PLM for Medical Devices - Usage

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1. Overview of PLM for Medical Devices

About PLM for Medical Devices

The PLM for Medical Devices solution helps medical device manufacturers achieve product quality through multidomain collaboration and ensuring regional regulatory compliance. For the planning and development of any medical device, the technical documentation that contains details about the user needs, quality, standards, compliance, associated risks and hazards, and various tests associated with the device must be reviewed and approved by the required authorities through a proper workflow.

Using this solution, you can manage the technical documentation and submission quality for the design and development of medical devices. The collection and management of all the records of a medical device are done using the Design History File (DHF). The records pass through several phases for review and approval.

Where do I go from here?

Business User	
What is the role of the design history file?	The **Design History File (DHF)** is a compilation of records that describes the design history of a completed device. The DHF represents all the steps and processes carried out during the design phase and acts as a basic guideline for developing a product.
How do I manage risks associated with a medical device?	To analyze the risks associated with the user needs and specifications of the medical device, see **Risk management for medical devices**.
How do I create and add user-needs specifications to the DHF?	Before the design and development of a medical device, the user needs of a medical device must be defined. Collating user needs is the **requirements** gathering phase for the medical devices.
How do I perform tests?	PLM for Medical Devices supports the verification and validation process to ensure that the medical device meets the requirements and specifications established to fulfill its intended purpose. To perform tests and take the necessary mitigation actions, see **Test management for medical devices**.
How to manage changes?	PLM for Medical Devices allows you to manage changes required for parts, documents, and drawings. For help on how to manage changes, see **Managing changes in PLM for Medical Devices**.

How do I manage reviews using workflows?	PLM for Medical Devices supports your business processes for managing medical device and its engineering data, from the start of the project to its release and production. As part of it, it provides predefined workflows to manage the reviews and release of **records**, **design phases**, and the **DHF**.
How do I manage labeling and UDI data for the medical devices?	PLM for Medical Devices provides the capability to manage **the SKU data for the medical devices, the *Unique Device Identifier* (UDI) records**, and the **labeling data** into regulatory submissions and the production of compliant label designs.

Terms used in PLM for Medical Devices

The PLM for Medical Devices solution works in accordance with world wide regulations and standards to support a phase-gate structured method for the design and development of medical devices. The following terms are frequently used in the PLM for Medical Devices solution:

Design History File

A Design History File (DHF) is the documentation that describes the design history of a completed medical device. Its purpose is to demonstrate that a medical device is developed using the design control processes that are required to meet the FDA requirements.

Design Phases

The phases are a set of quality control practices and procedures that are used during the design and development of a medical device. It helps you to keep track of the design phase of a medical device as per the user needs and approved design plans. It also includes all the stages and processes through which the design phase of a medical device evolves and finalizes. Design controls may include user needs, design and development planning, design input, design output, design review, design verification, design validation, design transfer, design changes, and additional phases depending on the need of the regulatory requirements of the medical device.

- **User Needs**

  User Needs is the requirements gathering phase for the medical devices. The user needs phase describes how the medical device is going to be used and allows you to establish the framework required to design the medical device. This is a mandatory phase for any medical device.

  User needs includes:

  - **Intended use** that describes the clinical issue the medical product addresses.
  - **Indications for use** that relates to the clinical applications use, environment, and end user.

- **Design and development planning**

  The Design and development planning phase includes the design plans to establish, maintain, and document all the design and development activities for a medical device. It describes all the Design Controls applicable for the design and development of the medical device, when the design reviews should happen, and also define all the users and roles involved during each phase.

- **Design input**

  Design inputs are the initial requirements that describe the medical device to be produced based on the user needs and user requirements. The various sources of design inputs can be feedback from customers, quality standards, marketing surveys, competitor products, and so on.

- **Design output**

  Design outputs are the final specifications of a device that conform to the input requirements and the user needs defined for a medical product.

- **Design review**

  The design review is a formal review of the medical device design by all stakeholders. The design review must be documented in the DHF and include review date, participants, reviewed design version, and the review results

- **Design verification**

  Design verification is a process to make sure the design output is as per the design inputs defined. It includes documents about the design verification process, the testing required to verify the designs, inspection and analysis of the device, and the approved test results of the design verification stage. Design Verification is about proving you designed your medical device correctly (that is, the Design Output meets the Design Input requirements).

- **Design validation**

  Design validation ensures that the medical devices conform to defined user needs and intended uses. When you finish design verification, you can start preparing for a regulatory submission. It includes procedures and testing conditions used for design validation, and the approved results of the design validation process. Design validation is about proving you designed the correct medical device (that is, the medical device meets the needs of the end user).

- **Design transfer**

  Design transfer ensures correct designs are transferred to production. The process of transferring a medical device from product development to production begins during the design validation stage.

- **Design changes**

  Design changes includes the design change process for the identification, documentation, validation, verification, review, and approval of the design changes before implementation.

Collection

A collection contains all of the information and specifications required for the production of a medical device from start to finish. The type of collections that you can generate are *Transfer files*, *Device Master Record (DMR)*, *Pre-market Notification 510(k)*, or *Post-market Reporting*.

For example, you may create a DMR for sending a compilation of instructions, drawings, manufacturing and packaging details, and other records for the quality testing of a product. A Pre-market Notification 510(k) collection may be created for collecting and sending all records that contain information about the design controls used for the designing of the medical device, non-clinical testing results, clinical testing results and evidence, labeling regulations, and other information, as applicable, for a pre-market submission. Once you have prepared the appropriate pre-market submission for your device, you must send your submission to the FDA for regulatory approval for assuring risk free and effective use of the medical device.

User roles and groups

The PLM for Medical Devices solution contains multiple user roles associated with a group. Each of these roles carries out a defined set of tasks throughout the different phases of the business process. The user roles and groups can be configured as required by your administrator. The table below describes these groups and roles and the tasks performed by a user role.

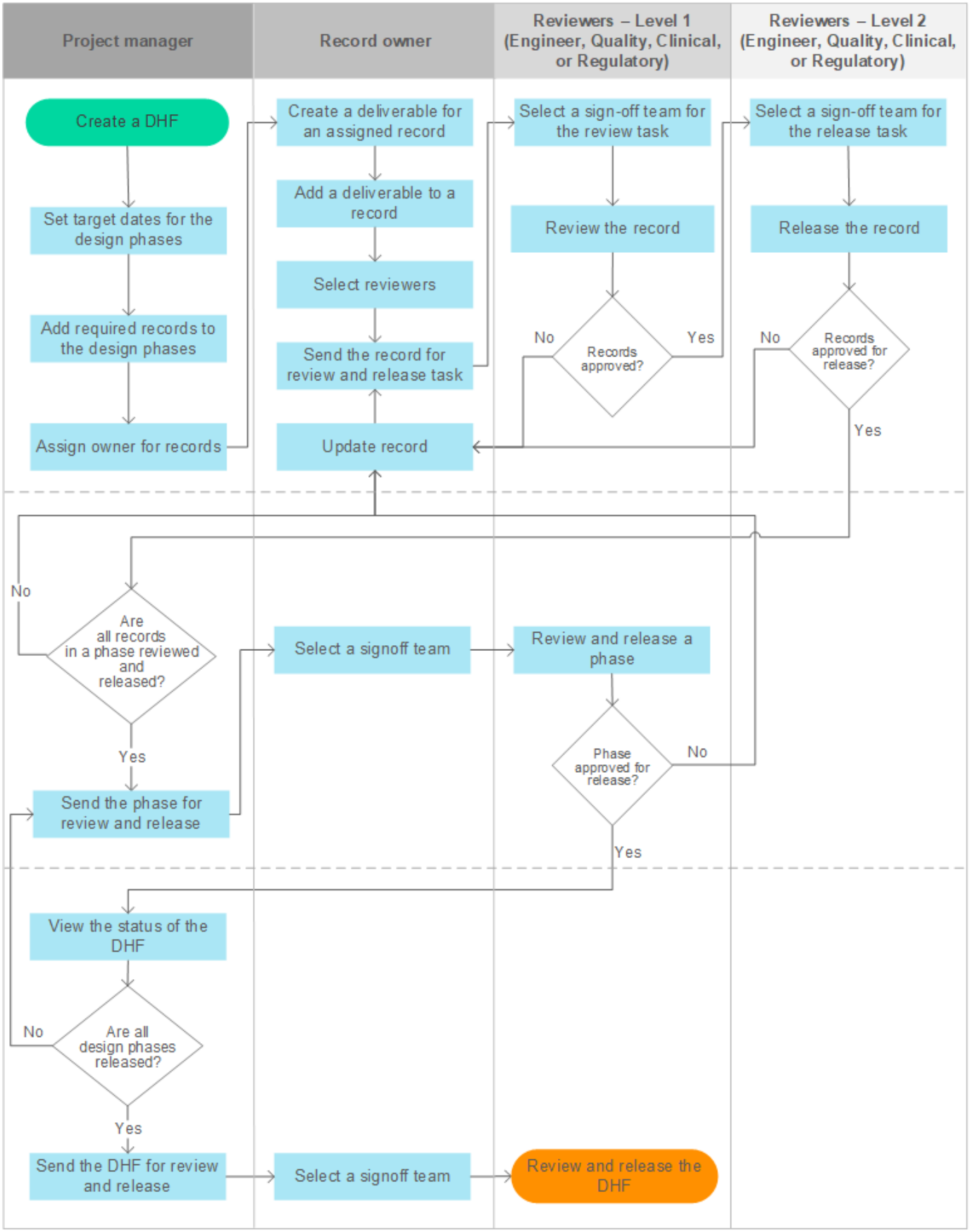
Group	Role	Description of tasks
Engineering	Project Manager	**Creates and Manages the DHF:** • Manages the project, defines Design History File (DHF), and defines deliverables. • Manages project status, reviews, and various phases of the process.
	Engineer	**Manages design of product:** • Defines technical requirements and performs risk assessments. • Participates in ECAD, MCAD, software design and development.
Quality & Regulatory	Quality	**Manages quality and process:** • Is responsible for process qualification and audits design control.
	Regulatory	**Ensures compliance with regulatory agencies:** • Reviews deliverables for compliance.
	Clinical	**Manages Clinical Validations:** • Manages plans, studies, and tests specific to the medical device.
Manufacturing	Engineer	**Manages manufacturing of product:**

Group	Role	Description of tasks
		• Participates in manufacturing tasks related to the product.
Marketing and Sales	Product Manager	**Manages design of product:** • Defines business and product requirements. • Manages and leads the product design, planning, documentation, and compliance.

2. Managing design and development using the Design History File

A sample task flow of using PLM for Medical Devices

The sample task flow of managing the design and development of a medical device using the PLM for Medical Devices solution is as follows. However, this taskflow can be configured differently for the different types or classes of the medical device development project.



Understanding the process of designing and developing a medical device using an example

To understand how the PLM for Medical Devices solution helps the medical device manufacturers in the design and development of a medical device, let us consider an example of a next generation portable infusion pump being designed to extend a medical device company's portfolio into the home use market for the United States.

Typically, the project manager begins by **creating a DHF in Teamcenter for the infusion pump device** and selects the project template applicable for the device. For example, FDA classifies the infusion pump as a class II device so the project manager selects the DHF template for the US – Class II. This sets the project phases and deliverables required by the company's quality management system.

The project manager then **adds the type of records** that are required for each design phase of the infusion pump, associate users to work on each record, and **set target dates** for the review and release of each record within a design phase.

Once the required records are listed in the user needs phase, the owner of a record **adds the documents** associated with the records. For example, the intended use of the infusion pump is outlined in the user needs phase. The user needs phase may also include, market analysis, **requirements specifications**, **risk analysis**, **test details**, or any other documents required for the new infusion pump.

Once all the documents for a record are added by the record owner, they must be reviewed and approved by stakeholders for accuracy and compliance. The records are **sent for a review** once all the deliverables are marked as complete.

When the records within the user needs phase are **reviewed** and **released**, the design phase is **sent for a review** through a predefined workflow.

Similarly, the documents required for the next design phase within the DHF are also added and managed by the respective owners of the records.

At any phase during the design process, users can create and export a **collection** of all records for an internal or external quality review, for a regulatory approval, or for transferring the final records for the manufacturing of the medical device. For example, the infusion pump example would select the 510(k) pre-market submission template to establish a collection for coordination with the FDA.

As a project manager, you can view the status of all the deliverables, records, design phases, and the collections associated with a DHF object to verify if the target date of each of these is met or not and take necessary action.

By managing the documents and records using this solution, you can illustrate that a medical device is developed using the design control processes required to meet the regulatory requirements.

Gathering the specifications required to begin the design process

Before the design and development of a medical device, its user needs must be defined. The user-needs phase describes how the medical device is going to be used and allows you to establish a framework required to design the medical device. Defining user needs is the requirements gathering phase for the medical devices. This is a mandatory phase for any medical device. The users needs describe the actual requirements of the users and the intended use of the device through these specifications. This phase requires documents that may include:

- Market analysis.
- Competitive assessment.
- Design suggestions.
- **Risk assessment**.
- **Requirements specifications**.
- **Test methods** to be used.

Creating and managing a DHF

About the DHF and the design phases in PLM for Medical Devices

The PLM for Medical Devices solution helps medical device manufacturers manage and track the design control processes through the Design History file or the DHF.

DHF

A DHF is a compilation of records that describes the design history of a completed device. It represents all the steps and processes carried out during the design phase and provides a basic guideline for developing a medical product. The type of records within a DHF include user requirement specifications, component drawings, risk analysis and risk assessments, system and component tests, and validation activities for the different design phases within which the design and development of a medical device is managed.

All medical devices are classified into different regulatory classes (for example, class I, class II, or class III) based on the level of control necessary to assure the safety and effectiveness of the device. The classification defines the regulatory requirements for a generic medical device type. Some devices may be exempt from *Premarket Notification 510(k)*, while some may require *Premarket Notification 510(k)* or a *Premarket Approval* based on how the device is classified. The classification of a medical device is also based on the risk involved for the patients or the users of the device.

The PLM for Medical Devices solution allows you to define templates for use in the DHF and Collections. These templates are set according to the medical device classification by a health authority in order to align deliverables required from the start to the finish throughout the design and development process. This template defines the applicable design phases and the records required for each design phase.

The classification and associated templates can be configured as required by your administrator.

In PLM for Medical Devices, DHF can be configured and customized for different types and classes of a medical device as per the regulatory requirements. Creating a DHF is the first step to start the design control process for your medical device design.

Design phases

Design phases are a set of management practices used to control the process of design and development of a medical device. Each phase provides an iterative design process with regular checks against the specifications, designs, and relevant regulations that are required in planning and designing the medical device.

Each design phase in turn requires a set of deliverables required to design and develop a medical device. These may include market analysis, user needs, device specifications, production and process specifications, quality assurance procedures and specifications, risk and hazard analysis documents, test records, instructions for manufacturing processes, drawings, and labeling and packaging requirements. While some deliverables may be mandatory for a specific design phase, other optional supporting deliverables can be added for reviews or reference as required.

The phases within the DHF for any medical device are active depending on the classification of that device. The *User Needs* phase is active for all classes by default. To view the records for any of the design phases, the phase must be activated. The following color codes indicate the state of a phase in a DHF:

Color	State
	Not active
	**Released**
	**Current object** or **Newest**
	**Working**
	**Less than 3 Days until due**
	**Past due**
	**Missing** or **Obsolete**

Create a DHF

Typically, a project manager creates the DHF to define the records and add the user-needs specifications related to the medical device. The classification selected while creating the DHF object impacts the deliverables needed for review and approval, applicable design phases, and the regulation required.

Procedure

1. Navigate to and open a folder, for example, **Newstuff**.
2. Click **Add** ⊕.
3. In the **New** tab of the **Add** panel, search for the **DHF** object type using the filter box.
4. Specify the required properties and select the classification from the **DHF Classification** list:

   The classification selected for the device selects the template that defines the applicable design phases and the records required for each design phase.
5. Click **Add**.

Activate a design phase

The phases within the DHF for any medical device are active depending on the classification of that device. For example, for a class 2a medical device, all phases are active by default. However, for a device with class 2b classification, all phases may not be active at the beginning. The User Needs phase is active for all classes by default. To view the records for any of the design phases, the phase must be activated.

Procedure

1. Select and open the DHF object, and click the **Phases** tab.
2. Select a phase that is not active, for example, **Design planning**, and click **More Commands** ••• > **Manage** > **Activate Phase**.

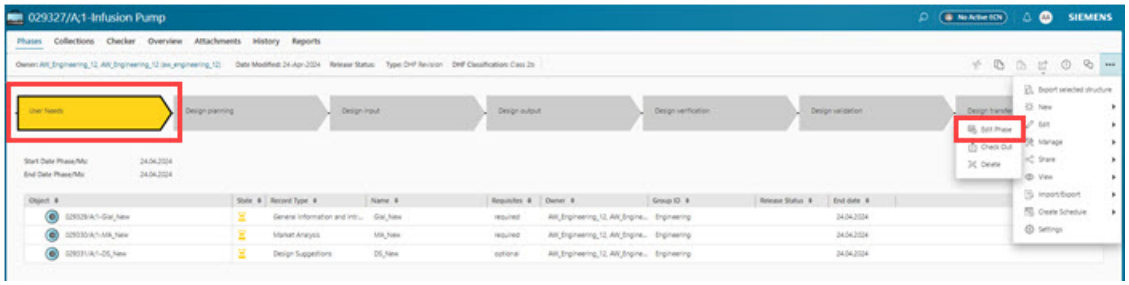
The design phase gets activated and you can now view or add records to the activated design phase. You can also set target dates for the phase.

Set a target date for a design phase

PLM for Medical Devices supports the phase gate system for the design and development of a medical device. This ensures that if one phase is completed or released, the next design phase cannot be released. You can set or modify the target date for any phase by when all the deliverables within that phase must be reviewed and released. The color of the phases represents whether the end date of a phase has already passed, is about to end, or is still active.

Procedure

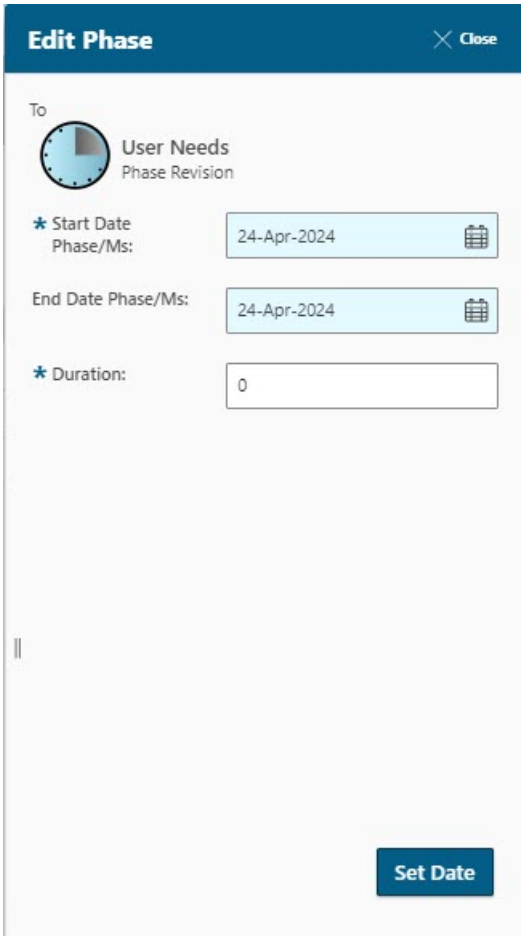
1. Select and open the DHF object, and click the **Phases** tab.
2. Select a phase, for example, **User Needs**, click **More Commands** ••• > **Edit** ✎ > and click **Edit Phase**.



3. In the **Edit Phase** panel, the **Start Date Phase/Ms** and the **End Date Phase/Ms** are set to the end date of the previous phase by default.

   You can do any one of the following:

   - Modify the dates in the **Start Date Phase/Ms** and the **End Date Phase/Ms** fields as required. The duration is automatically updated.
   - Specify the number of days required for a phase in the **Duration** field. The end date of the design phase is adjusted according to the duration set.



4. Click **Set Date**.

Add a record to a design phase in DHF

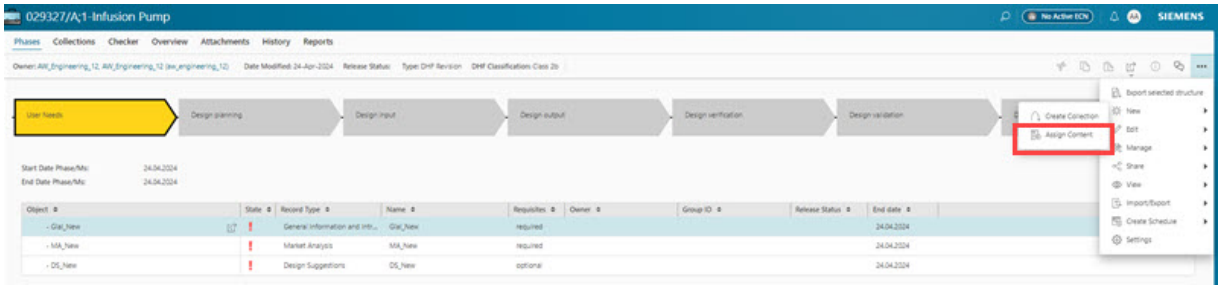
Records are containers to add the information and specifications required to design and develop a medical device from start to finish. Based on the classification of the medical device, some record types are marked as required for a design phase, while some record types may be marked as optional. For the record types marked as required, you must assign a record. Some records are listed in the table for each design phase by default. If they are not, you must manually add a record to the phases that are marked as required. Additionally, you can add any other optional records for your medical device for reference or review purposes.

Procedure

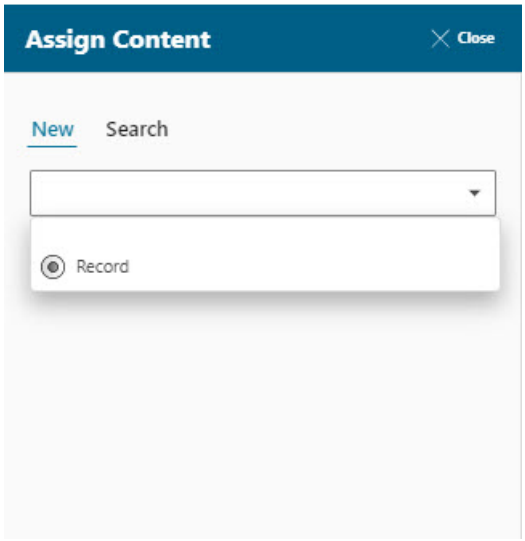
1. Select and open the DHF object to which you want to add a medical record.
2. Click the **Phases** tab and select a phase, for example, **User Needs** to which you want to assign records.
3. To add a record do one of the following:

Add a record for a specific record type:

a. Select a record type row in the table, click **More Commands** ••• > **New** ✳ > **Assign Content**.



b. In the **Assign Content** panel, under the **New** tab, select the **Record** object type.



c. Specify the required details and click **Add**.

Add a record for a new record type not listed in the table:

a. Click **Add to** ⊕.

b. In the **Add** panel, **New** tab, select the **Record** object type.

c. Specify the required details and select a new **Record Type** for the record.

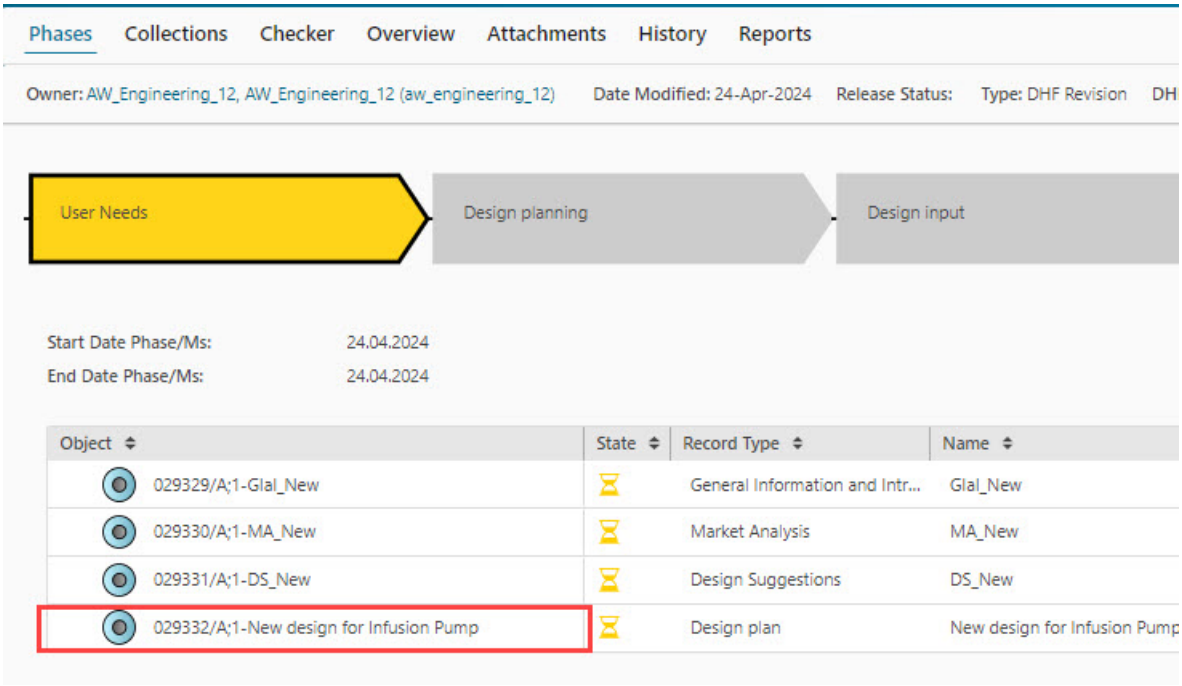
d. Click **Add**.

Add a new record type to the table and then add a record:

a. Add a record type row to the table by clicking **More Commands** •••> **New** ✳ > **Create Entry**.

b. In the **Add Entry** panel, select the **Type** of record you want to add from the list of record types displayed.

c. Click **Add Entry**. A new record type is now listed in the table.



d. Proceed to add a record for the new record type as explained in the ***Add a record for a specific record type*** procedure.

Add a visual representation of your medical device

You can add an image to the DHF object which provides a visual representation of the medical device.

Procedure

1. Select and open the DHF object and click the **Attachments** tab.
2. Under **Files** section, click **Add To** ⊕.
3. Click **Select File** and browse to select and upload an image file.
4. The file **Name** and **Type** are added automatically in the **Add** panel.

   The **Relation** is also selected by default from the list based on the record type for which you are adding this deliverable.
5. Click **Add**.

Add reference files as attachments to a DHF

You can attach other reference files or documents of a medical device to the DHF object.

Procedure

1. Select and open the DHF object and click the **Attachments** tab.
2. Under **Files** section, click **Add To** ⊕.
3. Click **Select File** and browse to select and upload a file.
4. The file **Name** and **Type** are added automatically in the **Add** panel.

   The **Relation** is also selected by default from the list based on the record type for which you are adding this deliverable.
5. Click **Add**.

Add deliverables and specifications to a record

Types of documents required for different design phases

Each design phase requires a set of documents required to design and develop a medical device. While some documents may be mandatory for a specific design phase, other optional supporting documents may be added for reviews in each phase as required. An engineer, who is the owner of a record, generally **adds the required documents** to the records in a design phase. The records are then **sent for review**.

Examples of the type of documents that may be required for each of the design phases are as follows.

Design phase	Examples of the type of deliverables required
User needs	Market analysis, user requirements, risk analysis, and intended use of the product
Design planning	Design and development plan, quality plan, regulatory plan, risk management plan, and SWOT analysis
Design input	Product specifications, risk analysis, test methods, and drawings
Design output	Drawings, product specifications, instructions for use, design verification plans, risk evaluation, risk assessment, packaging and labeling specifications, and test methods
Design verification	Traceability matrix, design verification reports, design validation plans, manufacturing plans, and risk control

Design phase	Examples of the type of deliverables required
Design validations	Clinical evaluation reports, Premarket Notification 510k, certificate of conformity, and design validation reports
Design transfer	List of suppliers, product SOP, and packaging and labeling specifications

Add a document to the record

When a record is added to a design phase, you can proceed to add supporting files or documentation called as *deliverables* to the records. The type of documents required may include device specifications, production and process specifications, quality assurance procedures and specifications, risk and hazard analysis documents, test records, instructions for manufacturing processes, drawings, and labeling and packaging requirements.

Procedure

1. Select and open the DHF object to which you want to add a deliverable.
2. Click the **Phases** tab and select a phase, for example, **User Needs**.
3. Select a record from the design phase table to which you want to add the deliverable and click **Open** . For example, for the instructions for user record, you can attached a document that contains all information about how the device must be used.
4. Click the **Attachments** tab.
5. Under **Files** section, click **Add To** ⊕.
6. Click **Select File** and browse to select and upload a file.
7. The file **Name** and **Type** details are added automatically in the **Add** panel.

   By default, the **Relation** is selected from the list based on the record type for which you are adding this deliverable.
8. Click **Add**.

Searching for data to add to the records

During the different phases of managing design data, you may want to reuse data such as documents, specifications, and parts previously created in the solution instead of creating the content from scratch. To do this, you can search for specific data using global search, quick search, or an advanced search.

