	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie

1. INTRODUCTION

GxP Genie is an application that allows life sciences companies to plan and execute computer systems validation (CSV).

2. PURPOSE

The purpose of this document is to define the functional requirements necessary for the GxP Genie CSV system. The intended audience of the document includes the product owner and stakeholders. Detailed design specifications will be defined in a subsequent design specification document.

3. REVISION CHANGE SUMMARY

VERSION	CHANGED BY	CHANGED DATE	DESCRIPTION
1.00	Cosmo Politan	Sat Jul 06 00:56:12 GMT 2024	Initial Revision

4. RELATED DOCUMENTS

DOCUMENT #	TITLE
GxP-URS-01	GxP Genie User Requirements

5. DEFINITIONS


TERM	DESCRIPTION
CSA	Computer Software Assurance

6. ROLES AND RESPONSIBILITIES


FUNCTIONAL ROLE	RESPONSIBILITY	INDIVIDUAL
System Owner	Ultimately responsible for the system and maintains project oversight.	Cosmo Politan
System Owner	Ultimately responsible for the system and maintains project oversight.	Lavan Lella

7. REQUIREMENTS


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-1-1	Master Validation Plan - Header	The system shall contain a highlights header for each MVP record to include:~†Artifact Id, Title, Artifact Number, Owner.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-1-2	Master Validation Plan - Detail	<p>The system shall contain the following Mast Validation Plan details:</p> <p>Top Section:Left Column:</p> <ul style="list-style-type: none"> • Artifact Id • Artifact Number • Title • Project • Project Title <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Record Type • Application • Application Name <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Introduction • Purpose • Strategy • Risk Management • Acceptance Criteria • Deliverables Responsibility Matrix • Change Control • Standard Operating Procedures • Supporting Processes • Training • Document Management 	Critical
FRS-1-3	Master Validation Plan - Template	The system shall contain an MVP print template that produces a PDF file. See attached file for format.	Critical
FRS-1-4	Master Validation Plan - Deliverables Matrix	<p>The system shall provide the ability to create a Deliverables Matrix for an MVP to include:</p> <ul style="list-style-type: none"> • Deliverable • Artifact • Title • System Owner • Project Manager • Technical Rep • Quality Rep • I'S. Compliance • Test Director • Validation Engineer • Tester 	Critical
FRS-1-5	Validation Summary - Header	The system shall contain a highlights header for each Validation Summary record to include:~†Artifact Id, Title, Artifact Number, Owner.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-1-6	Validation Summary - Detail	<p>The system shall contain the following Mast Validation Plan details:</p> <p>Top Section:Left Column:</p> <ul style="list-style-type: none"> • Artifact Id • Artifact Number • Title • Project • Project Title <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Record Type • Application • Application Name <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Introduction • Purpose • Approach • Test Results Summary • Test Deviation Details • Conclusion 	Critical
FRS-1-7	Validation Summary - Template	The system shall contain a VSR print template that produces a PDF file. See attached file for format.	Critical
FRS-1-8	Traceability - URS to FRS	<p>The system shall contain a report that displays the relationship between user requirements to functional requirements.</p> <p>Fields:</p> <ul style="list-style-type: none"> • URS Sequence • URS Subject • URS Requirement # • URS Backlog Id • FRS Sequence • FRS Subject • FRS Requirement # • FRS Backlog Id 	Critical
FRS-1-9	Traceability - User Requirements Test	The system shall provide the ability to trace user requirements to performance qualification test cases.	Critical
FRS-1-10	Traceability - Design Specification	The system shall provide the ability to link design specifications to functional requirements.	Critical
FRS-1-11	Traceability - Functional Requirements Test	The system shall have the ability to trace function requirements to operational qualification test cases.	Critical
FRS-2-1	User Requirement-Header	The system shall contain a highlights header for each user requirement record to include: Backlog Id, Record Type, RREQ #, Subject, Lifecycle, Owner.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-2-2	User Requirement - Detail (Backlog)	<p>The system shall contain the following User Requirement Specification (Backlog) details:Top Section:Left Column</p> <ul style="list-style-type: none"> • Backlog Id • Record Type • Project Title <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Sprint • Application Name <p>Artifact Section:Left Column:</p> <ul style="list-style-type: none"> • Artifact • Artifact Title <p>Right Column:</p> <ul style="list-style-type: none"> • Requirement Prefix • Requirement Sequence • Regulation <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Criticality • Subject • Description 	Critical
