1. PURPOSE
   1. This procedure outlines the overarching process for governing Polarion Application Lifecycle Management (ALM) system at Johnson & Johnson Vision.
2. SCOPE
   1. This guidance procedure is applicable to all JJVC and JJSV R&D sites.
   2. This document provides an overview by defining commonly used terms, establishing end-user roles and responsibilities, change management governance, and identifying resources for support.
   3. JJV owns the Vision configuration(s) in the J&J MedTech Polarion ALM instance. JJV is responsible for the following with respect to the Vision configuration(s).
      1. User management limited to JJV projects.
      2. Change Management of JJV configuration.
      3. Configuration management of JJV configurations.
      4. Periodic review of the JJV configurations.
   4. JJV does not own the J&J MedTech Polarion ALM instance. JJV is not responsible for the following. This procedure does not cover the following.
      1. Archiving of data
      2. Audit trail review
      3. Backup and Restore
      4. Business continuity plan
      5. Disaster recovery
      6. Incident and problem management
      7. Security management
      8. Data Review
      9. Application installation
      10. Maintenance of the application
      11. Desktop security for the application.

The J&J MedTech Polarion governance procedure is 501348031 Polarion Governance SOP accessible through ThingWorx DocViewer.

1. RESPONSIBILITY
   1. Polarion System Owner
      1. Polarion system owner is responsible for compliance to this procedure.
      2. Polarion system owner is responsible for assigning training to Users and Approvers through compliance wire.
      3. Polarion system owner is responsible for approving enhancement requests and assigning appropriate resources to implement the enhancement requests.
   2. Polarion Administrator
      1. Polarion administrator is responsible for compliance to this procedure.
      2. Polarion administrator is responsible for maintaining the Polarion JJV configurations in a validated state per JJV procedures.
      3. Polarion administrator is responsible for processing and implementing the enhancement requests.
      4. Polarion administrator is responsible for proactively gathering information about possible changes to JJV procedures and templates.
   3. Viewers
      1. All personnel with *Polarion\_user* level access in Polarion is considered Viewers. Viewers can only view the data. Viewers cannot create or modify data in a project.
      2. Viewers are responsible for compliance to this procedure.
   4. Users
      1. All personnel with *Polarion\_Assignable* level access in Polarion is considered Users. Users can create data in Polarion system.
      2. Users are responsible for compliance to this procedure.
      3. Users are responsible for submitting enhancement requests to the Polarion owner and/or Polarion Administrator.
      4. Users are responsible for communicating the defects to the Polarion owner and/or Polarion Administrator.
   5. Approvers
      1. All personnel with *Polarion\_Approver* level access in Polarion is considered Approvers.
      2. Approvers have all the privileges and responsibilities of the Users.
      3. Approvers can set the status of data in Polarion environment to ‘Approved’ or ‘Rejected’. Approvers are responsible of the data that gets exported from the Polarion system.

The approval workflow in Polarion does not signify the formal approval of the data. The approved reports in PLM systems must be considered as the *source of truth*.

* 1. Business / Process owners
     1. Business / process owners can either be Users or Approvers in the Polarion environment.
     2. The responsibilities of the business / process owners depend on the level of access provided with in the Polarion environment.
     3. Additionally, Business / process owners are responsible for notifying the Polarion Administrator of possible updates to JJV procedures and templates.

1. TERMINOLOGY

| **Term or Acronym/ Abbreviation** | **Definition** |
| --- | --- |
| PLM systems | In the context of this guidance document, PLM systems refer to following.   |  |  | | --- | --- | | Agile | JJSV | | Teamcenter | JJVC | | eDMS | JJVC | |
| DHF | Design History file |
| RMF | Risk Management file |
| OOTB features | Out-Of-The-Box feature or functionality are built-in functionalities of Polarion ALM system that comes directly from the Siemens and works immediately when the product is placed in service.  In the context of Polarion ALM system, examples include creating work item types, adding fields to work items, and modifying link roles. |
| Enhancement Request | Any user-requested changes to the Polarion configuration are classified as enhancement requests. |