Procedure

1. Log on to Active Workspace and navigate to the home page.
2. To search for a specific document or object already available in Active Workspace, do any one of the following:

   Perform Global Search
   a. Click the **Search** icon located on the right top corner of the screen.
   b. In the **Search** field, type the keywords **`*(asterisk)`** to search for a specific object.
   c. Click **Search** on the right side of the **Search** field. Verify the results of the **`* asterisk`** search display.
   d. In the **Results** panel toolbar, ensure the **List with Summary** display type is selected.
   e. Use the **Filters** on the left to filter the results by their respective properties. Additional options are available by clicking the 3 dots on the **Results** panel toolbar.
   f. You can also provide the exact name of the object in the **Search** field to locate the object.

   Perform a Quick Search using the Item ID
   a. Click the **Search** box located on the right top corner of the screen.
   b. Click **Advanced Search** below the **Search** field.

      When the **Advanced Search** task panel opens, verify that the **Quick** page is selected.
   c. In the first field, that is, the **search type** field, select **Item ID**.
   d. In the **Item ID** field, provide a part or full item ID you want to search for and, click **Search**.

   Perform an Advanced Search to find an assembly owned by you
   a. In the **Advanced Search** task panel, select the **Advanced** page.
   b. In the **Select** a search field, select **General...**.
   c. Click **Clear All**.
   d. In the **Name** field, provide the name of the assembly in part or in full.
   e. In the **Owning User** field, select the user and then click **Search**.

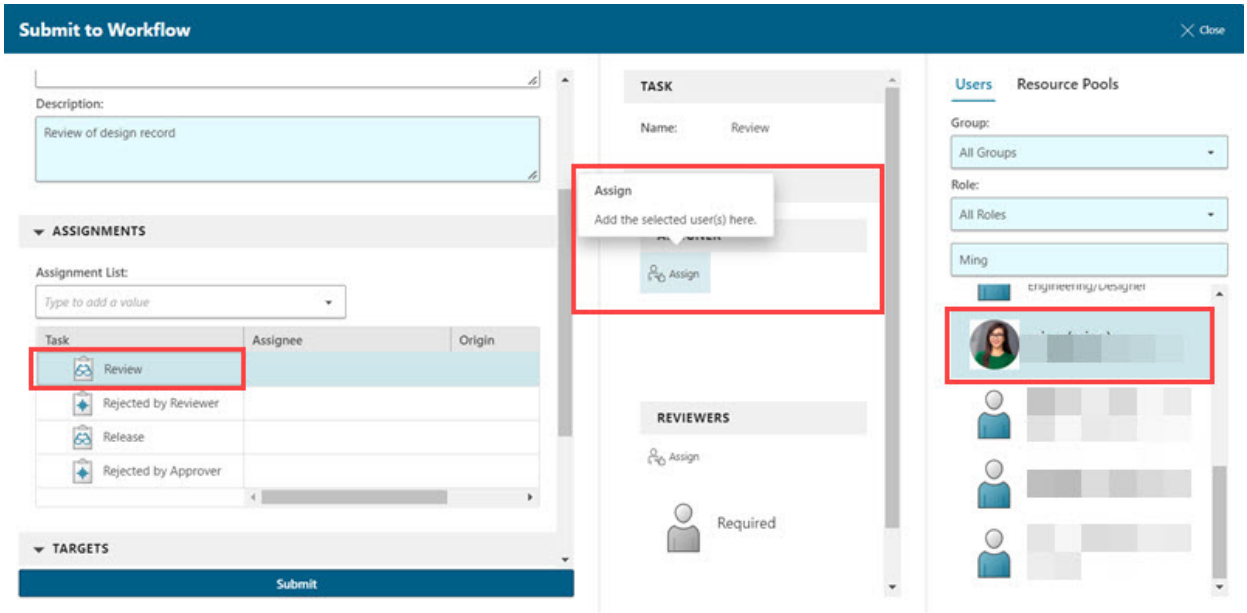
Submit a record for review

Once the deliverables are added to a record, you, as the owner of a record, must send the records for a review through a predefined workflow. Submitting records to a workflow sends it through a series of required tasks for different stakeholders to perform reviews and approvals for releasing the record. All tasks in a workflow are sent automatically to the responsible participant's inbox. The PLM for Medical Devices solution supports a two-stage review for all records, that is, the *review* and *release* of records.

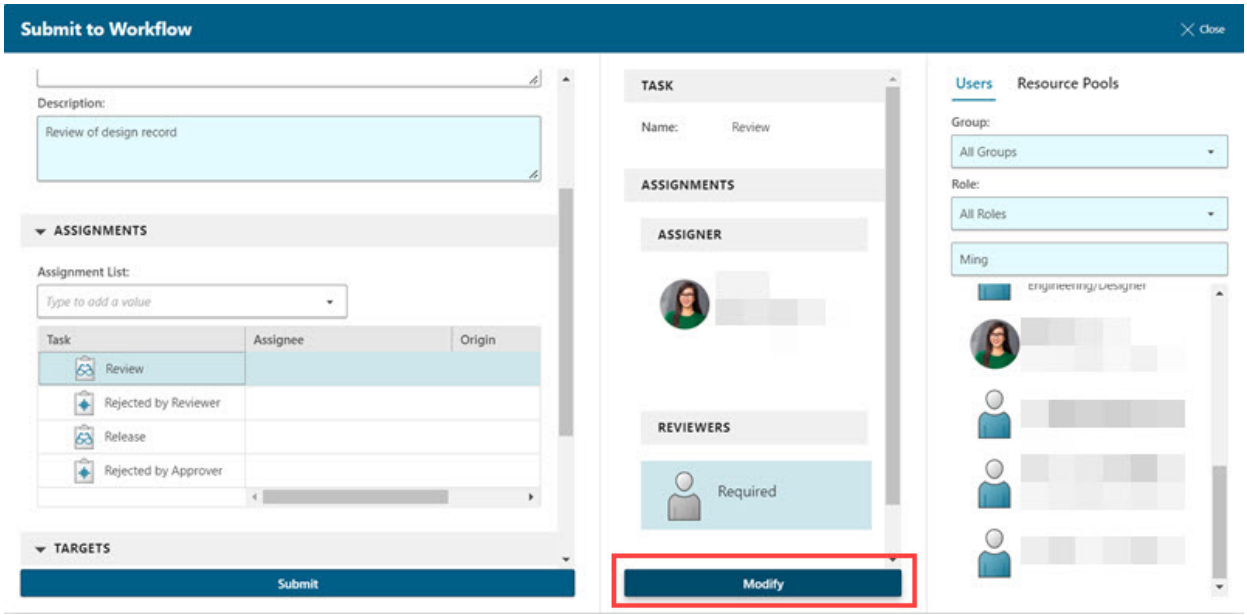
Procedure

1. Select a record from the design phase table that you want to send for a review.

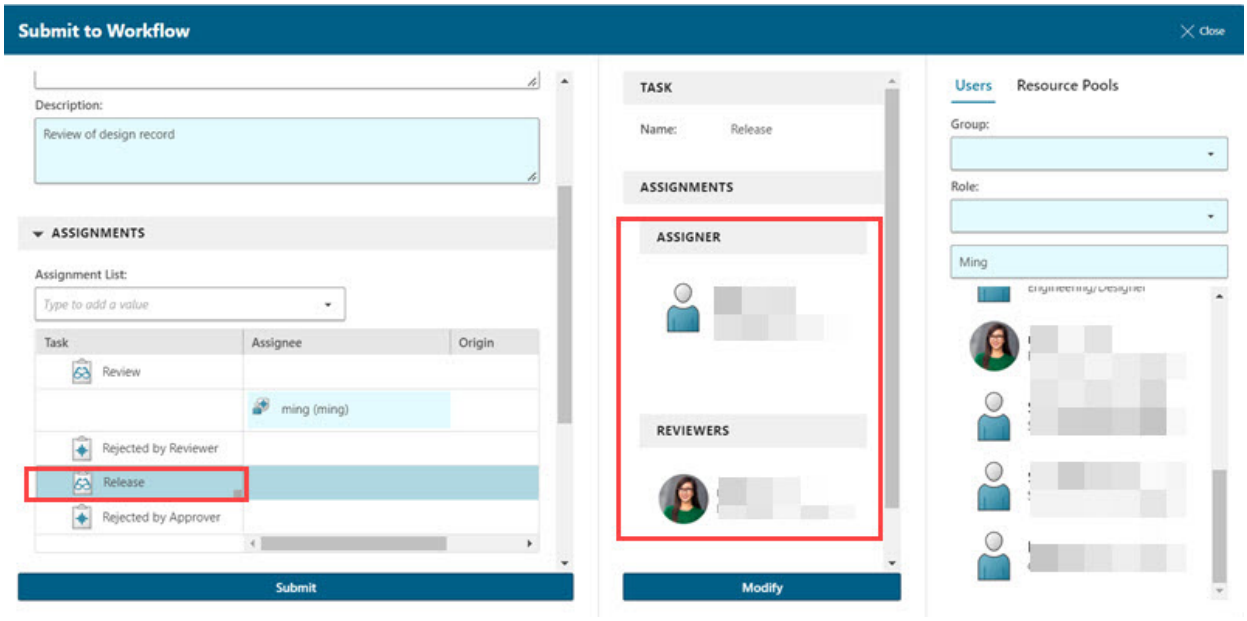
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow**.
3. In the **Submit to Workflow** panel, select the **Record Release** template from the **Templates** list.
4. In the **Assignments** section, assign participants for the **Review** and the **Release** tasks. The selected participants will receive a task in their inbox to select a sign-off team that will review or release the records.
   a. Select a task row, for example, **Review**.
   b. Search and select **Users** to select as an **Assigner** or a **Reviewer** for that task, and click **Assign**.



   c. Click **Modify**.



   d. Repeat the process for another a task row, for example, **Release** and assign a user.



5. Click **Submit**.

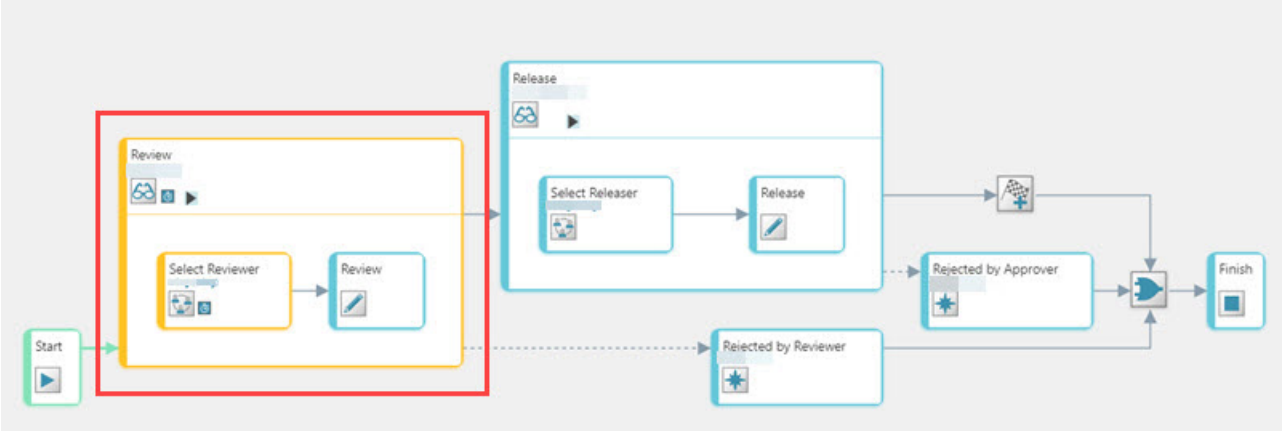
Reviewing, validating, and releasing a record

Process of reviewing and releasing records

Once the record owner adds the required deliverables to a record, the record is **submitted for a review though a workflow** by the record owner. Each record may be reviewed by a specific user role based on the type of deliverable being reviewed. In addition, the review passes through different set of reviewers, for example, those involved in design review, clinical review, regulatory review. The records are first reviewed and then released by a different users assigned to the review and release task.

Review record process

The review of record is a two-stage process with the *Select Reviewer* and the *Review* tasks.



1. **Select a sign-off team for reviewing a record**

   The record is first sent to the participants added in the submit for a review workflow by the record owner as a **Select Reviewer** task. The participant must select a sign-off team with one or more users who will review the deliverables attached to the record.

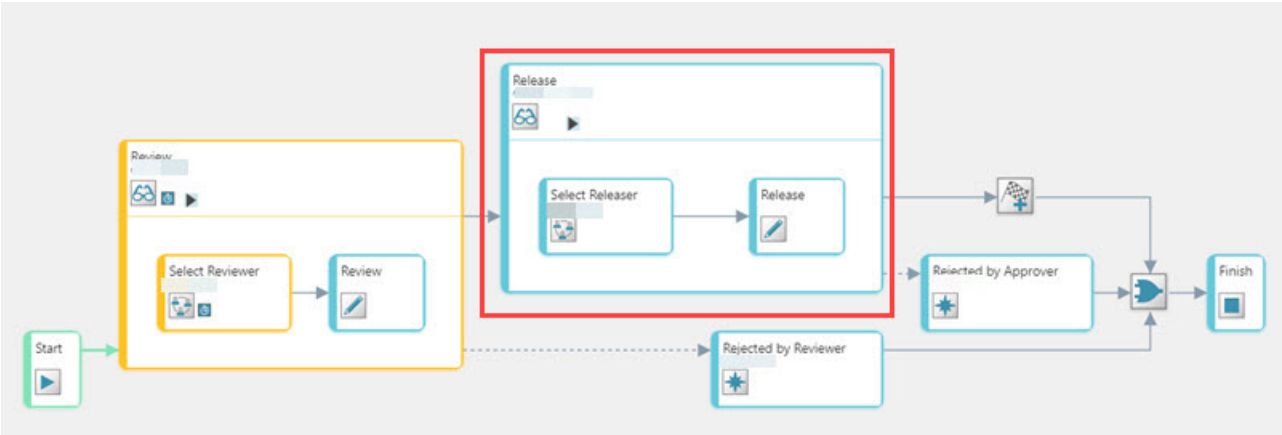
2. **Review and sign-off a record for the release task**

   The users selected as a the sign-off team will receive a task notification to **Review** the deliverables and then approve or reject the records.

Once the record is reviewed and approved, the task will proceed to the *release record workflow*.

Release record process

The release of records is a two-stage process with the *Select Releaser* and the *Release* tasks.



1. **Select a sign-off team for releasing a record**

   The record is first sent to the participants added in the submit for a review workflow by the record owner as a **Select Releaser** task. The participant must select a sign-off team with one or more users who will release the deliverables attached to the record.

2. **Validate and release a record**

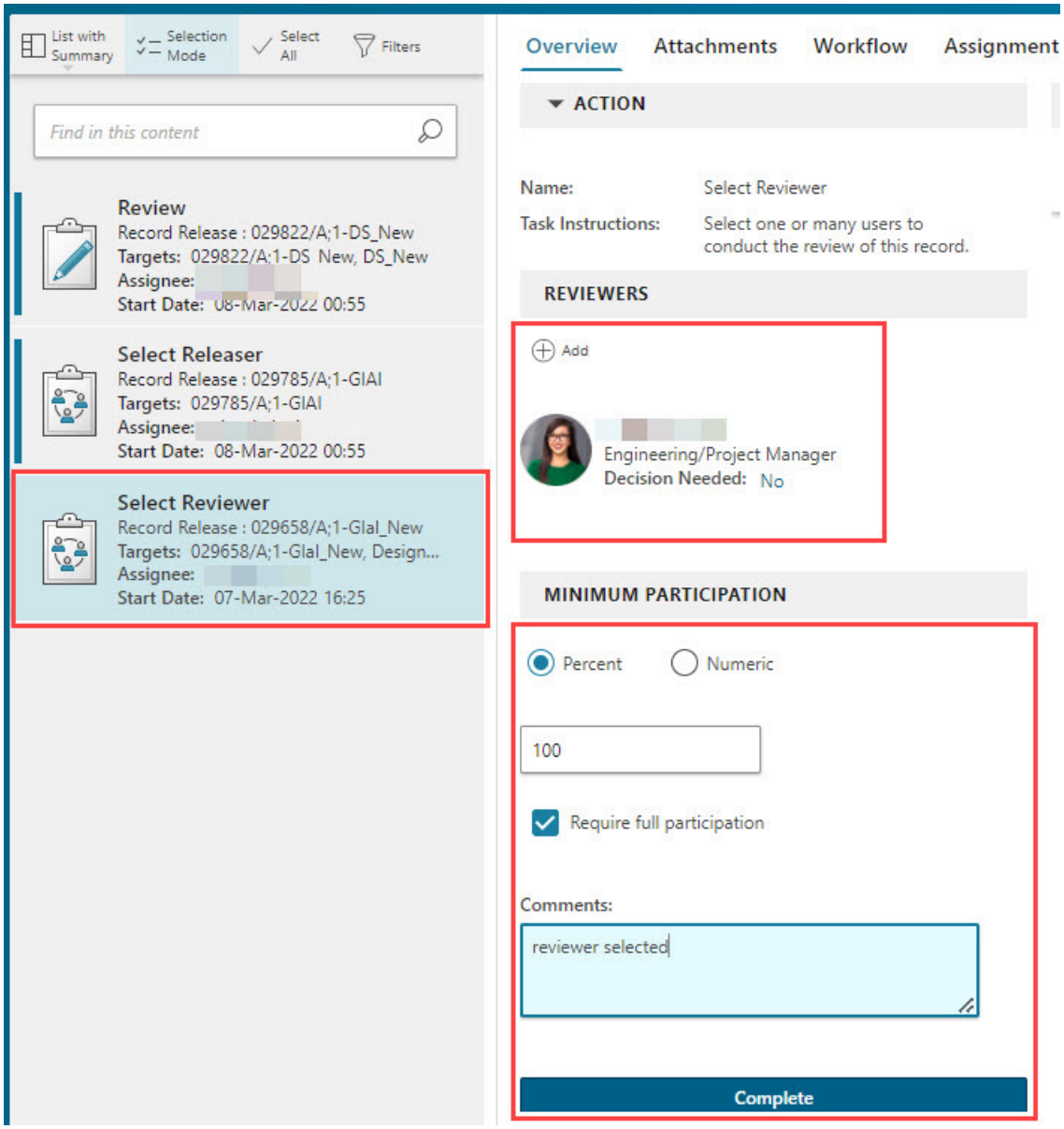
The users selected as a the sign-off team will receive a task notification to validate and **Release** the record.

Select a sign-off team for reviewing a record

You must select a sign-off team with one or more users who will review the deliverables attached to the record when you receive a task to select the reviewers in your inbox. The selected users will then receive a task notification to review the deliverables and then approve or reject the records.

Procedure

1. From your **Inbox**, open the **Select Reviewer** task assigned to you.



2. In the **Overview** tab, under **Targets**, you can view the record and associated deliverable shared for review.
3. Under the **Action** > **Reviewers** section, click **Add** to add reviewers to the task.
4. Specify the participation levels as needed for the reviewers under **Minimum Participation**.
5. Click **Submit**.

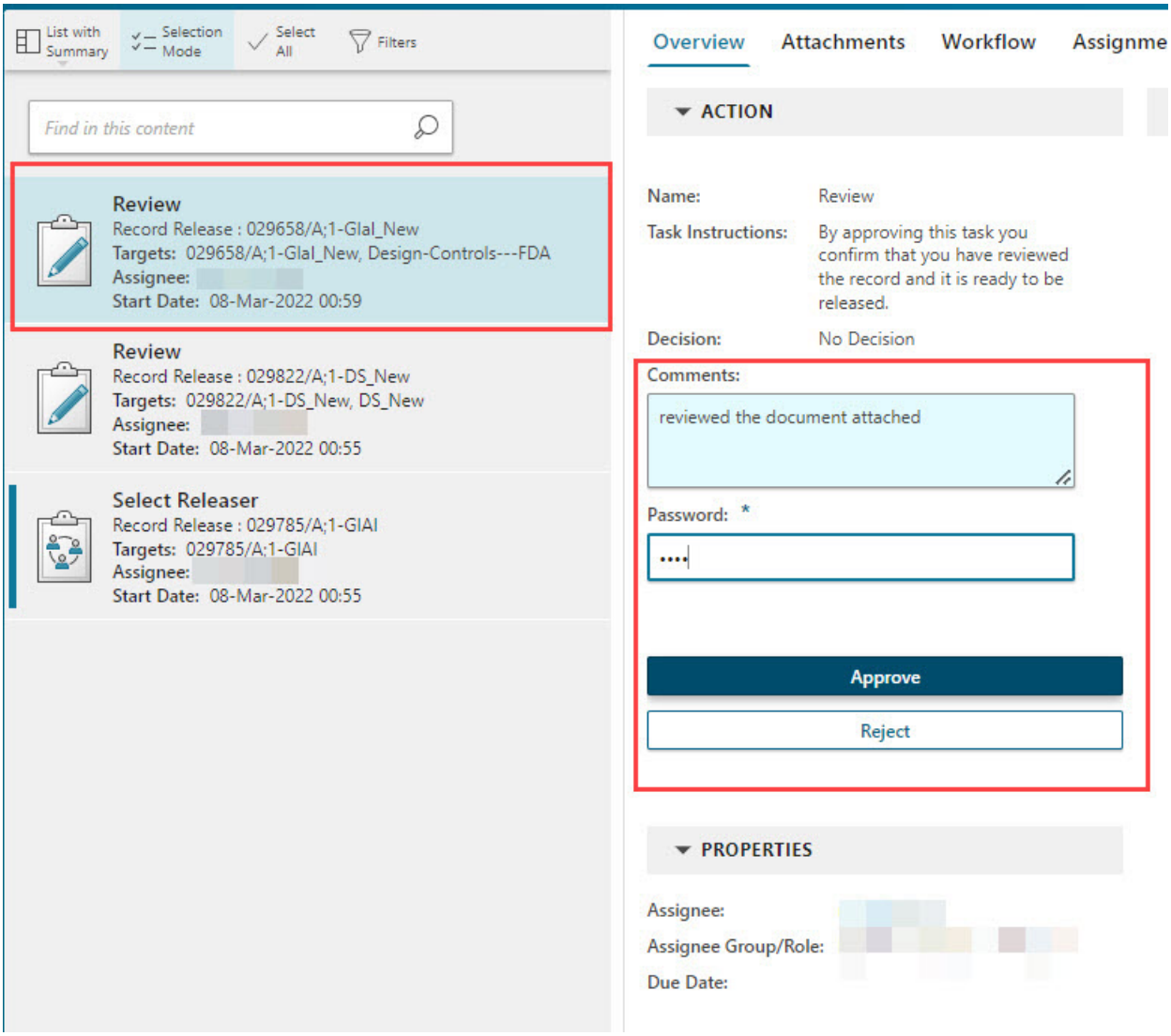
   The **Select Reviewer** task now proceeds to the **Review** task.

Review and sign-off a record for the release task

As a reviewer, you must review the deliverables attached to a record for correctness and compliance. Once you approve the record, the task will proceed to the release record workflow.

Procedure

1. From your **Inbox**, open the **Review** task assigned to you.



2. In the **Overview** tab, under **Targets**, you can view the record and associated deliverable shared for review.
3. Under **Action**, provide your **Comments** related to the review task.
4. Specify the **Password**.
5. Click **Approve** or **Reject** and mark the review task as **Complete**.

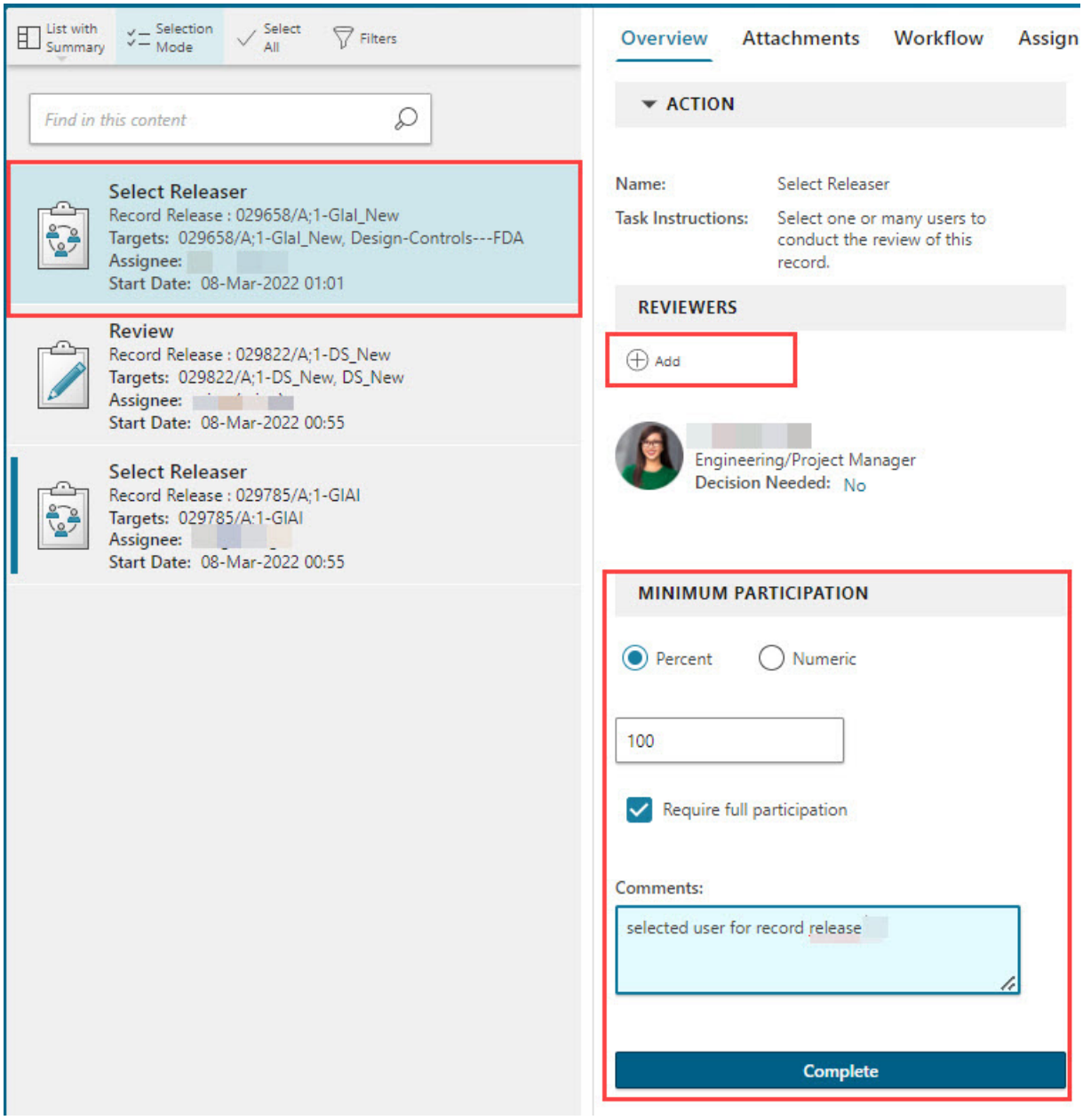
   If the review task is approved, it proceeds to the next stage of releasing the record. Based on who is assigned the task of releasing the record, the workflow sends the record for the **selecting the users to release the record** and the **release** task.

Select a sign-off team for releasing a record

You must select a sign-off team with one or more users who will release the deliverables attached to the record when you receive a task to select the reviewers in your inbox. The selected users will then receive a task notification to release the record.

Procedure

1. From your **Inbox**, open the **Select Releaser** task assigned to you for the record release task.



2. In the **Overview** tab, under **Targets**, you can view the record and associated deliverable shared for review.

3. Under the **Action** > **Reviewers** section, click **Add** to add reviewers to the task.
4. Specify the participation levels as needed for the reviewers under **Minimum Participation**.
5. Click **Submit**.

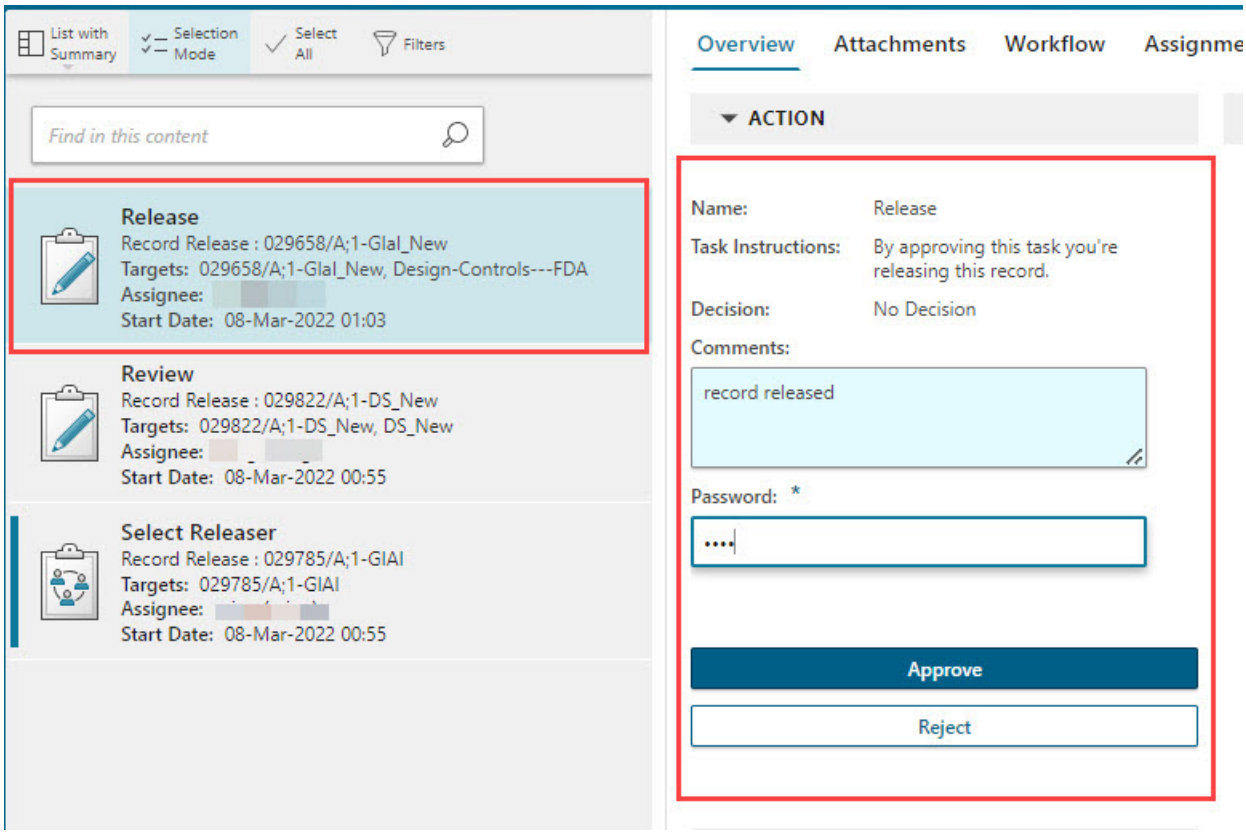
   The **Select Releaser** task now proceeds to the **Release** task.