FRS-2-3	User Requirement - Child Requirements	The system shall provide a list of functional requirements for each user requirement to include the Backlog Id, REQ #, Subject, Criticality, Lifecycle, Lifecycle Date. The Backlog Id must contain a link to the functional requirement record.	Critical
FRS-2-4	Functional Requirements Template	The system shall contain an FRS print template that produces a PDF file. See attached file for format.	Critical
FRS-2-5	Functional Requirement - Header	The system shall contain a highlights header for each functional requirement record to include: Backlog Id, Record Type, REQ #, Subject, Lifecycle, Owner.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-2-6	Functional Requirement - Detail (Backlog)	<p>The system shall contain the following Functional Requirement Specification details:Top Section:Left Column:</p> <ul style="list-style-type: none"> • Backlog Id • Record Type • REQ # • Project Title <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Sprint • REQ # • Parent of Functional Requirement • Parent of Functional Req. (Subject) • Application Name <p>Artifact Section:Left Column:</p> <ul style="list-style-type: none"> • Artifact • Artifact Title <p>Right Column:</p> <ul style="list-style-type: none"> • Requirement Prefix • Requirement Sequence • Regulation <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Criticality • Subject • Description 	Critical
FRS-2-7	Functional Requirement - Child Stories	The system shall provide a list of stories for each functional requirement to include the Backlog Id, Subject, Lifecycle, Lifecycle Date, and Record Type. The Backlog Id must contain a link to the story record.	Critical
FRS-2-8	Functional Requirement Traceability to User Requirement	The system shall provide the ability to trace functional requirements to user requirements.	Critical
FRS-3-1	Design Specification Template	The system shall contain a design specification print template that produces a PDF file. See attached file for format.	Critical
FRS-3-2	Design Specification - Header	The system shall contain a highlights header for each design artifact record to include: Artifact Id, artifact Title, Artifact Number, Owner	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-3-3	Design Specification - Detail	<p>The system shall contain the following design specification details:Top Section</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Artifact Id • Artifact Number • Title • Project <p>Right:</p> <ul style="list-style-type: none"> • Owner • Record Type • Application • Application Name <p>Details Section:Single Column:</p> <ul style="list-style-type: none"> • Introduction • Purpose • System Overview • System Details 	Critical
FRS-3-4	Design Specification - Child Design Components	The system shall provide a list of design components for each design specification to include the Design Id, Functional Requirement, REQ#, Requirement, Design Approach, Component Reference.	Critical
FRS-3-5	Design Component - Header	The system shall contain a highlights header for each design component record to include: Design Id, DS #, REQ#, REQ Subject, Owner.	Critical
FRS-3-6	Design Component - Detail	<p>The system shall contain the following design component details:Top Section</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Design Id • Artifact • Backlog • REQ # • REQ Subject <p>Right:</p> <ul style="list-style-type: none"> • Owner <p>Details Section:Single Column:</p> <ul style="list-style-type: none"> • Type (Configuration, Customization, Integration) • Design Approach • Component Reference 	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-3-7	Code Review - Header	<p>The system shall contain a highlights header for each design component record to include:</p> <ul style="list-style-type: none"> • Artifact Id • Title • Artifact Number • Owner 	Critical
FRS-3-8	Code Review Template	The system shall contain a code review print template that produces a PDF file. See attached file for format.	Critical
FRS-4-1	System Risk Assessment - Header	The system shall contain a highlights header for each SRA record to include: Risk Id, Risk Level, Risk Category, Owner.	Critical
FRS-4-2	System Risk Assessment Template	The system shall contain an SRA print template that produces a PDF file. See attached file for format.	Critical
FRS-4-3	System Risk Assessment - Detail	<p>The system shall contain the following System Risk Assessment details:</p> <p>Top Section:Left Column:</p> <ul style="list-style-type: none"> • Risk Id • Risk Category • Risk Level • Residual Risk Level <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Backlog • REQ# • Artifact <p>Detail Section:</p> <ul style="list-style-type: none"> • Risk Description • Risk Control Activities 	Critical
