

Insife

How to Configure Reporting Rules

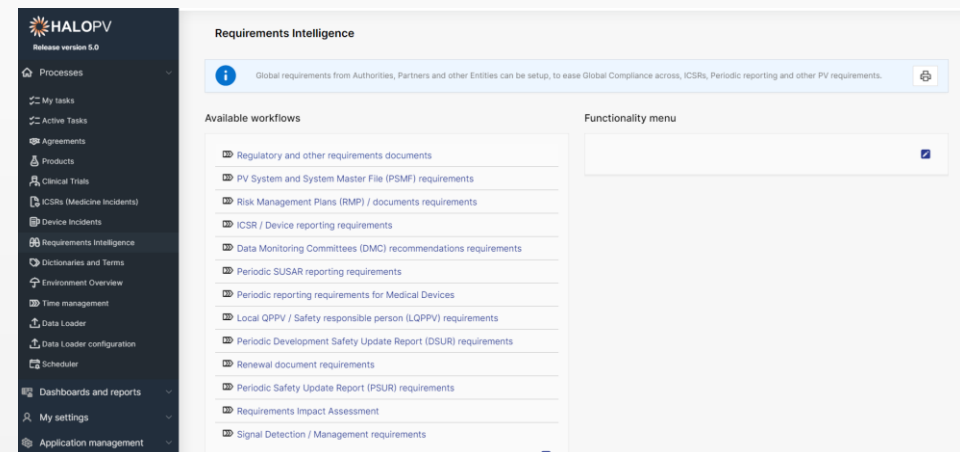
Version 1.0, For HALOPV 5.0



About Regulatory Reporting Rules

- The Reporting Requirements vary depending on the region, type and the regulatory authority.
- Pharma companies are required to report safety information to regulatory authorities according to specific timelines –
 - Expedited Reporting
 - SUSAR (Suspected Unexpected Serious Adverse Reaction) cases are reported within 7 calendar days to the NCA (national competent authorities)/HA (health authorities).
 - While clinical trial other serious cases and safety issues are reported within 15 calendar days.
 - Periodic Reporting
 - PSUR (Periodic safety Update Report) Or PBRER Or PADER (Periodic Adverse Drug Experience Report (US)) Or DSUR (Drug Safety Update Report).
 - The timing and content of periodic report for marketed products are based on local requirements (i.e. every 6 months, every year, every 3 years, etc.)
- HALOPV supports all types of regulatory Reporting for –
 - ICSR's and Devices Or PSMF, DMC and QPPV Or Any Custom.
- HALOPV is an inclusive solution which allows creation of a reporting rule and application of it, on respective data records to enhance compliance.

Note – This is just a small summary of reporting requirements, please refer to other sources to get into details.



Content

- › [About Regulatory Reporting Rules](#)
- › [Prerequisite](#)
- › [Getting to Reporting Rules](#)
- › [Review Existing Reporting Rules](#)
- › [Creating Reporting Rules - Record](#)
- › [Creating Reporting Rules - Details](#)
- › [Creating Reporting Rules - Data Form](#)
- › [Creating Reporting Rules - Complete Workflow](#)
- › [About Insife](#)

Prerequisite

Configuring a Reporting Rule

Pre-requisite to be able to configure a Reporting Rule are –

- User must have access to Requirements Intelligence module.
- User must have ADD/ EDIT permission on Requirements Intelligence.
- User must have access to the required workflow, for e.g. –
 - PV System and System Master File (PSMF) requirements
 - Risk Management Plans (RMP) / documents requirements
 - ICSR / Device reporting requirements
 - Data Monitoring Committees (DMC) recommendations requirements
 - Periodic SUSAR reporting requirements
 - Periodic reporting requirements for Medical Devices
 - Local QPPV / Safety responsible person (LQPPV) requirements
 - Periodic Development Safety Update Report (DSUR) requirements
 - Periodic Safety Update Report (PSUR) requirements
 - Etc.
- User/ Users must have access to complete the workflow steps (i.e. Create/ Review/ Approve).

Note – This list may vary at your instance as per your organisation access.

