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1) HALO PV

User Manual - Release 3.0 (JUNE 2021)

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2) Preface

Where to Find More Information

The latest product information including release notes for HALOPV is available at

<https://www.halopv.com/>

Insife Support

Insife Support team can be reached out at Support@insife.com

3) Introduction

3.1) Purpose

This User Manual describes the process workflow for Requirements Intelligence in HALO PV.

HALO PV Requirement Intelligence Management allows managing local and global requirements and obligations. HALO PV users can drive automation with auto-build reporting rules and auto-schedule activities. Thus, ensuring efficiency and quality of PV processes.

3.2) Benefits

HALO PV user can help users track the following requirements:

A master list of Regulatory and other requirements documents and associated requirements (rules):

- a. ICSR reporting requirements
- b. PV System and System Master File requirements
- c. Data Monitoring Committees recommendations requirements
- d. Periodic SUSAR reporting requirements
- e. Periodic reporting requirements for Medical Devices
- f. Local QPPV/safety responsible person requirements
- g. Periodic Safety Update Report (PSUR) requirements
- h. Renewal document requirements
- i. Development Safety Update Report (DSUR) requirements
- j. Risk Management Plans (RMP)/documents requirements
- k. Update Argus Expedited reporting rules
- l. Signal Detection / Management Requirements

3.3) Key Features



Maintain an overview of Global Requirements ("Obligations") towards partners and authorities. Allow for local personnel to make updates of e.g., a spontaneous ICSR rule. An approval from central is potentially all it takes to auto-configure your safety database.



Auto-generate ICSR rules in the safety database or use the rules to auto-schedule HALO records.



Link to submissions, i.e., track the number of actual reports sent out based on the requirement.



Link to SDEAs for establishing a loop between what is in the contract and what is implemented in practice.



Configurable and simple user interface means less training needed and shorter time to go live.

3.4) SDEAs as data sources

PV Requirements can come from Regulatory documents, but also from SDEAs with partners etc. If you select "Yes" as a reporting destination in the Entities and Agreement management, any Partner, Agency etc. can be linked with a requirement in the Requirements Intelligence module.

3.5) Requirements that determine activities in other module of HALOPV

Times for creating/updating a record in other modules may be driven by requirements that are setup in the Requirements Intelligence module. Examples of records that may automatically be initiated / set in workflow are:

- ICSRs
- SDEAs

- PSMFs
- SUSARs
- Risk Management Plans
- Entities and Agreements
- Renewal Documents
- Periodic Reporting

4) Requirement Intelligence

Global requirements from authorities, partners and other entities can be set up, to ease global compliance across, ICSRs, periodic reporting, and other PV requirements

4.1) Requirements Intelligence Workflow

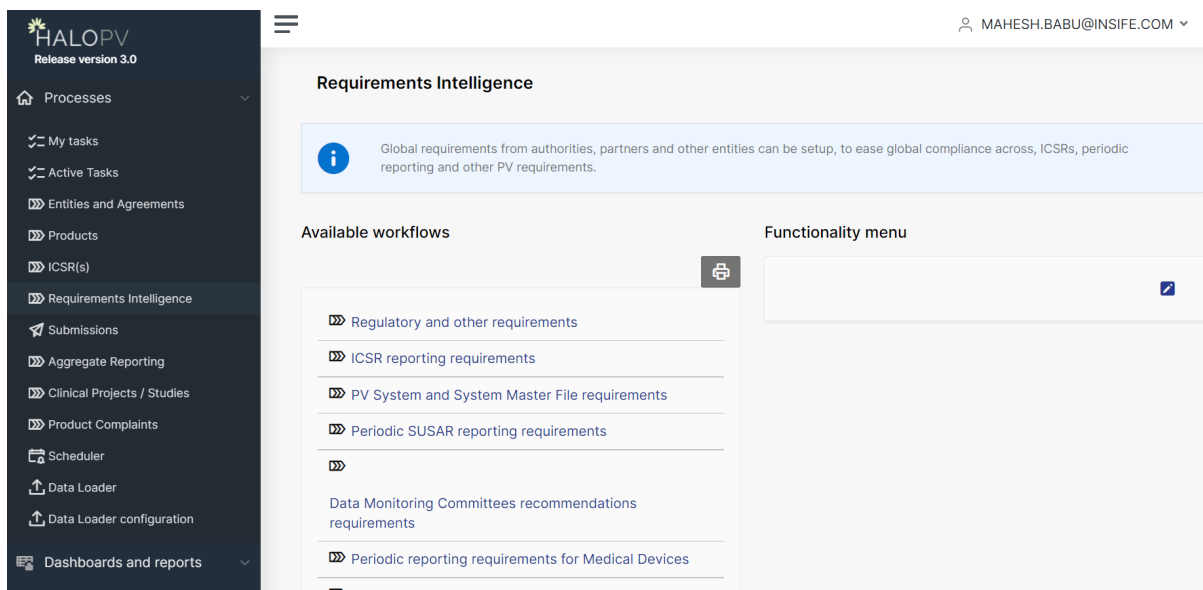
In the first example of the Requirements Intelligence user’s guide, you will learn how to create a rule and link it to a parent record, and in the second example, you will learn how to add rules and assessment to a parent record. But first, let’s start identifying the main features of the Requirements Intelligence module in HALO.

