OpenText™ ALM

ALM Workflows for Validated Applications Best Practices Guide

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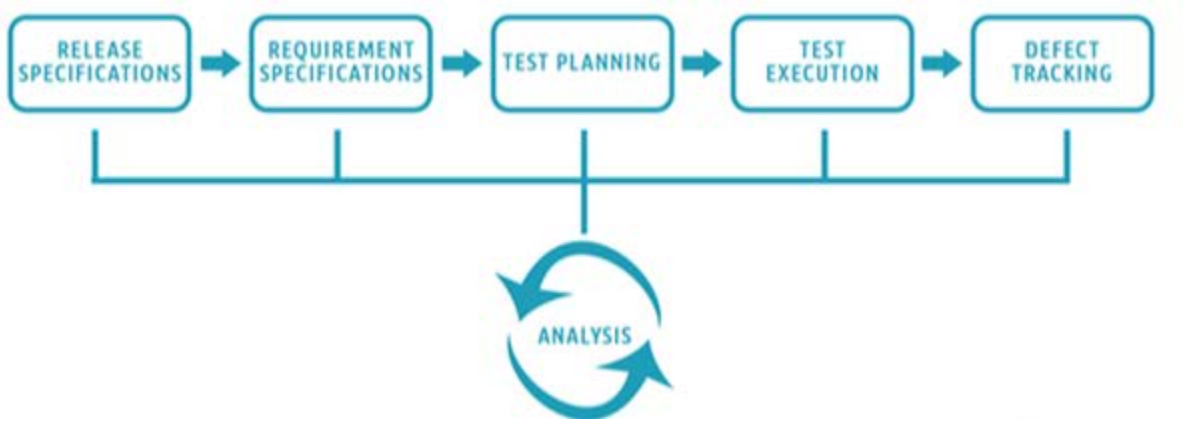
1. ALM Purpose and Relevance in Validated Applications

OpenText Application Lifecycle Management (ALM) is a product developed and marketed by OpenText for application development and testing. It includes tools for requirements management, test planning and functional testing, performance testing, developer management, and defect management.

ALM can be customized and integrated with eApproval applications to comply with regulations and guidelines like GxP, 21 CFR Part 11, EU Annex 11 etc. setup by regulatory bodies like FDA(USA), EMEA(Europe), MHRA(UK), TGA(Australia), ICH etc. for validated applications.

ALM WORKFLOW



2. Modules in ALM

Below are the modules that can be customized to make ALM compliant for validated applications:

- **Dashboard**
- **Requirement**
- **Test Plan**
- **Test Lab**
- **Test Run**
- **Defect**

3. Out of the Box features of ALM

3.1 Cross Project Customization *available only with the ALM edition

ALM provides below features which is beneficial while working with multiple projects.

- **Template Project**:
  Template Projects enable the user to define and maintain a common set of project customizations for multiple projects.
  After creating a Template, user can link it to several projects. This enables the Template Administrator to apply Template customization changes to the linked projects.
  User can create a Template project by copying an existing Template/Project. This option copies both customization and project data from the source Template/Project.

- **Shared Libraries**:
  Libraries can be created for requirements and test Cases which can be shared across multiple projects by importing them.

  Importing library enables the user to share or reuse an existing set of entities in projects across the enterprise. User can import a library by selecting a baseline in another library from which to import. User can import a library from the same project, or from a different project.

  When user imports a library, the library is added to the current project libraries tree and the library's entities are copied to the corresponding modules in the project. If the library includes associated entities, such as requirements that have test coverage, this relationship is also copied. In addition, any related entities outside of the library that the tests in the library need in order to run are also imported, such as called tests and test resources.

- **Cross Project Reporting**:
  ALM provides cross-project reporting and pre-configured business views for reports such as aggregated project status metrics, application quality metrics, requirements coverage, and defect trends for both an enterprise release and individual projects.

3.2 Baseline

Baseline is a snapshot of a library at a specific point of time. User can use functionality to mark any significant milestone in the application lifecycle management baseline process. A baseline includes all the entities defined in the library which includes requirements, tests, test resources, and business components.

Baseline includes relationships between the entities in the library, such as traceability and coverage. It also enables user to track changes made to project over time.

4. Offline Testing (Quality of Things)

To enable Test Execution and Defect submission in offline mode, ALM QoT (Quality of Things) application can be leveraged. User can run manual tests and submit defects while connected to ALM in online mode, or work in offline mode and upload test results and defects when reconnected.

The ALM can be customized to facilitate QOT as per below rules to comply with pharma regulations

For Entities which are in Approved status:

- Users will be able to execute offline the approved test cases from ALM and the Execution results will be uploaded back to ALM.

For the Entities which are in Not Approved status:

- Restrict upload/download test cases for offline Execution.
- Restrict the upload/download of Defects.

In the QoT application the administrator can configure:

- Allow to run tests only if they are in approved status
- Force the submission of defect if the test is marked as failed.

More details about QoT are available in the below link:

ALM Quality of Things (QoT) 2.3

5. Version Controlling in ALM

In a version control enabled project, you can create and manage Application Lifecycle Management (ALM) entities while maintaining previous versions of these entities. This includes requirements, tests, test resources, business process models, and business components.

To make ALM a controlled and validated tool, the Version Control feature can be enabled for the projects so that each user action is recorded with details of the action performed along with user details.
When an entity is created or edited, the entity will be "Check Out" to the editing user. While the entity is "Checked Out", no other users can edit or transition it.
With Version Controlling, the user can see history of each entity like requirement, test case, test run.In history tab, audit log each action is recorded with action details, user details (with time stamp)

More details about Version Control module are available in the below link:

Version control

6. History and Audit Trail

ALM provides History feature for all the entities, which enables users to view list of changes made to the selected entity, along with history of baselines. History can be enabled for those standard & custom fields where user wants to record, and display changes applied in chronological order. History can be enabled for requirement, test plan, test lab, test run and defect entities.

Under History below Tabs are displayed:

- Baseline– This tab displays baseline history of a selected entity. User can view and compare all versions of the entity that are stored in a baseline.
- Version– This tab displays version history of a selected entity in a version control enabled project.
- Audit Log– This tab displays the date and time of the change and the name of the user who made the change to the entity along with old and new value of the field.

7. Quality Assurance Protocols - Pharma

Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) represent Quality Assurance protocols in pharma Industry. **Requirements, Test Case, Test Run and Defects in IQ, OQ, PQ will undergo eApproval process as mentioned in below sections to comply with Pharma regulations. The eApproval component needs to be purchased separately either from OpenText professional service group or from one of the certified partners.**

These protocols help to ensure that QA standards will be met when the software/equipment is used in Pharma Industry. Verification of software/equipment specifications is required by FDA and is especially important in highly regulated industries such as the production of pharmaceuticals and medical devices.

ALM supports Validation Life Cycle artifacts which are part of below set of protocols

7.1 Installation Qualification (IQ)

Installation Qualification (IQ) is used to verify that the software/equipment has been delivered, installed and configured in accordance with a pre-determined and approved installation checklist or the manufacturer's specifications. IQ is important as the performance of the software/equipment will depend on how it is installed.

7.2 Operational Qualification (OQ)

Once IQ is complete, the next step is Operational Qualification (OQ). During OQ, software/equipment features are tested separately to ensure that they meet the operating ranges specified by the manufacturer. In particular, OQ looks at any features that could have an impact on the quality of the final product.

7.3 Performance Qualification (PQ)

Finally, once IQ and OQ are complete, Performance Qualification (PQ) can commence. At this point, the software/equipment is tested under real-world conditions to check that it will function as expected.

8. User Groups & Permissions

User can control access to ALM projects and modules by customizing the user groups.

ALM includes predefined groups with default privileges. Each group has access to certain ALM tasks. The default user groups include: TDAdmin, Tester, Test Manager, Defect Manager and Viewer.

ALM provides option to customize the user groups, these user groups can have specific set of permissions defined for each module. Each user can be assigned to multiple user groups for module specific access. When a user group member logs into a project, only the authorized modules are displayed.