Validate and release a record

Reviewing the record is a two-stage process, *Review* and *Release*. Different users are assigned the task to review and release a record. If you have been assigned the task to release a record, you will be notified of the review task in your **Inbox**.

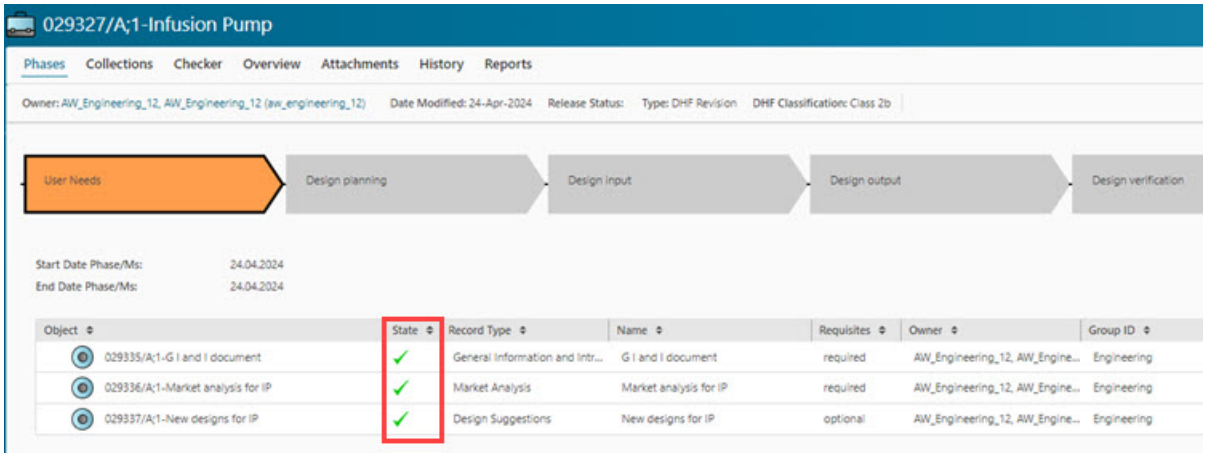
Procedure

1. From your **Inbox**, open the release task assigned to you.



2. In the **Overview** tab, under **Targets**, you can view the record and the associated deliverable shared for review.
3. Under **Action**, provide your comments related to the review task.
4. Specify the **Password**.
5. Click **Approve** or **Reject** and mark the review task as **Complete**.

6. Once the record is released, the state of the record is marked as *released* in the table where the record is added.

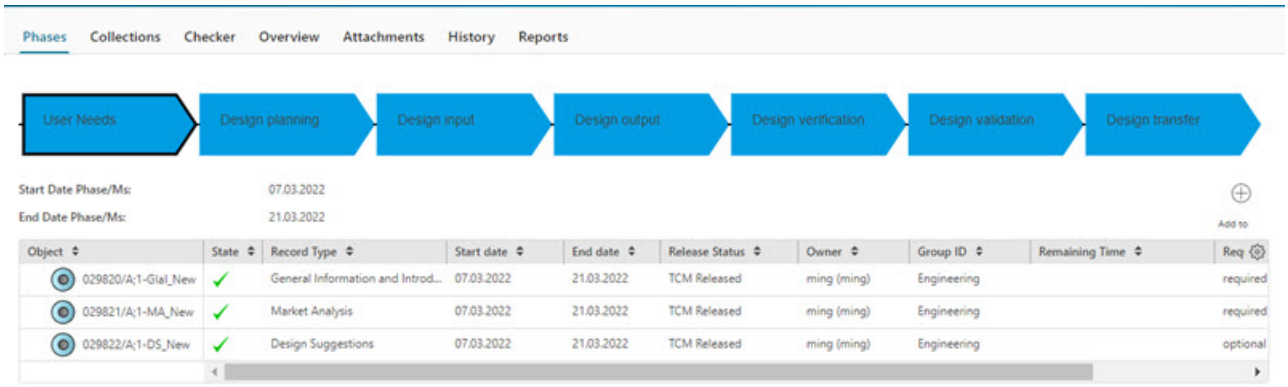


Submit a design phase for release

Once all the records within a design phase are reviewed and released, you must send the phase for validation and release through a predefined workflow. Submitting content to a workflow sends it through a series of required tasks such as selecting the signoff team and performing the approvals to release a phase, which are carried out by different user roles. To proceed to the next phase of the design process, the current design phase must be validated and released.

Procedure

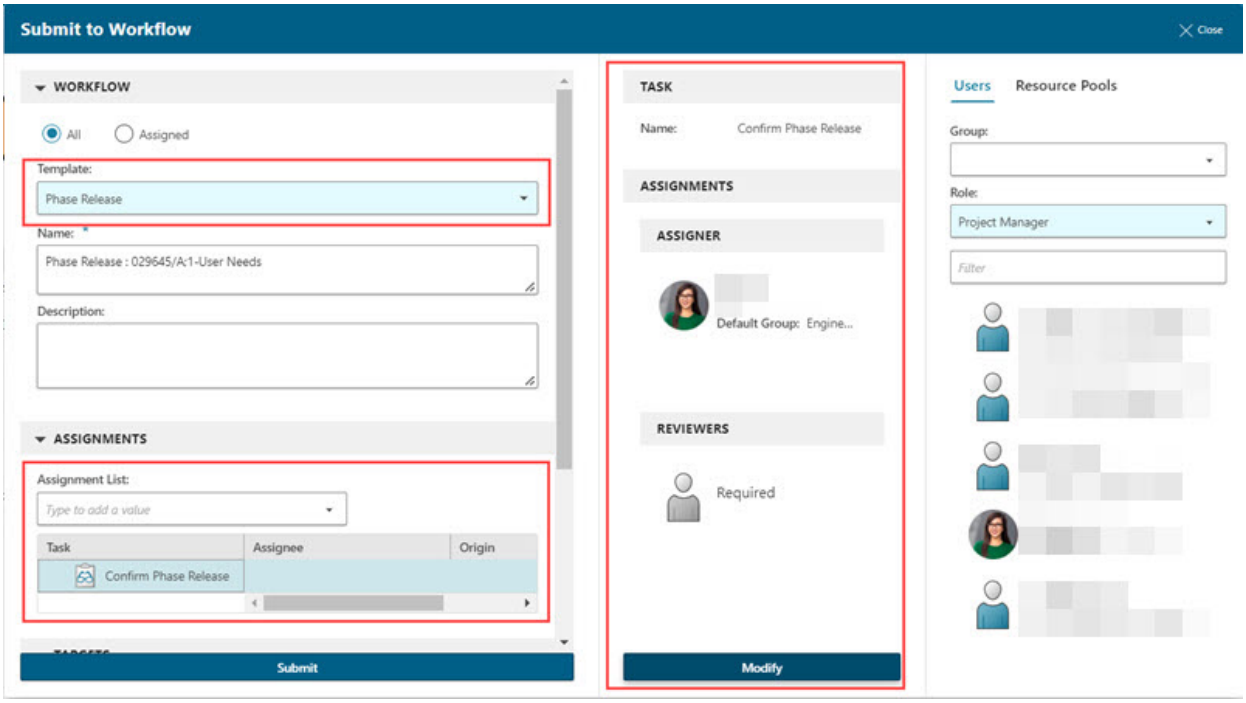
1. Open the DHF object, and click the **Phases** tab.
2. Select a phase that you want to validate and release, for example, **User Needs**.



3. Click **More Commands** ••• > **Manage** > **Submit to Workflow**.
4. In the **Submit to Workflow** panel, select the **Phase Release** template from the **Templates** list.
5. In the **Assignments** section, assign users for the **Confirm Phase Release** task.

a. Select the **Confirm Phase Release** task row.

b. Search and select **Users** to select as an **Assigner** or a **Reviewer** for that task, and click **Assign**.



c. Click **Modify**.

6. Click **Submit** to send the phase for release.

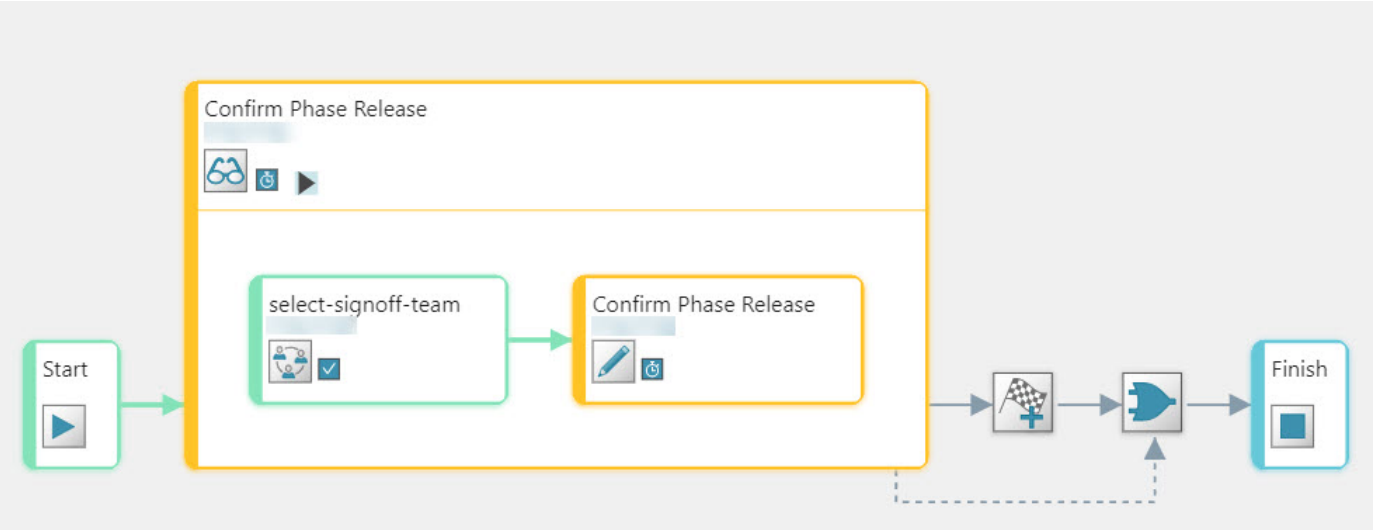
   A similar workflow can be used for each design phase of a DHF, after releasing the records for that phase.

Validating and releasing a design phase

Process of releasing a design phase

To proceed to the next phase in the design process, the current design phase must be validated and released. All records from the phase must be reviewed and released before releasing the phase. For the phase release process, the phase is sent to the owner to select

the signoff team and the record is then **sent for a release task** to the selected users.

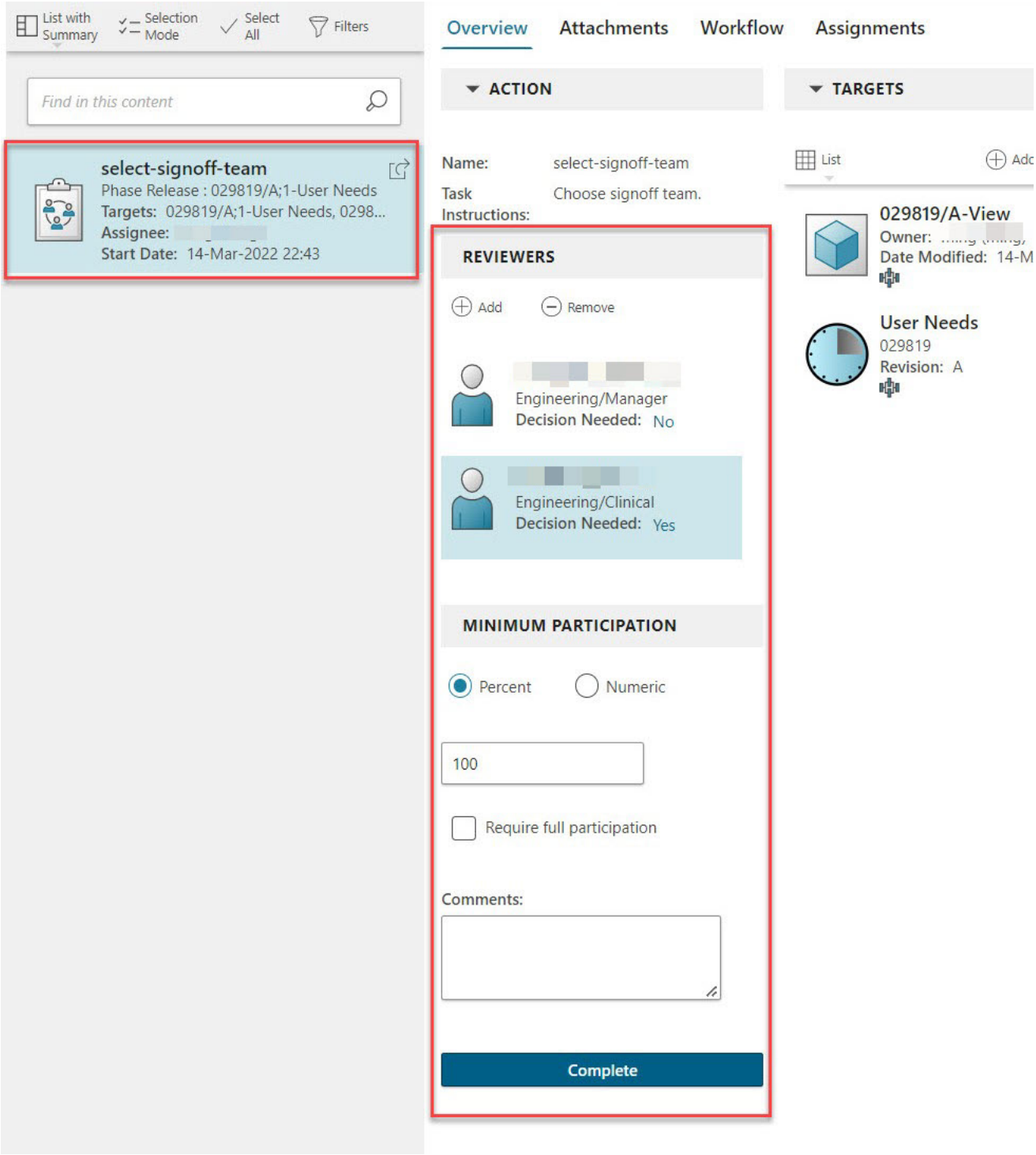


Select a signoff team for validating and releasing a phase

Once all records within a design phase are reviewed and released, the design phase is sent for a *review and release* process though a workflow. First, the record is sent to the owner to select the signoff team who will then validate and release the phase.

Procedure

1. From your **Inbox**, open the **select-signoff-team** task assigned to you for releasing the record.



2. In the **Overview** tab, under **Targets**, you can view the phase sent for review.
3. Under the **Action** > **Reviewers** section, click **Add** to add reviewers to the task.
4. You can specify whether each reviewer must make a decision by selecting a **Yes** or a **No** option against their name.
5. Specify the participation levels as needed for the reviewers under **Minimum Participation**.

6. Click **Submit**.

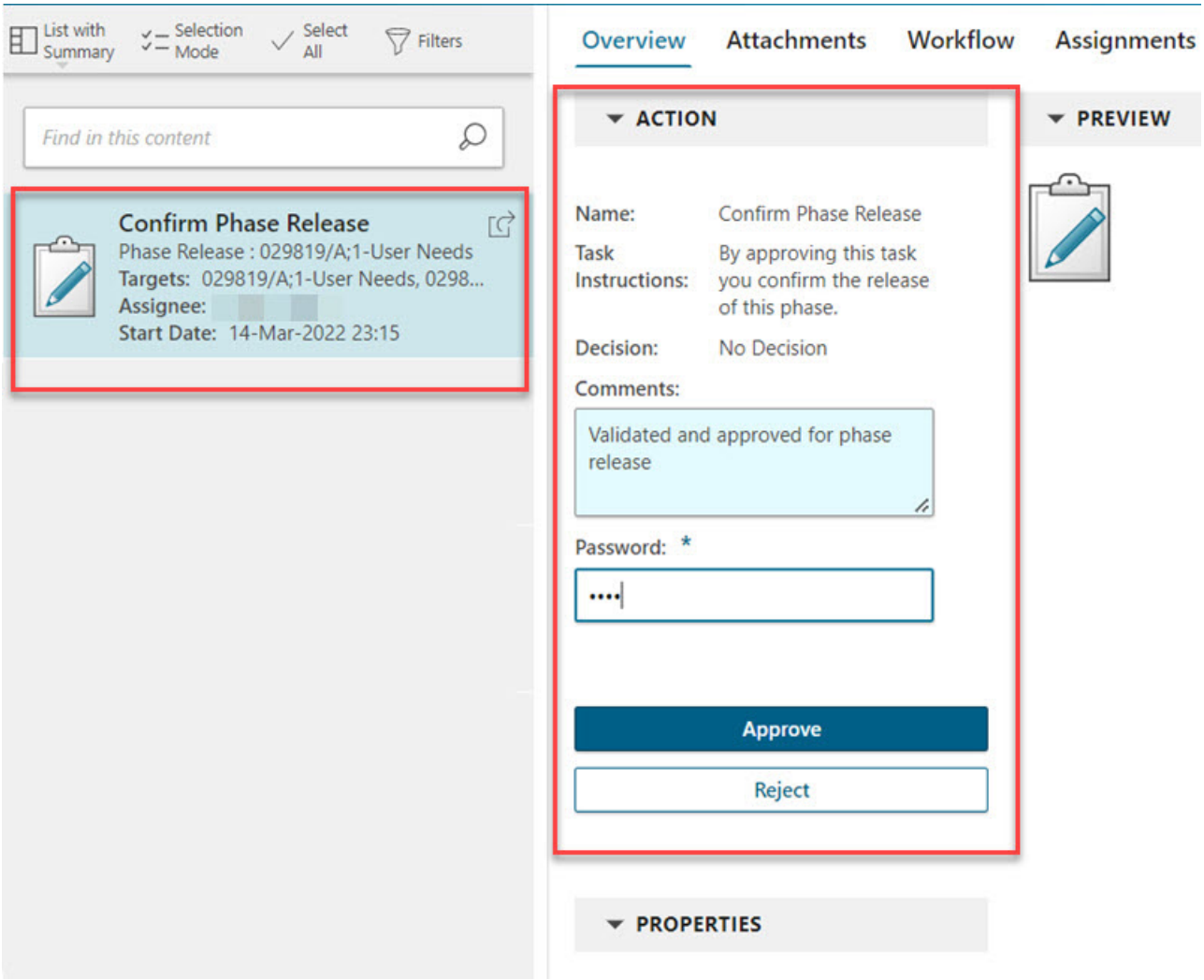
   The **select-signoff-team** task now proceeds to the **Release** task.

Validate and release a phase

To proceed to the next phase of the design process, the current phase must be validated and released. All records from a phase must be reviewed and released before releasing a phase.

Procedure

1. From your **Inbox**, open the release task assigned to you.
2. In the **Overview** tab, under **Targets**, you can view the design phase shared for review.
3. Under **Action**, provide your **Comments** related to the review task.
4. Specify the **Password**.
5. Click **Approve** or **Reject** and mark the review task as **Complete**.



Once the phase is released, the state of the phase changes from blue to green.

Creating a collection of records

About collections

A collection contains all the information and specifications required for the production of a medical device from start to finish. At any phase during the design process, users can create a collection of all records for an internal or external quality review, for a regulatory approval, or for transferring the final records for the manufacturing of the medical device. The PLM for Medical Devices solution provides pre-defined templates for creating collections such as, *Device Master Record (DMR)* or a *Pre-market Notification 510(k)*. For example, you may create a DMR for sending a compilation of instructions, drawings, manufacturing and packaging details, and other records for the quality testing of a product. For example, a 510(k) pre-market submission to create collection of the records and documents that can later be shared with the regulatory body for a pre-market approval.

A collection may accordingly contain:

- Device specifications that include drawings, composition, formulation, component specifications, and software specifications.
- Production process specifications that include the appropriate equipment specifications, production methods, production procedures, and production environment specifications.
- Quality assurance procedures and specifications with the acceptance criteria and the quality assurance equipment to be used.
- Packaging and labeling specifications along with the methods and processes used.
- Installation, maintenance, and servicing procedures and methods.
- Transfer files.

Create a collection

You can create a collection of all documents and reports for a premarket clearance or to transfer files to manufacturing systems for production. You can create a collection of records for a phase or at the end of all design phases to include all deliverables within a DHF.

Procedure

1. Select and open the DHF object and click the **Phases** tab.
2. Select a phase, for example, **User Needs**, for which you want to create a collection of all records.
3. Click **More Commands** ••• > **New** ✳ > **Create Collection**.
4. In the **Add Collection** panel, select a type of collection you want to create from the available options.
   - **Device Master Record (DMR)**
   - **Pre-market Notification 510(k)**
5. Provide other required information and select **Classification**.
6. Click **Add Collection**.

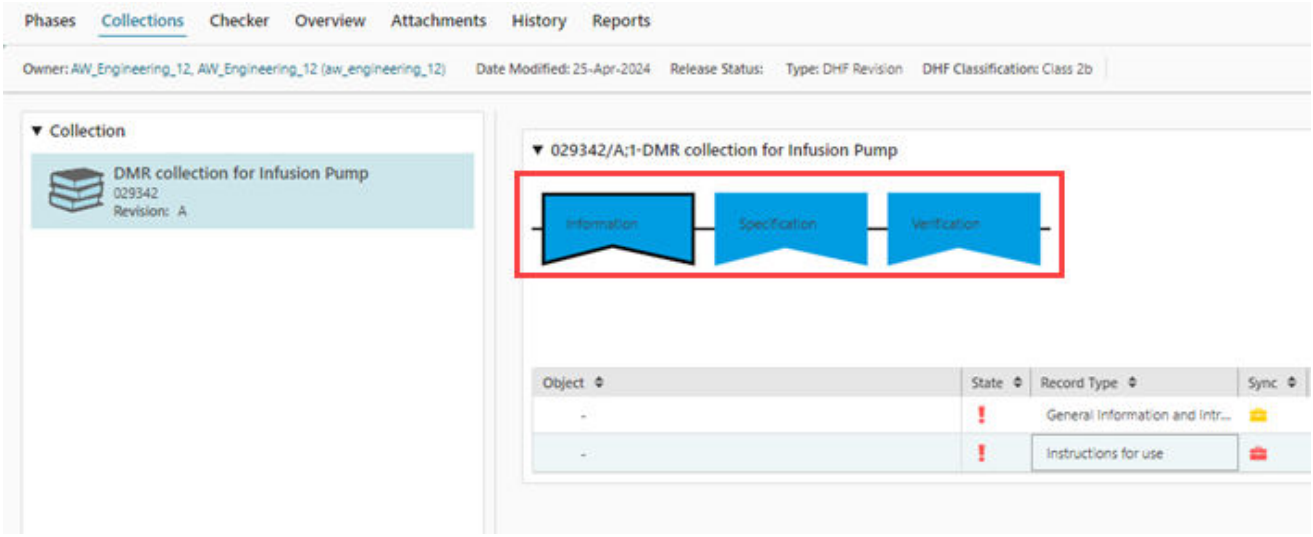
Add records to the collection

In some scenarios, you may want to add records to a collection if the records were not previously added in a design phase.

Procedure

1. Select and open the DHF object and click the **Collections** tab.

2. Select a collection to which you want to add more records. You can add a record under any of the three categories within a collection:
   - **Information**
   - **Specification**
   - **Verification**



3. To add a record to the collection, do one of the following:

Add a record for a specific record type:

   a. Select a record type row in the table and click **More Commands** ••• > **New** ✳ > **Assign Content**.

   b. In the **Assign Content** panel, **New** tab, select the **Record** object type.

   c. Specify the required details in the **Assign** panel and click **Add**.

Add a record for a new record type directly to the table:

   a. Click **Add to** ⊕.

   b. In the **Add** panel, **New** tab, select the **Record** object type.

   c. Specify the required details and select a new **Record Type** for the record.

   d. Click **Add**.

Add a new record type to the table and then add a record:

   a. Add a record type row to the table by clicking **More Commands** ••• > **New** ✳ > **Create Entry**.

   b. In the **Add Entry** panel, select the **Type** of record you want to add from the list of record types displayed.

   c. Click **Add Entry**. A new record type is now listed in the table.

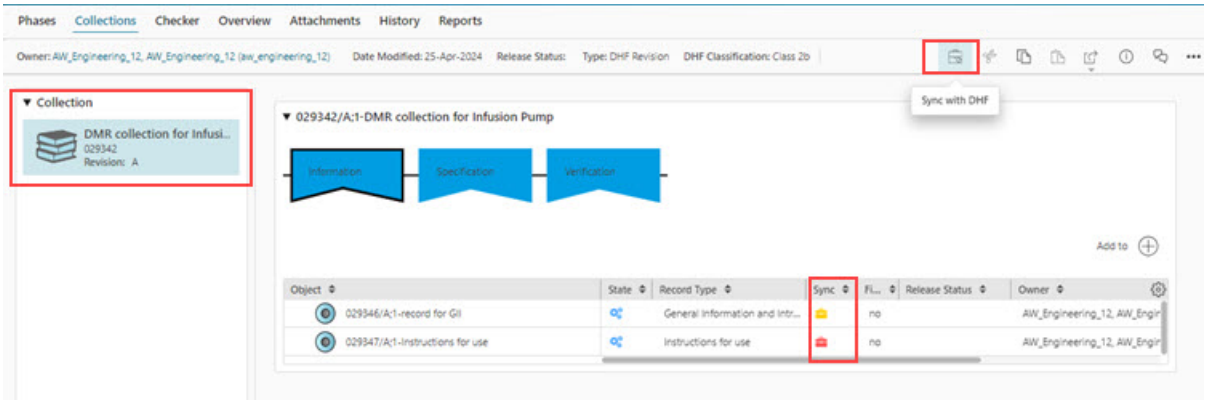
   d. Proceed to add a record for the new record type as explained in the ***Add a record for a specific record type*** procedure.

Synchronize the records in a collection

In some scenarios, a record can be added to a phase in the DHF after a collection is generated, whereas, in others, records may be directly added in a collection. Before exporting a collection of the records for a review or a regulatory approval, you must synchronize all the records in the collection with the DHF records to ensure that the latest records are included within the collection. There are colored icons indicating the synchronization state of the records within a collection with respect to the status of records within the DHF.

Procedure

1. Select and open the DHF object and click the **Collections** tab.
2. Select a collection you want to synchronize with the DHF records, and click **Sync with DHF**.



The records within the collection are synchronized with all the latest records associated with the DHF object.

Following table lists the colored icons that indicate the synchronization state of the records within a collection with respect to the status of records within the DHF:

Icon	State of the record	Definition of the state
	In sync	The record listed in the collection is exactly the same as in the DHF.
	To be synchronized	The entry can be synchronized for the following reasons: • Same record – in DHF, there is exactly one record that can be synchronized.

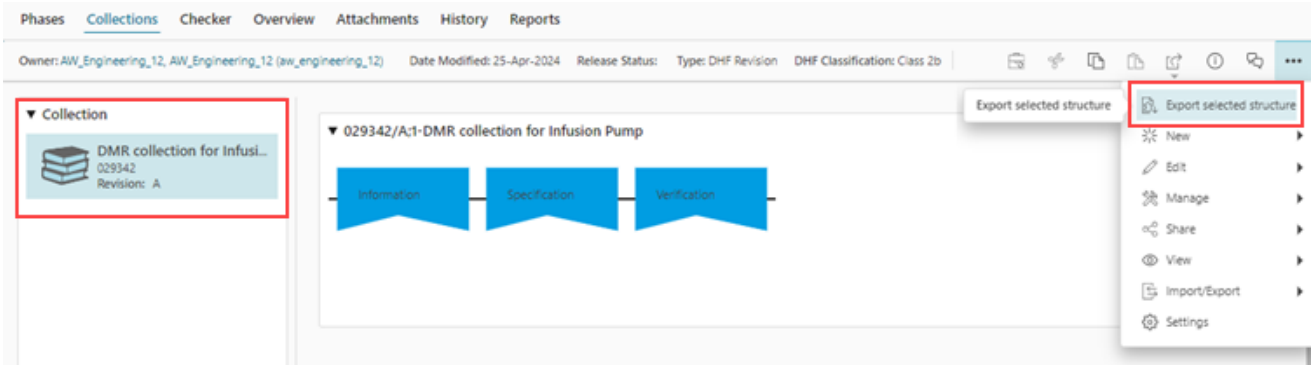
Icon	State of the record	Definition of the state
		• Alternate record – in DHF, there are more records that can be synchronized.
	Out of sync	The record cannot be synchronized for the following reasons: • Orphaned - defined only in collection. • Empty - defined in DHF but without content. • Replaced - assigned a different content in DHF.

