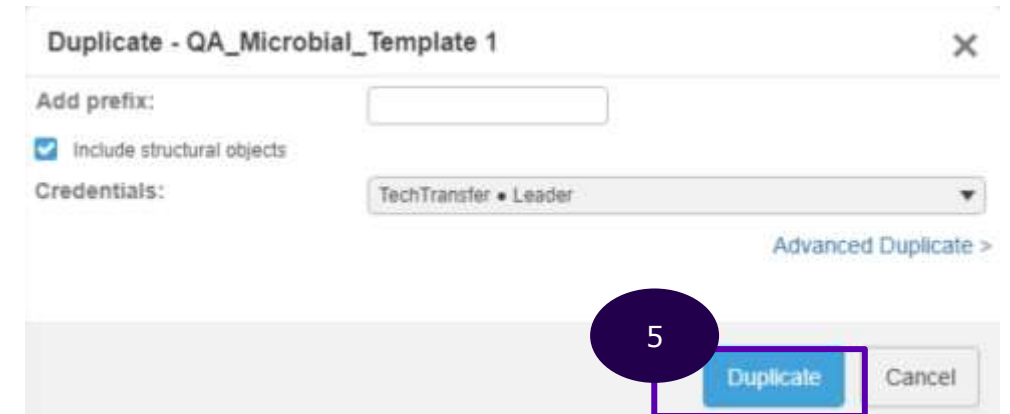
4. Select the QA Template and open the Lifecycle tab in the bottom Menu and select 'Duplicate' icon.



Creation of Product Specific Quality Attribute List

5. On the Duplicate pop-up window, click on the Duplicate button.

6. The Product specific Quality Attribute List is created with same name as the QA Template. Double-click on the QA List to rename.(For Example: Antibody_Product_QA_List)



Creation of Product Specific Quality Attribute List

7. For the Product specific QA List, on Requirement Specification Editor under Quality Attributes add the Target Values.

8. Right-click the Quality Attribute, select "Information". On the Information pop-up, click on "Edit" button to edit the Quality Attribute extension attributes - Criticality, Justification, Rationale and Impact on Safety/Efficacy .

The figure consists of four screenshots from the ENOVIA software interface, illustrating the steps to create and edit a Product Specific Quality Attribute List.

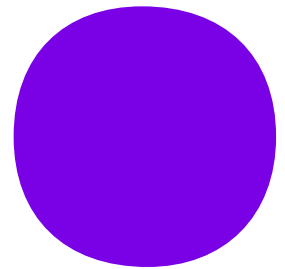
- Top Left:** ENOVIA - Requirements Structure Editor. A table lists requirements:

Title	Revision	Type	Refine
Antibody_Product_QA_List 1	1	Requirement	
- Top Right:** ENOVIA - Requirements Specification Editor - Antibody_Product_QA_List. Shows the "1 - Identity" section with two entries:
 - 1 - 1 Antigen Identity: Target Value NA
 - 1 - 2 Carrier Identity: Target Value NA
- Bottom Left:** ENOVIA - Requirements Structure Editor. A tree view shows the hierarchy:
 - Antibody_Product_QA_List 1
 - Identity 1
 - Antigen Identity 1
 - Carrier Identity 1
 A context menu is open for "Antigen Identity 1" with "Information" highlighted.
- Bottom Right:** ENOVIA - Information - Antigen Identity 1. A pop-up window showing the "Quality Attributes" section:

Attribute	Value
Criticality	CQA
Impact on Safety/Efficacy	S
Justification	Testing
Rationale	Compliance

Arrows and a central circle labeled "7" indicate the flow from the Structure Editor to the Specification Editor, and from the Information pop-up to the Specification Editor. A circle labeled "8" points to the "Information" option in the context menu.