Below user groups can be customized to support eApproval process:

Role	Responsibility
Tester	Executes test run entities under Test Lab and Test Run
TDAdmin	Performs Admin related functionalities
Business SME	Review and approve Requirements, Test Cases from Business point of view
Defect Manager	Manage, prioritize & coordinate resolution of defects in Defect module
Defect Resolver	Provide fixes for defects in Defect module
eApprove Administrator	Configures ALM functionalities and user roles as per the project requirement
Requirement Author	Create and manage Requirements entities within Requirements module

Role	Responsibility
Requirement Manager	Manage, prioritize & decision making for Requirements module
Test Manager	Manage, prioritize & decision making for Test Plan module
SOX Approver	Review the SOX compliance of requirements
Technical SME	Review and approve the technical aspects of requirements & test cases
Test Designer	Create & manage Test Scripts under Test Plan module
Test Set Designer	Create & manage Test Sets under Test Lab module
Validation SME	Review and approve QA aspects of requirements & test cases
Viewer	Can only view ALM entities and cannot create/update/approve/reject entities

9. Dashboard

ALM allows users to generate reports and graphs at any time during the software development process. Project reports in ALM enable users to design and generate customized reports by accessing the project information which will help stakeholders in taking informed decisions.

- User can create graphs or project reports in the Analysis View module. They can also save the graphs and reports in the Analysis View module for future references.

The below reports can be configured in ALM based on the validated fields that are configured in other modules:

S.No	Report Name	Details
1	Requirement Traceability Report	This report can be configured to retrieve all the requirements and their linkage to any requirements or test cases
2	Requirement Risk Assessment Report	This report can be configured to fetch all the requirements with the risk details associated to them
3	URS_FRS_Trace To_FMEA	This report provides the list of URS requirements which are traced against FRS Requirement and FMEA (Failure 19Mode effective analysis) or Risk Assessment
4	URS-FRS-Design_Traceability Report	This report provides the list of test cases that are mapped against the URS and FRS requirements
S.No	**Report Name**	**Details**
5	Test Coverage Report - URS, FRS and FMEA	This report provides the list of test cases that are mapped against the URS, FRS requirements and FMEA (Failure Mode effective analysis) or Risk Assessment
6	Requirement Approval Pending More than N Business working days	This report can be configured to yield the list of requirements which are pending for approval for more than N business working days along with the approver details
7	Requirement in Checked Out Status more than N Business working days	This report can be configured to retrieve the list of requirements which are in Checked-Out status for more than N working days

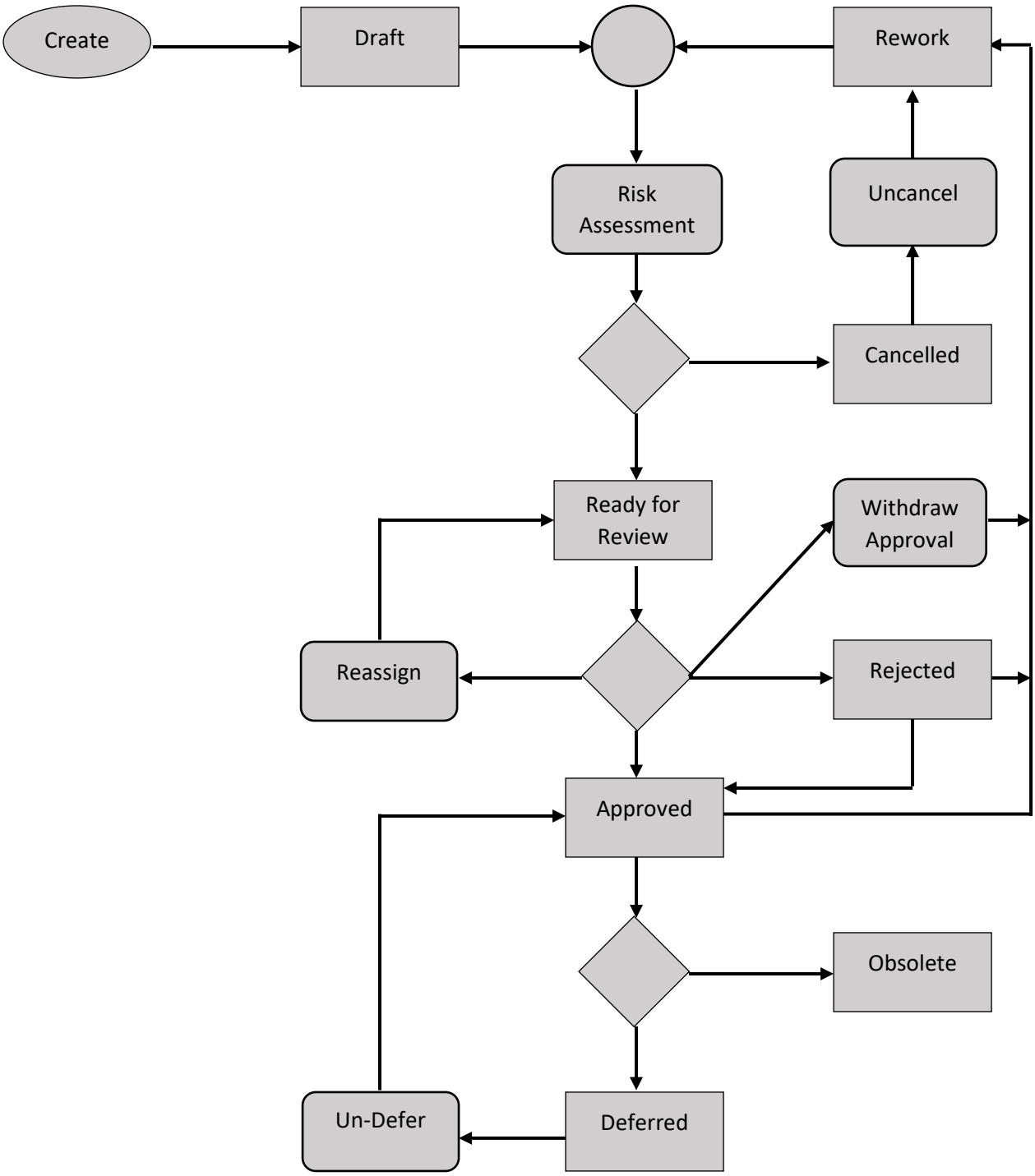
S.No	Report Name	Details
8	Test Case Approval Pending More than N Business working days	This report can be configured to fetch the list of test cases which are pending for approval for more than N business working days along with the approver details
9	Test Case without any steps seeking Evidence	This report can be configured to get the list of test cases which don't have any test steps asking for evidence to be attached
10	Test Case in Checked Out Status more than N Business working days	This report can be configured to fetch the list of test cases which are in Checked-Out status for more than N working days
11	Test Case without Linked Requirement	This report can be configured to retrieve the list of test cases which are not linked to any requirements
12	Test Planning Report	This report can be configured to get all the test sets with the test cases mapped to them
13	Test Run Approval Pending More than N Business working days	This report can be configured to get the list of Test Runs which are pending for approval for more than N business working days along with the approver details
14	Failed Test Run without Linked Defect	This report can be configured to get the list of Failed Test Runs which are not linked to any Defects.
15	Test Run without Evidence Attached	This report can be configured to get the list of Test Runs which don't have any supporting evidence attached to them
16	Test Execution Report	This report can be configured to get the details of all the test cases executed along with their execution status
17	Defects without Evidence Attachment	This report can be configured to retrieve the list of Defects which don't have any evidence attached to them
18	Defect Linkage Report	This report can be configured to get all the Defects along with their details and associated test run status
19	Defect Approval Pending More than N Business working days	This report can be configured to get the list of Defects which are pending for approval for more than N business working days along with the approver details
20	Users not logged in since last N months	This report can be configured to retrieve the list of Users which haven't logged into ALM since last N months

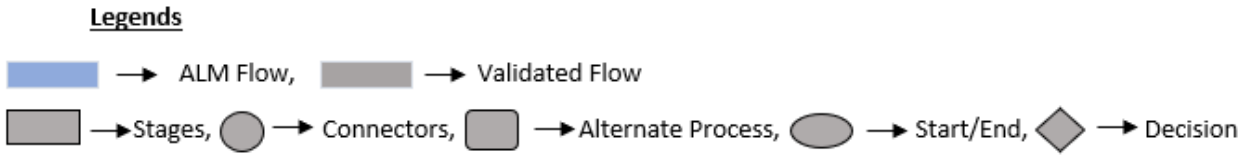
Note: N: Number of days/months which can be configured as per the project requirement.