The screenshot shows the HALOPV Requirements Intelligence module interface. The top navigation bar includes 'Processes', 'My tasks', 'Active Tasks', 'Agreements', 'Products', 'Clinical Trials', 'ICSRs (Medicine Incidents)', 'Device Incidents', 'Requirements Intelligence', 'Dictionaries and Terms', 'Environment Overview', 'Time management', 'Data Loader', 'Data Loader configuration', and 'Scheduler'. The main content area is titled 'Requirements Intelligence' and features an information icon with the text: 'Global requirements from Authorities, Partners and other Entities can be setup, to ease Global Compliance across, ICSRs, Periodic reporting and other PV requirements.' Below this, there are two sections: 'Available workflows' and 'Functionality menu'. The 'Available workflows' section lists various requirements categories, each with a plus icon and a checkmark icon, indicating they are available for configuration. The 'Functionality menu' section is currently empty.

Getting to Reporting Rules

- On the navigation menu (left-hand side of the screen Deep Sea Blue), under “Processes” parent menu there will be a submenu -
 - Requirements Intelligence – this menu is used to configure/ review reporting rules.
- Click on the required workflow link to begin with Review/ Creating a new Reporting Rule on the selected workflow.

HALOPV
Release version 5.0

Processes

My tasks

Active Tasks

Agreements

Products

Clinical Trials

ICSRs (Medicines Incidents)

Device Incidents

Requirements Intelligence

Dictionaries and Terms

Environment Overview

Time management

Data Loader

Data Loader configuration

Scheduler

Dashboards and reports

My settings

Application management

Requirements Intelligence

Global requirements from Authorities, Partners and other Entities can be setup, to ease Global Compliance across, ICSRs, Periodic reporting and other PV requirements.

Available workflows

- Regulatory and other requirements documents
- PV System and System Master File (PSMF) requirements
- Risk Management Plans (RMP) / documents requirements
- ICSR / Device reporting requirements
- Data Monitoring Committees (DMC) recommendations requirements
- Periodic SUSAR reporting requirements
- Periodic reporting requirements for Medical Devices
- Local QPPV / Safety responsible person (LQPPV) requirements
- Periodic Development Safety Update Report (DSUR) requirements
- Renewal document requirements
- Periodic Safety Update Report (PSUR) requirements
- Requirements Impact Assessment
- Signal Detection / Management requirements

Functionality menu

Review Existing Reporting Rules

User can review an existing Reporting Rule by selecting/ clicking on the required workflow from list of available workflows in the Requirement Intelligence module.

- At the top of the page, you will see the selected workflow (Breadcrumb).
- Followed by the process and workflow description (Stages).
- Followed by Records Status/ Stage filter checkboxes –
 - Completed records? – Select to view the completed records (Reviewed and Approved).
 - In workflow records? – Default Selected, select to view the records which are in progress.
 - Nullified records? – Select to view the nullified records.
 - Assigned to others? – Select to view the records assigned to other users (not you).
- Based on the selected record status, application will list the records fall in the status in the Records Grid.
 - You can view/ review/ approve Any records in the grid by using the links available in the “Record ID” Or “Requirement Title” column, followed by Opening the data form using “Data Form” link.

Note – We have used the “Periodic Safety Update Report (PSUR) requirements Records” workflow in this example, the options at other workflow will remain more of same.

The screenshot displays the HALOPV Requirements Intelligence interface. The breadcrumb at the top reads "Periodic Safety Update Report (PSUR) requirements Records". Below this, the "Process and workflow description" section shows a flow: "Register / Update Aggregate/Periodic reporting requirements" → "Review and Approve Aggregate / Periodic reporting requirements". A blue circle with the number "3" is positioned next to the second step. Below the description, there are filter checkboxes: "Completed records?" (unchecked), "In workflow records?" (checked), "Nullified records?" (unchecked), and "Assigned to others?" (unchecked). A "Create from Wizard" button and a "Batch and case assignment" button are also visible. The "Records" section features a search bar, a "Go" button, and a dropdown menu set to "1. Primary Report". The records grid has columns for Record ID, Requirement title, Type, Destination, Master Description, Master Url, Overall Due Date, Prefix, Revision, Workflow, Organization, Assigned to, Last updated, Master Creation, and Master Production. Two records are listed:

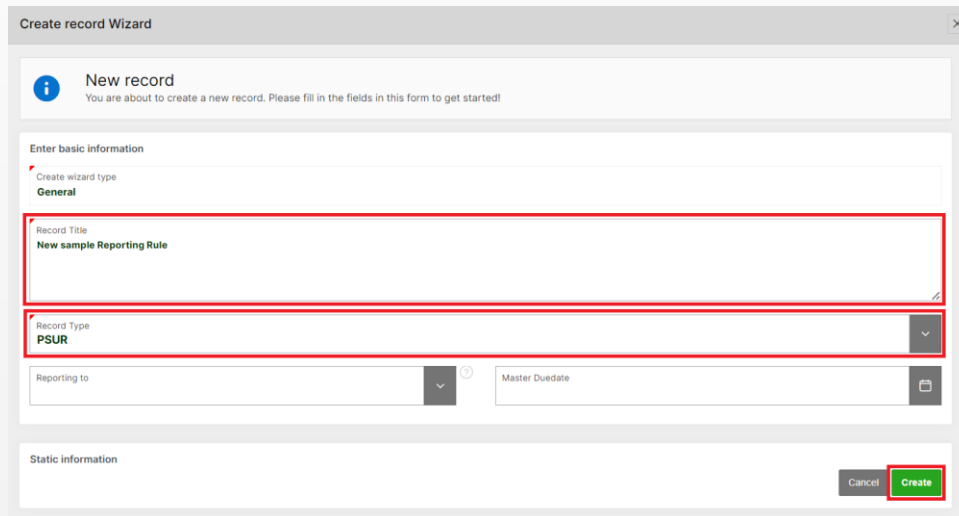
Record ID	Requirement title	Type	Destination	Master Description	Master Url	Overall Due Date	Prefix	Revision	Workflow	Organization	Assigned to	Last updated	Master Creation	Master Production
REQ-PSUR-31842880	OQ-820-08	PSUR	-	-	-	21-DEC-2023	REQ-PSUR	1	Periodic Safety Update Report (PSUR) requirements	Root organization	-	16-NOV-2023 09:17	19-NOV-2023 09:17	
REQ-PSUR-6405707	PSUR requirements -Denmark (DK)	PSUR	EMA	-	-	27-DEC-2022	REQ-PSUR	1	Periodic Safety Update Report (PSUR)	Root organization	-	22-NOV-2022 11:06	22-NOV-2022 11:06	

Creating Reporting Rules - Record

The first step of creating a new Reporting Rule is identify and select the workflow from list of available workflows in the Requirement Intelligence module.

- On the top of Records Grid, you can find the CREATE FROM WIZARD button (in Green colour).
 - On click on the button Application opens “Create record Wizard” popup.
- Enter the basic details like –
 - Record Title
 - Record Type
 - Reporting To – Select the Reporting destination organization (Not mandatory)
- Click on CREATE button to create a record.

Note - Options and View of a Record Data Form vary as per selected workflow. In this Example we are using PSUR workflow.



The screenshot shows a 'Create record Wizard' window with the following fields and elements:

- Header:** 'New record' with a sub-message: 'You are about to create a new record. Please fill in the fields in this form to get started!'
- Section: Enter basic information**
 - Create wizard type:** 'General'
 - Record Title:** 'New sample Reporting Rule' (highlighted with a red box)
 - Record Type:** 'PSUR' (highlighted with a red box)
 - Reporting to:** (Dropdown menu)
 - Master Duedate:** (Text field)
- Static information:** (Section header)
- Buttons:** 'Cancel' and 'Create' (highlighted with a red box)

Creating Reporting Rules - Details

Once you create a new record or select a record from Records Grid, you can view the basic details of the record in the “View/ edit record” popup.

- At the top you will see the selected workflow (Breadcrumb)/ workflow description (Stages).
- You can click on the Record Name Link to view/ update the basic details.
- Further on the Left Bottom you can View/ Update the Assigned User for the record and the Tags (if any).
- At the centre of the page there are links for –
 - Data Forms – This link opens the Record Form.
 - Depending on the selected workflow the number of links in Data Form will vary.
 - Links/ other activities – This link can be used to link the record with other Workflows of the application.
 - Status
- Click on “Data Form” link to view/ update the record data form.

Note - Options and View of a Record Data Form vary as per selected workflow. In this Example we are using PSUR workflow.