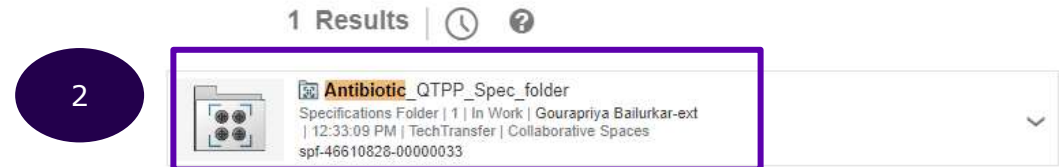
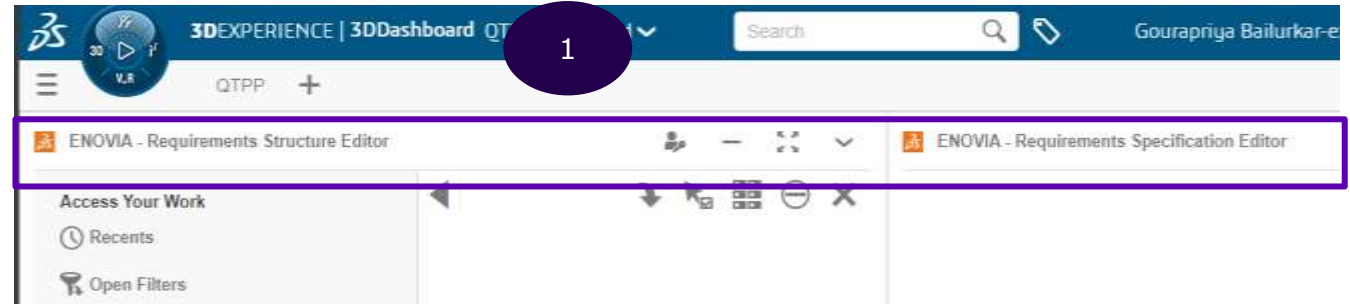
07 Creating link between QTPP and Product Specific Quality Attribute List



Creating link between QTPP and Product specific Quality Attribute list

To create link between QTPP and Product specific Quality Attribute List,

1. In 3D Dashboard, Create a tab. Click on 3D Compass, Search for Requirements app and Drag and Drop the app in the New tab created in 3D Dashboard.
2. Search and open the Product specific QTPP.



ENOVIA - Requirements Structure Editor

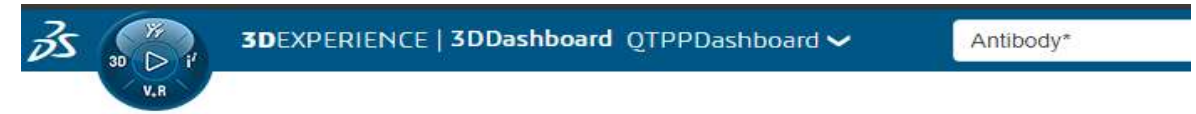
Antibiotic_QTPP_Spec_folder 1

	Title	Revision	Type	R
1	Antibiotic_QTPP_Spec_folder 1	1	Specifications Folder	
2	Finished_Product 1	1	Requirement Specific...	
3	Degradants and impur...	1	Requirement	
4	Dosage Form 1	1	Requirement	
5	DP Strength and Conc...	1	Requirement	
6	Condition for dilution a...	1	Requirement	
7	DS & FDS Formulation 1	1	Requirement	
8	Drug_Product 1	1	Requirement Specific...	

Creating link between QTPP and Product specific Quality Attribute list

3. Search and open the Product specific Quality Attribute List.(For Example let us take the Product specific Quality Attribute List from Slide 29)

4. Select the QTPP attribute for which the Quality Attribute will be linked and right-click and select 'Start Link'.



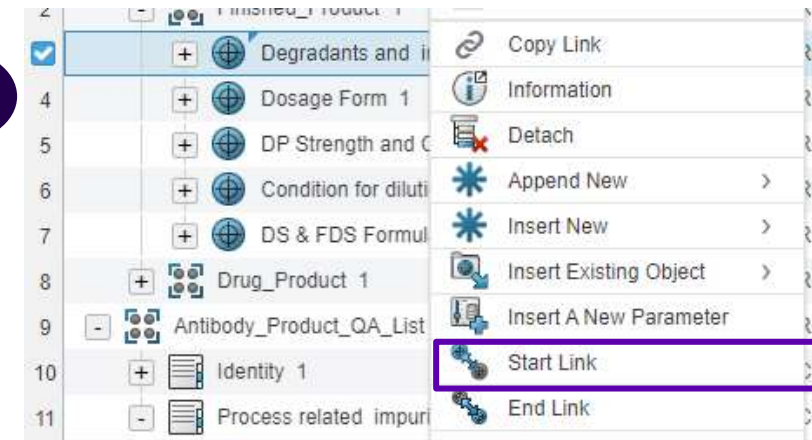
3

9	-	Antibody_Product_QA_List 1	1	Requirement Specific...
10	+	Identity 1	1	Chapter
11	-	Process related impurities 1	1	Chapter
12	+	Residual cellular DNA 1	1	Requirement
13	+	Host Cell residual DNA...	1	Requirement
14	+	Residual inactivated a...	1	Requirement
15	+	Host Cells Proteins 1	1	Requirement
16	+	Extractables / leachabl...	1	Requirement
17	+	Elementary impurities 1	1	Requirement
18	+	Other residuals potenti...	1	Requirement

