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How to Configure Reporting Rules

Version 1.0, For HALOPV 5.0

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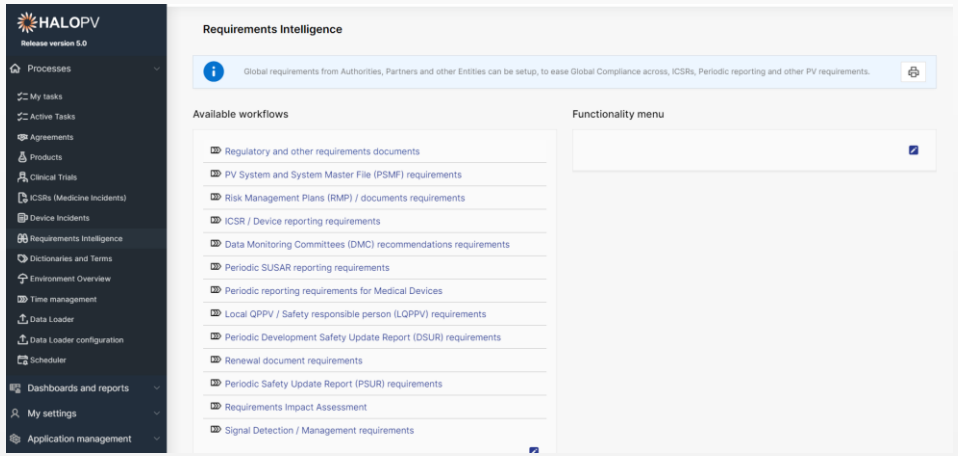
About Regulatory Reporting Rules



- 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.

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Content

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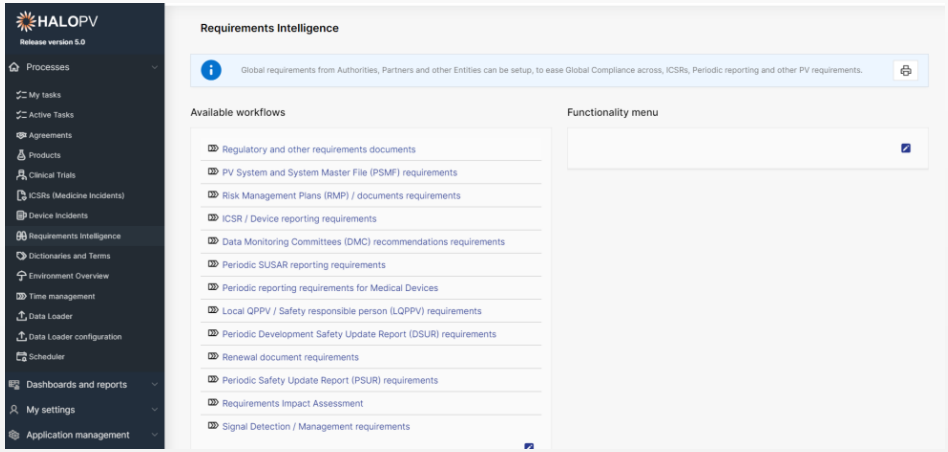
Prerequisite

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.

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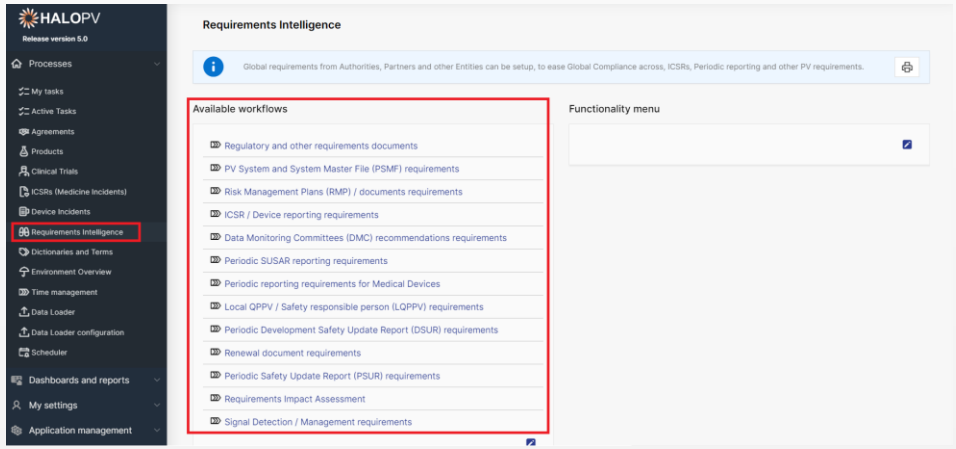
Getting to Reporting Rules



- 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.