View/edit record

Register / Update Aggregate/Periodic reporting requirements → Review and Approve Aggregate / Periodic reporting requirements

Complete task

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New sample Reporting Rule (REQ-PSUR-32516326) - PSUR (Revision 1) Periodic Safety Update Report (PSUR) requirements

Task instructions
Registration of the Aggregate/Periodic safety reporting requirements

Reporting destination
South Korea Ministry of Food and Drug Safety - MFDS

About
Priority: Set priority
Role to process task: Requirements Intelligence processing
Assigned user: Assign user | Assign to me | Auto-assign

Task activities (red status means mandatory)

Data forms	Status	Links / other activities
Periodic PSUR/PBRER reporting form	●	Associate Regulatory source

Description

Description

Creating Reporting Rules - Data Form

The screenshot shows a web browser window titled "PSUR Periodic reporting form" with a sub-header "New sample Reporting Rule - 236". A "Save" button is highlighted with a red box. The form is divided into two tabs: "Periodic reporting" (active) and "Implementation details". Under "Periodic reporting", there are several sections:

- Country (territory):** A dropdown menu with "Korea (the Republic of) (KR)" selected.
- 1. Are PSURs required?** Radio buttons for "Not selected", "Yes", and "No". "Yes" is selected.
- 2. Is there a local guideline?** Radio buttons for "Not selected", "Yes", and "No". "Yes" is selected.
- Guidance to be followed:** A dropdown menu with "ASEAN" selected.
- 3. Additional / local content:** A section with checkboxes for "Information from the global PSUR/PBRR copied into a local template" (checked), "Local tabulation", "Local exposure", "Local case evaluation" (checked), "Separate exposure for all dosage forms", and "Other".
- 4. Reporting language:** A dropdown menu with "Other local language" selected.
- 5. Are references required?** Radio buttons for "Not selected", "Yes", and "No". "Yes" is selected.
- How should they be submitted?** A dropdown menu with "PDF" selected.
- 6. Is the International birth date ("global" IBD) accepted for determining DLP of PSUR/PSUR report?** Radio buttons for "Not selected", "Yes", and "No". "Yes" is selected.
- 7. What is the submission date after DLP?** A dropdown menu with "30 calendar days for quarterly/biannual reports, 60 calendar days for annual reports" selected.
- 8. When are the reports required?** A dropdown menu with "Every 6 months during first 2 years, then annually the next 3 years; Subsequently every 3 years" selected.
- 9. Regulatory name for periodic documents:** A text input field with "MFD (Ministry of Food and Drug Safety)" entered.

The second Step in creating a reporting rule is to complete the Data Form for the selected workflow.

- Select/ Insert the details in the data form as per regulatory requirements.
- Click on SAVE button to save the changes.
- Click on RETURN to return to "View/ edit record" popup.

Note - Options and View of a Record Data Form vary as per selected workflow. In this Example we are using PSUR workflow.

Creating Reporting Rules - Complete WF

The third and final Step in creating a reporting rule is to complete the workflow (WF) for the selected workflow, i.e. Review and Approve the Rule.

- On the “View/ edit Record” popup there is a COMPLETE TASK button at top right corner (Green Colour).
 - Based on your role may not be able to Complete Task/ move the rule into next workflow stage.
 - Please contact your system administrator to get the required role.
- Click on COMPLETE TASK button.
- Now, the Record Reviewer/ Approver will be able to –
 - Review approve or send back the record using respective buttons.
 - QC Check the Record (Quality Check).
- Once a record is Approved using the COMPLETE TASK button by Approver the record will reach Lock state (cannot be edited can only be up-versioned) and will be visible in “Completed Record?” list of records.

The screenshot shows a web application interface for managing reporting rules. At the top, there is a breadcrumb trail: 'Register / Update Aggregate/Periodic reporting requirements' followed by 'Review and Approve Aggregate / Periodic reporting requirements'. Below this, a green button labeled 'Complete task' is highlighted with a red box. To its left is a 'Send back task' button. The main content area is titled 'New sample Reporting Rule (REQ-PSUR-32516326) - PSUR (Revision 1) Periodic Safety Update Report (PSUR) requirements'. It contains several sections: 'Task instructions' with a yellow background, 'Reporting destination' (South Korea Ministry of Food and Drug Safety - MFDS), 'About' (Priority: Set priority, Role to process task: Requirements Intelligence approval), and 'Assigned user' (Assign user | Assign to me | Auto-assign). The 'Task activities' section shows a table with columns for 'Data forms', 'Status', and 'Links / other activities'. One activity is listed: 'Periodic PSUR/PBRER reporting form' with a green status indicator and a link to 'QC check (Same user CANNOT can sign)'. Below this is a 'Description' field with a text area.