10. Requirement Module

The Requirements module enables you to define, manage and track requirements at all stages of the application lifecycle management. More details about this module are available in the below link: https://admhelp.microfocus.com/alm/en/latest/online_help/Content/UG/t_use_requirements.htm

The Requirement Module can be customized as per below workflow to comply with pharma regulations





10.1 Create Requirement

This task defines how to define and update your requirements in the Requirements Module.

The requirements can be created by the requirement author user group by clicking on New Requirement icon from the Requirements toolbar. Also, requirements can be uploaded in bulk by using ALM excel add-in.

The system displays the New Requirement window with predefined fields. In the New Requirement screen, attributes can be configured to populate below pharma relevant fields in addition to other predefined fields to enable ALM supported for validated applications

- **Requirement Type**
- This field can be added to the new requirement screen and it can have values which specifies the type of requirement the user is going to create. This field can be configured to contain a list of requirement type values like Functional, Business, URS, FRS, GxP, SoX etc. Once the user selects a Requirement Type, the system will display the predefined template with specific fields to be filled in.
- **GxP**
- This field can be configured to the new requirement screen, to indicate if the requirement belongs to a GxP regularized pharma application. The field can have value as Y or N, the default value can be configured in the project parameters.
- **SoX**
- This field can be configured in new requirement screen, to indicate if the requirement is subjected to SoX regulations. This field also can have value as Y or N, the default value can be configured in the project parameters.
- **Approval Status**
- For the validated software's, it is mandatory to have all the requirements go through approval process and duly signed. Approval Status attribute can be enabled for requirements to view and track the approval process. Once a new requirement is created the default value can be set as "Draft" and it can be automatically updated appropriately by the system as the requirement goes through different approval stages like Ready for Review, Approved, Rejected, Cancelled, Rework etc.
- **Revision Number**
- This field can be configured to requirement screen to track the number of changes being performed on the requirement. The default value can be set as 1 and upon each changes the value can be incremented by the system.
- **Approved By**
- This field can be configured to display all the approver details of the requirement. This field can fetch and store the Name/ID/Email ID of the approver and can be customized for multiple approvers.
- **Approver Pending**
- This field can be configured to requirement details screen to notify the user about the current approver with whom the requirement approval is pending. This field can contain the Name/ID/Email ID of the pending approver.

- **Rejection Reason**
- This field can be configured to requirement screen to store the rejection reason. The rejection reason can be viewed by the Requirement Author who can work on the action item and re-route for approval.
- **Signature**
- This field can be configured to requirement screen to store e-signature of the approver with their username, name, roles, approval comments and time stamp.

* Above mentioned fields can be customized as mandatory or optional fields. For the multi select attributes, values can be configured to let the user select value from a predefined list.

Note :*To accommodate simple, effective review and approval process,* ***"ALM needs to be integrated with eApproval applications available in the market"****. This integrated eApproval application provides the below functionalities which needs be further customized based on the rules available in both ALM and the integrated eApproval application.*

Additionally, to perform the functionalities related to eApproval, ALM panes will be customized with required buttons.

10.2 Delete Requirement

This option can be customized to restrict the users to delete a requirement which has a signature trail. Deletion is only allowed when the requirement status is Draft, and no signature trail is present.

10.3 Clone Requirement

This option can be customized where users can clone a requirement with summary, description, field values same as the original requirement.

Note:
The cloned Requirement will not retain any linkages or traceability, Approval Pending, Approval Status, Revision History, Rejection Reason, Signatures and Revision Number fields.

10.4 Bulk Transition

This option can be customized to enable respective user groups to select child requirements within a folder and Bulk Approve them

10.5 eApproval Process

Approval of requirements, documentation of the signature and review process are vital for pharma application in order to comply with GxP guidelines.

eApproval workflow can be customized with below flows:

10.5.1 Start eApproval Flow

Once a requirement is created and ready to be sent for review/approve, user can trigger the eApproval process which allows the user to assign approvers and route entities for approval. Multiple level of approvers can be assigned to a requirement based on the project requirement.

Action	Before State	After State	Role
Start eApproval flow	Draft	Ready for Review	Requirement Author

- When a requirement is created by the Requirement Author the status will be Draft and once it is routed for approval the status will change to Ready for Review.
- The Requirement Author will be able to assign/modify Approvers to a requirement.
- Approvers are shown in the Approval Pending field until the approver approved the requirement

10.5.2 Withdraw eApproval Flow

When a requirement needs to have modifications or to be updated before getting approved, user can withdraw the approval flow and send the requirement to Rework state so that it is editable. Users can select single or multiple Requirements to Withdraw from Approval route

Action	Before State	After State	Role
Withdraw eApproval flow	Ready for Review, Rejected	Rework	Requirement Author, eApprove Administrator

The selected requirements are updated as follows when the Approval Route is withdrawn.

- Approval Status of the Requirement is set to Rework.
- Approvers with pending approval task will receive an email notification stating that the approval task has withdrawn.
- eSignatures of the Approvers are removed from the Signature Details field.

10.5.3 Cancel

When a requirement is no more valid for the project, then the user can mark it as cancelled. Requirements in Draft & Rework status can only be cancelled.

Action	Before State	After State	Role
Cancel Requirement	Draft, Rework	Cancelled	Requirement Author

Once marked Cancelled, the selected requirements are updated as follows:

- Cancelled Requirement cannot be editable.
- Approval Status of the requirement is set to cancelled.
- Requirement cannot be routed for approval flow.

10.5.4 Uncancel

Uncancel option can be used When a user wants to make the Cancelled requirement to be editable and route them for approval

Action	Before State	After State	Role
Uncancel Requirement	Cancelled	Rework	Requirement Author

Uncancelling the requirements are updated as follows:

- Status of the Uncalled Requirement is set to Rework.

- The Uncancelled Requirements can be routed for approval flow.
- Requirement details can be edited.

10.5.5 Defer

When a user wants to defer a requirement if the related functionality is deferred to a subsequent sprint or release.

Action	Before State	After State	Role
Defer Requirement	Approved	Deferred	Requirement Manager

Upon Deferring, the selected requirements are updated as follows:

- Approval Status of the requirement is set to Deferred.

10.5.6 Un-Defer

When a user wants to Un-Defer a Deferred requirement, Requirement Manager can move back requirement to Un-Defer Status.

Action	Before State	After State	Role
Un-Defer Requirement	Deferred	Approved	Requirement Manager

Upon Un-deferring, the selected requirements are updated as follows:

- Approval Status of the Deferred Requirement is set to Approved.

10.5.7 Approve

After a requirement is routed for approval, users from Approver User Group can approve them by providing their electronic signature along with their Username and Password. The approver can approve either by selecting a single requirement or multiple requirements.

Action	Before State	After State	Role
Approve Requirement	Ready for Review	Approved	Approvers (BO/TO/QA)

The Approved Requirement will be updated as below:

- Approval status is updated to Approved.
- The eSignature details of the approver are appended to the signature section along with timestamp.

10.5.8 Rejection

If the approver finds the requirement being incorrect or more details to be added, they can reject the requirement.

Approver can Reject with appropriate Rejection Reason.

Action	Before State	After State	Role
Reject Requirement	Ready for Review	Rejected	Approvers (BO/TO/QA)

The Rejected requirements will be updated as below:

- Requirement approval status is updated to Rejected.
- Rejection Reason field value will be updated.
- If the Requirement Author finds the rejection reason invalid, then they can trigger an email to the approver for approving the same.

10.5.9 Reassign

Approvers can Reassign their approval task to another user from Approver group.
The user can select single or multiple requirements to Reassign. The approval status of the reassigned requirements will be same and only the approver details will be changed.

Action	Before State	After State	Role
Reassign Requirement	Ready for Review	Ready for Review	Approvers (BO/TO/QA)

While Reassigning Approver of a requirement below features can be configured:

- Approver can select single or multiple requirements to reassign.
- While selecting another user only the users with approver role are available to be selected.

10.5.10 Obsolete

Requirement Manager can mark requirements as Obsolete if the functionality is no longer valid.
The user can select one or more requirements to Obsolete.

Action	Before State	After State	Role
Obsolete Requirement	Approved	Obsolete	Requirement Manager

The Obsolete Requirements are updated as follows:

- Obsolete Reason is updated.
- Approval Status is updated as Obsolete.

10.5.11 Rework

User can edit Rejected, Withdrawn and Uncancelled Requirements using this option. Once the changes are applied the requirement can be routed for approval.

