



Instructions for Use Swiss AR Issue Tracker

Doc. Nr.: DOC-00025

Valid from: 01.07.2023



www.swissarservices.ch/issues

Instructions for use

Standard processes for communication between AR - Manufacturer



Content

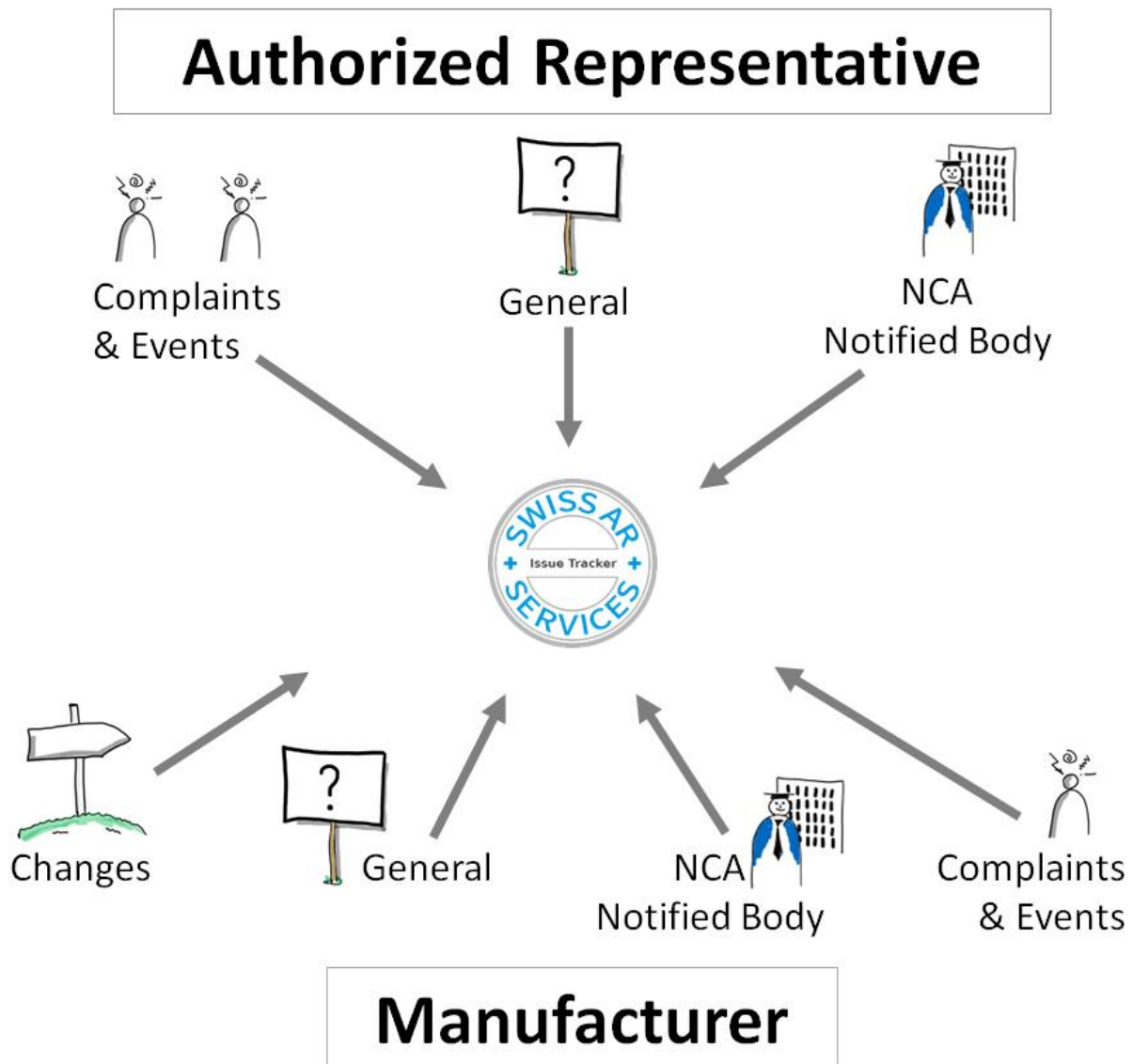
1	Goal	3
2	Principle	3
2.1	Projects	4
2.2	Process	5
2.3	Issue Lifecycle / States	6
3	Detailed instructions	7
3.1	Link	7
3.2	Dashboard	7
3.2.1	Area 1: Project Switch	7
3.2.2	Area 2: Toolbox	8
3.2.3	Area 3: Workarea	8
3.2.4	Area 4: Quick Selector	8
3.3	Setup Preferences	9
3.3.1	Set email notifications in Tab “Preferences”	9
3.3.2	Tab “Manage Columns”	9
3.4	Report issue	9
3.4.1	Issue Categories	11
3.4.2	Issue Severity	12
3.5	View Issue Details Mode	12
3.6	Assign issue	13
3.7	Execute actions	13
3.8	Resolve issue	14
3.9	Final check and closure	14
3.10	Report CAPA Issue	14
3.11	Show Roadmap	15
4	Standard Pathways for special cases	16
4.1	Customer Complaints	16
4.2	Request for Samples by an NCA or a notified body	17
5	Training	18
6	History	18

