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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

Process **Products** can be found under Processes (left pane).

Products process sets the workflow specific for configuring products with three different layers:

(Product Family Management >>> Product Management >>> Product License Management). Family is at the highest level of hierarchy, products coming in middle and licenses at the bottom.

4) Product Family Management

Maintains an overview of product families / groups sharing the same active ingredient. Each family is defined by unique ingredient of product.

- Where can I see all product families?

After opening the **Product Family Management** workflow, under **Records** all product families that are available can be seen. Clicking on the Record ID or Title/Identifier (columns) of **Records** view will open the respective record i.e. Product Family.

- How to create a new Product Family?

Under **Product Family Management** workflow, new family can be created by clicking on **Create from Wizard**. **Create record Wizard** will allow to enter basic information in Record Title (which could be Product name). Clicking on **Create** button, will take user to **View/edit record** where more product information could be entered in **Description** and **Notes** field. High level product family details can be entered in **Product Family details Form** with information like key ingredients, substance information.

[Note: Currently it is only one role that can create family, product and licenses]

- How to create a new Product from within Family?

New product can also be created from within product family by clicking on **Create new Product**. **Create related record** form will allow to add new product name details [Parent record i.e. family name is auto-populated if previously associated], product type, organizational entity (should be the organization name of the user) etc.

[Note: Once a product is created, its details are populated under **Associated Product** in view/edit record form of product family]

Once product family details are saved and completed, **Complete task** button will allow to complete the workflow.

5) Product Management

All the products are defined here based on different formulations / strengths, or different combinations etc.

- Where can I see all products?

After opening the **Product Management** workflow, under **Records** all products that are available can be seen. Clicking on the Record ID or Title/Identifier (columns) of **Records** view will open the respective record i.e. Product.

Title/Identifier refers to product name, where as **Parent record** refers to associated product family. Blank parent record means, no family is associated to that specific product.

- How to associate an existing Product to a Family?

Open the concerned product record from the overview and click on **Associate Product Family**. Choose the correct family name under parent record to associate with an existing family.

- How to create a new Product?

Under **Product Management** workflow, new product can be created by clicking on **Create from Wizard**. **Create record Wizard** will allow to enter basic information in Record Title (which could be product name) and Record Type (which is product type). Clicking on **Create** button, will take user to **View/edit record** form where more product information could be entered in **Description** and **Notes** field. High level product details can be entered in **Product details Form** with information like MAH name, generic name (Non Proprietary name), formulation, active substance (see section on creating new substance to know how the values get populated here) etc.

[Note: Units are UCUM (Unified Code for Units of Measure) coded which is a consolidated list of how units can be coded. Failure to comply with UCUM could result in failure during submission to EMEA].

[Note: Once a product is created, its details are populated under **Associated Product** in view/edit record form of product family]

Once product details are saved and completed, **Complete task** button will allow to complete the workflow.

- How to create a new Product license from within Product?

New product license can also be created from within product by clicking on **Create new Product License**. **Create related record** form will allow to add new license name details [Parent record i.e. product is auto-populated if previously associated], license type, organizational entity (should be the organization name of the user), country/territory etc.

[Note: Once a product license is created, its details are populated under **Associated Product license** in view/edit record form of product]

Once product license details are saved and completed, **Complete task** button will allow to complete the workflow.

6) Product License Management

License is equivalent to marketing authorization or clinical license. Licenses are geographically contextual (i.e. depending on the country) as well as contextual to the trade names (which is country specific)

- Where can I see all product licenses?

After opening the **Product License Management** workflow, under **Records** all product licenses that are available can be seen. Clicking on the Record ID or Title/Identifier (columns) of **Records** view will open the respective record i.e. Product license.

Title/Identifier refers to product license name, where as **Parent record** refers to associated product. Blank parent record means, no product is associated to that specific product license.

- How to associate an existing Product license to a Product?

Open the concerned product license record from the overview and click on **Associate Product**. Choose the correct product name under parent record to associate with an existing product.

- How to create a new Product license?

Under **Product License Management** workflow, new product license can be created by clicking on **Create from Wizard**. **Create record Wizard** will allow to enter basic information in Record Title (which could be product license name) and Record Type (which is product license type). Clicking on **Create** button, will take user to **View/edit record** form where more product license information could be entered in **Description** and **Notes** field. High level product license details can be entered in **Product License details Form** with information like tradename (country specific), license number and other registration details in the specific market. Most of the fields are free-text field an self-explanatory.

[Note: Once a product is created, its details are populated under **Associated Product** in view/edit record form of product family]

Once product details are saved and completed, **Complete task** button will allow to complete the workflow.

7) Product tree overview

In the **Products** process overview page, **Product tree overview** gives an overview of the tree of products where the hierarchy can be seen).

8) Cloning records

To avoid time consumption when creating a new record (whether product family / product / license), it is possible to clone an existing record. Record which needs to be cloned should be opened first and in the More Menu (three dots at the top right corner of **View/edit record** form) **Clone record** should be selected. Once the user confirms the cloning in the pop-up window, cloned editable form appears which needs to be edited as per the requirement.

9) Creating new substance

Creating new product substance is currently not at workflow but at application management level. In application management, active substances can be registered under list values. User with appropriate role will be able to create active substance here which will then allow the value to be chosen at product family and product level.