

Polarion ALM System Requirement Specification



1 PURPOSE

This document describes the business processes and needs, as well as the functional abilities to support Compli ance Group's deployment of the system defined in 3 - SYSTEM OVERVIEW of this document.

The requirements contained in this document are intended to define general business needs and functional configurations necessary. This document is created in compliance with and under the guidance of procedure CSV-SOP-001, *Computer Software Assurance*.

2 DEFINITIONS

Term	Definition
ALM	Application Lifecycle Management
ВРО	Business Process Owner
so	System Owner

3 SYSTEM OVERVIEW

This section displays the identifying characteristics of the system defined by this document. These characteristics include the system name, intended use, and currently validated version.

Polarion ALM

Polarion provides Application Lifecycle Management (ALM) and validation management capabilities. This includes the following high-level system capabilities:

- · Document and requirement authoring and approval
- Test case authoring, approval, execution, and review
- · Defect creation and management including approval
- · Reporting and metrics



4 SYSTEM REQUIREMENTS

4.1 Validation Documents

WFD-6047, ✓ Approved - Polarion shall have the ability to manage validation documents including validat...

Polarion shall have the ability to manage validation documents including validation plans and reports, requirement specifications, and other relevant documents.

Version	2.0
	has parent: WFD-6051 - Validation Documents , is assessed by: WFD-5980 - Polarion ALM ,
Linked Work	is verified by: WFD-6053 - Validation Document Management (UAT) ,
Items	is refined by: FWFD-6048 - Polarion shall have the ability to create validation documents.,
	is refined by: FWFD-6050 - Polarion shall have the ability to control the workflow of validation
	documents.

WFD-6048, ✓ Approved - Polarion shall have the ability to create validation documents.

Polarion shall have the ability to create validation documents.

Version	2.0
Risk Rating	High
Testing Type	Scripted Testing
Linked Work	has parent: WFD-6051 - Validation Documents , refines: WFD-6047 - Polarion shall have the ability to manage validation documents including validat

WFD-6050, ✓ Approved - Polarion shall have the ability to control the workflow of validation documents.

Polarion shall have the ability to control the workflow of validation documents.

Version	1
Risk Rating	High
Testing Type	Scripted Testing
	has parent: WFD-6051 - Validation Documents ,
Linked Work	refines: MFD-6047 - Polarion shall have the ability to manage validation documents including
Items	validat,
	is verified by: WFD-6054 - Default Document Workflow (E2E)



4.2 Risk Assessments

WFD-6056, ✓ Approved - Polarion shall have the capability to perform risk assessments.

Version	1
Linked Work Items	has parent: WFD-6052 - Risk Assessments , is assessed by: WFD-5980 - Polarion ALM , is refined by: WFD-6061 - Functional requirement #1 , is refined by: WFD-6062 - Functional requirement #2

WFD-6065, ✓ Approved - New risk assessment work item.

New risk assessment work item.

Version	1
Linked Work Items	has parent: WFD-6052 - Risk Assessments

4.3 Functional User Requirements

4.3.1 Platform Requirements

This section may be used for any system that utilizes a modular approach with a hub of functions at the platform level.

4.3.2 Security / User Roles

Add user roles specific to any modules or workflows. Insert a new requirement for each role. Adjust to suit the system's needs.

4.3.3 Regulatory Requirements

These examples are identical to the ones in the functional section. The recommended approach is to use the FS for these requirements, unless it is a SaaS solution, and the vendor is providing the FS. If both user and functional requirements are in scope of the project, use a high-level requirement for ERES.



4.3.3.1 Electronic Records

4.3.3.2 Electronic Signatures

4.3.4 General Requirements

Add requirements as needed and build requirements for general business functionality.

4.3.5 Business <Functional Group 1> Requirements

Add requirements as needed and build requirements for business functionality.

4.3.6 Business <Functional Group 2> Requirements

Add requirements as needed and build requirements for business functionality.

4.3.7 Business <Functional Group n> Requirements

Add requirements as needed and build requirements for business functionality.