1 Goal

This manual describes the use of the Swiss AR Issue Tracker on www.swissarservices.ch/issues

2 Principle

The Swiss AR Issue Tracker (SIT) is mainly used as communication tool between the Authorized Representative and the manufacturer. It tracks tasks, requests and open issues related to products (e.g. complaints or requests from a national competent authority) or to the business relationship between the AR and the manufacturer (e.g. audits deviations or general tasks).





Instructions for Use Swiss AR Issue Tracker

Doc. Nr.: DOC-00025

Valid from: 01.07.2023

2.1 Projects

Each Manufacturer has access to the following projects:

[Companyname]

Main Project

Business

Subprojects

All issues related to the business relationship between Swiss AR and the manufacturer incl. CAPAs from Business & Products Project)

- Organized in groups (e.g. "Signing Contract" or "year")
- Topics like (General Questions, complaint, questionnaire, audit deviations from the check of technical documentation and sample requests of a NCA)

Products

Subproject.

All issues related to a product check of the manufacturer, e.g. Check of TechFile.

- Organized in groups (e.g. Year)
- The manufacturer has the rights to view these issues, but only the authorized representative will work in this project.
- All CAPA issues will be moved to the business project.

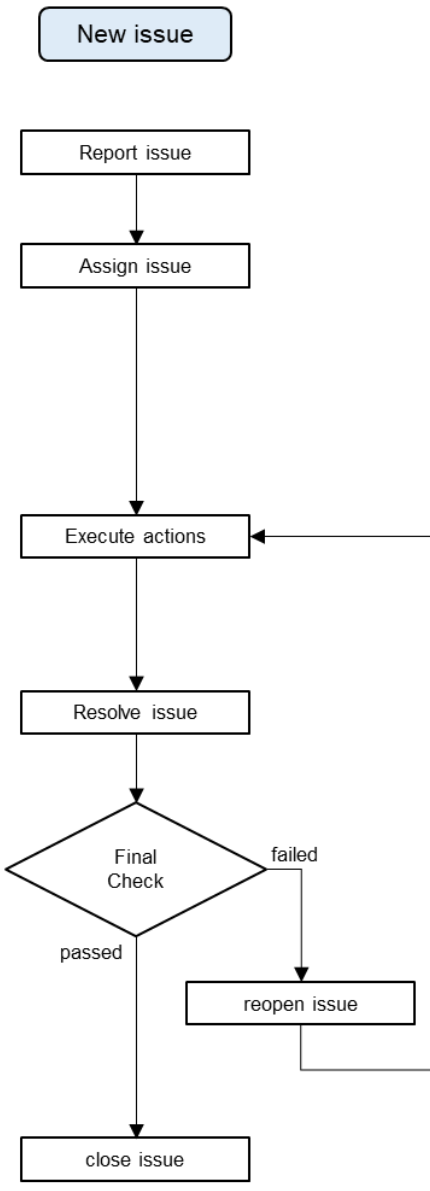
We track the product information in each of our Check of TechFiles Issues to track the status of your products.