FRS-5-1	Test Case (Script) - Header	The system shall contain a highlights header for each Test Case (Script) record to include: Test Case (Script) Name, Test Case No, Lifecycle, Lifecycle Date.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-5-2	Test Case (Script) - Detail	<p>The system shall contain the following Test Case (Script) details:Top Section:</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Topic • Test Case No <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Artifact • Design Object <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Test Case Name • Purpose • Prerequisite <p>Roles Section:Left Column:</p> <ul style="list-style-type: none"> • Author • Product Owner <p>Right Column:</p> <ul style="list-style-type: none"> • Quality Representative 	Critical
FRS-5-3	Test Case (Script) - Template	The system shall contain a Test Case print template that produces a PDF file. See attached file for format.	Critical
FRS-5-4	Test Case (Script) Workflow	The system shall have a workflow to approve the Pre-Execution Test Scripts.Draft --> Cancel --> ClosedDraft --> Submit for Review --> ReviewReview --> Approve --> EffectiveEffective --> Close --> Closed	Critical
FRS-6-1	Artifact Templates	The system shall have the ability to assign print templates to Artifacts.	Critical
FRS-6-2	Artifact Detail	<p>The system shall contain the following Artifact details:Top Section:</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Artifact Id • Artifact Number • Title • Project • Project Title <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Record Type • Application • Application Name <p>Artifact Section:Single Column:</p> <ul style="list-style-type: none"> • Introduction • Purpose 	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-6-3	Artifact Workflow	<p>The system shall contain the following artifact workflow for each artifact record type with the following steps.</p> <p>Draft --> Cancel --> Closed</p> <p>Draft --> Submit for Review --> Pending Review</p> <p>Checked Out --> Cancel --> Closed</p> <p>Checked Out --> Submit for Review--> Pending Review</p> <p>Pending Review --> Reject --></p> <p>DraftPending Review --> Approve --> Pending Release</p> <p>Pending Release --> Publish --> Effective</p> <p>Published --> Check Out --> Draft</p> <p>Published --> Obsolete --> Obsoleted</p>	Critical
FRS-6-4	Artifact List View	The system shall have the ability to filter custom lists of artifacts as Pre-Released, Effective, Closed, or Obsolete.	Critical
FRS-6-5	Artifact Preview	The system shall have the ability to preview artifacts in PDF format.	Critical
FRS-6-6	Artifact Relationships	The system shall have the ability to associate related artifacts to an existing artifact.	Critical
FRS-6-7	Artifact Responsibilities	The system shall have the ability to assign roles and responsibilities to artifacts.	Critical
FRS-6-8	Artifact Definition	The system shall provide the ability to add Terms to the definitions section of an artifact.	Critical
FRS-6-9	Artifact Release - Automation - Workflow	<p>The system shall automatically perform the following workflow steps:</p> <ol style="list-style-type: none"> 1. When an artifact's lifecycle changes to Pending Review, the system shall auto-promote the current artifact revision lifecycle to Pending Review. 2. When an artifact's lifecycle changes to Pending Release, the system shall auto-promote the current artifact revision lifecycle to Pending Release. 3. When an artifact's lifecycle changes to Effective, the system shall auto-promote the current artifact revision lifecycle to Effective. 4. When an artifact's lifecycle changes to Obsolete, the system shall auto-promote the current artifact revision lifecycle to Obsolete. 5. When an artifact's lifecycle changes to Closed, the system shall auto-promote the current artifact revision lifecycle to Closed. 	Critical
FRS-6-10	Artifact - Child Version - Auto Create	<p>The system shall automatically create an artifact version record when a new artifact is created and auto-populate the following fields:</p> <ul style="list-style-type: none"> • Action Attempt =0 • Artifact = Artifact Id • Changed By = Current User • Date of Change = now() • Change Description = "Initial Draft" • Version = 1 	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-6-11	Artifact - Child Template - Auto Create	<p>The system shall automatically create an output template record when a new artifact is created and auto-populate the following fields:</p> <ul style="list-style-type: none"> • Artifact = Artifact Id • Print Template = Print Template (see design spec for details) 	Critical
FRS-7-1	Action Comments	The system shall require action comments in order to complete an action when the route point indicates that a comment is required at the current stage.	Critical