On the left menu, you will find a list of core Processes available for your user profile. Please select Requirements Intelligence.

[NOTE: Requirements Intelligence can be adapted to multiple, local, or specific needs. The number of processes and workflows display on your screen varies according to your configuration and access.]

Once selecting Requirement Intelligence, the available workflows will be visible.

The image below shows a list of workflows that are available for Requirements Intelligence. These workflows control the tasks that the user can perform according to the roles assigned.



In this user's guide, you will be presented with different examples of workflows. By clicking in one of the available workflows, a list of records will be displayed. Each record represents a requirement that has been entered. Clicking on any of the titles will take you to the details view. For this example, we select ICSR reporting requirements.

The example shows records that correspond to the ICSR reporting requirements. By clicking on Record ID, a new window will display a form, which is configured to the ICSR reporting requirements workflow.

The screenshot shows the HALO PV Requirements Intelligence interface. The left sidebar contains a navigation menu with options like Processes, My tasks, Active Tasks, Entitles and Agreements, Products, ICSR(s), Requirements Intelligence, Submissions, Aggregate Reporting, Clinical Projects / Studies, Product Complaints, Scheduler, Data Loader, and Data Loader configuration. The main content area is titled 'Requirements Intelligence / ICSR reporting requirements Records'. It features a 'Process description' box with the text 'Maintain a list of requirements of ICSRs and their reporting rules to third parties.' Below this, there are filters for 'Display' (All, Active), 'Include nullified records', and 'Include records assigned to others'. There are buttons for 'Create from Wizard', 'Create New', and a refresh icon. A 'Records' section includes a search bar, a dropdown for '1. Primary Report', 'Rows 50', and an 'Actions' dropdown. A table displays the records with columns: Obs, Record ID, Parent record, Requirement title, Type, Active task, Countries, Organization, Created by, Assigned to, Dueby, Overall Due Date, Last updated, and Next Scheduled Event. The table contains three rows of data.

Obs	Record ID	Parent record	Requirement title	Type	Active task	Countries	Organization	Created by	Assigned to	Dueby	Overall Due Date	Last updated	Next Scheduled Event
	REQ-ICSR-677	-	-	-	Register / update requirements	-	Link Medical HQ	-	-	13-OCT-2021		15-SEP-2021 10:11AM	-
	REQ-ICSR-81	-	ABC reporting of all spontaneous cases	Spontaneous - Drug	Review and approve ICSR reporting requirements	-	ABC Company Ltd.	MARTIN.HOLM-PETERSEN@INSIFE.COM	-	13-JUL-2021	13-JUL-2021	07-JUN-2021 12:49PM	-
	REQ-ICSR-79	EMA GVP Module 14	DK-spontaneous	Spontaneous - Drug	Review and approve ICSR reporting	Denmark	EMA	MARTIN.HOLM-PETERSEN@INSIFE.COM	-	13-JUL-2021	13-JUL-2021	07-JUN-2021 12:47PM	-

4.2) Create a New Rule: Example: ICSR rule

On the left menu Processes, click on **Requirements Intelligence**, then select **ICSR reporting requirements** and then **Create new** (Create new can be seen in above pic)

4.2.1) First Step Register /Update ICSR reporting rule

Click on link below **Record and task information** to edit **Basic information**

Please, populate the following categories on Basic information:

- Requirement title: Introduce a title for the new rule.
- Type: Enter the type of case.
- Workflow to be completed: the due date for the record to be completed.
- Reporting to: Choose from the drop-down list, the entity that the system will recognize as the receiver of this reporting obligation rule (E.g., investigator or partner to whom you hold an obligation).