	<p>For in vitro diagnostic:</p> <p>a. Evidence of the fulfillment of requirements in accordance with Annex I IVDR or IVDD</p> <p>b. Risk management report of the in vitro diagnostic medical devices</p> <p>c. Performance evaluation</p> <p>d. List of documents in the technical files</p> <p>e. Summary list of complaints about the in vitro diagnostic medical devices in the last 3 years</p> <p>f. List of reports submitted to the authorities concerning the in vitro diagnostic medical devices in the last 3 years</p> <p>g. Master labels, labeling templates, and process descriptions that pertain to labeling</p> <p>h. EC certificate (insofar as the medical device class requires the involvement of a Notified Body)</p> <p>i. Declaration of conformity</p> <p>To upload the documents for a In-Vitro Diagnostika, Drag & Drop the Files into the Note Section of this issue.</p>
Tags	Keine Tags zugeordnet.
Tags zuordnen	(Trenne durch „“) <input type="text"/> Existierende Tags <input type="button" value="Zuordnen"/>
Class	Ila
Communicated to insurance	Yes
Custom made	No
EC Certificate Expiry Date	2023-03-23
EC Certificate No.	123456789
Exemption by CA	No
Implantable	No
Listed on Annex I	Yes
Name of Notified Body	TÜV Rheinland Industrie Service GmbH
Notified Body No.	
Regulation	MDD
Selfdeclaration available	Yes
Selfdeclaration Expiry Date	2027-06-15
<input type="button" value="Bearbeiten"/> <input type="button" value="Zuordnen zu"/> [Ich selbst] <input type="button" value="Status wechseln zu: Rückmeldung"/> <input type="button" value="Beobachten"/> <input type="button" value="Fixierung setzen"/> <input type="button" value="CAPA"/> <input type="button" value="Verschieben"/> <input type="button" value="Löschen"/>	



Check project switch so that the right project is set. Please report each issue in the Project "Business"!

2.2 Process

Process	Issue State	Tasks	Responsibility
 <pre> graph TD Start([New issue]) --> Report[Report issue] Report --> Assign[Assign issue] Assign --> Execute[Execute actions] Execute --> Resolve[Resolve issue] Resolve --> Final{Final Check} Final -- passed --> Close[close issue] Final -- failed --> Reopen[reopen issue] Reopen --> Execute </pre>			
	new	Choose Project Business	
Report issue	new	Report issue. Consider Priority and due date.	Reporter
Assign issue	→ assigned	Check Issue category, project, product, due date and priority. Define actions together with manufacturer and assign issue to a person.	Every User
Execute actions	assigned	Execute defined actions. Add notes to document progress. Upload documents if necessary.	Assigned person
Resolve issue	→ resolved	Once all actions are performed, resolve issue.	Assigned person
Final Check	resolved	Check if all actions are done and documented.	Every User
reopen issue	→ assigned	Reopen issue by reset state to «assigned». Discuss further actions with previous assigned person.	Authorized Representative
close issue	→ closed	Close issue	Authorized Representative



Instructions for Use Swiss AR Issue Tracker

Doc. Nr.: DOC-00025

Valid from: 01.07.2023

2.3 Issue Lifecycle / States

A typical lifecycle of an issue contains four states.

State	Description
New	Once an issue is created.
Assigned	As soon an issue is assigned to a person, the state changes to "assigned". In this stage, the issue is being processed. There may be more than one person working on the issue, however only the person currently in charge is assigned.
Resolved	Once all required actions has been executed, the assigned person may resolve the issue.
Closed	Once an issue is resolved, the Authorized Representative will check the results of the actions and will eventually switch to "closed". Once an issue is closed, it is seen as completed.
Feedback	This state is available as fallback from all states above. It is used if additional information is becoming available or required. If an issue was closed, this state will reopen the issue. The state "feedback" is equal to "New" in the lifecycle process.

3 Detailed instructions

3.1 Link

The link to the Swiss AR Issue Tracker is: www.swissarservices.ch/issues.

3.2 Dashboard

After logging in, you will see the dashboard. It is called *My View*.

The dashboard consists of several areas, which are explained in the following chapters.

The screenshot shows the 'TEST Axxos Issue Tracker TEST' dashboard. At the top right, there is a navigation bar with 'Report Issue', 'Invite Users', and a dropdown menu for 'All Projects' (marked with a red '1'). Below this, the user profile 'rabbit (Simon) Administrator' is shown (marked with a red '4'). The main content area is divided into several sections: 'Assigned to Me (Unresolved)' (1-1/1), 'Unassigned' (1-4/4), 'Reported by Me' (1-7/7), and 'Resolved' (1-2/2). The 'Unassigned' section is highlighted with a red '3'. On the right side, there is a 'Timeline' section showing a list of events. On the left side, there is a 'My View' sidebar with navigation options like 'View Issues', 'Report Issue', 'Change Log', 'Roadmap', 'Summary', and 'Manage' (marked with a red '2').