FRS-7-1	Route Stage Administration	The system shall provide the ability to create, edit, and view route stages.	Critical
FRS-7-2	Route Diagram	The system shall have the ability to generate a workflow diagram representation of a defined route.	Other (non-regulated)
FRS-7-2	Route Path Execution	The system shall display the full path of a routes workflow (route points) highlighting the current stage of the record in the path.	Critical
FRS-7-3	Route Administration	<p>The system shall provide the ability to create, edit, and view workflow routes. The route shall include the following information:</p> <ul style="list-style-type: none"> • Route Name: Name of the route. • Object Name: Name of the object associated with the route. • Record Type: The record type assigned to the route. 	Critical
FRS-7-3	Control Group Action Execution	The system shall display buttons for each available workflow action assigned to the action control group.	Critical
FRS-7-4	Quick Assign Action Execution	The system shall display buttons for each available workflow action assigned to the quick assignment list of users on the record.	Critical
FRS-7-4	Route Action Administration	The system shall provide the ability to create, edit, and view route actions.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-7-5	Route Point Administration	<p>The system shall have the ability to create, edit, and view route points representing a step in a business process. The route point includes the following information:</p> <ul style="list-style-type: none"> • Acknowledgment Message: The message which displays when an electronic signature is required.→† • Acknowledgment? : Indicates whether an electronic signature is required.→† • Action Control Group: Name of the group allowed to perform the action. • Action Control Type: Indicates whether the action is assigned to a group or a quick action assignment list. • Comments Required: Indicates whether a comment is required to complete an action.→† • End-Stage: The destination stage of a route point. • Is Return Action?: Indicates whether an action results in returning to a prior stage. • Lock File: Indicates if file attachments are locked at the current stage. • Lock Record: Indicates if the record is locked at the current stage. • Multiple Approvals Required?: Indicates whether all quick action assignee approvals are required to allow the record to progress to the next stage. • Object Name: Name of the object associated with the route. • Route: Name of the route. • Route Action: Name of the action that can be performed at the current stage. • Route Point Order: The order in which the actions will display. • Route Point Type: Indicates whether the route point is one of the following: <ul style="list-style-type: none"> • Default • Entrance • Termination • Start-Stage: The starting stage of a route point. 	Critical
FRS-7-5	Quick Assign Actions to Assignees	The system shall provide the ability to assign users to actions in an ad-hoc fashion when a route point action control type is designated as quick assign.	Critical
FRS-7-6	Quick Assign Action Assignee List	The system shall display the list of assignees and status of the action for records where the route point action control type is set to quick assign.	Critical
FRS-7-6	Action Requires Multiple Approvals	The system shall require all quick assign approvals in order to progress a record to the next stage when the route point indicates that multiple approvals are required.	Critical
FRS-7-7	Action Acknowledgement Message	The system shall display an acknowledgment message when an action acknowledgment is required.	Critical
FRS-7-7	Action Display Order	The system shall display route action buttons in the order indicated in the route points.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-7-8	Action Log	<p>The system shall log all route actions performed in the system to include the following fields:</p> <ul style="list-style-type: none"> • Object Name • User • Record Type • Action • Action Date • Start-Stage • End-Stage • Acknowledgment Required? • Acknowledgment Message • Comment Required? • User Full Name • Action Attempt • Multiple Approvals Required • Related Record Id 	Critical
FRS-7-9	Backlog Workflow	<p>The system shall contain a backlog workflow for each record type with the following steps. Funnel --> Submit for Analysis --> AnalyzingAnalyzing --> Approve --> BacklogBacklog --> Commit --> Implementingimplementing --> Submit for Validation --> ValidatingValidating --> Submit for Deployment --> DeployingDeploying --> Submit for Release --> Released</p>	Critical