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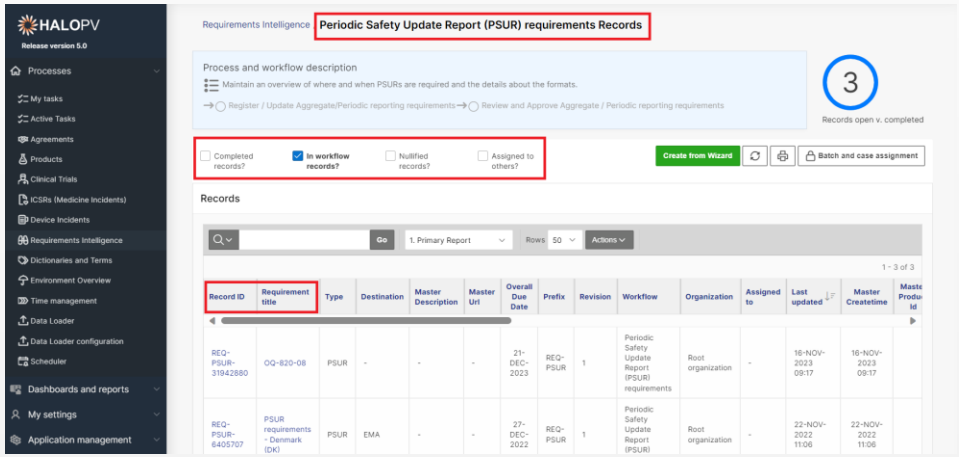
Review Existing Reporting Rules



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.

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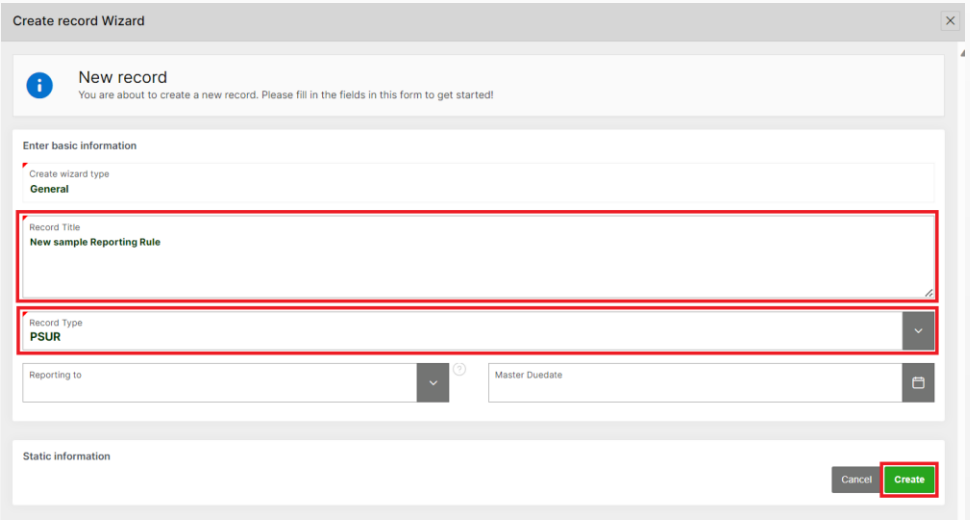
Creating Reporting Rules - Record



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.