3.2.1 Area 1: Project Switch

This is the project switch. You will only report issues in the selected Project, and you will only see issues within the selected project.

If you have chosen a top-level project, you will see the issues of the subprojects as well.



This area is the MOST (!) common source of errors and usually the reason, why you won't find or see your issues.



Instructions for Use Swiss AR Issue Tracker

Doc. Nr.: DOC-00025

Valid from: 01.07.2023

3.2.2 Area 2: Toolbox

This area contains the tools you will need for using the Swiss AR Issue Tracker efficiently.

- *My View** Dashboard as seen above
- *View Issues** Filter the issues according to various criteria. Resetting the filter allows you to see all issues in the project set (check project switch)
- Report Issue** To file a new issue
- Change Log** View resolved and closed issues, sorted according to Products or Groups, depending on subproject set.
- Roadmap** View open and resolved issues, sorted according to Products or Groups, depending on subproject set. It's a very helpful page to gain oversight of the progress.
- Summary** Summary page with reports and diagrams for trends and analysis
- Manage** Depending on your permissions, you may see or not see this button. *Manage* is used for set preferences affecting the Swiss AR Issue Tracker in general, for user management as well as to create/close and edit projects and related data.

**** Use "My View" or "View Issues" to see all the pending Issues.**

→ Note: Choose the correct Project as described in 3.2.1 first.

The screenshot shows the Swiss AR Issue Tracker interface. The top navigation bar includes 'Report Issue', 'Invite Users', 'All Projects', and a user profile 'mosad'. The left sidebar contains navigation options: My View, View Issues (highlighted with a red box), Report Issue, Change Log, Roadmap, Summary, Manage, and Time Tracking. The main content area displays a 'Filters' panel with various criteria like Reporter, Assigned To, Monitored By, Note By, Priority, Severity, View Status, and Show Sticky Issues. Below the filters is a table of issues with columns for Severity, ID, Due Date, Category, Product / Group, Status, Updated, and Summary. The table shows 0 issues out of 0 total.

3.2.3 Area 3: Workarea

Depending on which tool you selected, you will be presented with different information. That's the place you actually edit and view data.

3.2.4 Area 4: Quick Selector

In this area you will see the last 4 opened issues as quick links as well as a search box to access issues directly once you know their ID-number.

3.3 Setup Preferences

To access your own preferences, click in the top right corner on your username and choose *My Account*. You may need to enter your password again as a safety measure.

It's basically self explanatory, however two tabs in particular are quite important:

3.3.1 Set email notifications in Tab "Preferences".

In Tab *Preferences* you can set your email notifications as you prefer.

For Swiss AR Services:

The standard setup is any which means, you will receive for every simple change on an issue a new email. Which is usually too often to keep the inbox organized.

To explain how to set the preferences, the first line will serve as example:

Email on new with Minimum Severity of any

Means, if a new issue is being created and the severity is set to anything, you'll get an email notification (every time).

3.3.2 Tab "Manage Columns"

In this tab you will be able to override the standard columns setting for *View Issues* and *Print Issues* as well as for *CSV Columns / Excel Columns* if you export a list of issues.

The available columns are mentioned in the first box, however, not all columns are used by the Swiss AR Issue Tracker.

3.4 Report issue



**Before you even think of reporting a new issue:
Check project switch so that the right project is set.**

To report an issue, click in the toolbox on *Report Issue*. In the workarea a form will pop up, which has to be completed. After completing the form, click on the button *Submit issue* at the bottom of the form.

- Category** Choose the appropriate category according to chapter 2.1.
(Depending on your permissions, you may not see this field.)
- Severity** Reset the category to the appropriate setting according to chapter 0.
Standard is *Major – 2d* to ensure an efficient workflow and not to miss an highly critical incident even this field is not set correctly.
Important: Keeping this setting on *Major – 2d* creates an avalanche of email notifications to the manufacturer, to the Authorized Representative as well as to the Administrator!