4.3.8 Notification Requirements

Add high-level notification requirements, such as when records are in certain states.

4.3.9 Reporting Requirements

Add requirements as needed and build requirements for report types needed by the business.

4.4 Non-Functional User Requirements

This can be addressed in the User or Functional sections but is not required in both.

4.4.1 Technical Requirements

4.4.1.1 Hardware Requirements

Add requirements as needed.



4.4.1.2 Software Requirements

Add requirements as needed.

4.4.1.3 Network Requirements

Add requirements as needed.

4.4.1.4 Security Requirements

Add requirements as needed.

4.4.1.5 Interface Requirements

Add requirements as needed.

4.4.1.6 Availability / Performance Requirements

Add requirements as needed. Remove section if there are no Performance Requirements. Response times are not recommended unless absolutely needed. Suggested to make the UR that response times will be measured for key functions with zero load as a baseline and when significant changes are made.

4.4.1.7 Procedural Requirements

Add requirements as needed.

4.4.2 Records Hierarchy / Structure

The users of the system need to capture, update, and track information in support of the business process. The diagram below depicts the logical relationship between the records in the workflow.

4.4.3 Business Constraints

Describe any business-critical items for proper functioning. This is not necessarily tested, but is important to define business impact.

The system is dependent on data received from the XXXXX system. Should this interface fail, it would be non-operational.



5 Functional <System> Requirements

5.1 <Functional / System>

5.1.1 Record Workflows

This section is intended to introduce the record types and the workflows followed through the system. Showing how records progress through the system fosters a better understanding. Revise or create process flows (examples below) to reflect the actual system workflow.

5.1.2 Platform Requirements

This section may be used for any system that utilizes a modular approach with a hub of functions at the platform level.

5.1.3 User Roles and Permissions

Use this section to define each role and a more granular level of what rights come with it. If it is matrixed, include the matrix or denote the next role inherits the pervious role's right plus.

5.1.4 Regulatory Requirements

5.1.4.1 Electronic Records

Add requirements as needed

5.1.4.2 Electronic Signatures

Add requirements as needed.

5.1.5 General Functions

This section may be used for requirements that apply system-wide.



5.1.6 < Functional Group 1> Requirements

Add requirements as needed and build requirements for business functionality.

5.1.7 < Functional Group 2> Requirements

Add requirements as needed and build requirements for business functionality.

5.1.8 < Functional Group n > Requirements

Add requirements as needed and build requirements for general business functionality.

5.1.9 Notification Requirements

Add high-level notification requirements, such as when records are in certain states.

5.1.10 Reporting Requirements

Add requirements as needed and build requirements for details of each report, such as displayed fields, export types, etc.

5.2 Non-functional

5.2.1 Technical Requirements

Add requirements as necessary. This section may be addressed in the user requirements section or the configuration / design specification.

5.2.1.1 Hardware Requirements

Add requirements as necessary. This section may be addressed in the user requirements section or configuration / design specification.



5.2.1.2 Software Requirements

Add requirements as necessary. This section may be addressed in the user requirements section or configuration / design specification.

5.2.1.3 Network Requirements

Add requirements as necessary. This section may be addressed in the user requirements section or configuration / design specification.

5.2.1.4 Security Requirements

Add requirements as necessary. Most requirements below can be deleted if Active Directory is used. If defined in the user requirements, remove this section.

5.2.1.5 Interface Requirements

Add requirements as necessary. This section may be addressed in the user requirements section or configuration / design specification.

5.2.1.6 System Availability / Performance Requirements

Add requirements as necessary. This section may be addressed in the user requirements section.

5.2.2 Functional Constraints

Describe any technical critical items for proper functioning or key consideration.

The system requires technical integration with the XXXXX database and has a fail-over component.

6 APPENDICES

Not applicable.



7 REFERENCES

7.1 Internal References

XXXXXXX Computer Software Assurance

7.2 External References

Not applicable.

8 DOCUMENT APPROVALS

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