4

1	-	Antibiotic_QTPP_Spec_folder 1	1	Specifications Folders
2	-	Finished_Product 1	1	Requirement Specification
	+	Degradants and impurities 1	1	Requirement

4

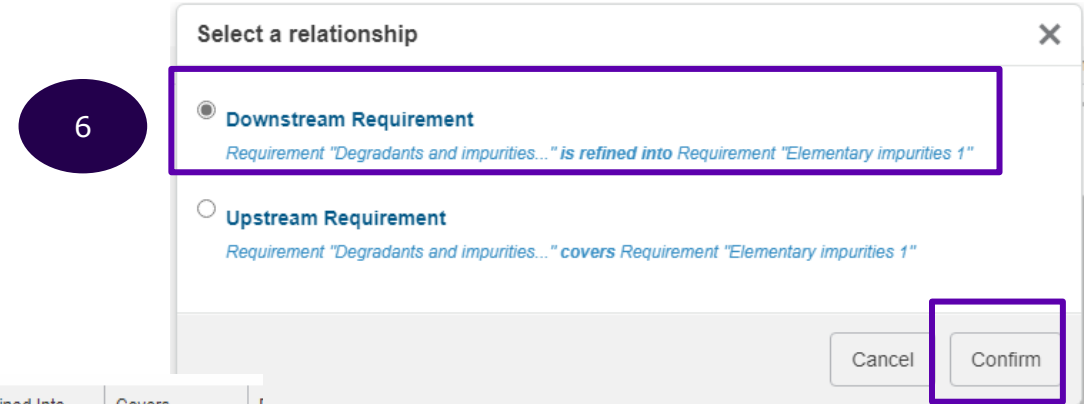


Creating link between QTPP and Product specific Quality Attribute list

5. Now select the Quality Attribute which must be linked to the QTPP attribute and right-click and select 'End Link'.



6. On the 'Select a relationship' pop-up window, QTPP attribute and Quality Attribute is displayed. Select 'Downstream Requirement' option and click on "Confirm" button.



7. The link is created. For the QTPP Attribute in the Refined Into column displays 'Suspect' and Covers displays 'None'. For Quality Attribute, 'Refined Into' column displays "None" and Covers column displays 'Suspect'.

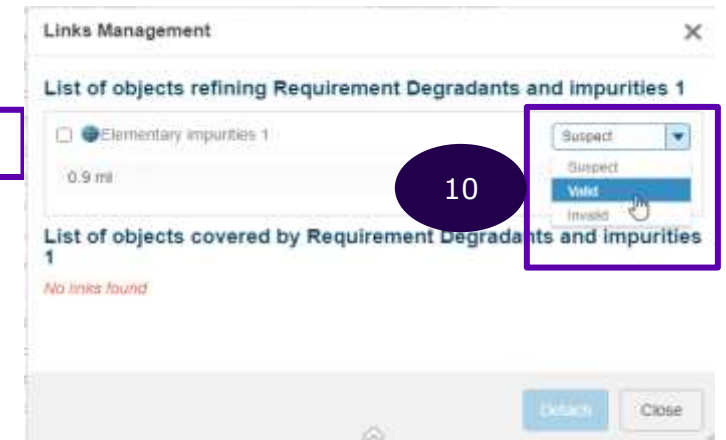
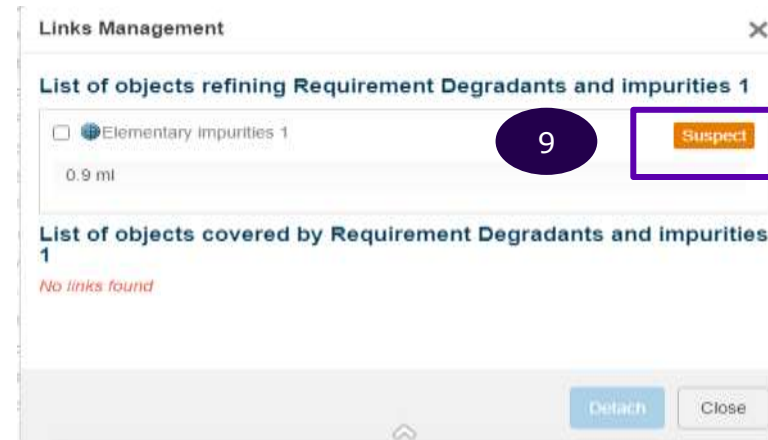
Title	Revision	Type	Refined Into	Covers
1 Antibiotic_QTPP_Spec_folder 1	1	Specifications Folder		
2 Finished_Product 1	1	Requirement Specific...		
3 Degradants and impurities 1	1	Requirement	Suspect	None
16 Extractables / Leachables 1	1	Requirement		
17 Elementary impurities 1	1	Requirement	None	Suspect
18 Other residuals potentially toxic	1	Requirement		