Instructions for Use Swiss AR Issue Tracker

Doc. Nr.: DOC-00025

Valid from: 01.07.2023

Priority	Because it's used as an optical trigger in <i>My View</i> , please set this field according to the Severity. No other use than that in the further process.
Due Date	Due Date is automatically set to + 2 days. So if an update of this field gets missed, it will trigger an overdue indication. Please set due date according to the selection of the severity. For the 30 days period simply choose the same day of the next month. The 30d period does not need to be highly accurate, however it is been used as a general timeframe for resolving issues.
Assign to	Depending on your permissions, you may not see this field. Please choose the person responsible for the defined actions within the issue. Important: Before assigning a person always try to contact the person by a phone call first. If not successful, assign the person but notify him/her by mail of the upcoming actions as well.
Product / Group	Choose the appropriate product (if in subproject <i>Products</i>) or the appropriate group (if in subproject <i>Business</i>). With this selection you assign an issue to the according roadmap.
Summary	A brief and exact summary of the issue. Will be shown in <i>My View</i> and <i>View Issues</i> .
Description	This is the place where you describe the issue as detailed as required. Especially if it is a customer complaint, every detail may be helpful for further investigations.
Immediate Action	If you already did some mitigation measures or other actions to prevent further damage, you may write them down in this field. You may write down actions as well, which still need to be executed as soon as possible.
Further actions and additional information	In this field you write down all the actions that needs to be executed in the further processing of the issue. You may enter additional information as well.
Attach Tags	Depending on your permissions, you may not see this field. Currently not used. But the administrator is open for suggestions. This field gives the opportunity for a further categorization of an issue for later analysis.
Notified by:	Only visible for issues in subproject <i>Products</i> . Please note the person that actually made the notification/complaint to the manufacturer or Authorized Representative.
Contact details:	Only visible for issues in subproject <i>Products</i> . Please note the contact details of the person that made the notification/complaint. It will be used for further information if necessary.



Instructions for Use Swiss AR Issue Tracker

Doc. Nr.: DOC-00025

Valid from: 01.07.2023

- Country of occurrence** Only visible for issues in subproject *Products*.
Despite the upper two fields are not compulsory, this one is. At least we want to know, in which country the complaint has occurred. This is important to contact the correct National Competent Authority.
- Upload files** You may upload additional supporting information as a file. Please consider maximum file size. If you need to upload a bigger file, please contact the administrator.
- Report Stay** This field does not add information to the issue.
Ticking the box allows you to report another issue with the same settings after clicking on *Submit issue*.

3.4.1 Issue Categories

There are different categories of issues:

Issue Category	Explanation / Comments
Customer Complaints	All Complaints from the customers
Event	Feedback and Questions from the customers Other requests related to a product.
Regulatory Authority	All requests from Notified body, National Competent Authorities or other official administrations: Examples are: <ul style="list-style-type: none">• Audits• Samples• Documentation
Audits	Deviations from Audits, e.g. from the check of the technical documentation, Yearly reviews etc.
General	Usually business related tasks and requests, e.g. Updating yearly sales, Insurance confirmation, change requests etc.
CAPA	Corrective Action / Preventive Action Issues in this category have to be a child of an issue. E.g. an Audit-Issue may have several CAPA-Issues.



3.4.2 Issue Severity

Priority and Severity are coupled, however they can't be set together automatically. Because they are used for different settings and reports, it is important to keep them up to date and to change them always simultaneously.

Priority	Severity	Description
Low	low	Basically all issues that doesn't need a reporting to NCA or are dependent on a due-date at all. Examples are: Requests for a yearly update of technical Documentation.
Normal – 30 d	Normal – 30d	All issues, that doesn't need a reporting but need to be resolved at a certain date. 30 days is the benchmark for open issues. Due-date field reflects the actual due date.
High – 15d	High – 15d	Issue that need to be reported to NCA within 15d Due-date field needs to be set.
Urgent – 10d	Very high – 10d	Issue that need to be reported to NCA within 10d Due-date field needs to be set.
immediate – 2d (STANDARD)	Major – 2d (STANDARD)	Issue that need to be reported to NCA within 2d Due-date field needs to be set.

3.5 View Issue Details Mode

Once you click on an issue link, either from *My View*, *View issues* or any other issue link, you will open the issue in *View Issue Details-Mode*.

This mode allows you to see all the relevant fields of the issue as well as processing the issue itself.

This is the common mode to process an issue.

