HALOPV


Regulatory and partner requirements and rules for global and local stakeholders with an intuitive user interface

# Requirements Intelligence

## MODULE EXPLAINER

HALOPV

the world's first fully comprehensive and cohesive solution.

insife

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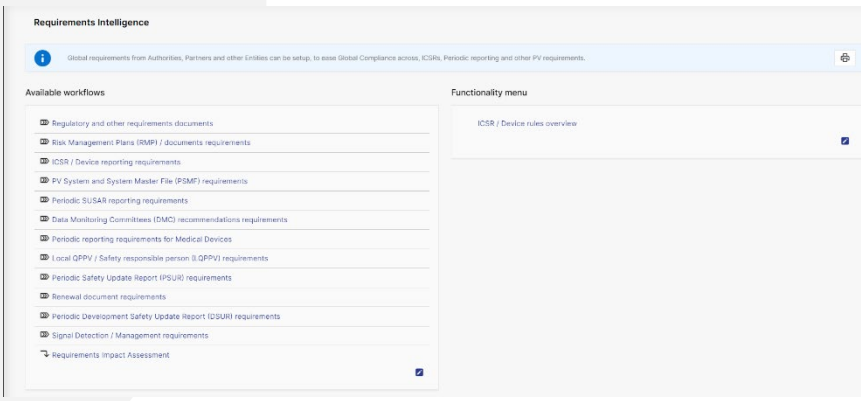
# Why use this module?

Requirements are the very fabric of pharmacovigilance, most of the work we do is to satisfy regulatory expectations – when we fail, the company's license to operate is in danger. Sometimes in collaboration with partners that may deal with co-marketing, distribution, patient support programs etc. It is difficult to keep track of the global regulations and requirements, especially if you are in many markets around the world. Therefore, it can be necessary to have a tool that can register and track all the requirements in once place, but still allowing the local responsibles to maintain their obligations.The Requirements Intelligence HALOPV module, is effective in doing just that. However, we thought that some additional service options would benefits some customers even more, so for the module, we are also offering an optional membership to GRIP (Global Regulatory Intelligence for PV), a club that joins the module together with a service that serves you all the global regulations from our team of regulatory intelligence professionals that scan and analyze new regulatory requirements. Finally, GRIP also includes a network for you to meet and discuss/get answers for difficult questions with peer professionals that work with regulatory intelligence.

Insife has considered carefully where the typical gaps are in Regulatory Intelligence services today. From experience, all past offerings all leave us with the significant gap of "translating" regulatory documents into actionable intelligence. We call actionable intelligence "rules". Rules can be directly plugged into the process and describes exactly the datapoints that are needed to operate a process. For example, for an ICSR rule, there are a number of datapoints that are needed, it is here crucial that all the needed points to configure a safety database such as Argus safety or HALOPV ICSRs module are there. The views are similar for DSUR, PSUR, RMP etc. We built the missing link into our service and technology; a combination that we are now offering to our clients. Currently, we are covering 160+ countries worldwide. When we expand to new countries, we do it in collaboration with you as the customer, to ensure that we make the offering as relevant to our customers as possible.

HALOPV
Requirements
Intelligence




*Example screen from the module. The workflows are designed to cater for distinct types of requirements from ICSR reporting to signal notifications*

# Requirements Intelligence
## Feature highlights

- Global and local regulations, guidelines, drafts can be logged and revision controlled, including categorization and marking whether it has been implemented into SOPs etc.
- Partners/other stakeholder requirements can be logged and managed too, can link to the HALOPV Agreements module, to align obligations from SDEAs
- Each requirement can store up to 1,000 attachments.
- Rules can be maintained for multiple purposes:
    - ICSR reporting, Device incidents, PV system and master file files, Periodic Safety Update Reports (PSURs, drug and device), Development Safety Update Reports (DSURs), SUSARs, Data Monittoring Committee (DMC) recommendations, Risk Management Plans (RMPs), local QPPVs and Renewals requirements. Each rules can be linked to one or more requirements documents.
- Manage impact assessments when new requirements are identified, in order to control planned activities related to regulatory change
- Utilize rules to auto-schedule activities, e.g. generate ICSR or device submissions to Authorities or Partners. (Requires ICSR/Devices module).
- Using our standard APIs, you can also integrate and transfer rules to or from your previous/existing Safety Database, .e.g. Argus Safety
- Through optional subscription, get 160+ country regulatory requirements + rules auto-loaded every month (requires GRIP membership)
- An interactive lookup report that allows for entering a few informations about an ICSR or device case then get all the requirements that will apply. Can be shown graphical or exported to Excel
- Plus of course all the usuals around GxP, audit trail, CFR21 part 11 and EU Annex 11 compliance

## Awarded innovation for our community

The HALOPV Requirements Intelligence module is powerful and configurable and is a core ingredient for success for significant regulatory agencies such as the MHRA as well as a number of pharmas, as it allows them. It is allows them to ease compliance

100%

The HALOPV Requirements Intelligence module enjoys 100% customer retention, as a proof to it's capabilities and performance to the community of PV professionals in the industry.

# Pre-configured workflows

The HALOPV Requirements Intelligence module comes with a complete package of pre-configured workflows that allow for standardized and effective handling of requirements and rules. The workflows typically are arranged with a review step, to ensure second set of eyes. If required, the new workflows can be configured to your specific processes.