Export a collection to a ZIP file

You can export all records and deliverables within a collection externally for review or sharing purposes through a compressed ZIP file.

Procedure

1. Select and open the DHF object and click the **Collections** tab.
2. Select a collection you want to export, and click **More Commands** ••• > **Export selected structure**.



The collection is downloaded as a ZIP file. Share the file as required.

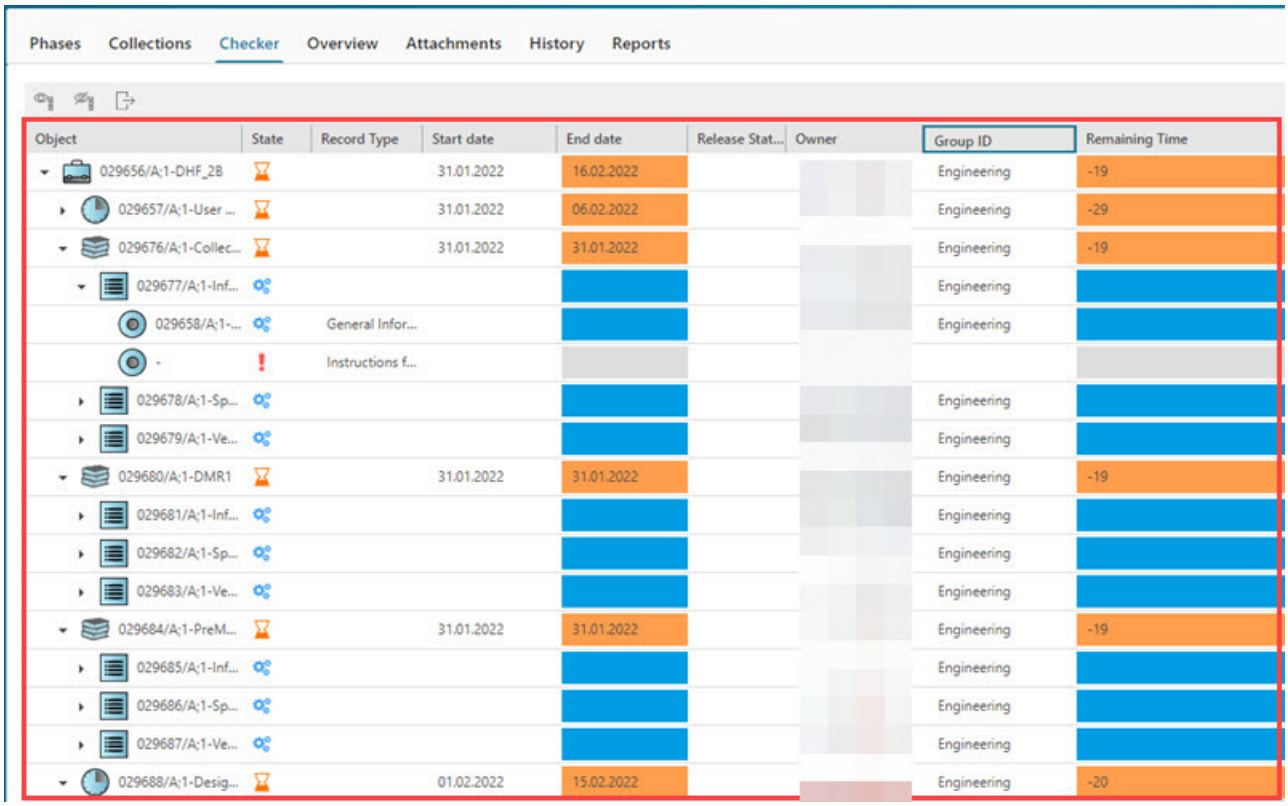
View the status of a DHF

As a project manager, you can view the status of all the deliverables, records, design phases, and the collection associated with a DHF object to verify if the target date of each of these is met or not. This

provides a complete status of all the objects associated with the DHF as well as the overall state of the DHF. You can take necessary actions on the objects for which the set target date is due or missed and send a notification to the assigned users for further action.

Procedure

1. Select and open the DHF object and click the **Checker** tab.
2. Expand the objects to view the state of all objects within the DHF object.

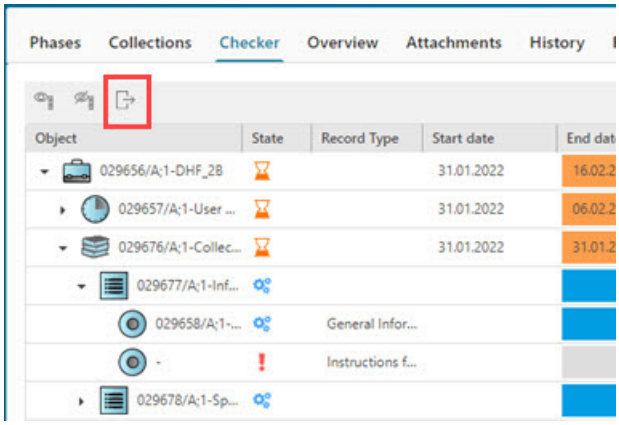


The following icons are used to indicate the state of an object within the DHF. It indicates which content is already created and released. It also shows whether the process is still in the scheduled time frame or not.

Icons	Status	Definition
!	missed / inactive	The object is unassigned or inactive (process element).
!	obsolete	The assigned object is obsolete.
⌛	late	The object is past the due date.
⌛	urgent	The due date of the object is in the next five days.
⚙	working	The assigned object is not released.
✓	released	The assigned object is released.

Icons	Status	Definition
	missed / inactive - outdated	The object is unassigned or inactive (process element), and a newer revision is available.
	obsolete - outdated	The assigned object is obsolete, and a newer revision is available.
	late - outdated	The object is past its due date, and a newer revision is available.
	urgent - outdated	The due date of the object is in the next five days and a newer revision is available.
	working - outdated	The assigned object is not released, and a newer revision is available.
	released - outdated	The assigned object is released, and a newer revision is available.

3. To export the status of all objects within the DHF to an excel file, click **Export to Excel**.



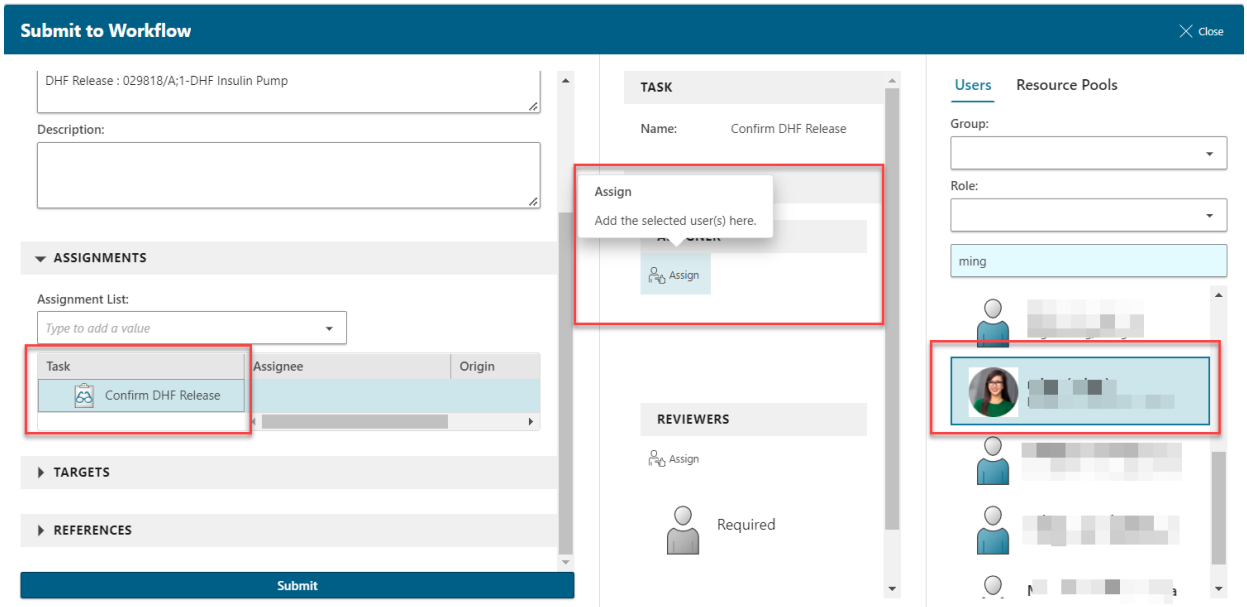
Release a DHF through a workflow

After all records and phases are reviewed, verified, and released, you can release the DHF. You can check the status of all the objects associated with the DHF before releasing the DHF through a workflow.

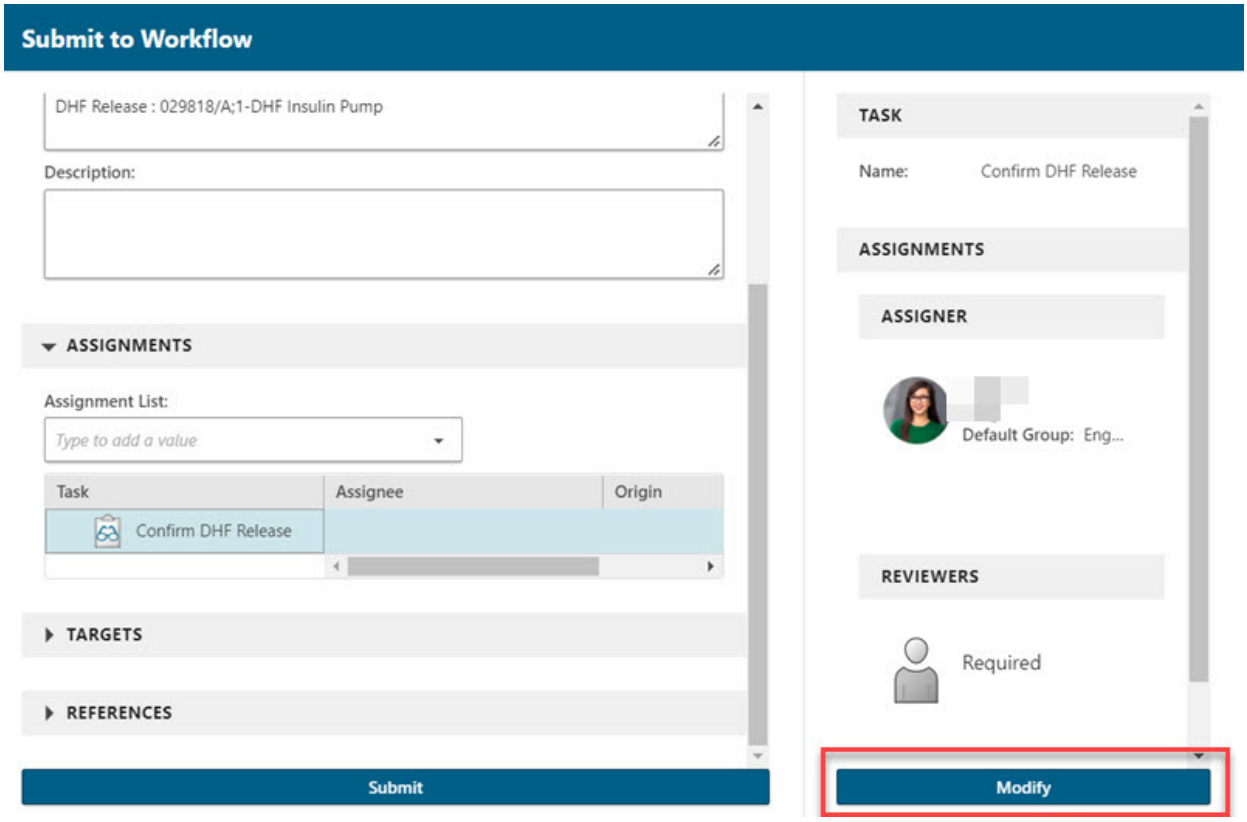
Procedure

1. From your **New stuff** folder, select a DHF object that you want to release.
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow**.
3. In the **Submit to Workflow** panel, select the **DHF Release** template from the **Templates** list.
4. In the **Assignments** section, you can assign participants for the **Confirm DHF Release** tasks.
   a. Select the **Confirm DHF Release** task row.

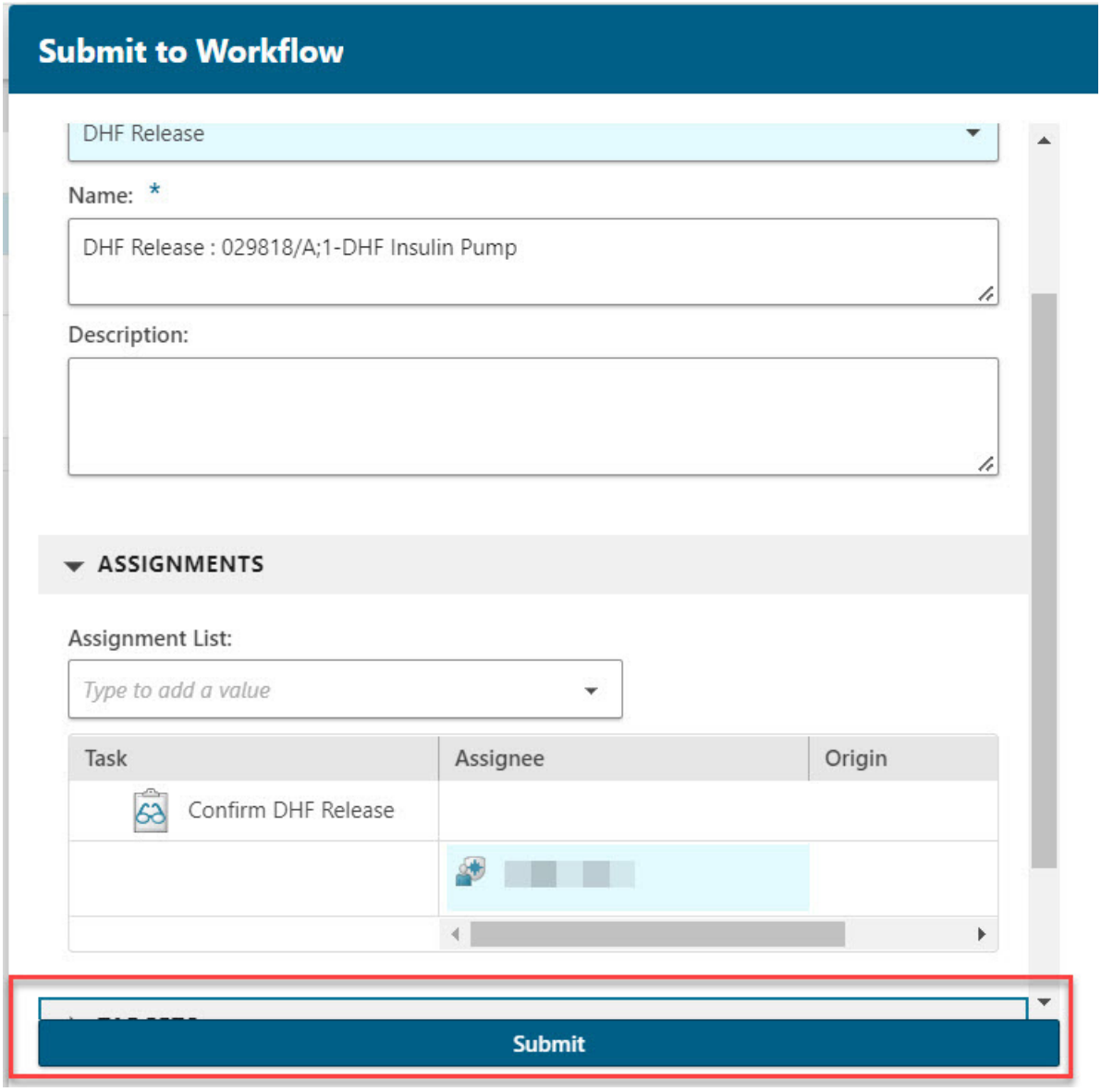
b. Search and select **Users** to select as an **Assigner** or a **Reviewer** for that task, and click **Assign**.



c. Click **Modify**.



5. Click **Submit**.



The users assigned the task of reviewing and releasing the DHF receive the task in their **Inbox**.

Select a signoff team for validating and releasing a DHF

Once all records within a design phase and all the design phases are reviewed and released, the DHF is sent for a review and release process though a workflow. It is sent to the participant selected while submitting the DHF for a review through a workflow. The participants must then select the signoff team who must validate and release the DHF.

Procedure

1. From your **Inbox**, open the **select-signoff-team** task assigned to you for the DHF release task.

In the **Overview** tab, under **Targets**, view the DHF object sent for review.

2. Under the **Action**>**Reviewers** section, click **Add** to add reviewers to the task.
3. You can specify whether each reviewer must record their decision by selecting the **Yes** or the **No** option against their name.
4. Specify the participation levels for the reviewers under **Minimum Participation**.
5. Click **Submit**.

   The **select-signoff-team** task now proceeds to the **Release** task.

Review and release a DHF

Once the DHF is submitted for a *review and release* task, you receive the task in your **Inbox**.

Procedure

1. From your **Inbox**, open the release task assigned to you.
2. In the **Overview** tab, under **Targets**, you can view the DHF shared for review.
3. Under **Action**, provide comments related to the review task.
4. Specify the **Password**.
5. Click **Approve** or **Reject**, and mark the review task as **Complete**.

3. Risk management

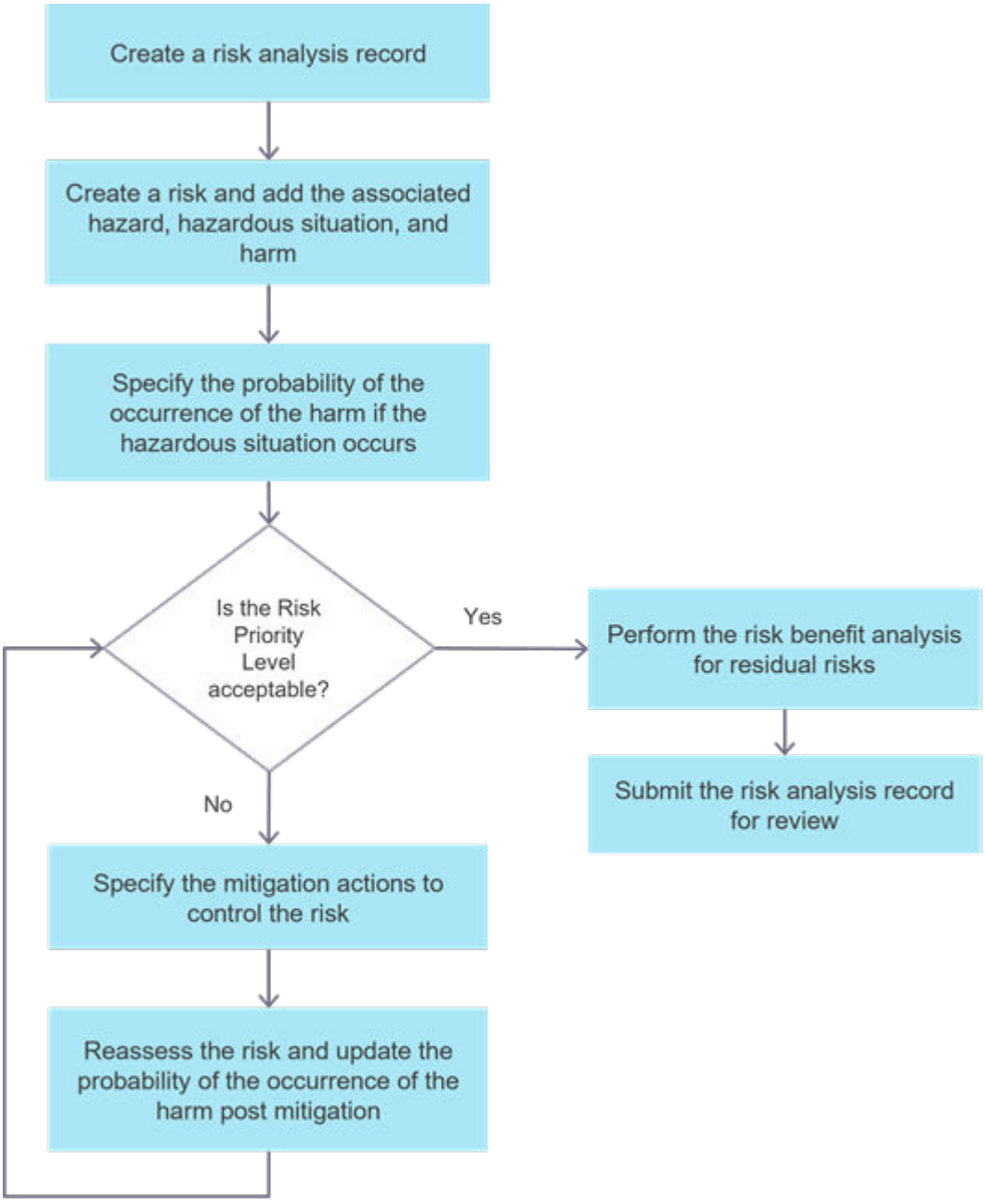
About risk management in PLM for Medical Devices

PLM for Medical Devices helps you analyze and document the risks and the associated hazards, hazardous situations, and harm at each phase throughout the lifecycle of the medical device. You can:

- Specify the intended use of the medical device and identify the associated risks.
- Specify the hazards, hazardous situations, and harms associated with the identified risks.
- Estimate the severity of the risks associated with each hazardous situation and the probability of the hazardous situation leading to harm.
- Identify and implement the mitigation actions to control the risks.
- Identify the residual risks and perform a risk-benefit analysis.

Task flow of risk management in PLM for Medical Devices

The following graphic explains how risk analysis is performed to manage the identified risks while designing and developing a medical device.



Create a risk analysis record

The risk analysis record is a container to which you can add the risks associated with the manufacturing and usage of the medical device. It helps you analyze and document the risks and the associated hazards, hazardous situations, and harm at each phase throughout the lifecycle of the medical device.

Procedure

1. Open the DHF.

2. Select the phase under which you want to create the risk analysis record.
3. Click **Add to** ⊕.
4. In the **Add** panel, in the **Type** list, type **risk analysis**, and from the results, select **Risk Analysis**.
5. In **Properties**, specify the values for the required options.
6. (Optional) Specify the owning project.
7. Click **Add**.

Results

After you create the risk analysis record, you **add the risks** to it and specify the hazards, sequence of events that lead to a hazardous situation, the hazardous situation that can occur, and the harms that can be caused due to the hazardous situation.

Create the hazards, hazardous situations, and harms associated with a risk

Create the hazards

As a part of risk analysis, after you identify the risks associated with the intended use and functioning of the medical device. A *hazard* is a potential source of harm related to the usage of a medical device. Depending on the situation, the hazards associated with a medical device can be inferred. This is done based on the intended use or misuse of the medical device and the characteristics related to safety.

Some examples of hazards are electricity, moving parts or sharp edges, bacteria, chemicals, radiation, pressure, and temperature.

Before performing a risk assessment of the medical device, you must create the possible hazards associated with it and establish a *hazards library*.

Procedure

1. Open the folder where you want to create the hazard, for example, the **Newstuff** folder.
2. In **Contents**, click **Add to** ⊕.
3. In the **Add** panel, in the **Type** list, type **hazard** and select **Hazard** from the results.
4. Specify the required properties.
5. (Optional) Specify the owning project.
6. Click **Add**.

Create the hazardous situations

After you have identified the *hazards* related to the safe use of the medical device, you must specify the *hazardous situations*. These are defined as a specific sequence of events that result in undesirable consequences. The sequence of events can include a series of causes and effects or a combination of concurrent events. A hazardous situation occurs when people, property, or environment are exposed to one or more hazards. Medical devices can cause harm if hazardous situations arise.

Procedure

1. Do one of the following:

   Create a hazardous situation in the Newstuff folder

   a. Open the folder where you want to create the hazardous situation, for example, the **Newstuff** folder.

   b. In **Contents**, click **Add to** ⊕.

   c. In the **Add** panel, in the**Type** list, type **hazardous** and select **Hazardous Situation** from the results.

   OR

   Create a hazardous situation linked to a hazard

   a. Open the hazard for which you want to specify the hazardous situation.

   b. In the **Hazardous Situations** section, click **Add to** ⊕.
2. In the **Add** panel, specify the **Name** and **Description**.
3. (Optional) Specify the owning project.
4. Click **Add**.

Create the harm that results from hazardous situations

After you have identified the *hazards* and *hazardous situations* associated with the intended use of a medical device, you can specify the *harm* that can occur if the hazardous situation occurs. Medical devices can cause *harm* if a hazardous situation results in injury, loss of function, or any other irreversible damages.

Before performing a risk assessment of the medical device, you must establish the *harm library*.

Procedure

1. Open the relevant folder where you want to create the harm, for example, the **Newstuff** folder.
2. In **Contents**, click **Add to** ⊕.

3. In the **Add** panel, in the **Type** list, type **harm** and select **Harm** from the results.
4. Specify the **Name** and **Severity**.
5. (Optional) Specify the owning project.
6. Click **Add**.

Create a risk and add the related hazards, hazardous situations, and harms

After you create the risk analysis record, you add the risks to it and specify the hazards, sequence of events that lead to a hazardous situation, the hazardous situation that can occur, and the harms that can be caused due to the hazardous situation.

Prerequisites

You must identify the potential hazards, hazardous situations, and the harms related to the usage of a medical device and establish the hazards and harms library.

Procedure

1. Open the risk analysis record to which you want to add the risk.
2. In **Analysis**, click **Add** ⊕.
3. In the **Add Risk** panel, specify the **Name**.
4. In **Hazard**, click **Add** ⊕.
5. Search for and add the hazard associated with the risk.

   You must **create the possible hazards associated with a risk** and establish a *hazards library*.
6. In **Sequence of Events**, enter the sequence of events that lead to the hazardous situation.
7. Select the hazardous situation from the list, or click **Add** ⊕ to add new or existing hazardous situations.
8. Search for and add the hazardous situation and click **Add**.

   You must **create the possible hazardous situations associated with a risk** before you can add it to the risk.
9. In **Harm**, click **Add** ⊕.
10. Search for and enter the harm that can be caused if the hazardous situation occurs.

    You must **create the possible harms associated with a risk** and establish a *harms library*.
11. Click **Add**.

Specify the probability of the occurrence of the hazard and harm

After identifying the risks and the sequence of events that may lead to a hazardous situation, you specify the probability of the occurrence of the hazardous situation and the probability of the hazardous situation leading to harm and causing injury.

Procedure

1. Open the risk analysis record.
2. In **Analysis**, select the risk for which you want to specify the probability of the occurrence of the hazard.
3. Double-click the **P1 (U)** cell, and select a value that corresponds to the probability of the occurrence of the hazardous situation.

   You can also edit the table by choosing **More Commands** ••• > **Edit** > **Start Edit** on the primary toolbar and selecting the required values.

   The following table shows an example of how the frequency of the occurrence for the hazardous situations can be mapped to the values of **P1 (U)**.

Frequency of the occurrence of the hazardous situation	Corresponding value of P1 (U)
Not analyzed	**0 - Unanalyzed**
>0 and <=1/100K	**1 - Improbable**
>1/100K and <=1/10K	**2 - Remote**
>1/10K and <=1/1000	**3 - Occasional**
>1/1000 and <=1/100	**4 - Probable**
>1/100 and <=1	**5 - Frequent**

4. Double-click the **P2** cell, and select a value that corresponds to the probability of the occurrence of the hazardous situation leading to a harm.

   You can also edit the table by choosing **More Commands** ••• > **Edit** > **Start Edit** on the primary toolbar and selecting the required values.

   The following table shows an example of the frequency of the hazardous situation leading to a harm or injury due to the harm and its corresponding values of **P2**.

Frequency of the hazardous situation leading to harm	Corresponding value of P2
Not analyzed	**0 - Unanalyzed**
<=5% Injury would be rare.	**1 - Rare**

Frequency of the hazardous situation leading to harm	Corresponding value of P2
6–25% Injury is conceivable but not likely.	**2 - Unlikely**
26–75% Injury may occur.	**3 - Possible**
76–95% Injury is expected to occur.	**4 - Likely**
>=96% Injury will occur.	**5 - Certain**

5. If you edit the table using the **Start Edit** command, click **More Commands** ••• > **Edit** > **Save Edits** to save your changes.

   The values of **P (U)** and **RPL (U)** are automatically updated to indicate the Risk Priority Level (RPL). The following table shows a sample of the RPL value and its description.