The following sections are visible:

View Issue Details

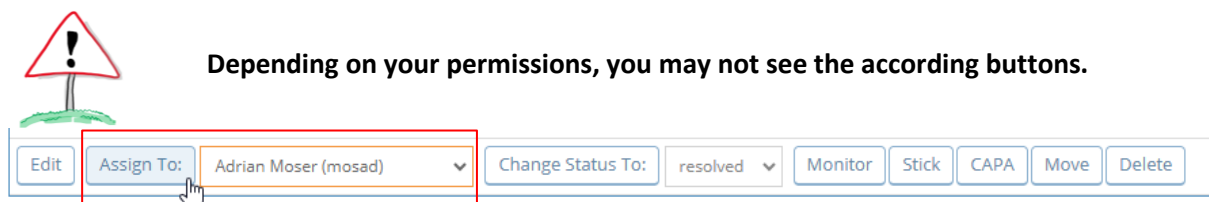
All fields of an issue. To edit those information, you need to click on the button *Edit* at the bottom of this section.

- Relationships** You can add or delete a relationship to another issue. Let's say, issue 001 is related to the topic of issue 002, so you can choose *related to*, write down number 002 and click *add*.
- This function is especially important, if you write an action of a particular issue as a separate issue (e.g. a corrective action out of an audit deviation). In this case you would choose in the issue of the corrective action "child of" and write down the number of the audit deviation.
- Users monitoring this issue** Even if you are neither assigned nor the reporter of a particular issue, you may enter your name to monitor this particular issue. You will get email notifications on change.
- Activities** All added notes will be listed in this section.
- Add note** **The most important section once processing the issue:**
In this field you will add the performed actions, their results and all other observations/information occurring during the issue lifecycle.
You may have the possibility to upload supporting documents.
- Issue History** Every (!) change of an issue is logged and can be seen in this section as an audit trail.

3.6 Assign issue

To assign an issue, click on the according issue link, you will open up the issue in *View Issue Details-Mode*.

Choose the according user from the choose-box at the bottom of the *View Issue Details* and click on the button *Assign To*.



3.7 Execute actions

Perform the actions as defined in the issue. If this is not possible, write down according reasons and edit the issue to adapt the fields *Description*, *Immediate Action* and *Further actions and additional information* as required.

Once you performed an action or if you want to add additional information, please use the *Add note* section in the *View Issue Detail* mode.

3.8 Resolve issue

Once all actions are done and documented, you may resolve the issue.

To resolve the issue you choose *Resolved* from the choose-box at the bottom of the *View Issue Details* section and click on the button *Change Status To:*.

An additional form will appear with the following fields to complete. After completion, click on button *Resolve Issue*.

Resolution	Not used. Leave it on <i>fixed</i> .
Duplicate ID	Not used. May be used if you have duplicated issue and you want to close one of them.
Assigned To	Leave it on suggested value. Usually the person that actually resolves the issue.
Due Date	Leave it on suggested value.
Product / Group	Choose appropriate Product (if in subproject <i>Products</i>) Choose appropriate Group (if in subproject <i>Business</i>)
View Status	Do not tick the box, otherwise it's only visible to the assigned person.
Add note	You may add an additional reason, why you think the issue can be resolved.

3.9 Final check and closure

Once an issue is resolved, it can be closed. The process is similar to resolving an issue according to chapter 3.8.



Before closing an issue, please re-check all entries and correct them if required. Also consider wording and context in regards for later reference.

3.10 Report CAPA Issue

A CAPA issue may be filed, if you have a dependency of another issue. For example:

Issue 009 = Audit deviation. As a consequence, you have identified some corrective actions as well as additional preventive actions.

In this case you may click on the button *CAPA* at the bottom of the *View Issue Details* section of issue 009.

Update the fields, especially add the agreed corrective actions.

Then add the relationship *Child of* to issue 009.