Creating link between QTPP and Product specific Quality Attribute list

8. To make the link valid, Double-click on the "Suspect" under 'Refined Into' column for the QTPP Attribute.

	Title	Revision	Type	Refined Into	Covers	P
1	Antibiotic_QTPP_Spec_folder 1	1	Specifications Folder			
2	Finished_Product 1	1	Requirement Specific...			
3	Degradants and impurities 1	1	Requirement	Suspect	None	
4	Dosage Form 1	1	Requirement			

9. On the Link Management pop-up window, Quality Attribute select in Step is displayed in the box under 'List of objects refining Requirement Degradants and impurities 1'. Click on the 'Suspect' button.



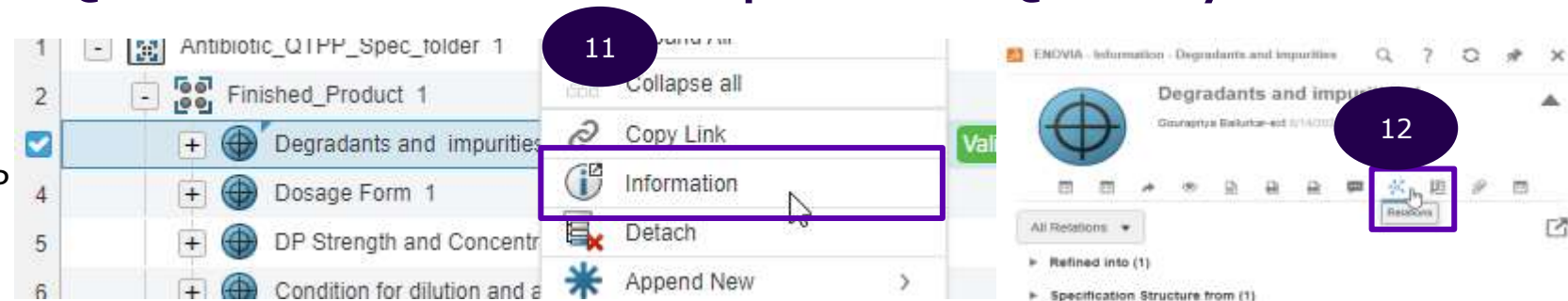
10. Select 'Valid' option in the dropdown. Once selected, 'Valid' is displayed in green box, making the link between QTPP Attribute and Quality Attribute valid. Now, click on 'Close' button on the 'Links Management' pop-up window.



	Title	Revision	Type	Refined Into	Covers	P
1	Antibiotic_QTPP_Spec_folder 1	1	Specifications Folder			
2	Finished_Product 1	1	Requirement Specific...			
3	Degradants and impurities 1	1	Requirement	Valid	None	
4	Dosage Form 1	1	Requirement			
16	Extractables / leachables 1	1	Requirement			
17	Elementary Impurities 1	1	Requirement	None	Valid	
18	Other residuals potentially t...	1	Requirement			

Creating link between QTPP and Product specific Quality Attribute list

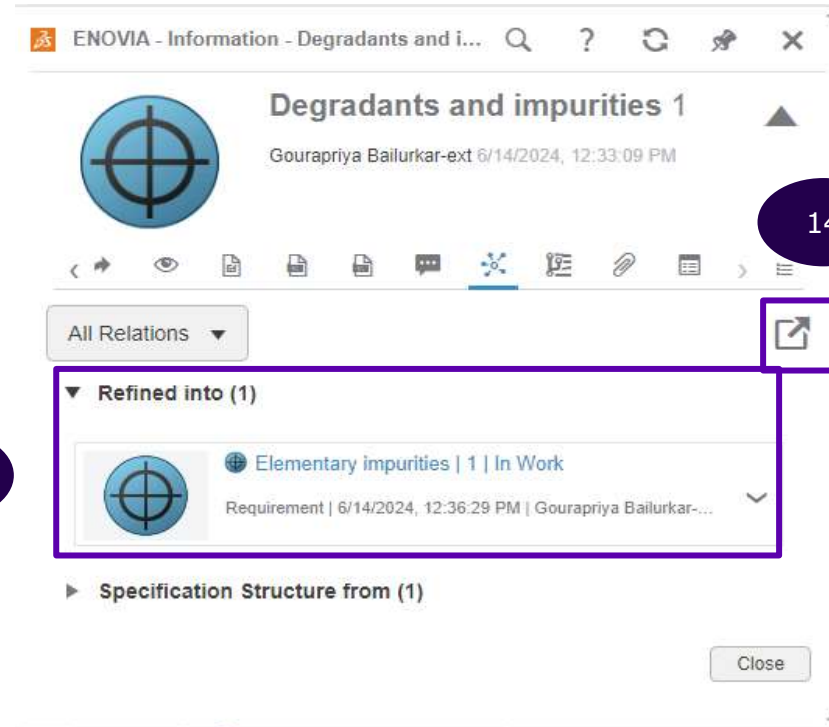
11. To view the relationship between the QTPP Attribute and Quality Attribute, select the QTPP Attribute, Right-click and select 'Information' option.