Action	Before State	After State	Role
Rework Requirement	Cancelled, Ready for Review, Rejected	Rework	Requirement Author

10.6 Requirement Risk Assessment

This tab enables you to determine the Business Criticality, Failure Probability, and Functional Complexity of a requirement by assigning them values directly or by assigning values to a set of criteria.

Risk assessment is also pivotal for validated applications as it deals with patient safety and regulations.

For risk analysis, the ALM tool can be configured with multiple customized fields, algorithms to generate **Risk Score**. Based on the Risk Score, Risk Mitigation is planned and performed.

Below fields can be customized to generate Risk Score:

- **Requirement Criticality**
  - This field measures how crucial a requirement is for the business or quality.

- **Failure Probability**
  - This field indicates how likely a Requirement will fail during Test Cases execution.

- **Compliance Impact**
  - User can select if the requirement is subject to any compliance domain like GxP, SOX.

- **Risk Influencer**
  - When there is need to perform more detailed risk assessment, risk influencers are considered. The tool can be configured to select Increase Risk Rating or Decrease Risk Rating as required to adjust the requirement's risk rating.

- **Risk Detectability**
  - This field indicates the ability to detect a failure before it causes the issue.
- **Functional Complexity**
  - This field measures how much essential the requirement is from the application functionality point of view.

- **Mitigation Strategy**
  - This field contains the process of planning, developing methods and options to reduce the identified risk.

10.7 Requirement Traceability

Traceability is "the ability to follow the life of a requirement, in both forwards and backwards direction, i.e., from its origins, through its development and specification, to its subsequent deployment and use, and go through periods of ongoing refinement and iteration in any of these phases".

ALM can be customized to have different types of requirements like URS, FRS, FDS, CSD etc. These requirement types can be further customized to have different dependent fields. Since Each requirement is closely related to each other we can utilize the requirement traceability feature in ALM to link these requirements. ALM also provides features, to link the requirement to test cases.

- Requirements can be traced from **URS** → **FRS** → **FDS/CSD** → and then each FDS/CSD can be linked to **Test Cases**.

- **Direct Cover Status** field in ALM can be customized to get the execution status for the FRS and CSDs.

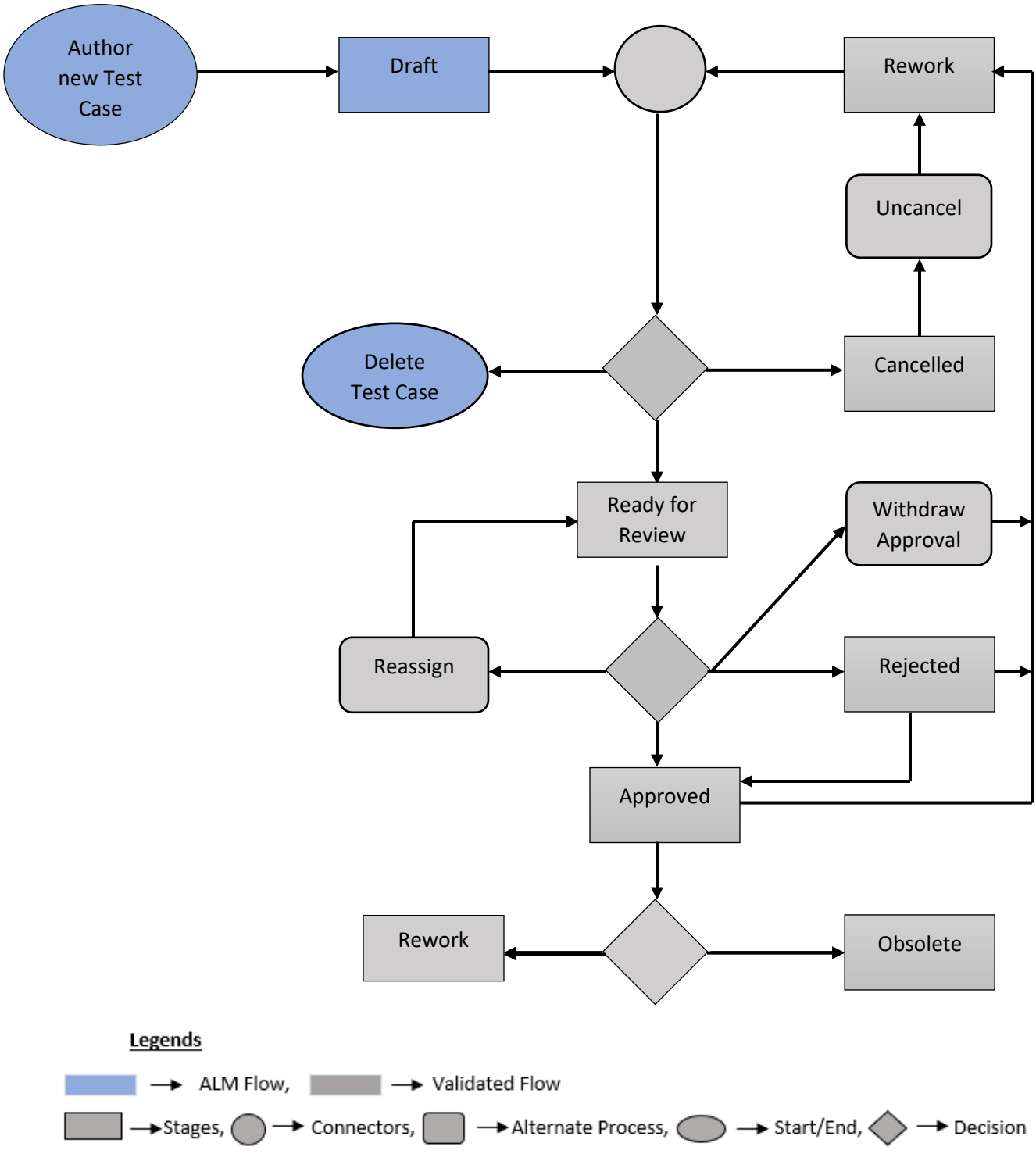
11. Test Plan Module

Test plan empowers to assess the quality of Application under test in all the phases of testing life cycle. Test Plan module enables user to develop and manage tests in ALM. Tests can be linked to requirements and Defects. More details about this module are available in the below link:

https://admhelp.microfocus.com/alm/en/latest/online_help/Content/UG/t_plan_tests.htm

To comply with pharma guidelines and regulations once Requirements are approved, user begins test planning phase in which testing goals and test strategy are defined.

The Test plan module is customized as per below workflow to comply with pharma regulations.


Author new Test Case
Draft
Rework
Uncancel
Delete Test Case
Cancelled
Ready for Review
Withdraw Approval
Reassign
Rejected
Approved
Rework
Obsolete
Legends
ALM Flow,
Validated Flow
Stages,
Connectors,
Alternate Process,
Start/End,
Decision

11.1 Create Test Case

Test case is created manually by clicking on New Test Case and entering test objective, test description and expected result. Test Cases are linked to appropriate requirements to ensure requirement-test case coverage is sustained.

Below is the list of fields that can be customized to comply with pharma regulations for validated applications:

- **Approval Status**
  - For the validated application in pharma, it is mandatory to have all the test cases go through approval process and are duly signed. Approval Status attribute enabled for test cases to view and track the approval process. The default value set as "Draft" and it is automatically updated appropriately by the system as the test case goes through different approval stages like Ready for Review, Approved, Rejected, Cancelled, Rework etc.
- **Revision Number**
  - This field can be configured for the test cases to track the number of approval cycles being performed on the Test. The default value is set as 1 and after test case is revised the value is incremented by 1.
- **Approved By**
  - This field can be configured to display all the Approver roles of the test case.
- **Approver Pending**
  - This field can be configured to display approver roles that are pending approvals for a test case.
- **Rejection Reason**
  - This field can be configured to display the rejection reason of the test case.
- **Evidence**
  - This field will be configured with values 'Yes' or 'No' to make user decide whether to attach evidence or not.

* Above mentioned attributes can be customized as mandatory fields.

Note :*To accommodate simple, effective review and approval process,* ***"ALM needs to be integrated with eApproval applications available in the market"****. This integrated eApproval application provides the below functionalities which needs be further customized based on the rules available in both ALM and the integrated eApproval application.*

Additionally, to perform the functionalities related to eApproval, ALM panes will be customized with required buttons.