Risk priority level (RPL)	Description
Unacceptable	Risks that fall in this category after risk control is applied are considered to be serious safety risks in the product. If further risk control is impractical, a risk-benefit analysis must be conducted to determine if the medical benefits outweigh the residual risk, which needs to be approved by Medical Affairs. The results of the risk-benefit analysis, along with any supporting information are documented in the risk management report.
Moderate	Risks that fall in this category after risk controls are applied are considered to be serious safety risks in the product. These risks require further analysis and may require a major change in product in order to allow the product to be used. If further risk control is impractical, a state-of-the art- discussion occurs to determine if the device performance is equivalent to or an improvement over the currently marketed devices. The results of the state-of-the-art discussion, along with any supporting information are documented in the risk management report.
Acceptable	Risks that fall within this category are considered to be residual risks that cannot be fully mitigated through practical means. Risk controls are specified that will reduce the risk of hazards in this region to the lowest possible level. Acceptable risks are considered to be adequately controlled as far as possible by the various risk and design control actions. These risks do not pose a serious safety concern.

Specify the mitigation actions to control the risks

If the Risk Priority Level (RPL) of a risk is not acceptable or moderate the risks are serious safety issues. In such cases, you specify the mitigation actions to be taken to control the risks.

Procedure

1. Open the risk analysis record.
2. In **Analysis**, select the risk for which you want to specify the mitigation actions.
3. On the primary toolbar, click **More Commands** ••• > **Edit** > **Start Edit**.
4. In the **Mitigations** column, click the cell to which you are specifying the mitigation action, and click **Add** ⊕.

   You can add user needs or requirements.
5. In the **Add** panel, click **Search**, and enter keywords to search for the required object.

6. Select the required object from the search results and click **Add**.
7. Click **More Commands** ••• > **Edit** > **Save Edits** to save your changes.

Reassess the risks and update the probability of their occurrence post mitigation

After you specify the mitigation actions, you re-evaluate the risks by updating the probability of the occurrence of the hazardous situations and the harm after the risk control actions are taken.

Procedure

1. Open the risk analysis record.
2. In **Analysis**, select the risk for which you want to update the probability of the occurrence of the hazard.
3. Double-click the **P1 (M)** cell, and select a value that corresponds to the probability of the occurrence of the hazardous situation after the mitigation actions are performed.

   You can also edit the table by choosing **More Commands** ••• > **Edit** > **Start Edit** on the primary toolbar and selecting the required values.

   The following table shows an example of how the frequency of the occurrence of the hazardous situations can be mapped to the values of **P1 (M)**.

Frequency of the occurrence of the hazardous situation	Corresponding value of P1 (M)
Not analyzed	**0 - Unanalyzed**
>0 and <=1/100K	**1- Improbable**
>1/100K and <=1/10K	**2 - Remote**
>1/10K and <=1/1000	**3 - Occasional**
>1/1000 and <=1/100	**4 - Probable**
>1/100 and <=1	**5 - Frequent**

4. If you edit the table using the **Start Edit** command, click **More Commands** ••• > **Edit** > **Save Edits** to save your changes.

   The value of **P (M)** and **RPL (M)** is automatically updated to indicate the Risk Priority Level (RPL) post the mitigation steps. The following table shows a sample of the RPL (M) value and its description.

Risk priority level (RPL)	Description
Unacceptable	Risks that fall in this category after risk control is applied are considered to be serious safety risks in the product. If further risk control is impractical, a risk-benefit analysis must be conducted to determine if the medical benefits outweigh the residual risk, which needs to be approved by Medical Affairs. The results of the risk-benefit analysis, along with any supporting information are documented in the risk management report.
Moderate	Risks that fall in this category after risk controls are applied are considered to be serious safety risks in the product. These risks require further analysis and may require a major change in product in order to allow the product to be used. If further risk control is impractical, a state-of-the art- discussion occurs to determine if the device performance is equivalent to or an improvement over the currently marketed devices. The results of the state-of-the-art discussion, along with any supporting information are documented in the risk management report.
Acceptable	Risks that fall within this category are considered to be residual risks that cannot be fully mitigated through practical means. Risk controls are specified that will reduce the risk of hazards in this region to the lowest possible level. Acceptable risks are considered to be adequately controlled as far as possible by the various risk and design control actions. These risks do not pose a serious safety concern.

Perform the risk-benefit analysis for residual risks

After performing a risk assessment and analysis, you must determine if the risk level is reduced to acceptable values. If not, you must perform the risk-benefit analysis, where you evaluate if the medical benefits of the medical device outweigh the risks. This risk-benefit analysis is reviewed before companies decide to proceed with the next steps of designing and manufacturing the medical device.

Procedure

1. Open the risk analysis record.
2. In **Analysis**, select the risk for which you want to update the probability of the occurrence of the hazard.
3. On the primary toolbar, choose **More Commands** ••• > **Edit** > **Start Edit** ✎.
4. Double-click the **Residual Risk Information** cell and click **Add** ⊕.
5. Specify the residual risks.

6. Double-click the **Benefit Analysis** cell and click **Add** ⊕.
7. Specify the risk-benefit analysis document.
8. Edit the **Essential Performance** value to indicate whether the risk affects the performance of the medical device.
9. Click **More Commands** ••• > **Edit** > **Save Edits** to save your changes.

Submit the risk analysis record for review

After you add the risk analysis record in a phase, you can start the review process for it. During the review, the stakeholders review the hazards, hazardous situations, or harms associated with the risk, and the risk-benefit analysis of the medical device. In most cases, you select a signoff team and submit the objects for their review and approval.

Procedure

1. Locate the object that you want to send for review, and on the primary toolbar, click **More Commands** ••• > **Manage** > **Submit to Workflow**.
   The **Submit to Workflow** panel and a list of workflow templates are displayed.
2. Enter a description for the workflow participants, select the appropriate workflow template, and click **Submit**.

   If a default workflow is defined for the risk analysis record, it is automatically selected as the workflow template.

   Depending on the workflow, you may be required to assign the signoff team to approve the requirement. You receive a task to create the signoff team in your **INBOX** tile on the **My Tasks** tab. An approval task is assigned to each signoff participant that you select.

   For more information on reviewing and releasing records, see **Process of reviewing and releasing records**.

4. User needs and requirements management

About user needs, user-need specifications and requirements

Gathering user needs and requirements for the medical device helps you to specify how the medical device is going to be used and allows you to establish the framework required to design the medical device. User needs includes:

- Intended use that describes the clinical issue the medical product addresses.
- Indications for use that relates to the clinical applications use, environment, and end user.

The users needs describe the actual requirements of the users and the intended use of the device through these specifications.

Consider that you are designing an infusion pump that administers fluids into a patient's body in a controlled manner. In this scenario, one of the *user need* is that the infusion pump must function in an operating room environment. For this, the *requirement* is that the electromagnetic radiation from other devices in the vicinity of the infusion pump must not affect the performance of the infusion pump or cause it to malfunction.

In Teamcenter, you document the user needs as *user-need specification* and the requirements as *user-need*. You then **add these user-need specifications as records to the required phase** in the DHF.

You can specify the user-need specifications using any of the following methods:

- **Create the user-need specification and add the user needs**
- **Create user-need specifications by importing them from Microsoft Word**
- **Create user-need specifications by importing them from Microsoft Excel**

After you have specified the user-need specifications and the associated user needs, you can create test cases for each user need to verify and validate the product design.

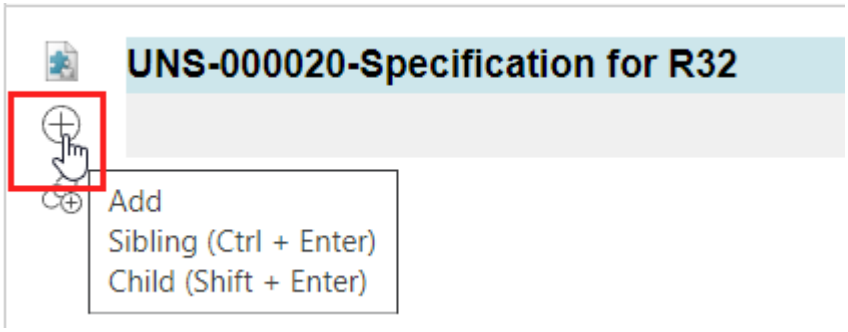
Create user-need specifications

Create a user-need specification and add the user needs

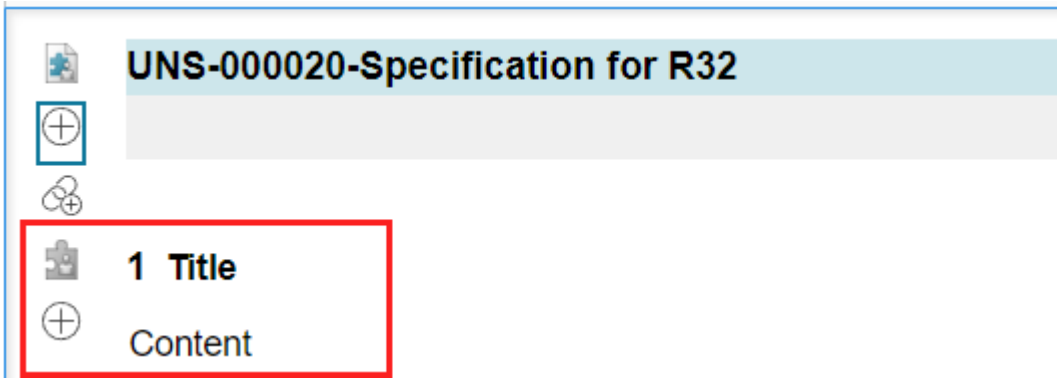
User-need specifications comprise text, graphics, paragraphs, and other specifications. You add content to the user-need specification using either a plain text editor, rich text editor, or Microsoft Word, depending on how your administrator has configured the environment. This procedure guides you through the most common process to create a user-need specification and then the add user needs and paragraphs to the specification using the text editor.

Procedure

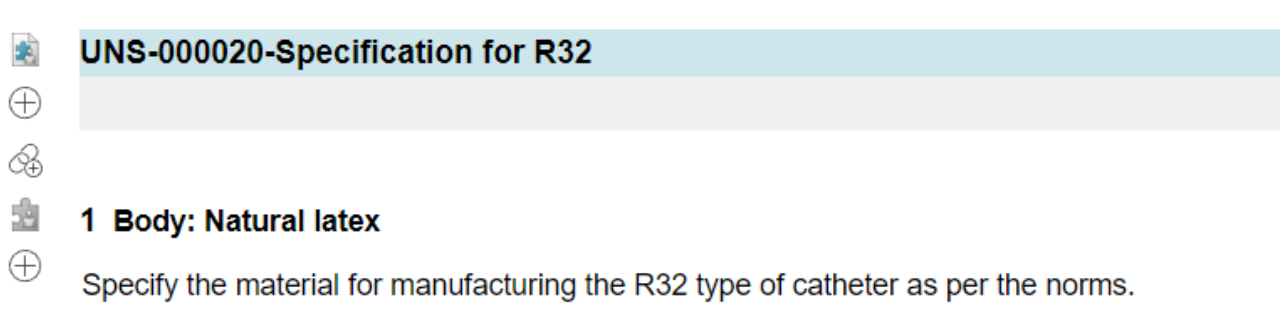
1. Open the folder to which you want to add the user-need specification, for example, **Newstuff**.
2. In **Contents**, click **Add to** ⊕.
3. In the **Add** panel, in the **Type** list, select **User Need Specification**.
4. Enter the properties for the new user-need specification, and then click **Add**.
5. Open the user-need specification under which you want to create the user need.
6. Click **Add** ⊕ and select **Sibling** or **Child** if the options are available.



A new entry appears and the paragraph numbers update automatically.



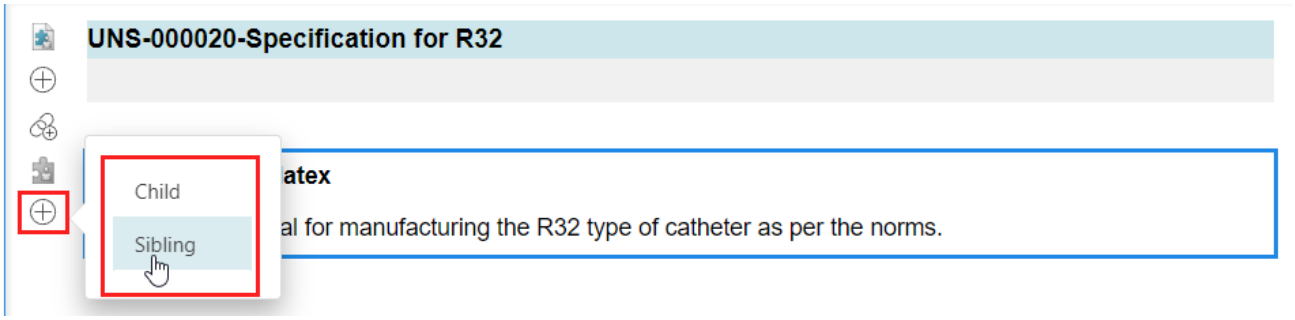
7. Edit the title and contents as required.



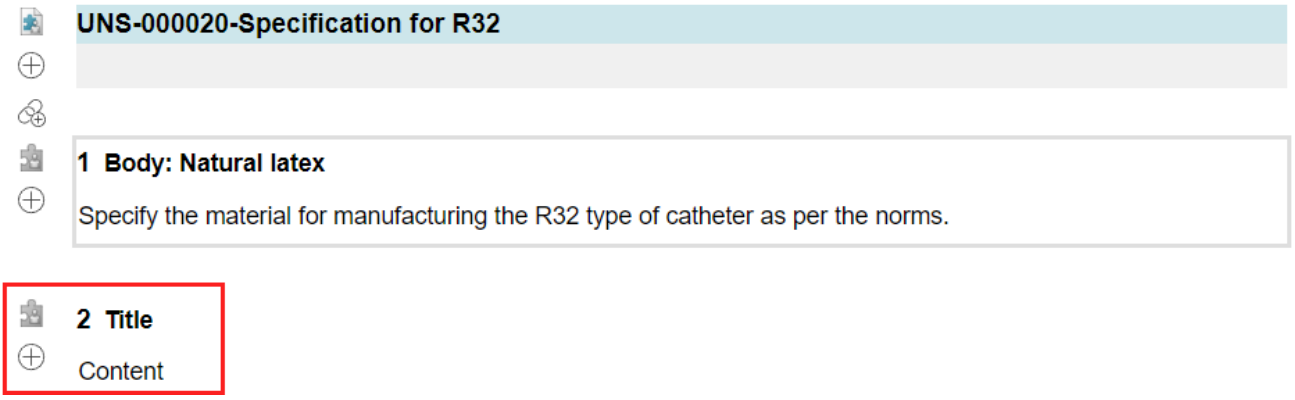
Note

Do not enter a requirement number in the title. The number is generated automatically.

8. To add another user need, on the left of the user need that you created previously, click **Add** ⊕ and select **Sibling** or **Child** as required.

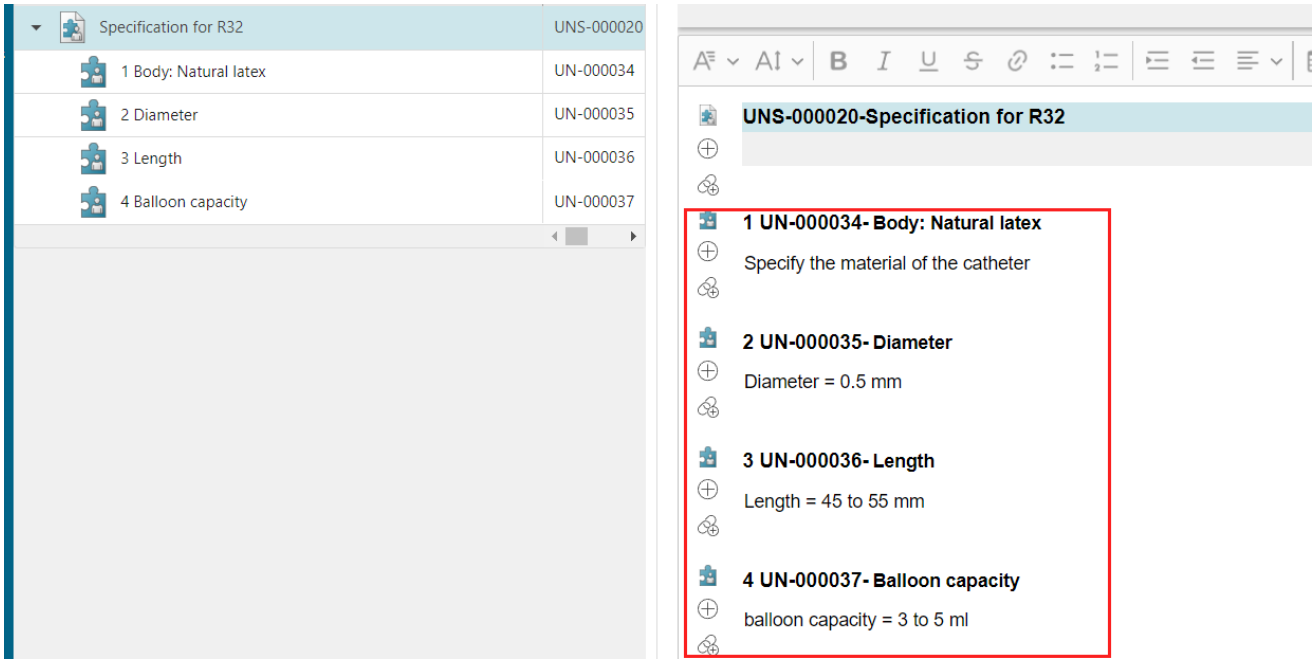


A new entry appears and the paragraph numbers get updated automatically.



9. Edit the title and contents as required. Repeat similar steps to specify the user needs for the user-need specification.

10. Save your changes.



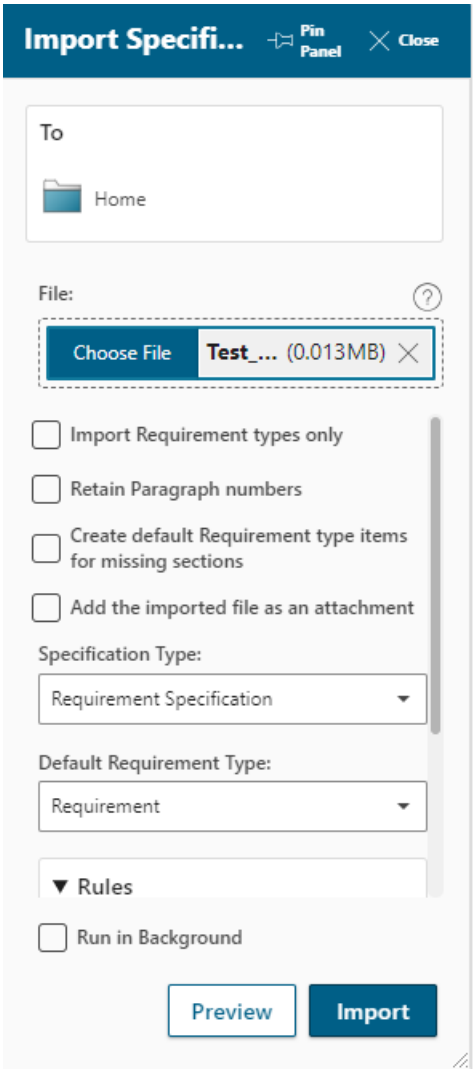
Create user-need specifications by importing a document from Microsoft Word

You can import Microsoft Word documents using heading styles or keywords into PLM for Medical Devices. During import, the system looks for keyword matches or style matches in paragraphs and imports such paragraphs (where matches are found) into separate user-need specifications. If there are no matches found among the given rules, then the paragraph is imported as the default type specified in the import panel.

Procedure

1. Click **Folders** and navigate to the folder where you want to import the user-need specification, but do not select any objects within the folder.
2. Click **More Commands** > **Import/Export** > **Import Specification**.
   The **Import Specification** panel opens.
3. Navigate to the Microsoft Word document location, and click **Open**.

   The import panel opens.

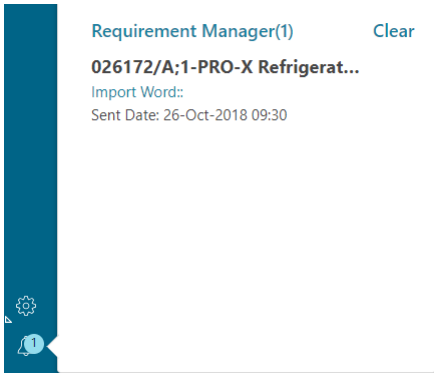


4. From the **Specification Type** list, select **Requirement Specification** and from the **Default Requirement Type** list, select **Requirement**, which is the default type when there is no match found for the supplied rules.
5. (Optional) To load saved rules, click the **Saved Rules** list.
6. (Optional) To create rules, click **Add Rules** ⊕.
7. (Optional) Perform any of the following:
   - To add another rule, repeat Step 6.
   - To save the rule, click **Save Rule**, and name the rule. Select **Global Rule** to apply the rule for all users.
8. (Optional) Click **Preview** to preview the user-need specification. If you add a rule, you can update this by clicking **Update Preview**.
9. Click **Import**.
   The import process begins and a scrolling bar at the top of the screen indicates the object ID and that the process is still running. You receive an alert when the import process is complete.

Note

If the requirements are already loaded, there is no way to determine if the import is complete. You must manually refresh the page to determine if the import is complete.

10. Click the alert icon and then select the **Requirement Manager** notification.



11. Click the specification name in the notification.
The specification opens in the **Table** view.

Create the Excel template for importing user-need specifications

You can create user-need specifications by importing a file from Microsoft Excel. However, the Excel files you want to import must follow a specific format. This procedure shows how to create the Excel template that you can use as a reference to create the Excel spreadsheet that contains the user-need specification data.

Procedure

1. Open a blank Excel spreadsheet.
2. **Cell A1** must contain the header **`Tc_Level`**, indicating the hierarchy within the specification. Here, 0 is the specification level, level 1 is the requirement level, level 2 is the paragraph level, and so on. Cell A1 is highlighted in the graphic.
3. **Cell B1** must contain the header **`Tc_ObjectType`**. **Object Types** include the highest level such as **RequirementsSpecification** and subtype levels such as **Requirement**, **Target**, and **Paragraph**. Cell B1 is also highlighted in the graphic.
4. Add other columns as necessary. All other fields represent the data that you want to import.
5. At the end of the file, **<endtag>** is required in column A, as shown in the following graphic.

	C	D	E
e	**Title**	**Information**	**Component Description**
pec	[redacted]cle Requirements	[redacted] Requirement	
	Complete Vehicle System	**REQ-10-Complete Vehicle System**	In principle, a complete vehicle control system involves [redacted] controls all aspects of the vehicle.
	Vehicle System Specification	**REQ-11-Vehicle System Specification**	[redacted] defines the set of vehicl
	Reserved	**REQ-12-Engine Compartment Installation**	The engine compartment wiring harness W32 connects th
	Engine Compartment Installation	**REQ-121-Noise - Exterior**	Dealing with exterior noise is an exceedingly common noi
	Fuel Economy	**REQ-20-Body System**	The motor system is the part of the central nervous syste with moveme
	Noise - Exterior	**REQ-21-Body Structure Subsystem**	This is part of motor system
	Noise - Interior	**REQ-211-Body Closure Subsystem**	[redacted] Functional Subsystem etc
	[redacted]	**REQ-2111-Rear Side Doors**	A vehicle typically has [redacted] doors: front doors an
	[redacted]	**REQ-212-Suspension System**	Suspension is the system of tires, tire air, springs, shock ab linkages that connects [redacted] between the two.
	Type Approval & Def/Class	**REQ-30-Frontt Wheel Alignment Specs**	[redacted]
	MATLs & Restricted Substances	**REQ-31-Front Springs**	[redacted]
	Vehicle System Specification	**REQ-40-Vehicle System Specification**	[redacted]
	Reserved	**REQ-50-Engine Compartment Installation**	The engine compartment wiring harness W32 connects th

Create user-need specifications by importing a document from Microsoft Excel

You create user-need specifications by importing a document from Microsoft Excel.

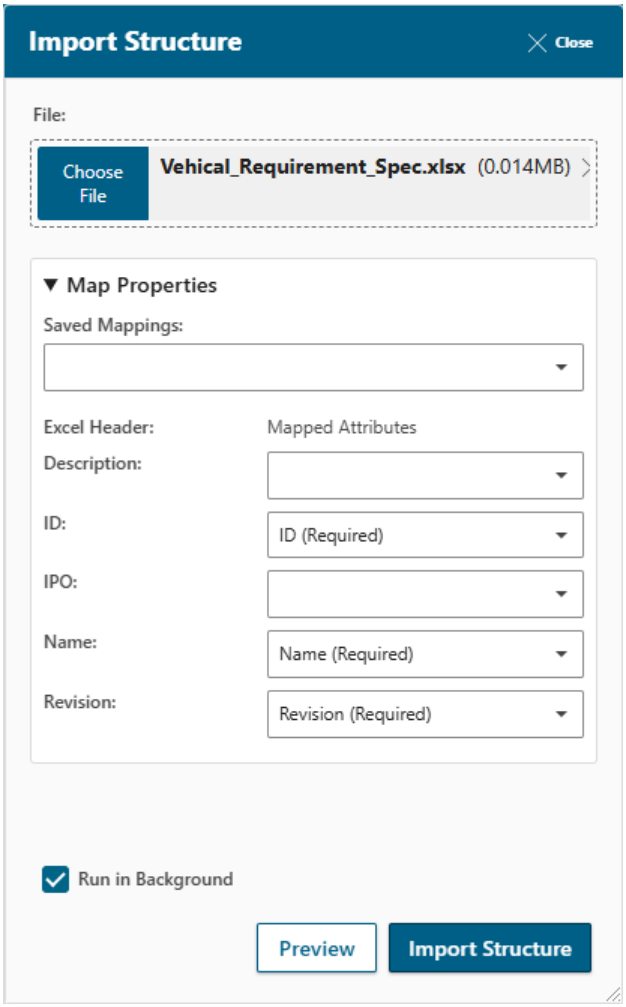
Prerequisites

You must first **create an Excel template** and use it to create that the Excel sheet that you want to import.

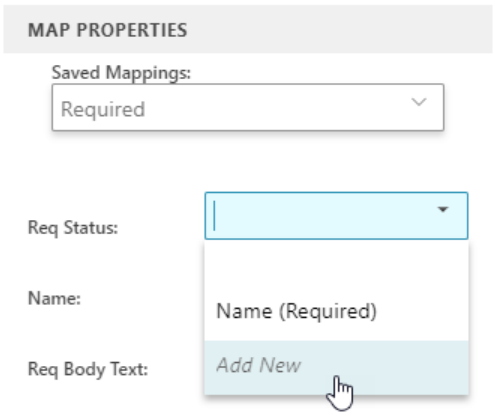
Procedure

1. Navigate to the folder where you want to import the requirement specification, but do not select any objects within the folder.
2. Click **More Commands** ••• > **Import/Export** > **Import Specification**.
3. Click **Choose File**, navigate to the Microsoft Excel file location, and then click **Open**.
   The **Map Properties** fields appear in the **Import** panel.

> **Note**
> It can take several seconds for the system to verify that the spreadsheet structure is valid.

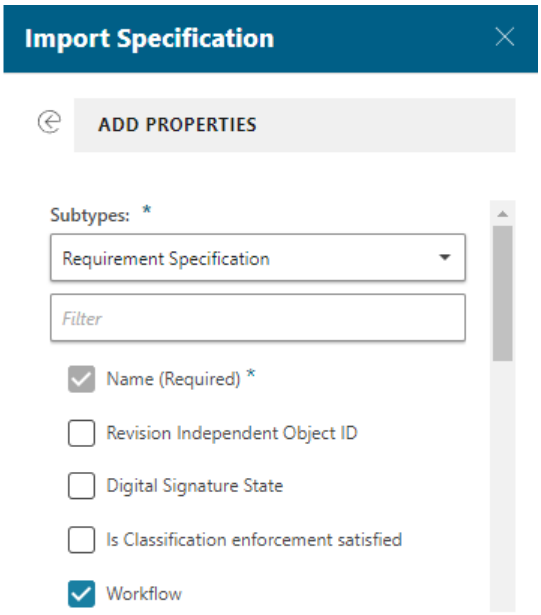


4. Do one of the following:
   - To use a saved mapping, click the **Saved Mappings** list, and select a mapping.
   - To create and save a mapping, click the **Saved Mappings** list, and click **Add New**.
5. Do one of the following:
   - If you are using a saved mapping, select the properties to match from each list.
   - If you are creating a mapping:
     a. Click a list and click **Add New**.



The **Add Properties** panel appears.

b. Select the check box for each property that you want to add.



c. Click **Add**

The added properties now appear in the lists.

6. Click **Import**.
The import process begins and a scrolling bar at the top of the screen indicates the process is still running. You receive an alert when the import process is complete.

7. Click the alert and then select the **Requirement Manager** notification.

8. Click the **Import Specification** notification, and then click the **Related Objects** to link it to your imported specification.

Submit user-need specifications and user needs for review

You can start a review process for any user-need specification, user need, or paragraph. In most cases, you select a signoff team and submit the objects for their review and approval.