12. On the 'Information' pop-up, select the 'Relations' tab.



13. Expand the 'Refined into(1)', it displays the Quality Attribute used in the link.

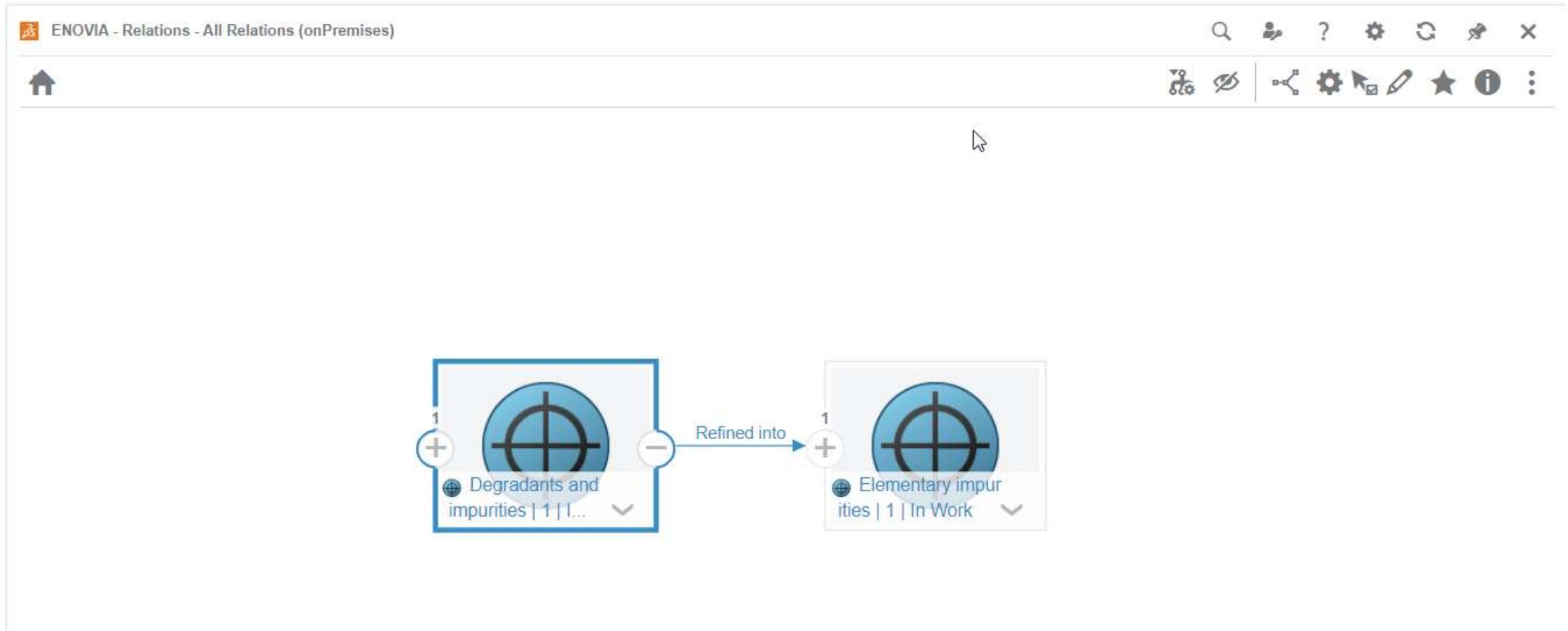


14. Click on the arrow in box icon (highlighted in the image) to view Graph view.



Creating link between QTPP and Product specific Quality Attribute list

Graphical view of the link between QTPP Attribute and Quality Attribute



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