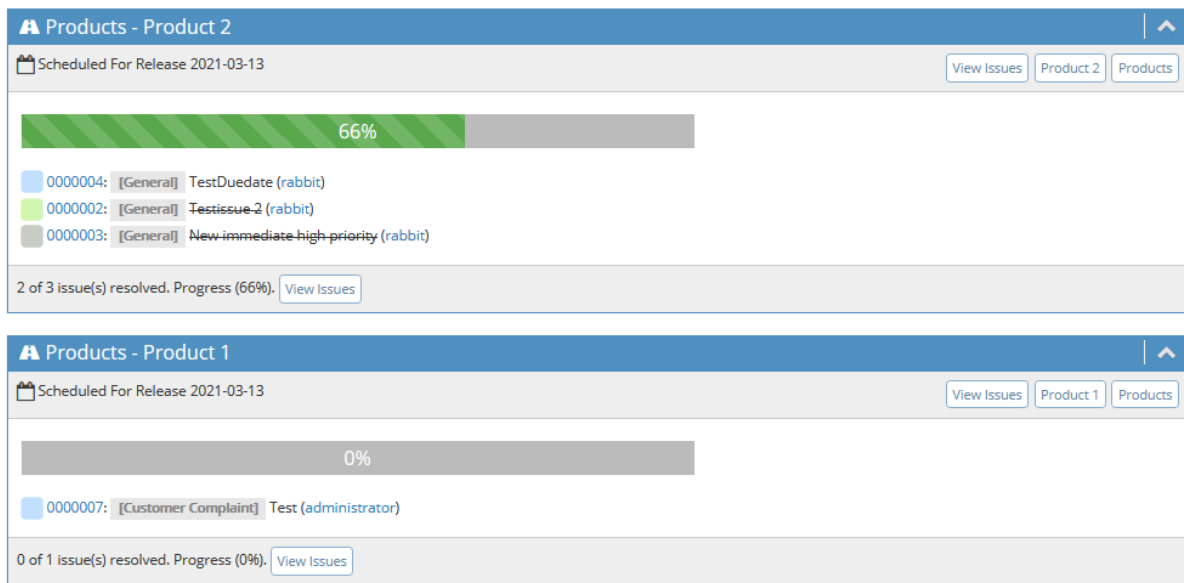


3.11 Show Roadmap

Click on *Roadmap* in the Toolbox.

The following screen will show up in the workarea

Products - Roadmap



It shows a summary of all issues related to a product (for subproject *Products*) or group (for subproject *Business*). Once the state bar reaches 100%, all issues are resolved. In case of a group for subprojects *Business* this indicates, that the group is complete and the next step may be started. Groups in *Business* usually contains the onboarding process (*Signing Contract*) and then a yearly group (e.g. for year 2023).