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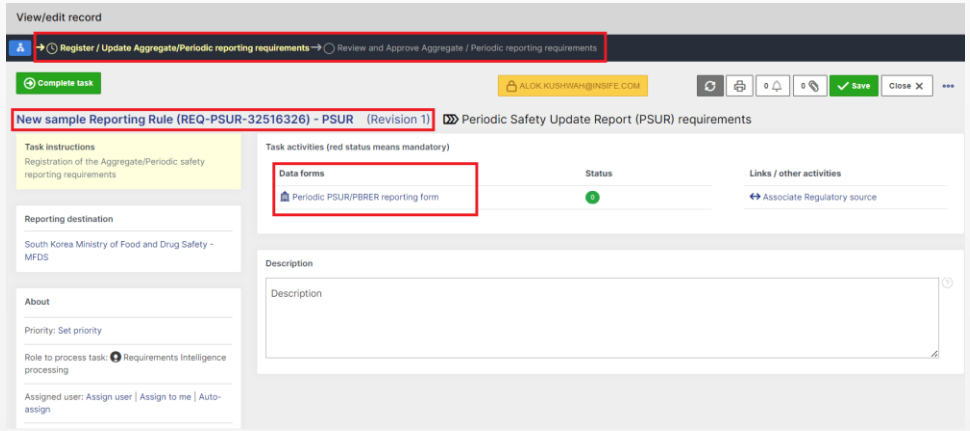
Creating Reporting Rules - Details



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.

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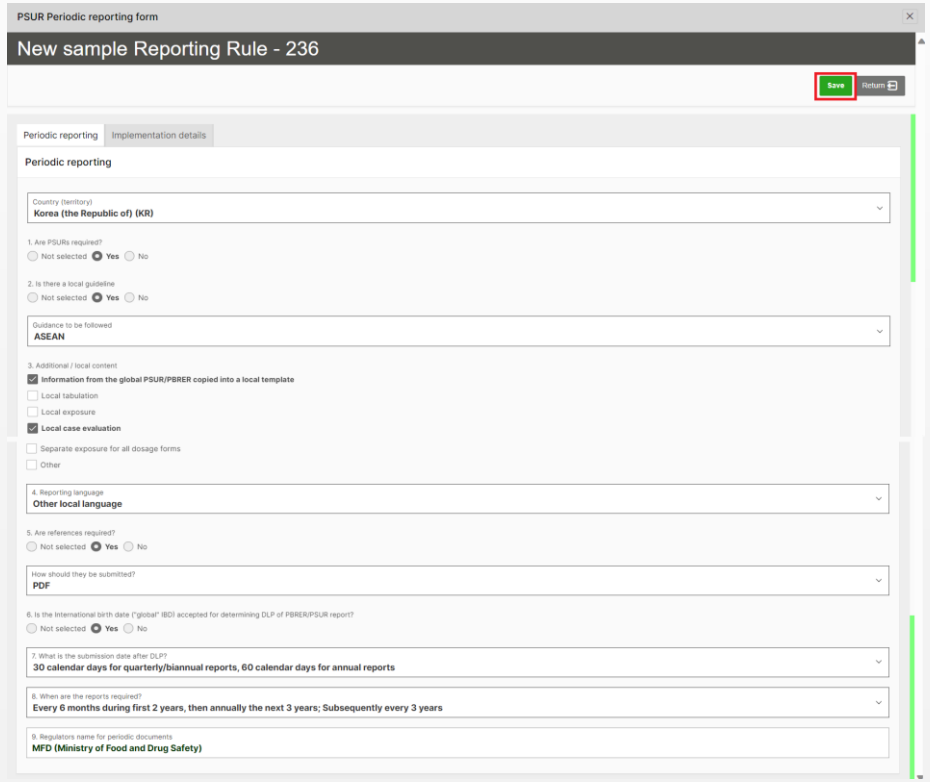
Creating Reporting Rules - Data Form



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.