1. REFERENCES

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| * 1. VAL-0016 | Change control using the Vibes – Global Application Change Control (GACC) control |
| * 1. AMO-05-S002 | CHANGE CONTROL |
| * 1. SOP501044 | REDLINING ITEMS FOR CHANGE CONTROL PROCESS |
| * 1. V370431 | Surgical Vision User guide |
| * 1. V370432 | Surgical Vision Administrator guide |
| * 1. ALM-TRM-001 | Vision Care User guide |
| * 1. ALM-TRM-002 | Vision Care Administrator guide |
| * 1. JJV-08-F008 | Polarion Application Request Form |
| * 1. JJV-08-F007 | Polarion Enhancement Request Form |
| * 1. JJV-08-D003 | Polarion ownership matrix |
| * 1. JJV-08-D002 | JJV Polarion Configuration Database |

1. ACCESS CONTROL
   1. In Polarion, access requests are granted at the project level.
      1. User shall send email to Polarion owner (JJV-08-D003) requesting access to project.
      2. Polarion owner shall assigns the Polarion user guide training through ComplianceWire.
      3. User shall complete the training in ComplianceWire.
      4. User shall complete the form Polarion Application Request Form (JJV-08-F008).
      5. Polarion global Administrator shall fulfill the IRIS requests.
   2. ComplianceWire training need not be completed for View only access.
   3. To create a project in Polarion, users can follow the steps outlined for acquiring access control.
2. CHANGE MANAGEMENT
   1. Enhancement requests
      1. Business owners, Process owners and users can propose changes to the Polarion configuration using the Polarion Enhancement Request Form JJV-08-F007.
      2. The enhancement request shall be sent to Polarion Request Submission Email for evaluation per Polarion Ownership Matrix (JJV-08-D003).
      3. The Polarion Administrator shall evaluate and complete the enhancement request form.
      4. The Polarion owner shall approve the enhancement request form.
      5. The Polarion Administrator shall log all Enhancement Requests in JJV Polarion project.
         1. The Polarion Administrator shall attach the completed Enhancement Request form in JJV Polarion project**.**
      6. The Polarion Administrator shall implement the enhancement.
         1. The Polarion administrator shall initiate the Change Request, if necessary.
   2. Change requests to the validated Polarion ALM software are managed through the current revisions of the following procedures.

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| **Procedures** | **Scope** | **Title** |
| VAL-0016 | JJ Vision Care | Change Control using the VIBES –Global Application Change Control (GACC) Module |
| AMO-05-S002 | JJ Surgical Vision | Change Control |

* 1. Changes that will not require creating a Change Request.
     1. User access management.
     2. Import document templates into Polarion.
     3. Exporting data from Polarion.
     4. Changes that use Polarion OOTB features and do not impact the DHF and/or RMF deliverables.
  2. Manage document templates in Polarion.
     1. The Polarion Administrator is responsible for actively gathering information on possible updates to document templates. This shall be accomplished by sending a monthly email to all Polarion users.
     2. Prior to revising the document templates, the Business owners and/or Process owners shall notify the Polarion Administrator (JJV-08-D003) by submitting the Polarion Enhancement Request Form (JJV-08-F007).
     3. Polarion Administrator shall follow the steps outlined for handling Enhancement Request to manage changes in document templates.
  3. Configuration Management
     1. List of the validation records for JJV Polarion configuration will be maintained in Polarion Configuration Management Database (JJV-08-D002).
  4. Dispute Resolution
     1. Disputes can raise when conflicting requirements are presented to Polarion system owner (JJV-08-D003) for configuration purposes.
     2. The Polarion owner shall attempt to resolve any disputes that may arise prior to completing the Polarion Enhancement Request Form.
     3. When the Polarion owner cannot resolve the dispute, the dispute shall be escalated to the JJV Polarion system owner as listed in Polarion ownership matrix JJV-08-D003.

1. APPLICATION HELP/ SUPPORT
   1. Training users to the Polarion functionality is the responsibility of the Polarion trainer (JJV-08-D003).
   2. Polarion ALM system is designed to be available 24 hours a day, seven (7) days a week. Support will be available for eight (8) hours a day and five (5) days a week in Easter Time Zone. When the system must be shut down, the Polarion Administrator will notify the end-users of the impending downtime and its expected duration.
   3. Below are the references to JJV Polarion user guide.

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| ALM-TRM-001 | Vision care user guide (electronic Document Management System) |
| V370431 | Surgical Vision user guide (JJSV Document management system- Agile) |

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| **Revision** | **Change Summary** |
| 01 | Initial Release |
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