11.2 Delete Test Case

This option can be configured to restrict the users to delete a test case which has a signature trail and allow only when the test case status is in Draft status

11.3 Clone Test Case

This option can be configured to allow users to clone a test case with test objective, step description, expected result and other field values same as the original test case.

Note:
The cloned test case will not retain any linkages or traceability, Approval Pending, Approval Status, Revision History, Rejection Reason, Signatures and Revision Number fields.

11.4 Bulk Transition

This option can be customized to enable respective user groups to select test cases within a folder and Bulk Approve them

11.5 eApproval Process

Approval of test cases, documentation of the signature and review process are vital for Pharma application in order to comply with GxP guidelines.

eApproval workflow can be customized with below flows:

11.5.1 Start eApproval Flow

Once a test case is created and ready to be sent for review/approve the user can trigger the eApproval process which allows the user to assign approvers and route entities for approval. Multiple level of approvers can be assigned to a test case based on the project requirement.

Action	Before State	After State	Role
Start eApproval flow	Draft	Ready for Review	Test Designer

- When a test case is created by the test designer the status will be Draft and once it is routed for approval the status will change to Ready for Review.
- Test esigner will be able to assign/modify approvers to a test case.
- Approvers are shown in the approval pending field until the approver approves the test case

11.5.2 Withdraw eApproval Flow

When a test case needs to have modifications or more details to be filled in before getting approved the user can withdraw the approval flow and send the test case to Rework state so that it is editable.

Action	Before State	After State	Role
Withdraw eApproval flow	Ready for Review	Rework	Test Designer, eApprove Administrator

The selected test cases are updated as follows when the Approval Route is withdrawn.

- Approval Status of the test case is set to Rework.
- Approvers with pending approval task will receive an email notification stating that the approval task has been withdrawn.
- eSignatures of the approvers are removed from the Signature Details field.

11.5.3 Cancel

If a test case is no more valid for the project, then the user can mark it as cancelled. Test cases in Draft & Rework status can be only be cancelled

Action	Before State	After State	Role
Cancel Test Case	Draft, Rework	Cancelled	Test Designer

Once marked Cancelled, the selected test cases are updated as follows:

- Approval Status of the test case is set to Cancelled.
- Test case cannot be edited and routed for Approval flow.

11.5.4 Uncancel

Uncancel option can be used When a user wants to make the Cancelled test case to be editable and route them for approval

Action	Before State	After State	Role
Uncancel Test Case	Cancelled	Rework	Test Designer

After Uncancelling the test case are updated as follows:

- Approval Status of the Uncancelled test case is set to Rework.
- The Uncancelled test case can be routed for approval flow.
- Test Case details can be edited.

11.5.5 Approve

After a test case is routed for approval, the users from Approver User Group can approve them by providing their electronic signature along with their Username and Password. The approver can approve either by selecting a single test case or multiple test cases

Action	Before State	After State	Role
Approve Test Case	Ready for Review	Approved	Approver (TO/BO/QA)

The approved test cases will be updated as below:

- Approval status is updated to Approved.
- The eSignature details of the approver are appended to the Signature section along with timestamp.

11.5.6 Rejection

If the approver finds the test case being incorrect or seeks more details to be added, they can reject the test case, so that it will again come to Rework status and the Test Designer can update and re-route them for approval. While rejecting the test case the approver must provide appropriate Rejection Reason.

Action	Before State	After State	Role
Reject Test Case	Ready for Review	Rejected	Approver (TO/BO/QA)

The Rejected test case will be updated as below:

- Test case approval status is updated to Rejected.
- Rejection Reason field value will be updated
- If the Tester finds the rejection reason invalid, then they can trigger an email to the Approver for approving the same.

11.5.7 Reassign

An approver can Reassign their approval to another user or to anyone in the Approval Role user group.
The user can select single or multiple entities. The approval status of the reassigned test cases will be same and only the approver details will be changed.

Action	Before State	After State	Role
Reassign Test Case	Ready for Review	Ready for Review	Approver (TO/BO/QA)

While Reassigning Approver of a test case below features can be configured:

- Approver can select single or multiple test cases to reassign.
- While selecting another user only the users with approver role are available to be selected.

11.5.8 Obsolete

Test Designer can mark test cases as Obsolete if the functionality is no longer valid. The user can select one or more test cases to Obsolete.

Action	Before State	After State	Role
Obsolete Test Case	Approved	Obsolete	Test Manager

The Obsolete test cases are updated as follows:

- Obsolete Reason is stored updated
- Approval Status is updated as Obsolete.

11.5.9 Rework

User can edit Rejected, Withdrawn and Uncancelled test case using this option. Once the changes are applied the test case can be routed for Approval.

Action	Before State	After State	Role
Rework Test Case	Cancelled, Ready for Review, Rejected	Rework	Test Designer

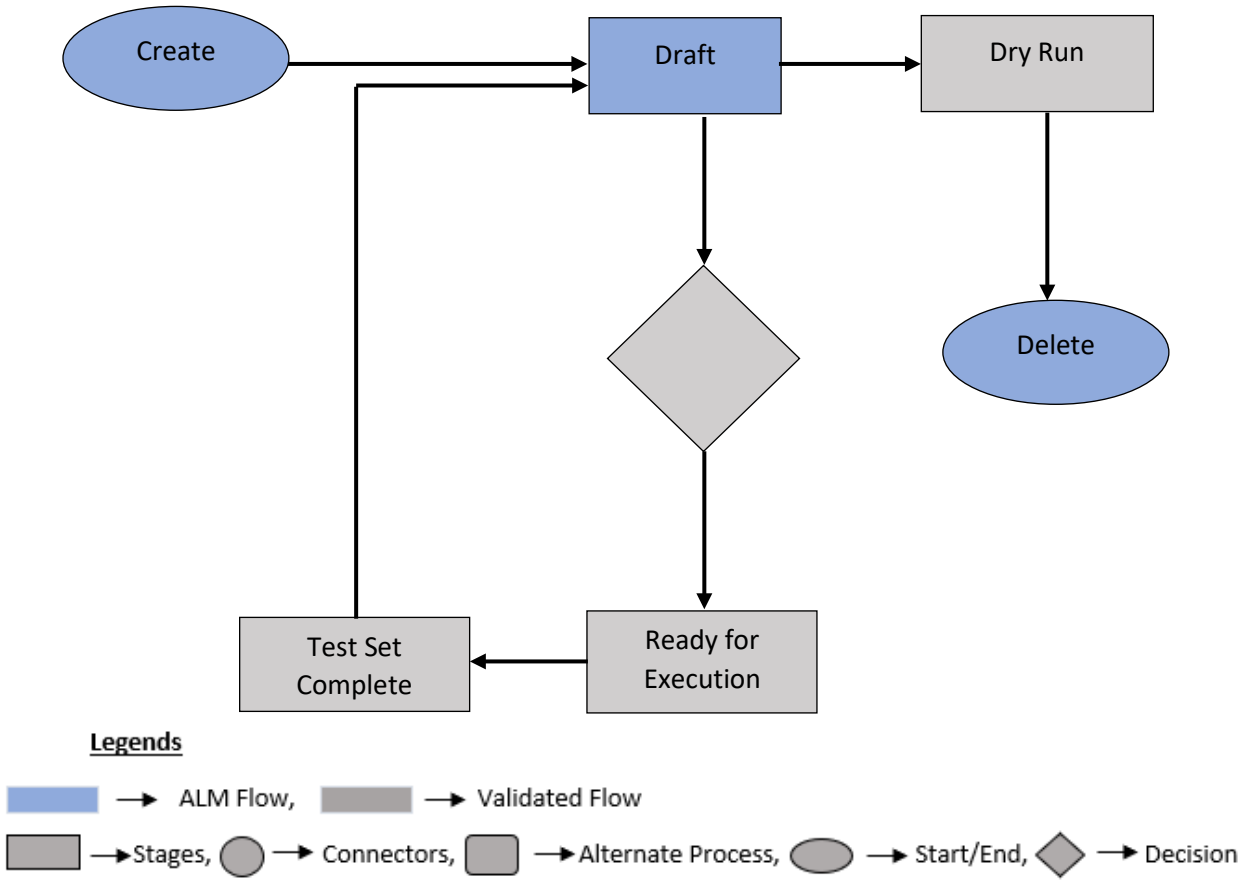
- Test case in Rework status can be editable.