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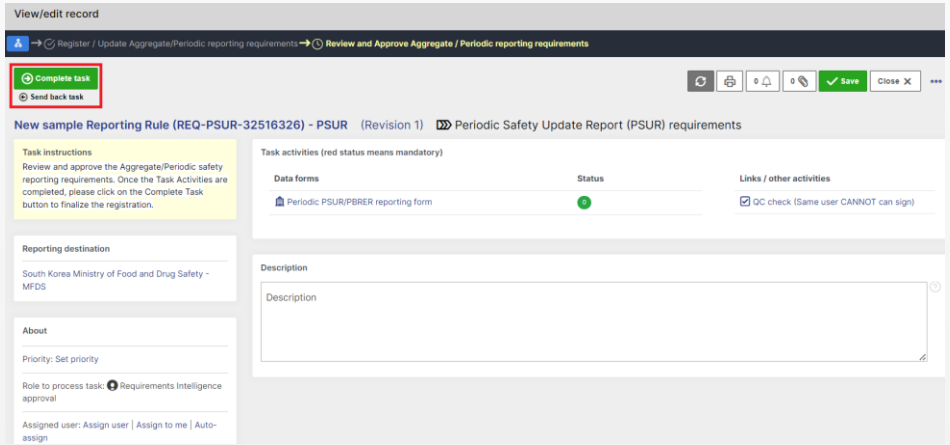
Creating Reporting Rules - Complete WF



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.

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

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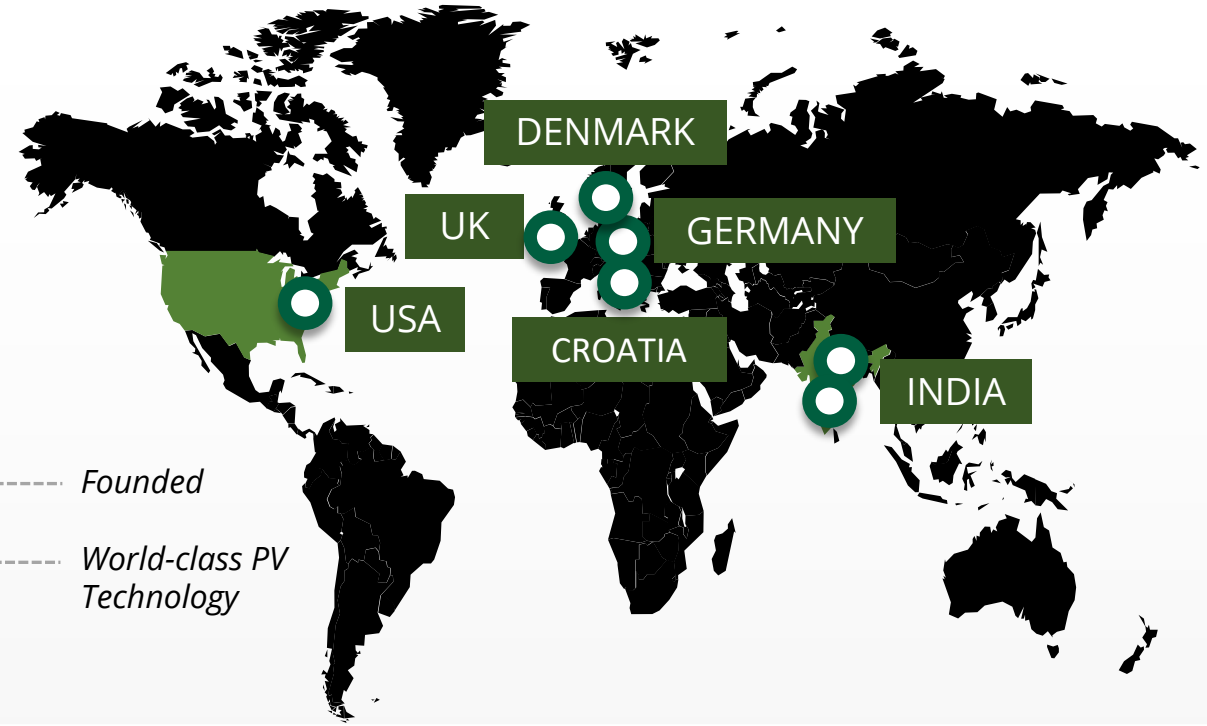
Insife are supporting our clients with best-in-class technology and domain expertise from our global footprint

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



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2
Tier-1 Regulatory Agencies

20+
SME pharma /biotechs

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