Procedure

1. Locate the user-need specification or user need that you want to review, and on the primary toolbar, click **More Commands** ••• > **Manage** > **Submit to Workflow**.
   The **Submit to Workflow** panel and a list of workflow templates is displayed.
2. Enter a description for the workflow participants, select the appropriate workflow template, and then click **Submit**.

   If a default workflow is defined for the selected object, it is automatically selected as the workflow template.

   Depending on the workflow, you may be required to assign the signoff team to approve the user-need specification or user need. You receive a task to create the signoff team in your **INBOX** tile on the **My Tasks** tab. An approval task is assigned to each signoff participant that you select.
3. To review your tasks, do any of the following:
   - You and your team must check your **Inbox** for workflow tasks and to view the related attachments, workflow, and targets.
   - Open the user-need specification or user need in the **Table Summary** view, and click the **Workflow** tab.

   For more information about reviewing and releasing records, see **Process of reviewing and releasing records**.

5. Test management

About test management in PLM for Medical Devices

PLM for Medical Devices use Test Management for the verification and validation process to ensure that the medical device meets the established requirements and specifications.

Validation assures that the product meets the demands of the customer and any other identified stakeholders. Verification, is meant to evaluate whether a product, service, or system complies with a regulation, requirement, specification, or other imposed condition. Validation can be expressed as *Are you building the right thing?* and verification by *Are you building it right?*. Building the right thing refers to the user's needs, while building it right checks that the specifications are correctly implemented by the system.

You can initiate and manage tests that fully describe a task (typically an analysis or test) that the tester performs. It references the related elements and also describes the purpose of the task in sufficient details such that the recipient understands:

- What they are asked to do.
- The context of the request.
- The location of the related data.
- Why they are asked to perform the task.
- The expected outputs of the task.

After the engineer specifies the user-need specifications and the user needs, the test engineer creates the test for every user-need specification. The test is then updated to include test cases, test steps, and parameters related to the testing of the medical device. After the tests are performed, the measured values are recorded in the test results. Depending on the minimum and maximum permissible values defined in the parameters and the actual measured value, the system automatically marks the test as passed or failed.

Create a test for the user-need specifications

After you create the user-need specification object and the user needs, you must specify the tests.

Procedure

1. Open the user-need specification or user need for which you want to specify the test.
2. Click **More Commands** ••• > **New** > **Create Test**.
3. In the **Create Test** panel, from the **Type** list, select **Test**.
4. In **Properties**, specify the following:

- **Name**
- **Description**
- **Inclusion Rule**

5. Select the **Open on Create** check box to open and view the test after you create it.
6. (Optional) In **Projects**, specify the project.
7. Click **Create**.
   The test revision object is created and opened in Teamcenter. You can add the requirements, various test cases, and test parameters. You can also view the summary and the test results.

   To assign other design engineers and test engineers to your test, click the **Participants** tab and specify the required users.

Submit a test to the test engineer

You can use your company's workflow to manage all assignments given to test engineers or assign other design engineers and test engineers to your test.

Procedure

1. The design engineer creates and populates the test. The design engineer:
   - Adds and configures each domain as a 150% structure, for example, the system model, requirements, and test cases.
   - Adds elements to the test.
   - Sets the input and output parameters.
   - Creates studies, simulation requests, test requests, test events, and runs for the test. The design engineer then adds elements, sets a variant rule on the domain and structures for the test package (if appropriate), and assigns the input and output parameters.
   - Assigns one or more test (simulation) engineers to the test by opening the **Participants** panel and clicking ⊕. On initial creation, no test (simulation) engineers are assigned to the test.
2. The design engineer marks the test as complete in the workflow task.
   The system locks the input data of the test and studies and assigns a review task to the test engineer.

   Caution

   Do not modify the domain structures once the test is complete. The structures must be static and released.
3. The test engineer reviews the configuration of the test and accepts it in the workflow task.
   The system sets the test to an analyzing state.

Note

If the test engineer rejects the test, the system returns it to the design engineer for rework.

4. The test engineer starts verification, performs the tests, and updates the outputs of the test and studies with measurements.
5. The test engineer marks the verification task as complete.
   The system locks the output data and assigns a review results (analyzed) task to the design engineer.
6. The design engineer reviews and accepts the results.
   The design engineer publishes the results from the test to the domain models. The system unlocks the domain structures, adds a baseline to the test, and releases the test revision. The workflow is now complete.

Specify the user needs for the test

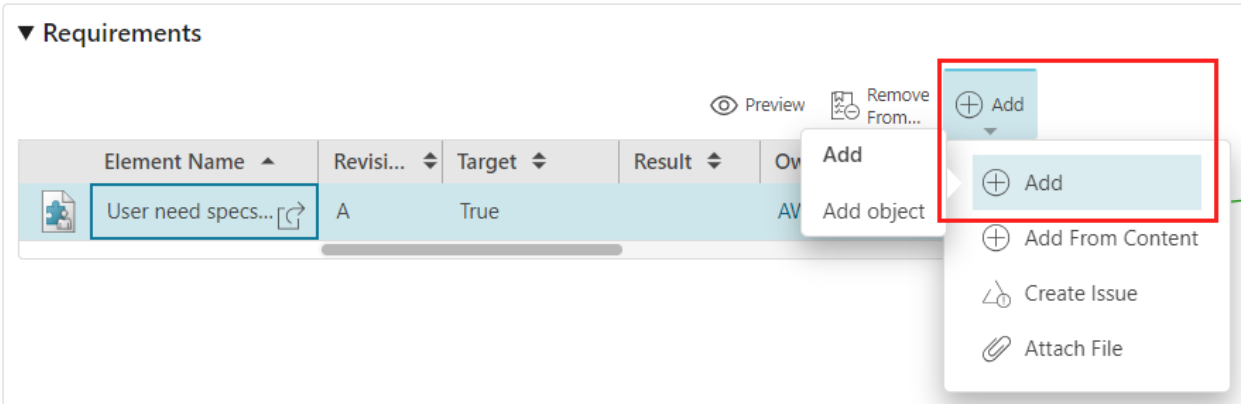
After you create the test, if it is not specified already, you can specify the user needs for which you are creating the verification and validation tests. You can create new user needs or search for and add existing user needs.

Procedure

1. To specify the user needs, do one of the following:

   Add existing or new user needs

   a. Open a test revision object and in the **Requirements** section, click **Add** ⊕.

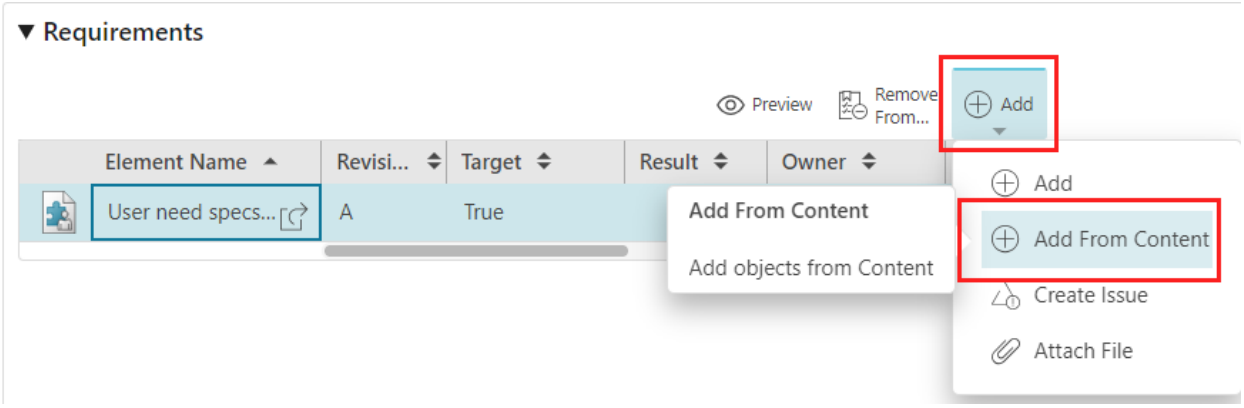


   b. In the **Add** panel, search for an existing requirement or create a new requirement.

   OR

   Create and add user needs from the Content tab

   a. Open a test revision object and in the **Requirements** section, click **Add From Content** ⊕.



b. In the **Add From Content** panel, add the required user needs.

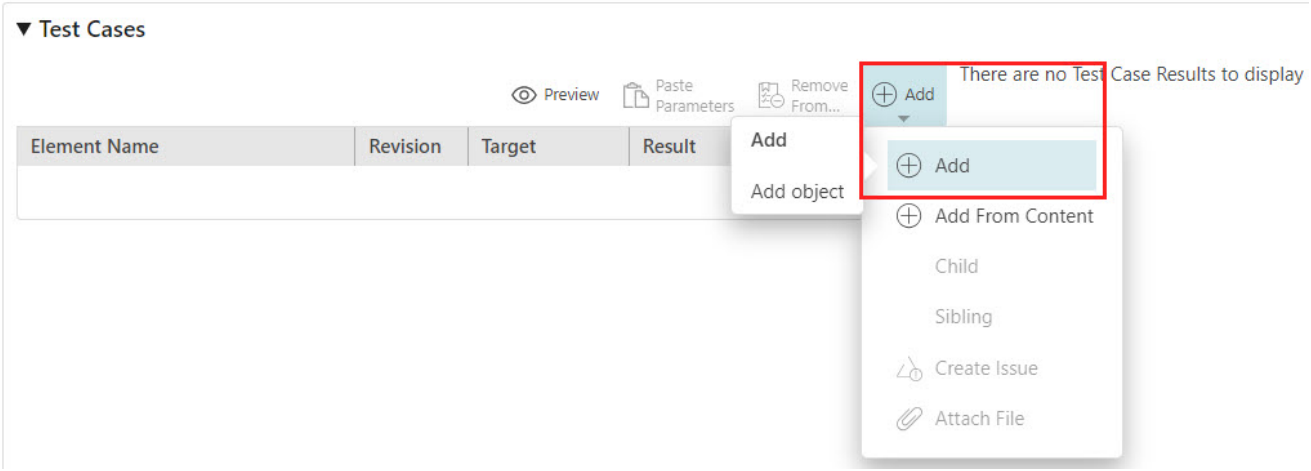
2. Click **Add**.

Create test cases

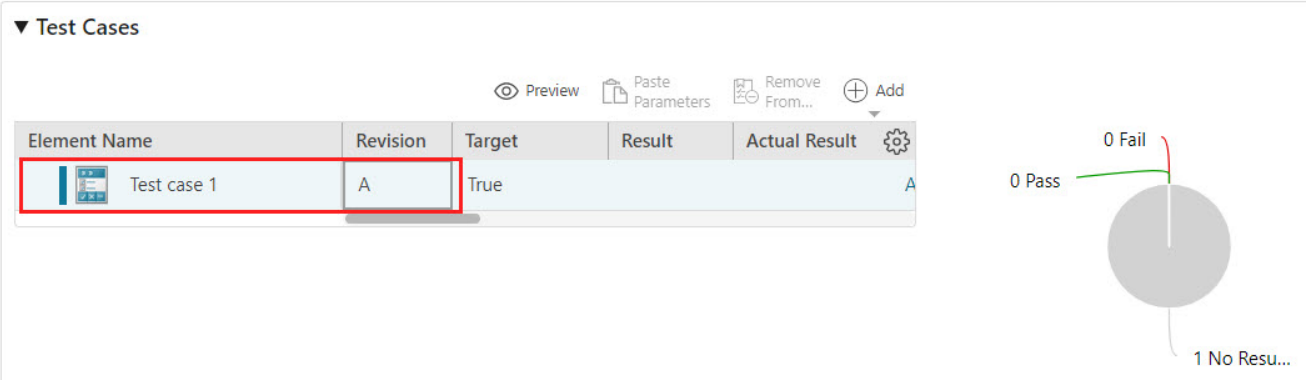
After you specify the tests for each user need, you can create the test cases.

Procedure

1. Open the test revision object.
2. In **Requirements**, select the specification for which you want to create a test case.
3. In **Test Cases**, click **Add** ⊕ to create a test case linked to the selected specification.



4. In the **Add** panel, specify the required parameters.
5. Click **Add**.

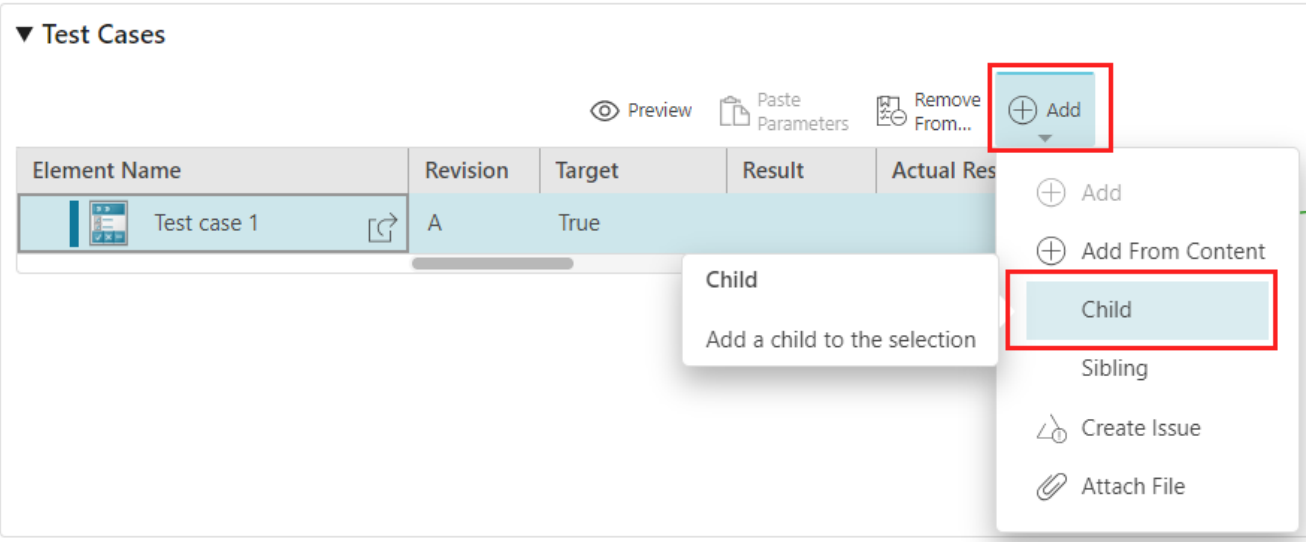


Create test steps for the test case

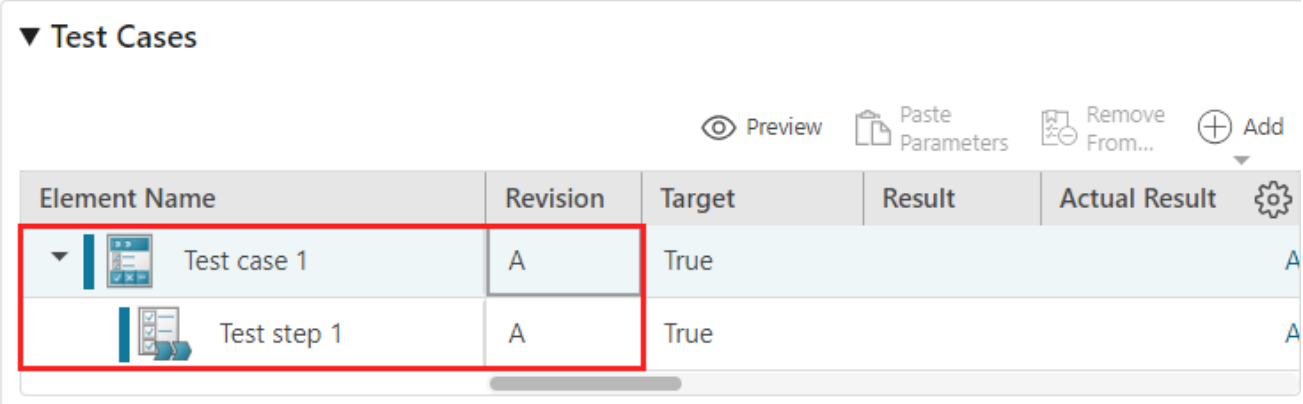
After you create the test case of each user need, you must specify the test steps.

Procedure

1. Open the test case revision object and in **Test Cases** select the test case for which you want to add the test steps.
2. Click **Add** ⊕ > **Child**.



3. In the **Add** panel, from the **Type** list, select **Test Step** and specify the required parameters.
4. Click **Add**.



5. Repeat steps 2 - 4 to add more test steps as required.

Results

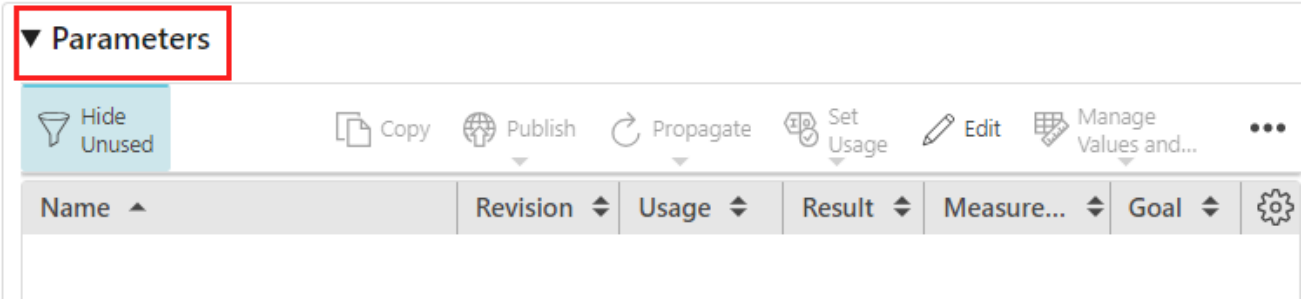
After you have specified the test steps for the test case, you can **create the parameters** for testing the medical device.

Create the parameters

Test parameters define the characteristic of a medical device that provide the measurement of form, fit, and function in terms of its expected behavior. These parameters are used as reference limits when the tests are performed. If the measured value is within the limit, the test is automatically marked as **Pass**. If not, it is marked as **Fail**. You must search for or create parameters before users can add them to the test cases.

Procedure

1. Open the test case revision and click **Parameters**.
2. Click **Add to** ⊕.



The **Add** panel initially displays all parameter definitions for all dictionaries associated with the project or group. If no parameter definitions are associated, it displays all parameters in the system.

> **Note**
> You can also search for a parameter and add it to the test step.

3. (Optional) Click the **Filters** tab and select one or more filters to refine the list of parameter definitions.

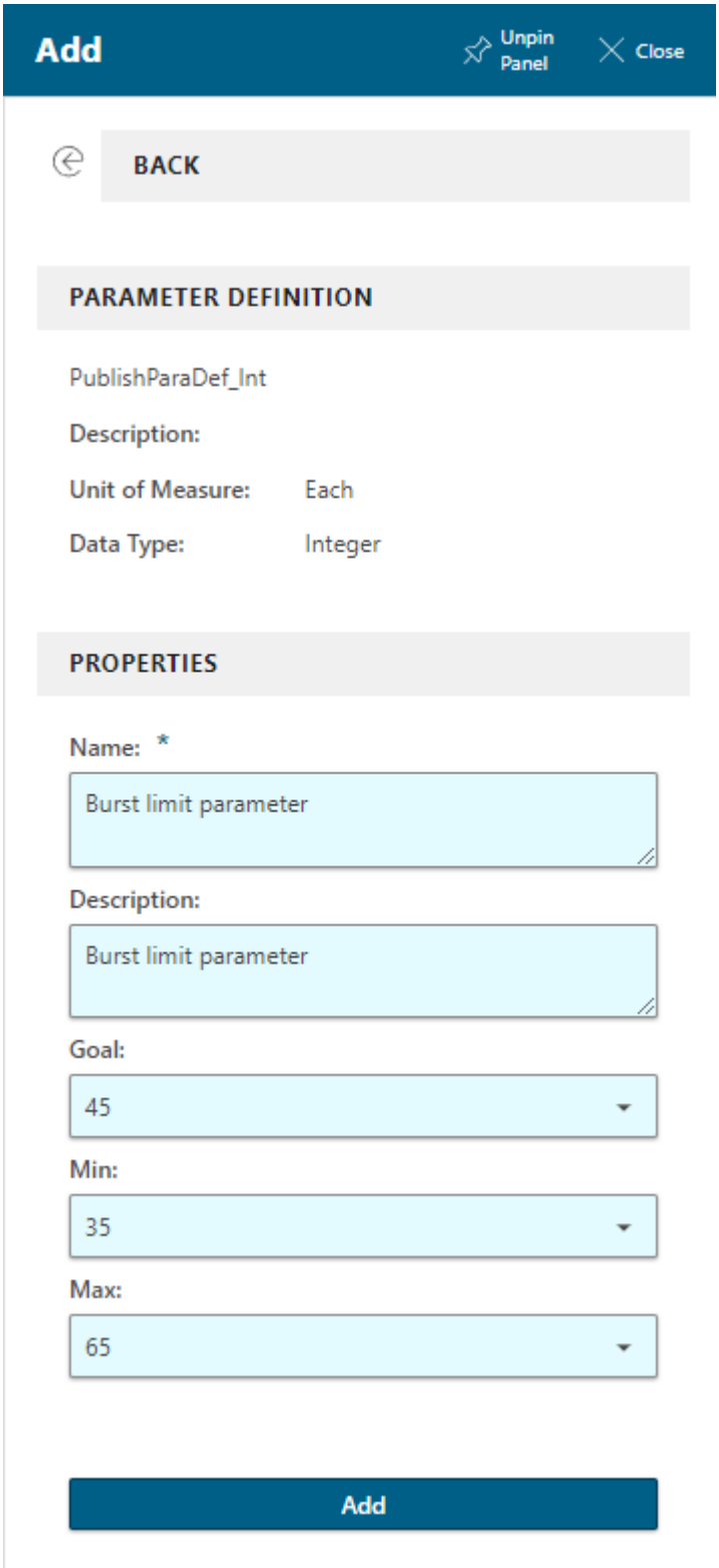
   Click the **Results** tab to see the list of filtered parameter definitions.

   You can also use the search box to further filter the list by parameter definition name.

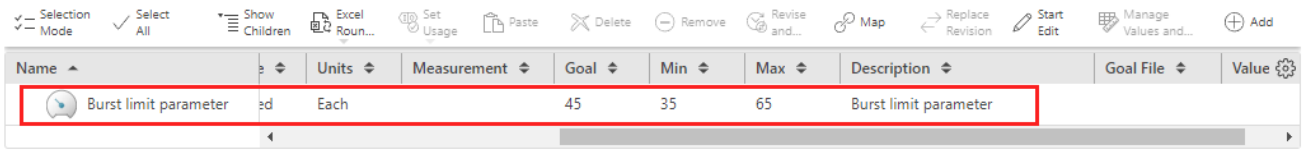
4. Select a parameter definition and click **Add**.

5. In **Properties**, enter the necessary property values.

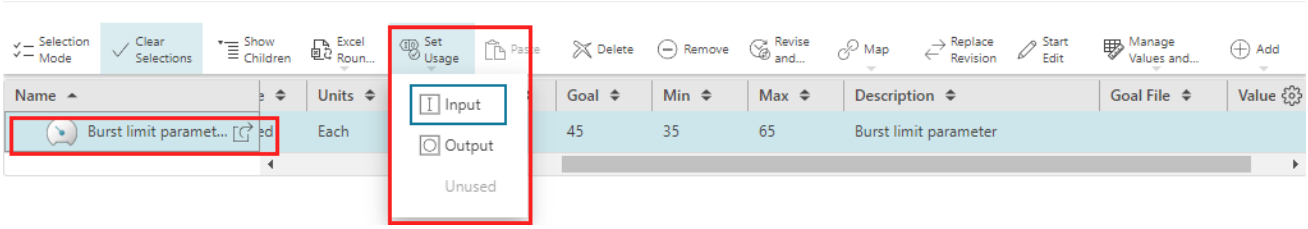
   The name, description, and value fields are prepopulated from a parameter definition but you can change the defaults if necessary. However, the parameter name must be unique.



6. Click **Add**.
The system creates the new parameter in the parameter table for the project or group.



7. After you create a parameter, you must specify its intent. To do this, select the parameter and click **Set Usage** at the top of the table, and choose **Input** or **Output** as appropriate.



Submit test management objects for review

After you add the test revisions, test cases, test steps, or parameters, you can start the review process for them. In most cases, you select a signoff team and submit the objects for their review and approval.

Procedure

1. Locate the object that you want to send for review, and on the primary toolbar, click **More Commands** > **Manage** > **Submit to Workflow**.
   The **Submit to Workflow** panel and a list of workflow templates is displayed.
2. Enter a description for the workflow participants, select the appropriate workflow template, and then click **Submit**.

   If a default workflow is defined for the risk analysis object, it is automatically selected as the workflow template.

   Depending on the workflow, you may be required to assign the signoff team to approve the requirement. You receive a task to create the signoff team in your **INBOX** tile on the **My Tasks** tab. An approval task is assigned to each signoff participant that you select.
3. To review your tasks, do any of the following:
   - You and your team should check your **Inbox** for workflow tasks and to view the related attachments, workflow, and targets.
   - Open the object in the **Table Summary** view, and click the **Workflow** tab.

   For more information about reviewing and releasing records, see **Process of reviewing and releasing records**.

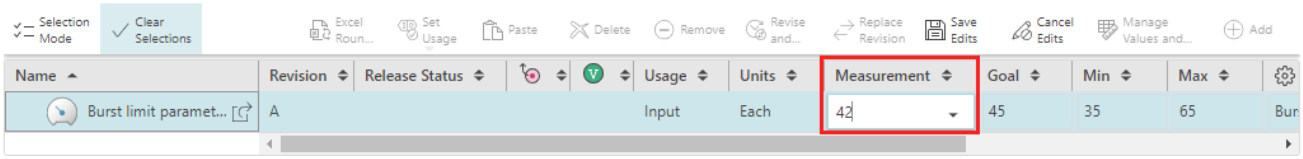
Record the test results

After you have created the test cases and the test steps for each test case, the test engineers perform the tests as specified and record the test results for each defined parameter.

Procedure

1. Open the user-need specification for which test cases are created.
2. In **Parameters**, select the test case revision and the test step for which you want to enter the test results.
3. Click **More Commands** ••• > **Edit** > **Summary** .

   The **Parameters** table can now be edited.
4. In the **Measurement** cell, enter the actual value that was recorded after the test was performed.



5. Click **More Commands** ••• > **Edit** > **Save Edits** to save your changes.

Results

If the actual measurement value is within the **Min** and **Max** values specified in the parameter definition, the system automatically marks the test step as **Pass**. If the value is not within the range, the test is marked as **Fail**.

Generate the test report

You can generate a test report to view or share the test results.

Procedure

1. Open a test and select the object for which you want to generate the report.
2. Click **More Commands** ••• > **New** > **Generate Report**.
3. In the **Generate Report** panel, select a report, complete the **FORMAT** dialog box (if available), and then click **Generate**.
   The system generates the report and downloads a local copy to your machine.

6. Labeling and UDI management

Overview of labeling and UDI management in PLM for Medical Devices

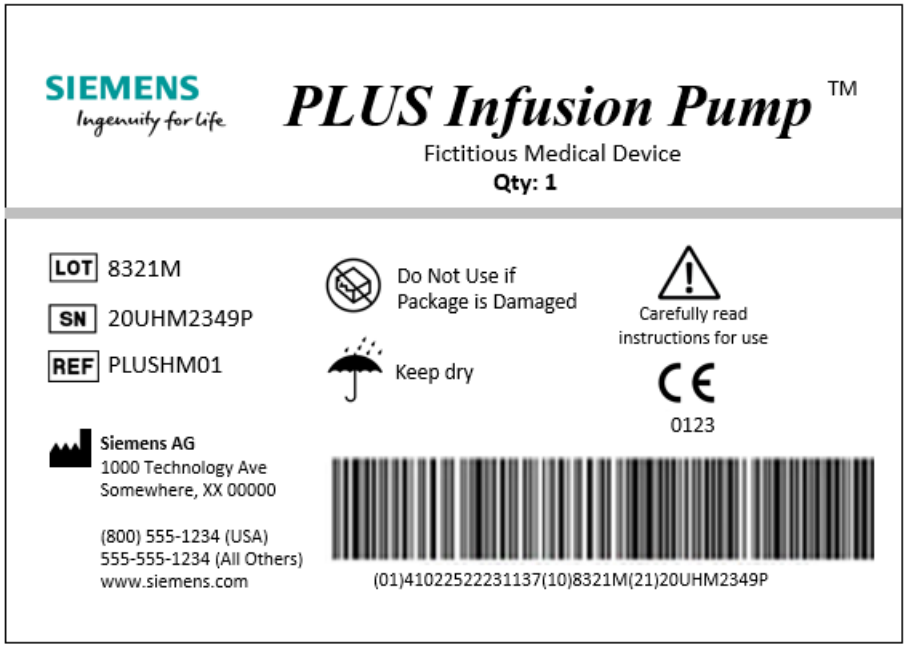
The process of labeling comprises the designing, generation, and management of all labels and other printed or graphical elements created for a medical device. It includes all physical or electronic content that is distributed regarding the usage and handling instructions, advertising, or any packaging of the medical device.