In this example, the last workflow step Auto-Complete will activate the rule, meaning that when the effective date / due date is reached, it will activate the record. So unless the last step is completed, it will not appear in the records' overview.

If you have an actual document, for instance, a pdf, you can click the attachment icon and upload the document from your PC to the GxP storage of HALO PV, by clicking "browse", finding your document, then clicking the upload button. Close the pop-up window to continue to the main window.

As seen below, the new workflow is populated, and the first step Register /Update requirements needs to be performed. Go to the section Task activities to proceed with the assigned tasks to your role.

View/edit record

→ Register / update requirements → Review and approve ICSR reporting requirements

Complete task

Record and task information

ICSR reporting requirements - Test HALO 3.0 (REQ-ICSR-815) - Spontaneous - Drug

Register or update the ICSR reporting rule - Add type and effective date on the main form and click the Details form action to populate rule details.

Requirements Intelligence processing 21-DEC-2021

MAHESH.BABU@INSIFE.COM Save X

Action	Status
ICSR Requirements details form	0
Associate Regulatory source	0

Description

Notes and linking

URL

Associated child (0/0)

Task activities

To populate the details of the rule, please check for actions assigned under Task activities overview, which displays the task assigned to your user role; in this case, 2 tasks has been assigned; **ICSR Requirement detail form** and **Associate Regulatory source**. Let's take the example of **ICSR Requirement detail form**.

View/edit record

Test HALO 3.0 - Spontaneous - Drug

Save Return

ICSR Rule options Requirement verbatim and notes Implementation details

Territory (country)
Sweden (SE)

Is submission of expedited reports required?
 Yes No

Reporting Criteria

Country

Domestic Foreign Only inside EEA? Only outside EEA?

Reporting criteria

Fatal Life threatening Other seriousness Non serious Other reporting criteria

MedDRA Standard Query Rule Show SMQ details

ICSR Rule Options

This tab allows you to configure all the rules for the ICSR. The list of available countries is restrained to the user profile.

- Reporting criteria: Select from the drop-down list a format.
- Causality (Relatedness): Since the record is identified as a 'Spontaneous-drug' case (in our example), the fields are automatically populated by HALO.

- Submission: Check 'Yes' if cases are submitted electronically by headquarter. In case you have local regulatory timelines, then check 'Yes'. When checking 'Yes', the section Timeline will appear.
- Timeline: Allows to register the days for the reporting timeline, in this case, 35 (days).

Rest of the details are self-explanatory.

Requirement verbatim and notes

On the Requirement verbatim and notes tab, the user can add additional information for the ICSR.

- Requirement Text in the original language: Allows to paste the original requirement text.
- Notes: Here, the user can add notes or details about the translation.
- URL of source: Allows to enter the URL of the source for this specific rule.
- Document process scope: Determines the types of requirements for the form. Here, the user can link a specific process scope.

Implementation details

On the Implementation details tab,

- Custom tags: Allows to target where this rule should appear in HALO's tabular reports. For instance, if it is relevant for case handlers, or the submission team to know about this rule. (Note: The workflow is configured automatically, so in this case, the user do not need to notify the Safety database configuration support team).
- Format (internal): Here, the user can specify what internal format is preferred, unlike the one required by the authorities.
- Internal timeline (days): Specify a number in days for internal timelines.
- Implementation notes: Allows you to add a note on how you have chosen to implement or will be implementing the requirement in your processes and procedures.

To proceed, click **Save** and then **Return**.

Once back on the central record, it is possible to continue completing the new rule. For instance, the next section, Associated child records, allows linking the rule to the overall requirement or parent record.

4.2.2) Second Step Review and approve ICSR reporting requirements

In the second step, the designated role can review and approve the ICSR reporting requirement. Go to the **Task activities** and click on **QC check**.

Comments can be added in the dedicated section and mark tick on **QC complete** checkbox. Click on **Approve** and then **Return**.

The screenshot shows a web interface titled "QC Check". At the top right, there are "Approve" and "Return" buttons. Below the title bar, there is an "Audit log" button. The main content area has two tabs: "Details" (selected) and "Record information". Under the "Details" tab, there is a section labeled "QC complete" with a red asterisk and an unchecked checkbox. Below this is a large text area labeled "Comments" with a small red icon in the top left corner and a pencil icon in the bottom right corner.

Now the rule is ready to be configured in the safety database. Click Complete task to continue.

NOTE: In case of incomplete data/files, select to **Send back task** the record to the previous user role.