12. Test Lab Module

After test design is completed, test execution takes place in Test Lab module by mapping test cases from Test Plan into Test Lab. More details about this module are available in the below link:

https://admhelp.microfocus.com/alm/en/latest/online_help/Content/UG/t_plan_tests.htm

The Test Lab module is customized as per below workflow to comply with pharma regulations.



12.1 Create Test Set

Test Set can be created by a user from Test Set Designer group. Once created, the Test Set approval status is automatically set as Draft. While creating the Test Set, user can link the Test Set to a release cycle.

Action	Before State	After State	Role
Create Test Set	-	Draft	Test Set Designer

When Test Set is in draft status:

- Tests can be added and removed from Test Sets.
- Test Set fields are editable

12.2 Test Set Dry Run

Users can perform informal execution (i.e. Dry Run) of Test Sets before doing formal testing to sanity check the application. User can start an informal execution by setting the Test Sets approval status to Dry Run.

Action	Before State	After State	Role
Test Set Dry Run	Draft	Dry Run	Test Set Designer

The Dry Run Test Sets will be updated as below:

- Test Dry Run mimics the formal execution process and forces the tester to attach screenshots, set pass/fail indicators and provide all actual results.
- Test Runs from Dry Run don't require eApproval process hence cannot be routed for approval.
- Both approved and unapproved tests can be executed if the approval status is set to Dry Run.
- Test Set fields can be editable in Dry Run status.

12.3 Ready for Execution

Formal execution can be started by setting the Test Set's approval status to "Ready for Execution". Test Runs as part of formal execution can be routed for eApproval process.

Action	Before State	After State	Role
Start Test Run	Draft	Ready for Execution	Test Set Designer

- Test Set approval status is changed to Ready for Execution.
- Test Set fields cannot be modified.
- Only approved tests can be executed.

12.4 Test Set Complete

User can restrict execution in a Test Set by setting the approval status to complete. Once marked as complete, tests from the Test Set cannot be executed.

Action	Before State	After State	Role
Test Set Complete	Ready for Execution	Test Set Complete	Test Set Designer

After changing the Test Set status to complete:

- Test Set fields cannot be modified.
- New Test Runs cannot be created.
- Test cases cannot be added or removed from the Test Set.

12.5 Revise Test Set

User can revise a Test Set with status “Complete” by setting the approval status to “Draft”.

Action	Before State	After State	Role
Revise Test Set	Complete	Draft	Test Set Designer

- New Tests can be added to the Test Set.
- Tests from the Test Set can be removed if the selected tests are not executed

12.6 Delete Test Set

User can delete Test Sets and Test Set Folders under certain conditions.

To delete a Test Set the following conditions must be met:

- Test Set status should set to Dry Run or it has no runs in it.
- Test Set should not have any formal runs.

To delete a Test Set Folder the following conditions must be met:

- Test Set Folder shouldn’t have any Test Sets in it.

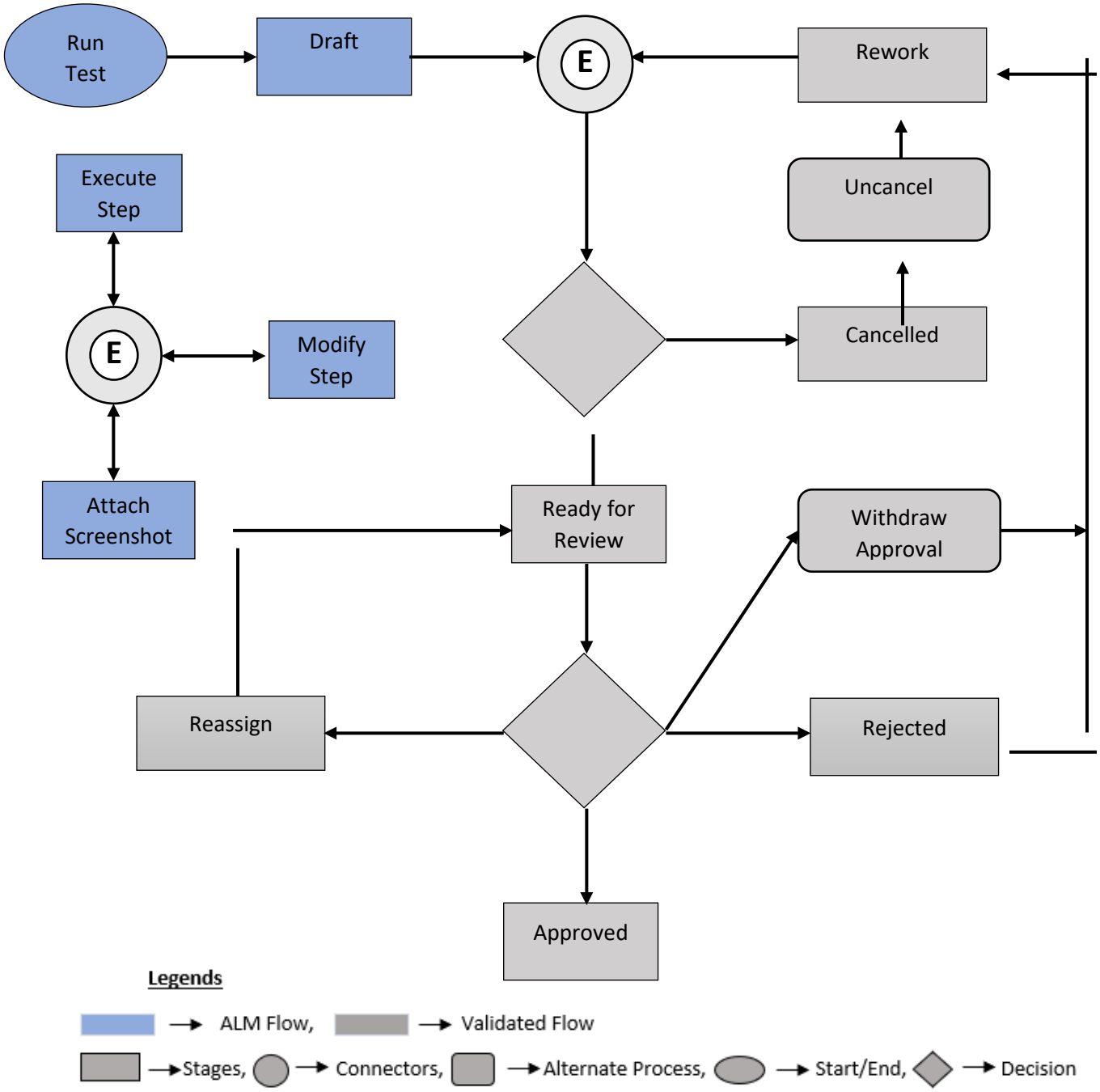
Action	Before State	After State	Role
Delete Test Set & Test Set Folder	Draft, Dry Run	-	Test Set Designer, eApprove Administrator

13. Test Run Module

Test Execution can be initiated by creating Runs from test instances (Tester’s group users). Also, the Test Run Status and results can be viewed in Test Run module. More details about this module are available in the below link:

https://admhelp.microfocus.com/alm/en/latest/online_help/Content/UG/viewing_test_runs.htm

ALM tool can be integrated with eApproval tool to incorporate eApproval process for the Test Runs, so that the created Runs go through approval life cycle process which in-turn helps to keep ALM a validated and GxP compliant tool suitable for pharma applications.



13.1 Run Test

User will be able to run the test set. Below conditions exist for run test module

- Test Runs with Test Set status as “Dry Run” Approval status cannot be routed for Approval
- Test Runs with Test Set status as “Ready for Execution” status can be routed for Approval

Action	Before State	After State	Role
Run Test	Draft	Not Complete, Passed, Failed	Tester

Below is the list of fields that can be customized to comply with pharma regulations for validated applications:

- **Approval Status**
  - This field can be configured to view and track the approval process. Once a new Run is created the default value can be set as "Draft" and it can be automatically updated appropriately by the system as the Runs traverse through different approval stages like Ready For Review, Approved, Rejected, Cancelled, Rework, Reassigned etc.
- **Approved By**
  - This field can be configured to display approver details of the Test Run. This field can store the Name/ID/Email ID of the approver and can be customized for multiple approvers.
- **Revision Number**
  - This field can be configured to track the number of changes being applied to the Test Run. The default value can be set as 1 and upon each changes the value can be incremented by the system.
- **Rejection Reason**
  - This field can be configured to display the rejection reason. Rejection reason can be viewed by the tester to work on the action item and re-route for approval.
- **Signature**
  - This field can be configured to display the e-signature of the approver with username, name, roles, approval comments and time stamp.
- **Testers**
  - This field can be configured to display all the Testers who has worked on the Test Run.