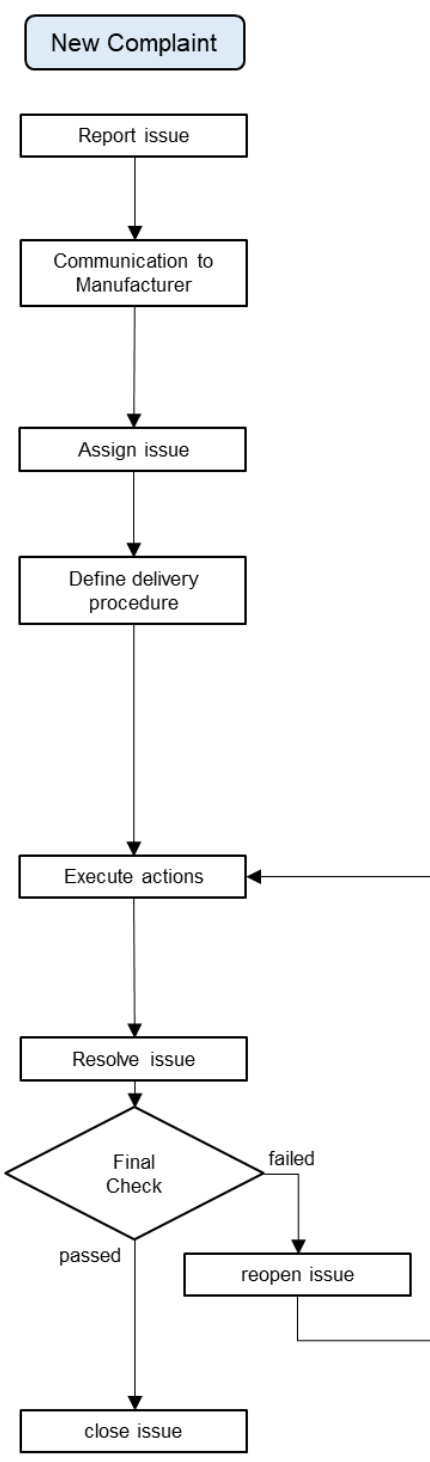
4 Standard Pathways for special cases

4.1 Customer Complaints

Process	Issue State	Tasks	Responsibility
<div style="border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block;">New Complaint</div>		Choose Project Business	
Report issue	new	Report issue. Consider Priority and due date. In doubt, leave it on <i>major - 2d</i>	Reporter
Communication to Manufacturer	new	Immediate Communication according to the following priorities: 1. <i>Phone call</i> 2. <i>Email</i> 3. <i>Swiss AR Issue Tracking</i>	Reporter
Assign issue	→ assigned	Assign issue to manufacturer.	Every User
<div style="border: 1px solid black; width: 100px; height: 100px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <div style="text-align: center;">Communi- cation to NCA?</div> </div>	assigned	Manufacturer decides on severity and required actions (e.g. FSN and FSCA) and if necessary, the requirement for communication to NCA	Assigned person (manufacturer)
<div style="border: 1px solid black; padding: 5px; display: inline-block;">Reset severity, Prepare IMDRF codes Prepare MIR</div>	assigned	Add IMDRF codes in field <i>Further actions or additional information</i> for further reference. Upload and attach complete communication to NCA to the issue.	Assigned person (manufacturer)
Execute actions	assigned	Execute defined actions. Add notes to document progress. Upload documents if necessary. If extensive actions required, use CAPA-issues for better structure.	Assigned person (manufacturer)
Resolve issue	→ resolved	Once all actions are performed, resolve issue.	Assigned person (manufacturer)
<div style="border: 1px solid black; width: 100px; height: 100px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <div style="text-align: center;">Final Check</div> </div>	resolved	Check if all actions are done and documented.	Authorized Representative
<div style="border: 1px solid black; padding: 5px; display: inline-block;">reopen issue</div>	→ assigned	Reopen issue by reset state to «assigned». Discuss further actions with previous assigned person.	Authorized Representative
close issue	→ closed	Close issue	Authorized Representative

Swiss AR as Authorized Representative may support you with the form *Manufacturer Incident Report (MIR)* to the NCA, however Swiss AR does not have the appropriate medical device knowledge to investigate the complaint (e.g. for the identification of the IMDRF codes) and to define appropriate FSN / FSCAs.

4.2 Request for Samples by an NCA or a notified body

Process	Issue State	Tasks	Responsibility
			
		Choose Project Business	
	new	Report issue. Consider Priority and due date.	Reporter
	new	Communication according to the following priorities: 1. <i>Phone call</i> 2. <i>Email</i> 3. <i>Swiss AR Issue Tracking</i>	Reporter
	→ assigned	Assign issue to manufacturer.	Authorized Representative
	→ assigned	Manufacturer decides - Which samples - How to deliver the samples to requester - Who communicates to corresponding NCA Manufacturer file actions/decision in issue field <i>Further actions or additional information</i> .	Assigned person (manufacturer)
	assigned	Execute defined actions. Add notes to document progress. Upload documents if necessary. If extensive actions required, use CAPA-issues for better structure.	Assigned person (manufacturer)
	→ resolved	Once all actions are performed, resolve issue.	Assigned person (manufacturer)
	resolved	Check if all actions are done and documented.	Authorized Representative
	→ assigned	Reopen issue by reset state to «assigned». Discuss further actions with previous assigned person.	Authorized Representative
	→ closed	Close issue	Authorized Representative



5 Training

Each user (except the administrators) is required to complete a training module for the Swiss AR Issue Tracker. The form can be self-study or with a trainer from Swiss AR Services.

The topics are:

- Set preferences
- Select appropriate project
- Report an issue
- Categories, Severity
- Assign a user to issue (for Permission level "Authorized Representative" and higher)
- Add notes
- View and find issues
- Resolve issues
- Close issues (for Permission level "Authorized Representative" and higher)
- Demonstration of the use of *Roadmap*, *View Issues* and *Summary*

In order to demonstrate competency, the each new user has to report an issue

- within the project "Company – Business"
- Within group: Signing Contract.
- Summary: Training documentation for user *username*
- Perform the following actions
 1. Add a note and upload a sample-file.
 2. Resolve the issue as soon as issue is assigned to you

6 History

Changes	Version	Effective from
Initial version	1	27.07.2021
Chapter 4: Process flows adapted to Swiss AR Issue Tracker Chapter 5: Self-study and requirements	2	23.09.2021
New Document Nr. According QSISTANT Overall Design Update (incl. adaption of print screens) Chapter 2: Updated handling of the Project "Products" Chapter 3: Defined Setup Preferences more detailed Chapter 4: Updated process flows with the handling of the Project "Products"	3	01.07.2023