Note - Options and View of a Record Data Form vary as per selected workflow. In this Example we are using PSUR workflow.

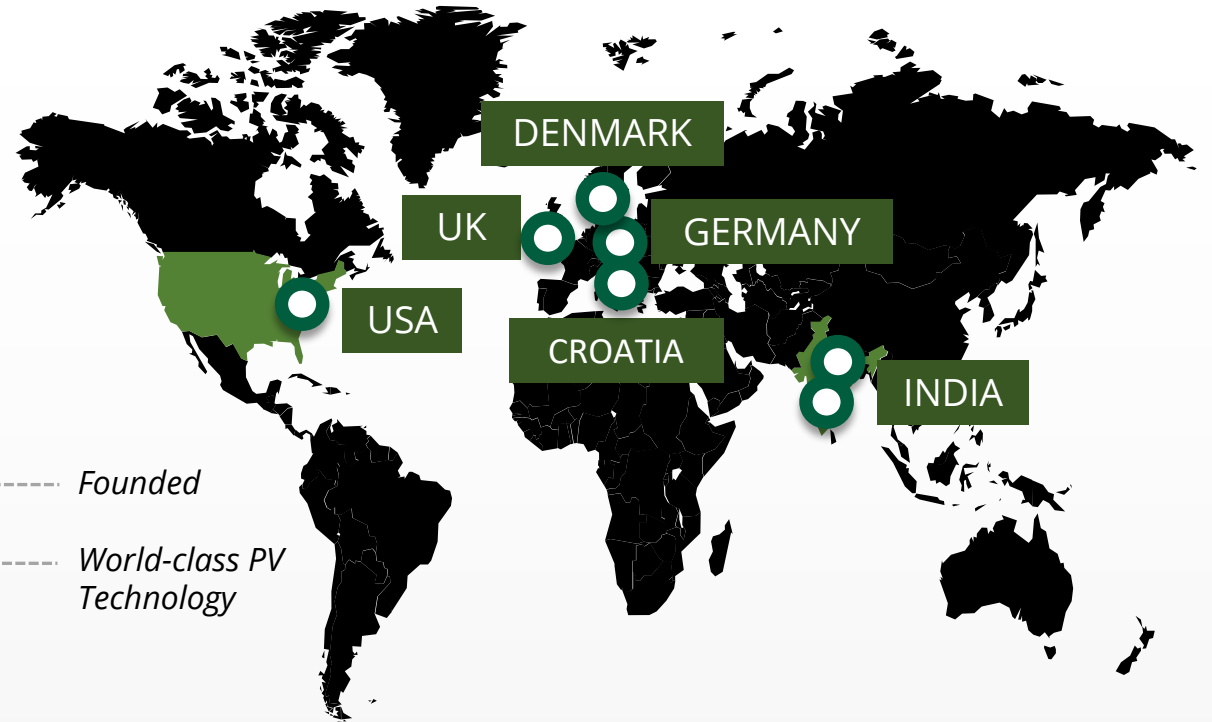
About Insife

Game-changing drug safety **technology** and consulting

Insife are supporting our clients with best-in-class technology and domain expertise from our global footprint

Insife consists of approx. 100 PV FTEs across the world, making us the biggest Europe-based company of its kind

We are ISO 9001, ISO 27001, ISO 14001 and GDPR certified



2017 ----- *Founded*

2023 ----- *World-class PV Technology*

Who are using our technologies?

5

Tier-1 Pharma companies

2

Tier-1 Regulatory Agencies

20+

SME pharma /biotechs

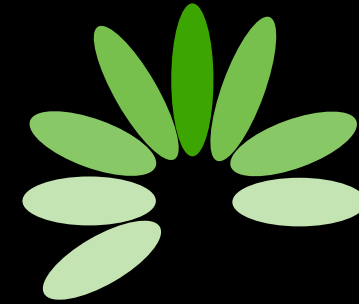
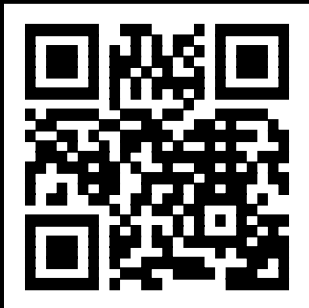


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