The labeling of medical devices is subject to complex regulations and requirements from regulatory bodies. One such global requirement is that the medical device labels must contain the *Unique Device Identifier (UDI)* information. The UDI is a combination of the device identifier (DI) and the production identifier (PI). The DI in turn consists of static information such as the barcode, logos, symbols, and label, whereas the PI contains dynamic information such as the lot code, serial number, and date of manufacture. The DI record aspect of UDI also contains additional data that must be controlled and submitted to the relevant regulatory bodies.

To generate a complete factory label, multiple design assets such as logos, claims, and warnings must be combined in addition to the UDI data.

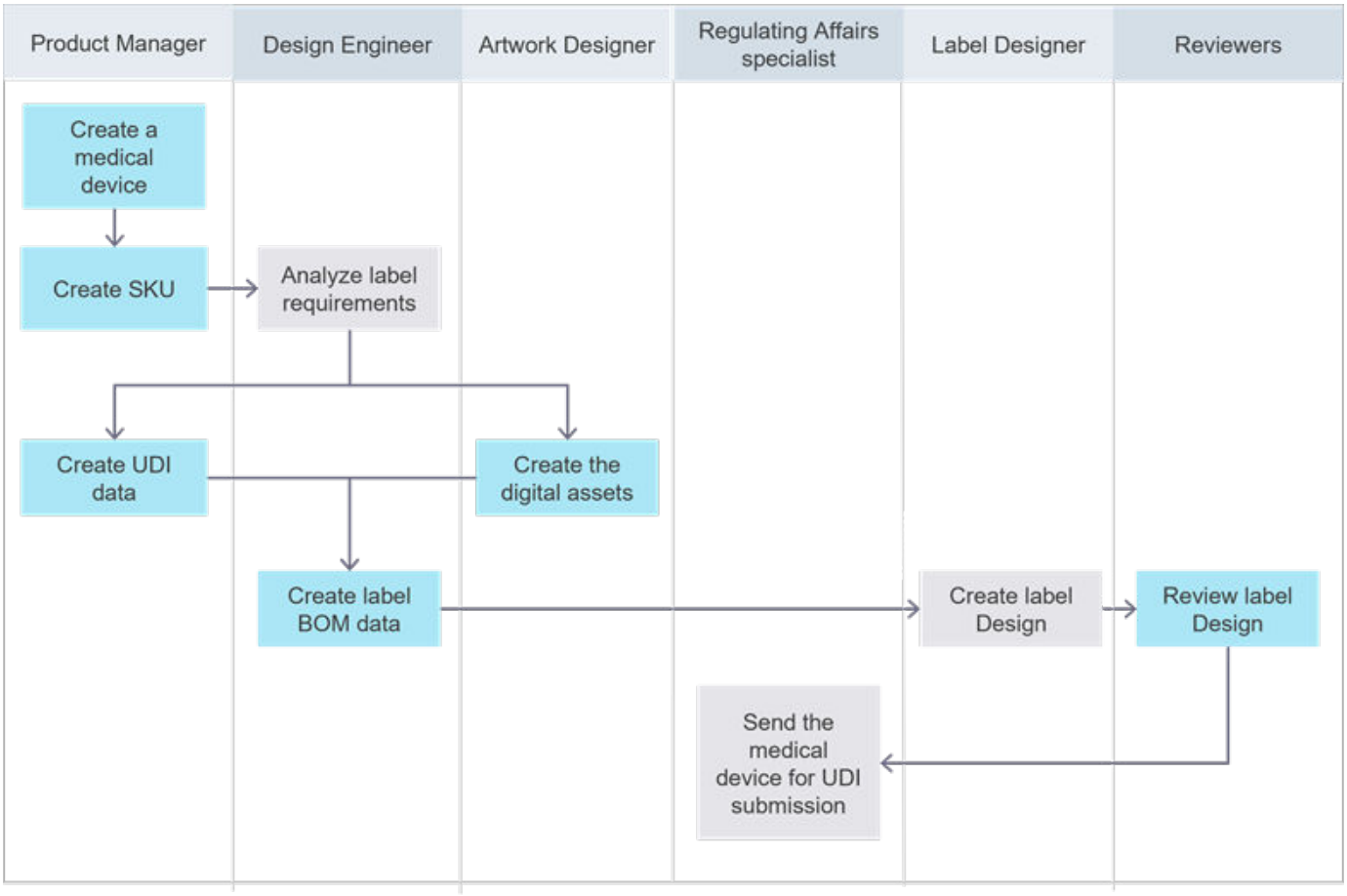
PLM for Medical Devices provides the capability to manage the records and labeling data for regulatory submissions and the production of compliant label designs. You can:

- Create and manage UDI records within the context of the product and SKU hierarchy.
- Integrate third-party tools required for authoring the software digital assets and UDI records.
- Submit the UDI records to regulatory authorities.



Task flow of labeling design management in PLM for Medical Devices

The following graphic shows the labeling and submissions management process in PLM for Medical Devices.



Create a medical device

Creating and managing a medical device

If you create a new medical device or variants of a device based on existing devices, you must create a SKU or the medical device identifier (DI) for each device variant. After creating SKUs, you can also create higher-level packaging SKUs, which specify the dimensions and specifications for multiple products for storage or shipping purposes.

UDIs can be created in the context of a medical device (for EU regulatory) or SKUs. To obtain a UDI you must perform the following tasks:

- **Create a medical device**.
- **Classify a medical device**.
- **Create a EU basic UDI record**.
- **Create a SKU for the device**.
- **Apply for a DI from the issuing agency externally**.
- **Specify the dimensional values for your device in the SKU**.
- **Update the value received from external agency in the SKU**.
- **Create the higher level packaging SKU**.
- **Create a DI record for your device within the SKU**.
- **Prepare the SKU device identifier record for UDI submission**.

Create a medical device

To manage the SKU, packaging, and labeling information for a device in Teamcenter, you start by creating a medical device object.

Procedure

1. Navigate to and open a folder, for example, **Newstuff**.
2. Click **Add to**.
3. In the **Add** panel, in **OTHER**, type **medical device** and select **Medical Device** from the results.
4. Enter the required properties for the new medical device.
5. In **PROJECTS**, click **Add Projects** to specify the related project.
6. Click **Add**.

Results

The **Medical Device** object is created in the specified folder. You can now add the dimensions and the storage and handling conditions for the medical device.

Classify the medical device

The medical device revision must be classified to enable standard device parameter access.

Procedure

1. Open the medical device revision that you want to classify and click the **Classification** tab.

2. In the **CLASSIFICATIONS** pane, click **Add**.
3. In the **Add Classification** panel, search and select the appropriate classification applicable to your medical device.

   Do one of the following:

   - In the **Filter** search box, type the name of the class and press Return.
   - Select subclasses from the list of available classes.
   - Search for a class based on classification parameters.
4. Click **Classify**.

What to do next

Once the medical device is classified, specify the device size and the storage and handling parameters that are used when creating SKUs in the device record table according to a standard values for the applicable regulatory board.

Add the clinically relevant device size

After you create the medical device object, you define the device size by specifying its properties, including the volume or weight of the device. These values then serve as a repository to choose from when coming up with the variations of the device. For different usage of the medical device, you may want variants of the device in different sizes. The actual dimensions for these are specified in the SKU panels.

Procedure

1. Open the medical device object to which you want to add the device size dimensions.
2. In the **Overview** tab, under **Required Device Size Dimensions**, click **Add** ⊕.
3. In the **Add** panel, under **PROPERTIES**, select the device size dimension **Name** from the list.
4. Enter the **Description** and select the **Precision** and the **Unit of Measure** values for the device size dimension.
5. Click **Add**.

Add the storage and handling conditions for the medical device

You can also define the storage and handling attributes applicable for the medical device. The different materials used in developing a device may also require different storage conditions. For example, for the infusion pump, you may want to include information about the different storage temperatures required to maintain the infusion pump. The actual value for the storage conditions is specified in the SKU panels.

Procedure

1. Open the medical device object to which you want to add the storage and handling dimensions.
2. In the **Overview** tab, under **Required Storage and Handling Conditions**, click **Add** ⊕.
3. In the **Add** panel, under **Properties**, select a **Name** for the storage and handling dimensions you want to define for the device. For example, you might want to define the *Special Storage Conditions* for the infusion pump.
4. Enter the **Description** and select the **Unit of Measure** for the selected storage or handling conditions dimension.
5. Click **Add**.

Create a Basic UDI record for the EU regulatory board

Apply for a Basic UDI number from the external issuing agency

If your medical device requires approval from the EU regulatory board, you must create an *EU Basic UDI* record for the medical device. The *EU Basic UDI* record is a unique code associated to the medical device for device-related information in the Eudamed database applicable to the EU regulatory body. It identifies and connects devices that have the same purpose, risk class, and essential design and manufacturing characteristics. It is not used in the packaging or labeling of the device. This DI information, which is enclosed within the Basic UDI record, is then applicable to the DI records for all SKUs associated with the medical device.

To create the EU Basic UDI record, you must first apply for a Basic UDI number from the external issuing agency affiliated with the regulatory body. When you receive this number from them, you can update the value in the **Basic UDI record** panel.

Create a Basic UDI record for the medical device

After receiving the Basic UDI number from the EU regulatory body, you must create a Basic UDI record for the medical device. The DI information within the Basic UDI record is then applicable to the DI records for all SKUs associated with the medical device.

Note

Currently, only the EU regulatory board requires a Basic UDI record to be created for a medical device.

Procedure

1. Open the medical device identifier object.
2. Click **More Commands** ••• > **New** ✳ > **Add Basic DI Record**.

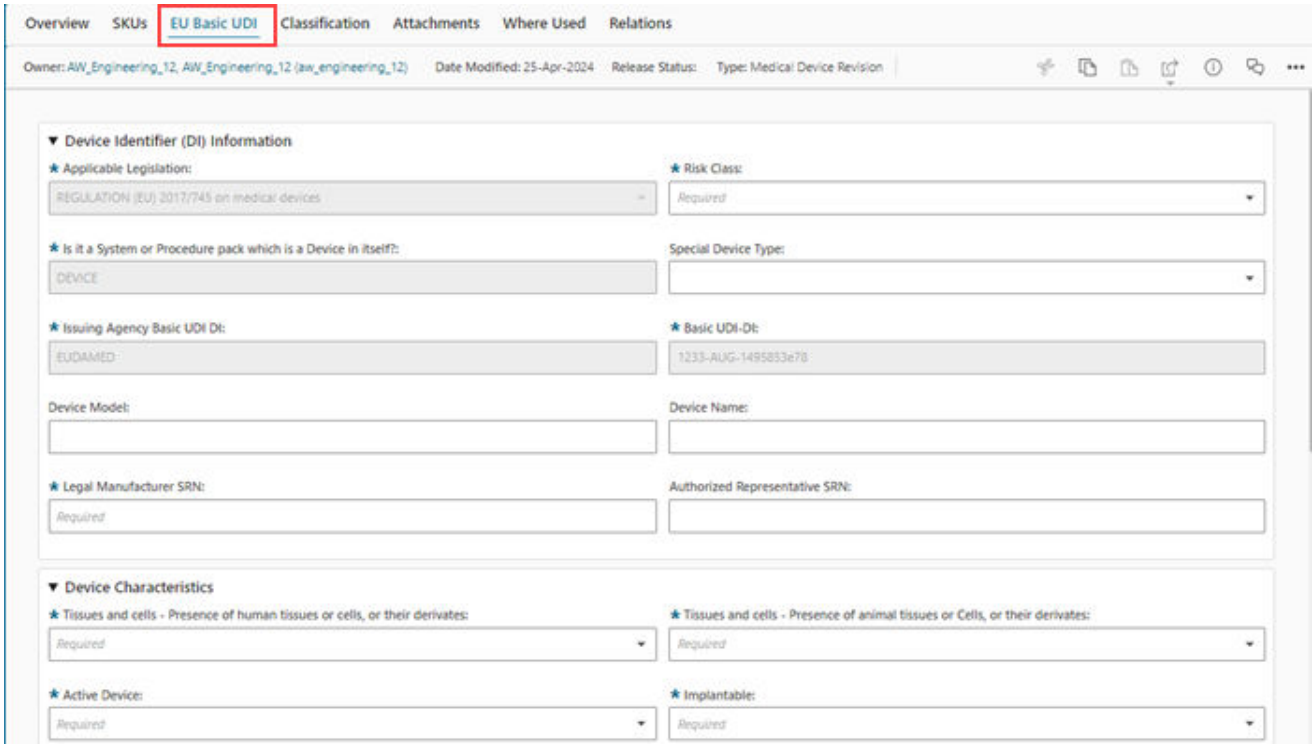
3. In the **Add** panel, specify a **Name** for the EU Basic DI record.

   Specify values for the other fields in the **Add** panel as necessary.

4. Specify the Basic UDI-DI value obtained from the issuing agency.

5. Click **Add**.

   A new **EU Basic UDI** tab is displayed for the medical device. The EU Basic UDI record is a form that displays different fields based on the regulatory body you selected for the medical device revision.



6. Specify values for all the fields displayed within the **EU Basic UDI** tab. Some fields in the EU Basic UDI record form are prepopulated with values.

7. Click **Save** to save the EU Basic UDI record with the specified values.

Delete a Basic UDI record

You can remove the basic UDI record from the medical device revision, if required. You must first delete the SKU revision to delete the basic UDI record revision.

Procedure

1. Open the medical device revision.

2. Click **More Commands** ••• > **Edit** ✎ > **Delete Basic DI Record**.

   The **EU Basic UDI** tab is disassociated from the medical device revision.

Create and manage SKUs

About SKUs for medical devices

Item SKU contains the specific Device Identifier information. The SKU will be created for a specific regulated market and the respective labeling requirements. The DI numbers are acquired from accredited issuing agencies such as GS1. The SKU object contains information such as the primary DI number, the issuing agency, related higher level SKUs, clinical size, and storage and handling information. Within the SKU object the complete DI record is managed as an attachment. There are many data validation rules imposed by the Health Authority. The DI form helps guide a user through these rules in order to achieve a successful submission.

Create a SKU

If you create a new medical device or variants of a device based on existing devices, you must create a SKU or the medical device identifier (DI) for each device variant. The SKU contains the device identifier information. The SKU is created for a specific regulated market as well as for a different dimension defined for the medical device. The DI numbers can be obtained from the issuing agencies affiliated with the selected regulatory body.

Procedure

1. Open the medical device object to which you want to add the SKU.
2. In the **SKUs** tab, click **Add** ⊕.
3. In the **Add** panel, under **PROPERTIES**, enter a **Name** for the medical device identifier.
4. Select the **Regulatory Body** applicable for your device from the list.
5. Select the **Issuing Agency** affiliated to the selected regulatory body that will issue the DI for your medical device.
6. Specify the effectivity dates for your SKU in the **Effective From** and **Effective To** fields.
7. Specify other details related to the SKU and click **Add**.

   The SKU is displayed in the **Overview** panel under **EFFECTIVE SKUS**.

What to do next

When you receive the DI number from the applicable issuing agency, you then update this value in the SKU panel. You may either update this value when you are creating a SKU or later by editing the SKU revision.

Specify the dimensions for the medical device in the SKU

You can specify values for the different dimensions you defined, such as, the device size and storage and handling conditions, you can specify the values for those dimensions in the SKU, that is, the medical device identifier revision.

Procedure

1. Open the SKU or the medical device identifier object.
2. In the **Overview** tab, under **DEVICE SIZE**, specify the **Value** of the device size. If the **Unit Of Measure** is not defined for the dimension, you can provide the value in the **Special Text** column.
3. In the **Overview** tab, under **STORAGE AND HANDLING**, specify the values for the storage and handling dimensions defined for your medical device.

Apply for a DI number from the external issuing agency

You must apply for a device identifier, DI value from the external issuing agency affiliated with the applicable regulatory body. When you receive the DI number from the issuing agency, you then update this value in the SKU panel. You may either update this value when you are creating a SKU or later by editing the SKU revision. Additionally, you must request a separate DI for the packaging of your device when applying for a DI for the SKU. This packaging DI value is used while creating the higher-level packaging SKU.

Create and manage UDI data

About unique device identifiers

PLM for Medical Devices provides the capability to manage the *Unique Device Identifier* or *UDI*. This allows medical device manufacturers to make their products globally identifiable and scannable and also include the product data in the UDI regulatory database. A UDI provides data and instructions for the generation of the factory labels such as the barcode for the medical device.

The UDI is a unique numeric or alphanumeric code that generally consists of the following:

- **Device identifier or DI**

  A mandatory, fixed portion of a UDI that identifies the labeler (manufacturer) and the specific version or model of a device. The DI record also contains additional data that must be controlled and submitted to the relevant regulatory bodies.

- **Product identifier or PI**

  A conditional or variable portion of a UDI such as the lot or batch code, serial number, date of manufacture, or expiry date of the device, which will subsequently be included on the label of a device.

Update the SKU with the device identifier value

Once you receive the device identifier (DI) from the issuing agency, you must update the SKU with the DI value.

Procedure

1. Open the SKU or the medical device identifier object.
2. Click **More Commands** ••• > **Edit** > **Start Edit**.
3. Under **PROPERTIES**, specify the **Device Identifier** value you received from the issuing agency.
4. Click **More Commands** ••• > **Edit** > **Save Edits**.

Create a higher-level packaging SKU for the medical device

After creating SKUs, you can also create higher-level packaging SKUs, for the packaging and quantity. The higher-level SKU corresponds to the package structure of the medical devices for different packaging levels. Package DIs are collected in the primary SKU DI record. Package quantities are specified in the higher-level SKU structure and are then reflected in the DI record.

Procedure

1. Open the SKU or the medical device identifier object.
2. In the **Overview** tab, under **Higher Level Packaging SKUs**, click **Add Higher Level SKU** ⊕.
3. In the **Add** panel, under **PROPERTIES**, enter a **Name** for the package device identifier.
4. Select the **Package Type** from the list based on what type of package levels you require for your medical device.
5. Specify the **Device Identifier** value you received from the issuing agency.
6. Specify the effectivity dates for your SKU in the **Effective From** and **Effective To** fields.
7. Specify the **Quantity** of the related lower level SKU that will be included in the package level.
8. Specify other details related to the packaging SKU and click **Add**.

   The higher-level SKU is displayed in the **Overview** panel under **HIGHER LEVEL PACKAGING SKUS**.

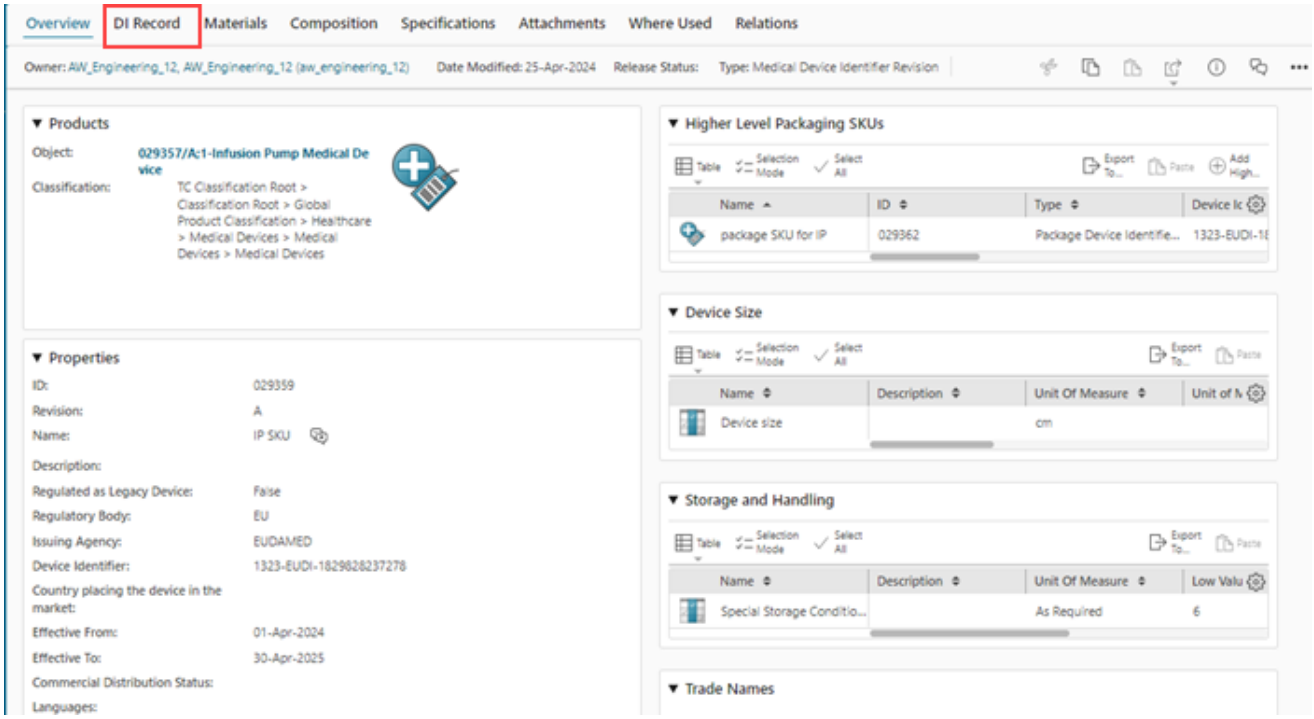
Add a device identifier record to the SKU

There are many data validation rules imposed by the health authority. The device identifier (DI) form guides you through these rules for submission. You can add DI records within the SKU revision. To create a DI record, you must have the DI information available in the SKU.

Procedure

1. Open the SKU or the medical device identifier object.
2. Click **More Commands** ••• > **New** > **Add DI Record**.
3. In the **Add** panel, specify a **Name** for the DI record.
4. Click **Add**.

   A new **DI record** tab is displayed for the SKU revision. The DI record is a form that displays different fields based on the regulatory body you selected for the SKU revision.



5. Specify values for all the fields displayed within the **DI Record** tab. Some fields in the DI record form are prepopulated with values.
6. Click **Save** to save the DI record with the specified values.

   This form can then be exported to the regulatory body to start the application process for the medical device.

Delete a device identifier record from the SKU

You can remove the device identifier (DI) record from the SKU, if required.

Procedure

1. Open the SKU or the medical device identifier object.
2. Click **More Commands** ••• > **Edit** > **Delete DI Record**.

   The **DI record** tab is removed from the SKU revision.

Prepare the SKU device identifier record for DI submission

Once a device identifier (DI) record is fully completed, the information must be provided to the relevant health authority to be included in their databases. The workflow will generate an output in TcXML file that can be further processed to submit to these databases. The workflow also allows you to view the status of the submissions. The external application can update the status if the record is accepted by the health authority and provide back a copy of the accepted or transformed data file for maintaining record.

Procedure

1. Open the Medical Device Identifier or the SKU revision that you want to send for review.
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow**.
3. In the **Submit to Workflow** panel, in the **Workflow** tab, select the relevant workflow from the **Template** list. This workflow will initiate the process of transferring the DI record for review and submission to the reviewing agency. For example, for the FDA, select the **MDLS FDA DI Review and Submission Process** template.
4. (Optional) Specify a name for the workflow or accept the default.
5. Click the **Assignments** tab.
6. In the **Assignment List**, enter keywords to search for the workflow participants.
7. To assign users who will review the DI record:
   a. In the table under the **Assignments List**, select the a task row, for example, **Send Notification**.
   b. Select the required user from the search results, and click **Assign** under the **ASSIGNER** or **REVIEWERS** section.

      The user assigned the task of specifying the sign-off team is listed in the **ASSIGNER** section.

      The users assigned the task of reviewing the DI record are listed in the **REVIEWERS** section.

   You can use the options under **FILTERS** to refine the search results based on type, group, or role.
8. (Optional) In **TARGETS** and **REFERENCES**, click **Add** to specify additional objects that you want to attach to the review workflow.

9. Click **Submit**.

Results

After you specify the workflow participants and initiate the workflow, the assigned users receive their respective tasks in their inbox.

Working with the TCXML file

Once a device identifier (DI) record is fully completed, the information must be provided to the relevant health authority to be included in their databases. The workflow will generate an output in TcXML file that can be further processed to submit to these databases. For example, for FDA DI submission, the TCXML file that contains the DI data can be used to generate the HL7SPL file which can be further submitted to the approving body, that is the FDA. The external application can update the status if the record is accepted by the health authority and provide back a copy of the accepted or transformed data file for maintaining record.

Create and manage digital assets

What are digital assets?

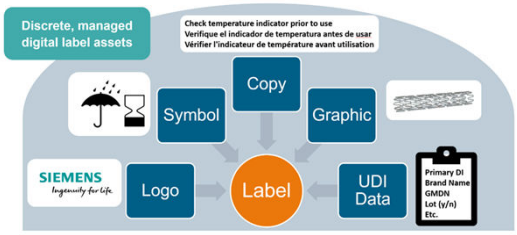
Digital assets comprise the textual or graphical entities that are required while designing the labeling and packaging of medical devices.

You can create the following type of digital assets in PLM for Medical Devices:

- Copy asset
- Graphical asset
- Symbol
- Logo

All the digital assets must be reviewed and approved by respective stakeholders before they can be included in the label design.

You can manage a digital asset library and reuse it across departments and partners.



Creating digital assets

Create a graphical asset

A *graphical asset* contains any images that are included on the label.

Procedure

1. Navigate to and open the folder where you want to create the graphical asset, for example, your **Newstuff** folder.
2. Click **More Commands** ••• > **New** ✳ > **Add** ⊕.
3. In the **Add** panel, select **Graphical Asset**.
4. In the **Add** panel, in **Properties**, accept the default value for the **ID**, enter the properties, and make selections as relevant.
5. Select the **Is Fixed** check box to indicate that the digital asset is fixed on the artwork.

   When you perform a **Save As** operation on the artwork, the fixed digital assets are copied as a reference. If you make changes to the original digital assets, these changes are reflected in the copies. If this check box is cleared, the digital assets are cloned.
6. To specify the master asset of the digital asset, click **Add** ⊕ next to the **Master Asset** label.
7. In the **Add Master Asset** panel, select the required master asset.

   Note

   You can link a master asset only if you are creating a localized asset.
8. Click **Add**.
9. In **Projects**, click **Add Project** ⊕ to assign the digital asset to a project.
10. Select the required project from the list, or search for the project that you want to add, and click **Assign**.
11. Click **Add**.
12. To attach an image of the digital asset, open the digital asset and click the **Attachments** tab.
13. In **Files**, click **Add to** ⊕.

14. In the **Add** panel, browse to select an image that represents the digital asset, and click **Add**.

Create a copy asset

A *copy asset* contains the textual information that is printed on the label of a medical device. You can create copy assets in the digital asset library and reuse them as required. You can create different types of copy assets in Teamcenter- master or local. A master copy asset can contain the copy text in the primary language, and the local copy asset can store the localized, translated versions related to the master asset. Some examples of copy assets are warnings, claims, disclosures, instructions, and boilerplate text.

Procedure

1. Navigate to and open the folder where you want to create the copy asset, for example, your **Newstuff** folder.
2. Click **More Commands** ••• > **New** > **Add** ⊕.
3. In the **Add** panel, from the **Type** list, select **Copy asset** from the list.
4. In **Properties**, accept the default value for the **ID**, and enter the following:
   - **Name** (Mandatory)
   - **Description**
   - **Market**
   - **Regions**
   - **Languages** (Mandatory)
5. Select the **Regulatory Clearance Required** check box to indicate that a regulatory approval is required for this digital asset.
6. Select the **Claim Clearance Required** check box if the claims included in the digital asset require clearance.
7. Select the **Is Fixed** check box to indicate that the digital asset is fixed on the artwork.

   When you perform a **Save As** operation on the artwork, the fixed digital assets are copied as a reference. If you make changes to the original digital assets, these changes are reflected in the copies. If this check box is cleared, the digital assets are cloned.
8. To specify the master asset for the digital asset, click **Add** ⊕ next to the **Master Asset** label.

   Note

   You can link a master asset only if you are creating a localized asset.
9. In the **Add Master Asset** panel, select the required master asset.
10. Click **Add**.
11. In **Projects**, click **Add Project** ⊕ to assign the digital asset to a project.

12. Select the required project from the list, or search for the project that you want to add, and click **Assign**.
13. Click **Add**.
14. To attach the files related to the textual data on the label, open the copy asset object and click the **Attachments** tab.
15. In the **Files** section, click **Add to** ⊕.
16. Search for the attachment containing the text you want to include and add it to the copy asset.

Create a logo

A *logo* is a type of a digital asset that is used on the labeling and packaging of medical devices to indicate the branding.

Procedure

1. Navigate to and open the folder where you want to create the logo, for example, your **Newstuff** folder.
2. Click **More Commands** ••• > **New** ✳ > **Add** ⊕.
3. In the **Add** panel, from the **Type** list, select **Logo**.
4. Accept the default value for the **ID**, and enter the properties and make selections as relevant.
5. Select the **Is Fixed** check box to indicate that the digital asset is fixed on the artwork.

   When you perform a **Save As** operation on the artwork, the fixed digital assets are copied as a reference. If you make changes to the original digital assets, these changes are reflected in the copies. If this check box is cleared, the digital assets are cloned.
6. To specify the master asset for the digital asset, click **Add** ⊕ next to the **Master Asset** label.

   Note

   You can link a master asset only if you are creating a localized asset.
7. In the **Add Master Asset** panel, select the required master asset.
8. Click **Add**.
9. In **Projects**, click **Add Project** ⊕ to assign the digital asset to a project.
10. Select the required project from the list, or search for the project that you want to add, and click **Assign**.
11. Click **Add**.
12. To attach an image of the digital asset, open the digital asset and click the **Attachments** tab.
13. In **Files**, click **Add to** ⊕.