13.2 eApproval Process

Approval of Test Runs along with the signature documentation, review process is mandated for Pharma applications in order to comply with GxP guidelines.

eApproval workflow can be customized with below flows:

13.2.1 Start eApproval Flow

Once Test Run is created, user can initiate the eApproval process by setting approval status to Ready for Review and selecting appropriate approval levels, approvers.

Action	Before State	After State	Role
Start Test Run Approval	Draft	Ready for Review	Tester

The selected Test Run are updated as follows:

- When a Test Run is created the status will be Draft and once it is routed for approval the status will change to Ready for Review.
- Tester will be able to assign/modify approvers to the Test Run.
- Approvers are shown in the approval pending field until the Approver approved the Test Run.

13.2.2 Withdraw eApproval Flow

Test Run routed for approval needs further modifications before it is approved the user can withdraw the approval flow and send the Test Run to Rework state.

Action	Before State	After State	Role
Withdraw Test Run Approval	Ready for Review	Rework	Tester, eApprove Administrator

The selected Test Runs are updated as below when the Approval Route is withdrawn.

- Approval Status of the Test Run is set to Rework.
- Approvers with pending approval task will receive an email notification stating that the approval task has withdrawn.
- eSignatures of the Approvers are removed from the Signature Details field.

13.2.3 Cancel

If a Test Run is not valid, user can mark it as cancelled provided it is not in approved/Withdraw/Ready for Review status.

Action	Before State	After State	Role
Cancel Run	Draft, Rework	Cancelled	Tester

Once marked Cancelled, the selected Runs are updated as follows:

- Cancelled Test Run cannot be editable.
- Approval Status of the Test Run is set to Cancelled.
- Test Run cannot be routed for Approval flow.

13.2.4 Uncancel

If the user wants to edit the Cancelled Test Run, Uncancel Test Run option would be selected.

Action	Before State	After State	Role
Uncancel Run	Cancelled	Rework	Tester

- Status of the Uncancelling Test Run is set to Rework.
- The Uncancelled Test Run can be routed for approval flow.
- Test Run details can be edited.

13.2.5 Rework

User can edit Rejected, Withdrawn and Uncancelled Test Run using this option. Once the changes are applied the Test Run can be routed for Approval.

Action	Before State	After State	Role
Rework Run	Cancelled, Ready for Review, Rejected	Rework	Tester

- Test Run in Rework status can be editable.

13.2.6 Approve

Test Run routed for approval can be approved by the Approver User Group with their electronic signature by entering their Username and Password. The approver can either select a single or multiple Test Runs for approving.

Action	Before State	After State	Role
Approve Run	Ready for Review	Approved	Approvers (BO/TO/QA)

- Approved Test Run cannot be editable.
- eSignature of the Approver is stored in the Signature section along with timestamp.

13.2.7 Rejection

If the approvers find the Test Run being incorrect or needs further details to be added, they can reject the Test Run, so that it will come to Rework status where the tester can update and re-route them for approval. While rejecting the approver must provide appropriate Rejection Reason.

Action	Before State	After State	Role
Reject Run	Ready for Review	Rejected	Approvers (BO/TO/QA)

The Rejected Test Run will be updated as below:

- Test Run approval status is updated to Rejected.
- Rejection Reason field value will be updated

13.2.8 Reassign

Approvers can Reassign their approval task to another user by selecting appropriate reason. The user can select single or multiple Runs to Reassign.

Action	Before State	After State	Role
Reassign Run	Ready for Review	Ready for Review	Approvers (BO/TO/QA)

While Reassigning Approver of a Test Run below features can be configured:

- Approver can select single or multiple Test Runs to reassign.
- While selecting another user only the users with approver role are available to be selected.

14. Defects Module

Defect/Exception/Deviation/Bug refer to unexpected events that occur during formal, planned verification in controlled environment. Defects in ALM enables user to create, track, resolve, prioritize defects and analyze defect data.

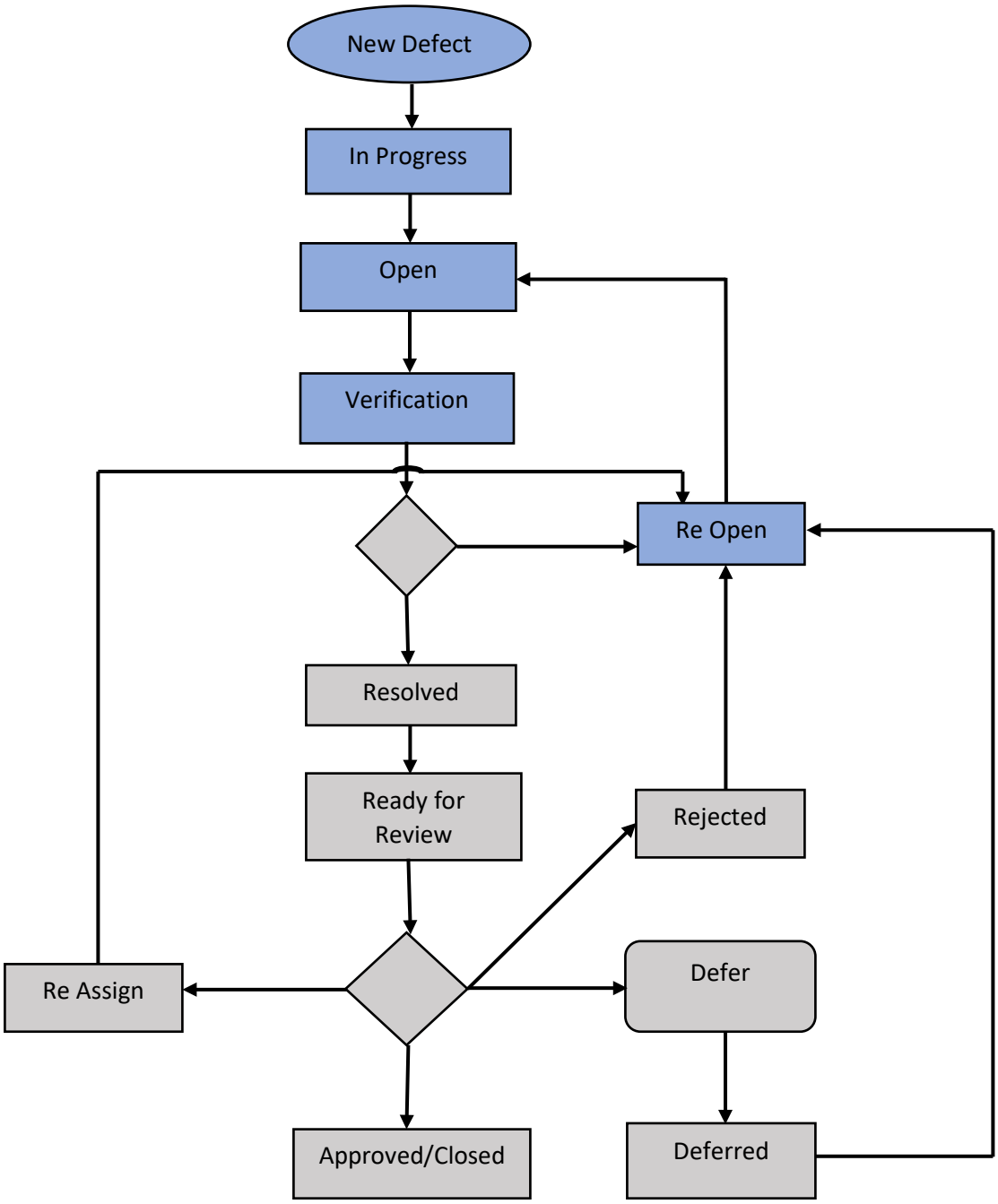
Defects are logged when,

- Actual outcome is deviated from Expected outcome or Test objective is not met.
- Test script documentation errors.
- Incorrect test evidence attached.

More details about this module are available in the below link:

https://admhelp.microfocus.com/alm/en/latest/online_help/Content/UG/menu_defects.htm

The Defect module is customized as per below workflow to comply with pharma regulations.