## Regulatory and other requirements documents

Workflow for managing and updating requirements from source documents. List out per country, per type etc.

## Device Incident reporting requirements

In this workflow, you can manage the rules for device incident reporting, including timelines, seriousness, timelines, etc.

## Periodic reporting for devices requirements

Manage requirements for periodic reporting of device such as PSURs etc. Define periodicity and content requirements.

## Data Monitoring Committee recommend. requirements

Workflow to ensure that DMC requirements related to recommendations are captured.

## Risk Management Plan requirements

Manage requirements related to RMP format, local contents and perioditicy in this workflow

## Renewal requirements

Manage requirements related to Renewal submissions, contents and perioditicy in this workflow

## ICSR reporting requirements

Manage detailed rules for ICSR reporting, including seriousness, causality, domestic/foreign, timelines, clinical or product specific – and much more.

## PV System and System Master File requirements

Define where a PV system is required and also detail out where the PSMF is needed. In this workflow

## Periodic SUSAR reporting requirements

Manage requirements for periodic SUSARs, including periodicity and contents.

## Local QPPV / Safety responsible requirements

Manage local requirements for where Local QPPVs and Safety responsible persons are mandatory, in this workflow

## Periodic Safety Update Report requirements

Manage requirements related to PSUR / PBRER format, local contents and periodicity in this workflow

## Development Safety Update Report requirements

Manage requirements related to DSUR format, local contents and periodicity in this workflow

## Requirements Impact Assessment

The workflow allows for setting up a number of impact assessments and related actions that can be linked to Regulatory document, e.g. if a regulation changes and there is a need to map out what changes are needed in the organization

# What can be configured in the module?

HALOPV, including the Requirement Intelligence module, is extremely configurable. Despite the fact that you get a functional starting point with the pre-configured workflows, it is possible to enhance and tailor the application to support your organization in the optimal way. Insife or one of our implementation partners are ready to help you make the most out of the possibilities.

Configurations include:

- Workflow name and order, worklist design, setup record types etc.
- Workflow tasks, task order, including assignment to roles, form actions as well as functionality links.
- Workflow rules for conditional routing of case records.
- Validation rules for each field in the forms
- All dropdown (list) values in forms
- Entity (organizational) ownership to case record for segration of case records
- Users and user details, such as email and experience level and assigned roles¨
- Actions to be performed for impact assessments, e.g. link to SOPs or add forms to structure assessments further
- Keyword for tagging to records and scripted auto-tagging based on case information
- Option to add document translation e.g. from Spanish to English
- Scheduling of activities, such as opening up for annual review of whether a document is still current
- Task timelines, KPIs and notifications of tasks upon task initiation or days to completion

## Nothing else on the PV tech market is this configurable.

### Configuration, not customization

We are big on configurability. Not customization. In fact, if you ask our team to help you configure HALOPV, you will also get advise as to how you will optimize the use of the platform, without breaking the boundaries of what we in our consulting capacity would consider industry standard.

### Frequent validated releases of the platform

In order to meet the needs of customers, we have developed a release and validation methodology that includes a bin-annual version with new innovation, optimizations, bugfixes etc. As a subscribing customer, you can get new versions along with a comprehensive validation package to document it.

### API driven

Do you have data or systems to integrate or migrate from? You would not be the first. Therefore, we have created a large number of standard APIs that are modern REST based tools that we can make good use of together with your IT colleagues.

# Additional resources

We hope you like what you see. Should you have questions, feel free to write to us at Insife. You can also explore the following additional resources

Requirements Intelligence module user manual and other user guides and manuals:

HALOPV guides and training

HALOPV including Requirements Intelligence module standar pricing and licensing:

HALOPV pricing and licence

The "GRIP" membership, more about how it works, pricing etc.

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General introduction to HALOPV:

HALOPV - A Safety Database and much more. The most comprehensive drug safety system available (insife.com)

An overview of all available modules of HALOPV

HALOPV Modules overview - the most comprehensive drug safety system available (insife.com)

Contact Insife:

Contact | insife the pharmacovigilance (drug safety) experts

Or write to

hallo@insife.com

# About insife

## Game-changing drug safety technology and consulting

Insife are supporting our clients with high-quality consulting and domain expertise from our global footprint

Insife can provide a fully integrated solution that aligns with the goals of many customers that can be implemented in a phased approach and supported by a global knowledgeable team. Our core values are aligned to the industry and forward-looking trends such as AI/automation and being committed to a sustainable future.

Insife was founded in Denmark in 2017, but is today a global business. We strive to work with you as locally as we can.,

Read more about us on insife.com


### Values

Our fabric is woven on industry standards. We are GDPR, ISO 9001, 14001 and 27001 certified. We are passionate about a sustainable environment and reducing climate change, in line with many customer's sustainability goals (see https://www.insife.com/sustainability)

### Modular Approach

HALOPV can cover all of the customer's desired scope & more (PSMF, PVAs, etc.)

Modular in nature by design, HALOPV eliminates the need for the "big bang" approach enabling core business processes to be replaced in a phased approach

### Knowledgeable Team

Knowledgeable team with extensive experience of transformational programs who understand what it takes to succeed, many of whom have had industry roles in the past

### Vision for the future

We believe in applying modern technology in a cost-effective way to aid our customers. We partner with customers to establish and realize a long term vision for PV and beyond, not just for singular engagements but across industry and the regulatory landscape