14. In the **Add** panel, browse to select an image that represents the digital asset, and click **Add**.

Create a symbol

A *symbol* is a graphical type of digital asset that indicates the standard or global representation of an object, a function, or a process. For example, you can use symbols to indicate if the medical device is fragile or if the packaging material of the medical device can be recycled.

Procedure

1. Navigate to and open the folder where you want to create the symbol, for example, your **Newstuff** folder.
2. Click **More Commands** ••• > **New** ✳ > **Add** ⊕.
3. In the **Add** panel, from the **Type** list, select **Symbol**.
4. Accept the default value for the **ID**, and enter the properties and make selections as relevant.
5. Select the **Is Fixed** check box to indicate that the digital asset is fixed on the artwork.

   When you perform a **Save As** operation on the artwork, the fixed digital assets are copied as a reference. If you make changes to the original digital assets, these changes are reflected in the copies. If this check box is cleared, the digital assets are cloned.
6. To specify the master asset of the digital asset, click **Add** ⊕ next to the **Master Asset** label.

   Note

   You can link a master asset only if you are creating a localized asset.
7. In the **Add Master Asset** panel, select the required master asset.
8. Click **Add**.
9. In **Projects**, click **Add Project** ⊕ to assign the digital asset to a project.
10. Select the required project from the list, or search for the project that you want to add, and click **Assign**.
11. Click **Add**.
12. To attach an image of the digital asset, open the digital asset and click the **Attachments** tab.
13. In **Files**, click **Add to** ⊕.
14. In the **Add** panel, browse to select an image that represents the digital asset, and click **Add**.

Initiate a review of the copy asset and digital assets

After you create the digital assets and copy assets, they must be reviewed and approved before they are included in the label design. In Teamcenter, you can do this using workflows. You can assign users who will review them and you can then transfer your assets to a third-party label management software so that label designers can use them to create the label design.

Procedure

1. Open the copy asset or digital asset that you want to send for review.
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow** .
3. In the **Submit to Workflow** panel, in the **Workflow** tab, select the relevant workflow from the **Template** list. This workflow will initiate the process of transferring the digital asset to the third-party label management software. For example, for logos, symbols, and graphical assets, select the **MDLS Digital Asset Transfer Process Async** template, and for copy assets, select **MDLS Copy Asset Transfer Process Async**.
4. (Optional) Specify a name for the workflow or accept the default.
5. In **Assignments**, assign users for the tasks listed in the table.
   a. In the table under the **Assignments List**, select the row for the task.
   b. In the **Users** section, select the required user from the search results.

      You can use the options under **FILTERS** to refine the search results based on type, group, or role.
   c. In **Assignee** or **Reviewer**, click **Assign** .

      The users who are assigned the task are listed in the **Assigner** or **Reviewer** section.
   d. Repeat steps 1 to 3 to assign users responsible for tasks listed in the table.
6. (Optional) In **Targets** and **References**, click **Add** ⊕ to specify additional objects that you want to attach to the review workflow.
7. Click **Submit**.

Results

After you specify the workflow participants and initiate the workflow, the assigned users receive their respective tasks in their inbox.

Specify the signoff team to review and approve the digital assets

After the workflow to review the digital assets is initiated, the users responsible for assigning users to a signoff team receive a task in their inbox. These users, identified as assigners in the system, therefore specify the reviewers who will review and approve the digital assets.

Procedure

1. Open the task from your inbox.
2. In the **Reviewers** section, click **Add** ⊕.
3. In the **Add** panel, select the reviewers.
4. In the **Minimum Participation** section, specify the required options and comments and click **Complete**.

Results

The specified signoff team members receive a task in their inbox. They can review the digital assets and to approve them, they can mark the task as complete.

Export the digital assets to the label management system

After the workflow to review the digital assets is initiated, if you are added as an assignee to the **Transfer Digital Asset** or **Transfer Copy Asset** task, you receive a task in your inbox. You review the digital assets and complete the task. These digital assets or copy assets are then exported to the third-party label management system, where label designers can use them to design the label.

Procedure

1. Open your inbox and search for the task assigned to you.
2. Review the digital assets.
3. Enter your comments and click **Complete**.

Results

After the task is completed, the digital assets are exported to the third-party label management system.

Review and approve the digital assets

After the review of the digital assets is initiated using workflows, and the signoff team is assigned in the system, you receive a task for review in your inbox. You approve or reject the task as appropriate. When the task is approved, the digital assets are transferred to the label management software.

Procedure

1. Open your inbox and search for the task assigned to you.
2. Review the digital assets.

3. Enter your comments and click **Complete** to approve the digital assets.

Results

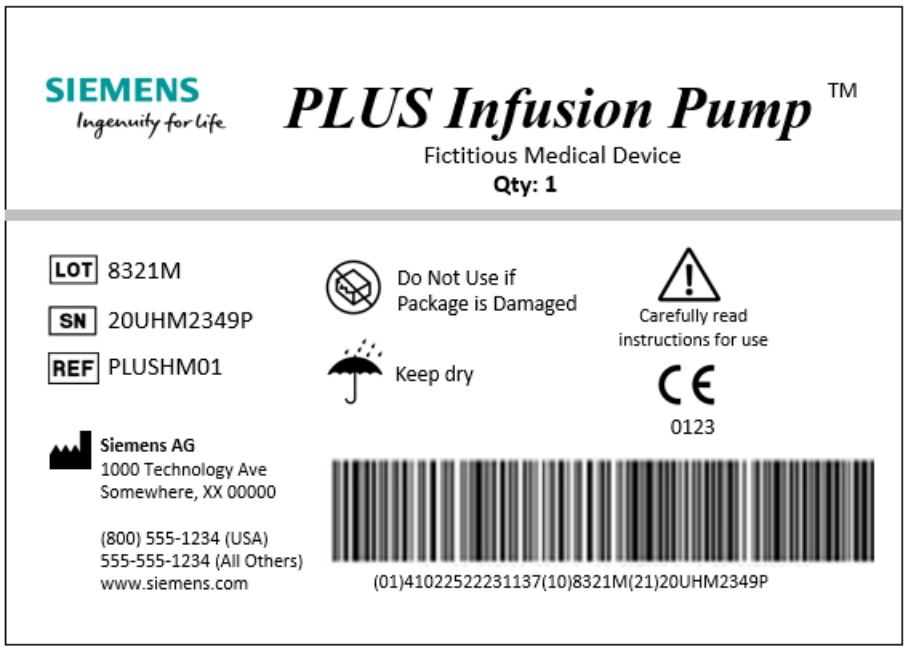
These approved digital assets can now be used in the label design of the medical device.

Create and send label BOM data for label design

About labeling design management in PLM for Medical Devices

The process of labeling comprises the designing, generation, and management of all labels and other printed or graphical elements created for the medical device. It includes all physical or electronic content that is distributed regarding the usage and handling instructions, advertising, or any packaging of the medical device.

One specific application of labeling is the development of the Unique Device Identifier (UDI) label. As per the requirements of regulatory bodies, many medical device labels must contain the UDI information. The UDI is a combination of the device identifier (DI) and the production identifier (PI). The DI in turn consists of static information such as the barcode, logos, symbols, and label, whereas the PI contains dynamic information such as the lot code, serial number, and date of manufacture.



PLM for Medical Devices helps you manage all the labeling data attributes for control, traceability, and compliance. You can:

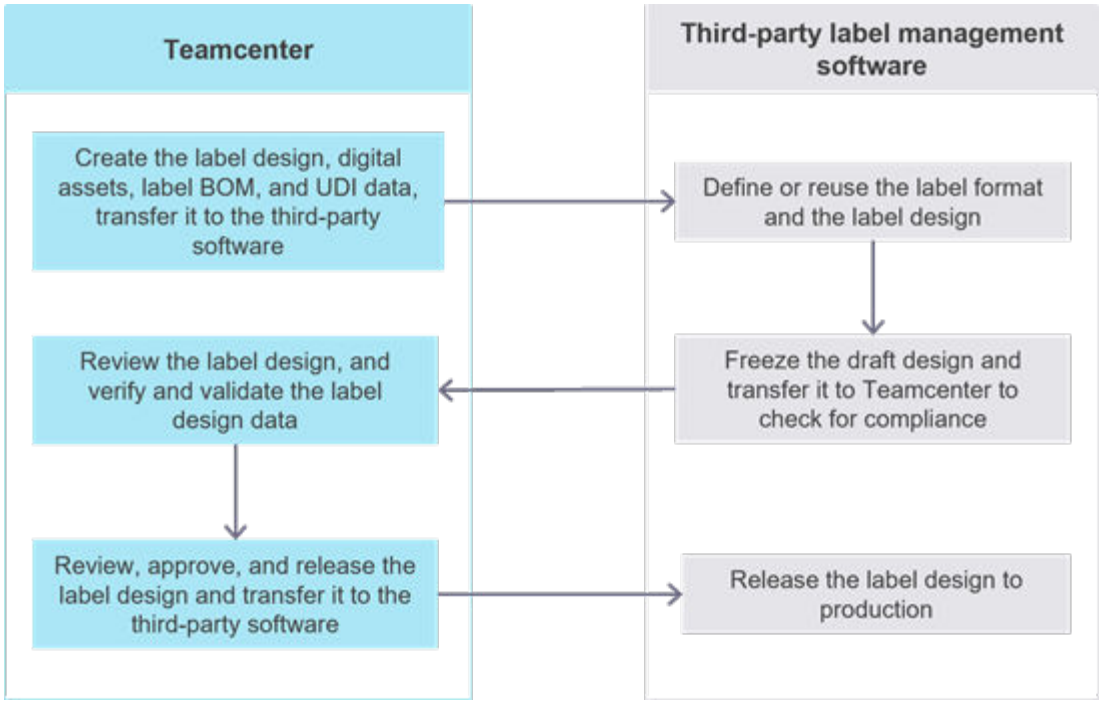
- Integrate the labeling data with the product development and manufacturing operations in accordance with the regulatory guidelines.

- Create and manage a library of digital assets that help you gather all the textual and graphical elements that must be included the labeling of the medical device.
- Reuse the label design objects, digital assets, and the corresponding requirements and testing specifications across multiple projects.

Label design data management process in PLM for Medical Devices

Typically, a third-party label management software, for example, Loftware, is used for the purpose of designing the label which includes the barcode.

The following graphic shows the process of transferring the label design data between Teamcenter and an integrated third-party label management software other than Adobe Creative Cloud applications. In cases where Adobe CC is used for designing elements such as package design, or graphical assets, refer to the Adobe integration help on Support Center.



Create the label BOM

The *label BOM* contains all the digital assets such as copy element, graphical element, logo, symbol, and panel that must be included on the label and packaging of the medical device. In Teamcenter, you create the label design revision, which is the label BOM, and then attach the required digital assets to it.

Procuring the device identifier record for the medical device and creating the label design can happen simultaneously. However, you can transfer the label design to the third-party label management software only after you add the device identifier information to the label design.

Procedure

1. Open the medical device for which you want to create the label design, and click the **Attachments** tab.
2. In the **Documents** section, click **Add to** ⊕.
3. In the **Add** panel,from the **Type** list, select **Label Design**.
4. In **Properties**, specify the following:
   - (Mandatory) **Name**
   - **Description**
   - (Mandatory) From the **Design Type** list, select **Design**.
   - **Design Agency**
   - **Production Process**
   - **Number of Colors**
   - **Based On** - Click ⊕ **Add** and specify additional references.
5. In **Projects**, click **Add Projects** to specify the project associated with the design.
6. Click **Add**.

Results

You can now **attach the required digital assets** to it.

Attach digital assets to the label BOM

After you create the label design revision and the digital assets, you attach all the required digital assets including the copy element, graphical element, logo, symbol, and panel to the label BOM.

Prerequisites

The digital assets must be created and approved before you include them in the label design.

Procedure

1. Open the label design to which you want to the attach the digital assets.
2. Click the **Content** tab.

3. Click **Add** > **Child**.
4. In the **Add** panel, click **Search**.
5. Enter keywords to search for the digital assets that you want to attach.
6. Select the required digital asset from the search results.
7. In **Element Properties**, specify the **Number of Elements** and the **Quantity**.

   Number of Elements specifies the number of times you want to repeat the digital asset at different locations on the label.
8. Click **Add** or **Add Copy**.

   If you click **Add Copy**, a copy of the digital asset is created and attached to the label design.

Transfer the label BOM to the label management software

After the label BOM is created you transfer it to the third-party label management software where label designers reuse the label format or define it to create the label design.

Procedure

1. Open the label design revision that you want to transfer to the label management software.
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow**.
3. In the **Submit to Workflow** panel, from the **Template** list, select the relevant workflow.

   For example, select the **MDLS Label BOM Transfer Process** template.
4. Specify a name for the workflow or accept the default.
5. In **Assignments**, assign users for the tasks listed in the table.
   a. In the table under the **Assignments List**, select the row for the task.
   b. In the **Users** section, select the relevant user from the search results.

      You can use the options under **Filters** to refine the search results based on type, group, or role.
   c. In **Assignee**, click **Assign**.

      The user who is assigned the task is listed in the **Assigner** section.
   d. In the **Results** section, select the required user from the search results, and under **Reviewers**, click **Assign**.

      The users who will be assigned the task of reviewing the label BOM are listed in the **Reviewers** section.
   e. Repeat steps 1 to 4 to assign users responsible for tasks listed in the table.
6. (Optional) In **Targets** and **References**, click **Add** ⊕ to specify additional objects that you want to attach to the review workflow.

7. Click **Submit**.

Results

After you specify the workflow participants and initiate the workflow, the assigned users receive their respective tasks in their inbox.

Review and approve the label design and label BOM

About reviewing the label design

After the label BOM and the attached digital assets are transferred to the third-party label management software, the label designing is performed in the third-party label management software. Once the design is ready it is sent back to Teamcenter for review and approval. In Teamcenter, you use workflows to initiate the review process so that the relevant designers and stakeholders can review and approve the label design.

Initiate the review of the label design

After the label BOM and the attached digital assets, along with the are transferred to the third-party label management software, the label designing is performed in the third-party label management software. Once the design is ready it is sent back to Teamcenter for review and approval. In Teamcenter, you use workflows to initiate the review process so that the relevant designers and stakeholders can review and approve the label design.

Procedure

1. Open the label design that you want to send for review and approval.
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow** .
3. In the **Submit to Workflow** panel, from the **Template** list, select the relevant workflow.

   For example, select the **MDLS Label Design Approval Notification Process** template.
4. Specify a name for the workflow or accept the default.
5. In **Assignments**, assign users for the tasks listed in the table.
   a. In the table under the **Assignments List**, select the row for the task.
   b. In the **Results** section, select the required user from the search results, and under **Reviewers**, click **Assign** .

      The users who will be assigned the task of reviewing the label BOM are listed in the **Reviewers** section.
   c. In **Assignee**, click **Assign** .

The user who is assigned the task is listed in the **Assigner** section.

d. Repeat steps 1 to 3 to assign users responsible for tasks listed in the table.

6. (Optional) In **Targets** and **References**, click **Add** ⊕ to specify additional objects that you want to attach to the review workflow.
7. Click **Submit**.

Results

After you specify the workflow participants and initiate the workflow, the assigned users receive their respective tasks in their inbox.

Specify the team to review the label design

After the workflow to review the label design is initiated, the user who is responsible to specify the reviewers receives a task in the inbox. The responsible user must specify the signoff team that will review and approve the label design.

Procedure

1. Open the task from your Inbox.
2. In the **Reviewers** section, click **Add** ⊕.
3. In the **Add** panel, select the reviewers.
4. In the **Minimum Participation** section, specify the required options and comments and click **Complete**.

Results

The specified signoff team members receive a task in their inbox. They can review the label design and mark the task as complete to approve it.

Review the label design

After the review of the label design is initiated using workflows, and the signoff team is assigned in the system, the responsible users receive a task for review in their inbox. The reviewers can approve or reject the task as appropriate. When the label design is updated as per the review feedback and the task is approved, the label design can be transferred to the label management software.

Procedure

1. Open your inbox and search for the task assigned to you.

2. Review the label design.
3. Enter your comments and click **Complete** to approve the label design or **Reject** to send the label design for updating it as per the feedback.

Update the label BOM

After the workflow is initiated, the responsible users, who are part of the signoff team to review the label design, receive a task in their inbox. They review the label design and submit their comments and suggestions. If the label design is rejected, the designers update the label BOM and re-initiate the review process so that the relevant stakeholders can review and approve the updated label BOM.

The approved label BOM is transferred to the label management software using workflows.

Transfer the updated label BOM to the label management software

When the designers and stakeholders review and approve the label BOM, it is transferred to the label management software using the **MDLS Label BOM Transfer Process Async** workflow.

Procedure

1. Open the label BOM that you want to transfer to the label management software.
2. Click **More Commands** ••• > **Manage** > **Submit to Workflow**.
3. In the **Submit to Workflow** panel, from the **Template** list, select the relevant workflow.

   For example, select the **MDLS Label BOM Transfer Process Async** template.
4. Specify a name for the workflow or accept the default.
5. In **Assignments**, assign users for the tasks listed in the table.
   a. In the table under the **Assignments List**, select the row for the task.
   b. In the **Results** section, select the required user from the search results, and under **Reviewers**, click **Assign**.

      The users who will be assigned the task of reviewing the label design are listed in the **Reviewers** section.
   c. In **Assignee**, click **Assign**.

      The user who will be updating the label design as per the updated label BOM is listed in the **Assigner** section.
   d. Repeat steps 1 to 3 to assign users responsible for tasks listed in the table.
6. (Optional) In **Targets** and **References**, click **Add** ⊕ to specify additional objects that you want to attach to the review workflow.

7. Click **Submit**.

Results

After you specify the workflow participants and initiate the workflow, the assigned users receive their respective tasks in their inbox. Once the designers update the label design as per the updated label BOM, the updated label design is sent to Teamcenter where stakeholders review and approve the label design changes.

Approve the label BOM

Once the designers update the label design as per the updated label BOM, the updated label design is sent to Teamcenter where stakeholders review and approve the label BOM.

Procedure

1. Open the label BOM that you want to review and approve.
2. Click **More Commands** •••>**Manage** > **Submit to Workflow** .
3. In the **Submit to Workflow** panel, from the **Template** list, select the relevant workflow.

   For example, select the **MDLS Label BOM Release Notification Process** template.
4. Specify a name for the workflow or accept the default.
5. In **Assignments**, assign users for the tasks listed in the table.
   a. In the table under the **Assignments List**, select the row for the task.
   b. In the **Results** section, select the required user from the search results, and under **Reviewers**, click **Assign** .

      The users who will be assigned the task of reviewing the label design are listed in the **Reviewers** section.
   c. In **Assignee**, click **Assign** .

      The user who will be updating the label design as per the label BOM is listed in the **Assigner** section.
   d. Repeat steps 1 to 3 to assign users responsible for tasks listed in the table.
6. (Optional) In **Targets** and **References**, click **Add** ⊕ to specify additional objects that you want to attach to the review workflow.
7. Click **Submit**.

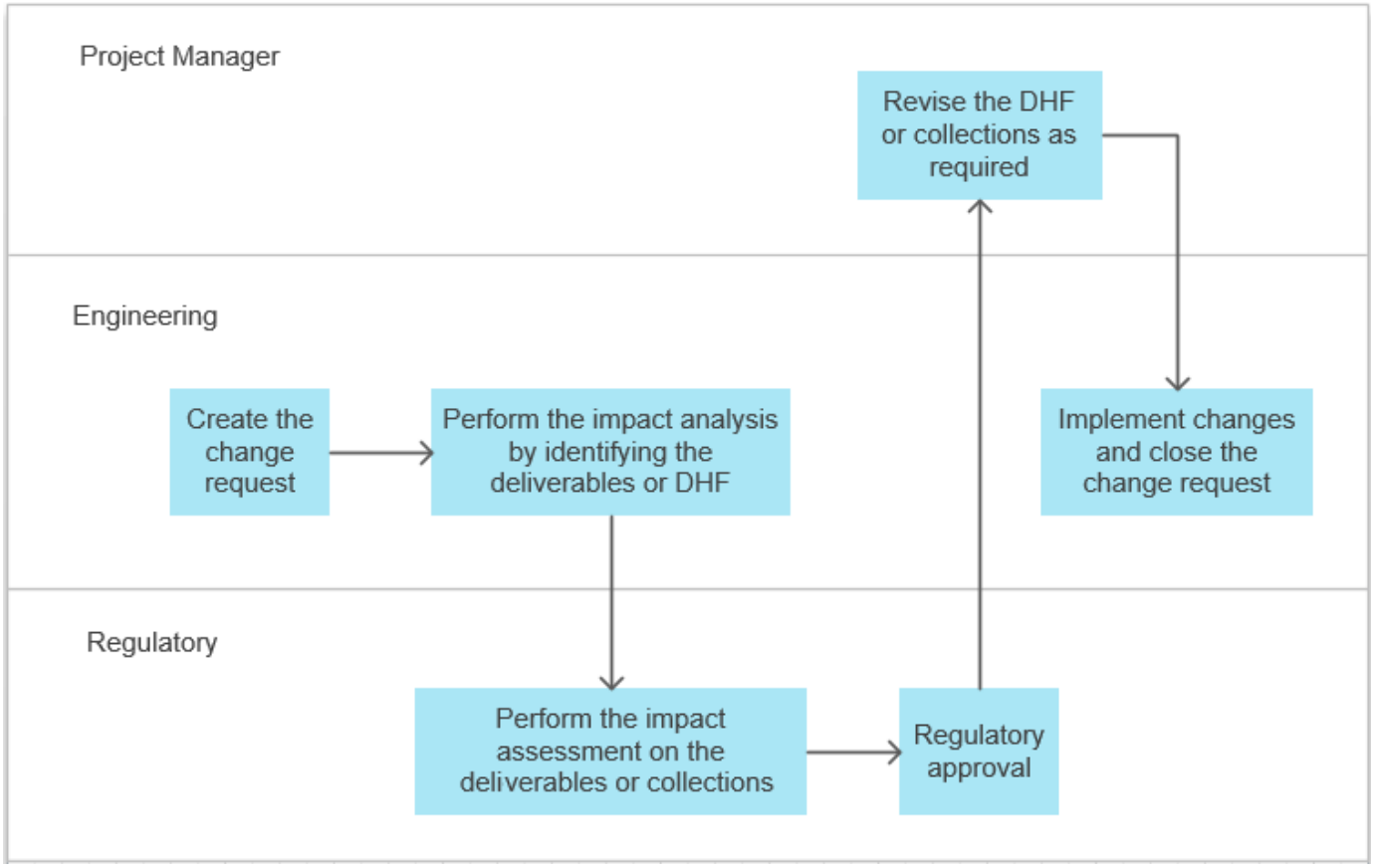
Results

After you specify the workflow participants and initiate the workflow, the assigned users receive their respective tasks in their inbox. Once the stakeholders review the label design and approve it the label BOM is released.

7. Change management

Using a simple change to manage reviews

PLM for Medical Devices uses Change Management to manage changes required for deliverables, documents, parts, and drawings in a Design History File (DHF). Because the solution is designed for the medical devices industry, the *simple change* functionality of Change Management is used for all changes in PLM for Medical Devices.



What is a simple change?

Simple change simplifies the process for creating and performing change revisions. It is designed for situations that do not require the detailed features of a change notice or detailed workflows, and it is used in the PLM for Medical Devices solution.

Example

Simple change is intended for minor changes where a single person or small team is responsible.

An engineer is tasked with a minor change to a part. Instead of managing the change using a standard, elaborate change notice, the team uses *simple change* to streamline the process.

A simple change contains the **Overview** and **Workflow** tabs.

- **Overview** - This tab displays all the information for the simple change, including the workflow it is assigned to, the tasks involved, the impacted items, details of the change, the change summary, and the change participants. The state of the change (**Elaborating**, **Contributing**, **Approving**, and **Released)** are also displayed.
- **Workflow** - This tab displays detailed information on the workflow process, including the current and completed tasks. A graphical representation of the workflow that shows the upcoming tasks is also displayed.

States of a simple change

A change has two key states that capture where in the change process it is and what decisions have been made about the change.

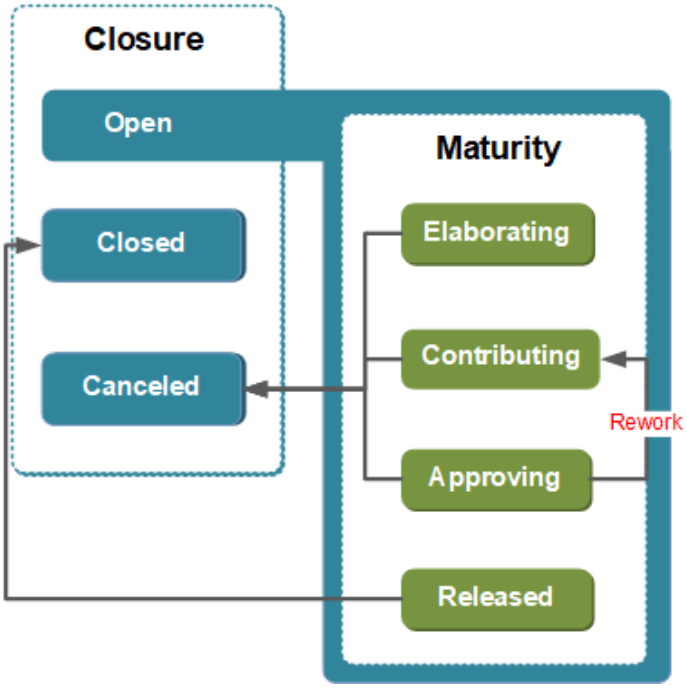
- Its status or *Closure* (for example, Open or Canceled).
- The degree of completion of the overall change process, that is, its *Maturity*.

The change states interconnect with each other and are dependent on the other change states. For example, *Maturity* is a substate of the *Closure* state. The states of a change are set during the workflow process.

Tip

You can view the states of a change in the **Overview** tab.

The following graphic illustrates the *simple change* states. For detailed information on change states, see *Change Management — Deployment and Rich Client Usage* in the Teamcenter help.



Create a simple change request

You can create a simple change when you need to submit a change to a DHF object, record, document, or drawing. Once the change is created, it is automatically submitted to the default *simple change* workflow.

Procedure

1. Select or open the object for which you want to create a simple change.
2. Click **More Commands** ••• > **New** ✳ > **Create Change**.
3. Select **Simple Change** from the list.
4. Complete the required fields and click **Create and Submit**.
   After the simple change is created, you can **add and revise the impacted items** and **add and manage the participants** who will review the object.

Assign, replace, or remove participants in a simple change

Once you have created your simple change, you can assign the change participants.

Procedure

1. In the *simple change*, navigate to the **Participants** section.

2. Select the participant type. You can choose from the following:
   - **Requestor**
   - **Contributor**
   - **Approver**
3. Once the participant type is selected, you can choose from the following actions:
   - **Add**. Opens the **Add** panel so you can add other users as participants.
   - **Remove**. Removes the selected user from the change participants.
   - **Replace**. Opens the **Replace** panel so you can choose a user to replace the selected participant.

Results

All users listed as a participants receive a workflow task in their inbox to complete.

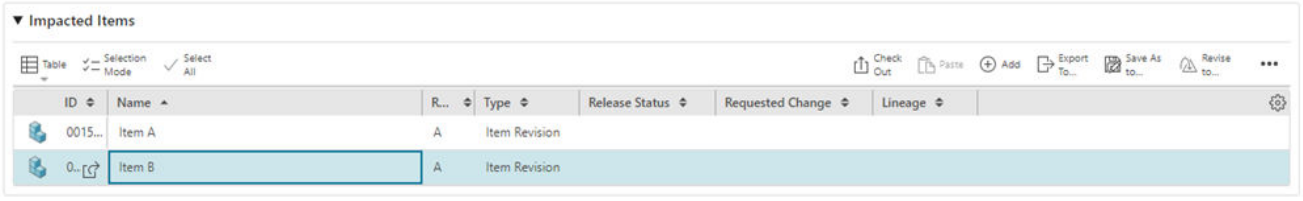
Add and revise additional impacted items to the simple change

When you create a *simple change* from an object, it is automatically added as an **Impacted Item**. You can add additional impacted items and revise them as required.

Procedure

1. Add one or more objects to a *simple change* by selecting **Add to** ⊕ in the **Impacted Items** section of the *simple change*.
2. Select an object and click **Add**.

   Repeat as necessary.
3. (Optional) Select an object from your folders and select **More Commands** ••• >**Manage** > **Add to My Changes**. Then select a *simple change* from the list of changes, and choose **`Impacted Items`** from the **Relation** list and click **Add**.
4. Select any object in the **Impacted Items** table and click **Revise** .



Complete the assigned task

If you are assigned as a participant in a simple change, you receive a change task in your inbox that you can complete or request for rework.

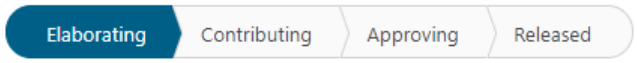
Procedure

1. Open the task from your **Inbox**.
2. Click the **Overview** tab.

   The current assigned task is listed under the **Task to Perform** section.
3. Review the task instructions and enter your comments in the **Comments** box.
4. Mark the task as **Complete** or **Rework**, as required.

Results

The completed tasks are reflected in the states of the **Progress Bar**.



After the tasks are completed and the change is approved, it is released, and the impacted items are revised.