Legends

ALM Flow, Validated Flow

Stages, Connectors, Alternate Process, Start/End, Decision

14.1 Log Defect

Below is the list of fields that can be customized to comply with pharma regulations for validated applications:

- **Approval Status**
  - For the validated application in pharma, it is mandatory to have all the Defects go through approval process and are duly signed. Approval Status attribute enabled for Defects to view and track the approval process. The default value is set as "Open" and it is automatically updated appropriately by the system as the test case goes through different approval stages like Defer, Approved/Closed, Rejected, Cancelled, Re Assign etc.
- **QA Required**
  - This field can be configured to have values 'Yes' or 'No' to make user decide whether to have required approvals or not.
- **Verification Evidence**
  - This field can be configured to have values Yes' or 'No' to make user decide whether to attach evidence or not.
- **Signatures**
  - This field can be configured to display the e-signature of the approver with username, name, roles, approval comments with time stamp.
- **Rejection Reason**
  - This field can be configured to display the rejection reason of the Defect.

14.2 eApproval Process

Approval of Defects along with the signature documentation, review process is mandated for pharma applications in order to comply with GxP guidelines.

Below steps will be executed to start eApproval flow.

14.2.1 Start eApproval Flow

Once Defect is created, user can initiate the eApproval process by setting approval status to Ready for Review and selecting appropriate approval levels, approvers.

Action	Before State	After State	Role
Start eApproval flow	Fixed/Resolved	Ready for Review	Approvers (BO/TO/QA)

The selected Defect is updated as follows:

- When a Defect is Fixed/Resolved, it can be routed for eApproval and once routed for approval the status will change to Ready for Review.
- Tester will be able to assign/modify approvers to the Defect.
- Approvers are shown in the approval pending field until the approver approved the Defect.

14.2.2 Defer

User can Defer a Defect if the functionality related to it is deferred to a subsequent sprint/release or defect resolved by creating a change order.

Action	Before State	After State	Role
Defer Defect	Ready for Review	Defer	Defect Manager

Upon deferring, the selected Defect is updated as follows:

- Ready for Review Status is updated to Deferred.
- Deferral Reason is logged in to the comments section field.

14.2.3 Un-Defer

The Deferred Defect can be moved back to Reopen status by the Defect Manager user.

Action	Before State	After State	Role
Un-Defer Defect	Defer	Reopen	Defect Manager

Upon Un-deferring, the selected Defect is updated as follows:

- Approval Status is updated to Reopen.
- Un-deferral Reason is logged to the comment section field.

14.2.4 Re Open

If the Tester/Defect Manager finds the Defect being valid and the status is cancelled/Deferred/Ready for approval, they can discard the Defect conclusion, so that it will again come to Re-Open status.

Action	Before State	After State	Role
Re open Defect	Rejected/Deferred/ /Resolved/Re Assign	Re Open	Defect Manager/ Tester

14.2.5 Approve

After a Defect is routed for approval, the users from Approver User Group can approve them by providing their electronic signature along with Username and Password. The approver can either select a single Defect or multiple Defects and approve them.

Action	Before State	After State	Role
Approve Defect	Ready for Review	Approved/Closed	Approvers (BO/TO/QA)

14.2.6 Re Assign

After a Defect is routed for approval, the users from Approver User Group can re-assign them to the tester. The approver can either select a single Defect or multiple Defects and Re assign them.

Action	Before State	After State	Role
Re Assign	Ready for Review	Reopen	Approvers (BO/TO/QA)

15. Glossary

Glossary 1

Term	Details
ALM	Application Life Cycle Management
TDAdmin	Test Design Administrator
Tester	Quality Assurance Tester
SME	Subject Matter Expert
BO	Business Owner
TO	Technical Owner
QA	Quality Assurance
Sox Approver	Sarbanes-Oxley Approver
Sox	Sarbanes-Oxley
URS	User Requirement Specification
FRS	Functional Requirement Specification
FDS	Functional Design Specification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
DQ	Design Qualification
CSD	Custom Solution Development

Glossary 2

Term	Details
Validated Systems	Validation is a process required to establish a documented evidence which provides guarantee that system being used will consistently meet the requirements.
Defect/Exception/Deviation/Bug	**Defect** is a physical, functional attribute of a product or service that exhibits that the product or service failed to meet one of the desired specifications.
Quality Assurance	All planned and systematic activities implemented within the quality classification that can be verified to provide confidence that a product will fulfill requirements for quality.
Quality Control	The operational techniques and activities used to fulfill requirements for quality
Quality Manual	Document that states the regulations for operating the processes within the **quality** management system. It includes guidelines for all parts of the business that affect ability to make high-**quality** products and meet customers' and ISO's requirements.
Quality Management System	Quality Management System document states the company's goals for operating the processes within the **quality** management system. It includes policies for all areas of the business that affect ability to make high-**quality** products and meet customers' and ISO's requirements

Term	Details
GxP	Good Practice (GxP) includes wide range of compliance-related activities such as Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), and others, where every Life Sciences Organization has to follow in their Product specific requirements.
21 CFR Part 11	21 CFR Part 11 is fragment of, Code of Federal Regulations by FDA for electronic documentation and electronic signatures in Life Sciences sector. It outlines the administration of electronic records in a medical device company's quality management system.
21 CFR Part 211	21 CFR Part 211 by FDA ensures Quality Management of systems (QMS) in Pharmaceutical Industry. QMS facilitates documentation, policies and SOPs of medical Industry.
21 CFR Part 820	21 CFR Part 820 by FDA ensures Quality Management of systems in Medical Devices Industry.
21 CFR Part 606	21 CFR Part 820 by FDA ensures Quality Management of systems in Blood Institutions.
EU Annex 11	Eu Annex 11 is detailed regulation from European union on computerized systems as part of GMP related activities. Annex 11 assures Risk Management throughout the life cycle of a Computerized System considering Patient Safety, Data Integrity & Product Quality
FDA(USA)	Food and Drug Administration (United States) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting public health through the control and management of food safety, pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED).
FDAMA	Food and Drug Modernization Administration is regulatory act for food, drugs, devices, and biological products by the FDA. It mainly acknowledges in the advancement of technological, trade, and public health complexities
NDA	New Drug Application (NDA) is a complete document that is submitted to FDA to request approval for marketing a new drug. Drugs submitted to NDA already passed through several clinical trials
NIH	National Institutes of Health (NIH) is the primary intervention responsible for biomedical and public health research.
EMA	European Medical Agency is an agency from Europe responsible for the scientific assessment, management, and safety monitoring of medicines. The EMA follows the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported

Term	Details
	adverse reactions to ensure the safety and effectiveness of medicines.
MHRA(UK)	Medicine and Healthcare Products Regulatory Agency is an administrative agency of the Department of Health and Social Care in the United Kingdom which is responsible for certifying that medicines and medical devices work and are acceptably safe.
GAMP5	Good Manufacturing Automation Practice is a fragment of International society of Pharmaceutical Industry (ISPE). GAMP5 is a Risk based framework of cost-effective best practices to ensure that computer systems are suitable for use and compliant with the legislation. It mainly focus on computer systems that impact Patient safety, Data Integrity and product quality.
TGA	Therapeutic Goods Administration is an administrative agency of the Department of Health and Social Care in Australia which is responsible for certifying that medicines and medical devices work and are acceptably safe.
ICH	International Conference on Harmonization is a committee that provides guidelines of Regulatory authorities that should be followed in Pharmaceutical Industry. ICH objects to provide even standards for technical requirements of pharmaceuticals for human use.
ICH Q9	ICH Q9 guideline provides principles and examples of tools for quality risk management of development, manufacturing, distribution, and the inspection and submission/review processes throughout the lifecycle of drug substances, drug (medicinal) products, biological and biotechnological products (including the use of raw materials, solvents, excipients, packaging and labeling materials in drug (medicinal) products, biological and biotechnological products) in pharmaceutical quality.

Glossary 3

Non - Pharma STLC Terminology	Pharma STLC Terminology
Testing	Validation
Requirement Validation	Design Qualification
Deployment	Installation Qualification
Functional Testing	Operational Qualification
Test Plan	Validation Plan
Test Cases	Test Scripts
Test Execution	Validation Execution
Test Results	Validation Results
Test Completion Report	Verification Summary Report
User Acceptance Testing	Performance Qualification
Defects	Deviations