FRS-8-5	Test Case (Execution) - Header	<p>The system shall contain a highlights header for each Test Case (Execution) record to include: --> Test Case Name, Test Case No, Test Cycle, Lifecycle, Lifecycle Date.</p>	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-8-6	Test Case (Execution) - Detail	<p>The system shall contain the following Test Case (Execution) details:Top Section: Left Column:</p> <ul style="list-style-type: none"> • Test Case (E) • Test Case No • Test Cycle (R) • Design Object <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Artifact • Test Case (R) <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Subject • Purpose • Prerequisite <p>Results Section:Left Column:</p> <ul style="list-style-type: none"> • Test Case Result • Executed By • Executed Date <p>Right Column:</p> <ul style="list-style-type: none"> • Reviewed By • Reviewed Date <p>Metrics Section:Left Column:</p> <ul style="list-style-type: none"> • Count Not Started • Count In Progress • Count Skipped <p>Right Column:</p> <ul style="list-style-type: none"> • Count Passed • Count Passed with Limitations • Count Failed <p>Approvers Section:Left Column:</p> <ul style="list-style-type: none"> • Author • Product Owner <p>Right Column:</p> <ul style="list-style-type: none"> • Quality Representative 	Critical
FRS-8-7	Test Case (Execution) - Template	The system shall contain a Test Case (e) print template that produces a PDF file. See attached file for format.	Critical
FRS-8-8	Test Case (Execution) Workflow	The system shall have a workflow to approve executed test scripts. Not Started --> Start --> In Progress In Progress --> Send for Review --> Reviewing In Progress --> Pass All --> Reviewing Reviewing --> Approve --> Completed	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-8-9	Test Case (Step Execution) - Header	The system shall contain a highlights header for each Test Case (Execution) record to include:→†Test Step (E) Name, Step Order, Lifecycle, Lifecycle Date, Test Step Result.	Critical
FRS-8-10	Test Case (Step Execution) - Detail	<p>The system shall contain the following Test Case (Step Execution) details:Top Section: Left Column:</p> <ul style="list-style-type: none"> • Test Step Id (E) • Step Order <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Artifact • Test Case (E) • Test Step (R) <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Subject • Test Procedure • Expected Result • Actual Result • Value(s) Required? • Remarks • Executed By • Execution Date 	Critical
FRS-8-11	Test Case (Step Execution) - Template	The system shall contain a Test Case (e) print template that produces a PDF file. See attached file for format.	Critical
FRS-8-12	Test Case (Step Execution) Workflow	The system shall have a workflow to execute test steps.Not Started --> Start --> In ProgressIn Progress --> Pass --> PassedIn Progress --> Pass with Limitations --> Passed with LimitationsIn Progress --> Fail --> FailedNot Started --> Skip --> Skipped	Critical
FRS-8-13	Test Case (Step Execution) - Inline Execution	<p>The system shall have the ability to execute all test steps for a test case in-line in a table.Table Columns:</p> <ul style="list-style-type: none"> • Step Order: read-only • Procedure: read-only • Expected Result: read-only • Actual Result: Editable • Remarks: Editable • Lifecycle: read-only <p>Table Actions:</p> <ul style="list-style-type: none"> • Pass • Pass with Limitations • Fail 	Critical
FRS-8-14	Test Exception - Header	The system shall contain a highlights header for each Test Case (E) record to include:→†TestException Id, Classification, Lifecycle, Priority, Severity, Date Due.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-8-15	Test Exception - Workflow	The system shall have a workflow for Test Exceptions..Not Started --> Start --> In ProgressIn Progress --> Pass --> PassedIn Progress --> Pass with Limitations --> Passed with LimitationsIn Progress --> Fail --> FailedNot Started --> Skip --> Skipped	Critical
FRS-8-16	Test Exception - Template	The system shall contain a Test Exception print template that produces a PDF file. See attached file for format.	Critical
FRS-8-17	Test Exception - Detail	<p>The system shall contain the following Test Exception details:Top Section: Left Column:</p> <ul style="list-style-type: none"> • Exception Id • Classification • Date of Occurrence • Date Due <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Test Case (E) • Severity • Priority <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Description <p>Investigation Section:Single Column:</p> <ul style="list-style-type: none"> • Resolution 	Critical
FRS-8-18	Test Case Lifecycle Counts	The system shall update the lifecycle metrics (count passed, count passed with limitations, count skipped, count failed, count not started, count in progress), in the test case whenever an action is performed on a child test step.	Critical
FRS-8-19	Test Step Automation - Completion (Passed)	The system shall update the test case lifecycle status to passed when at least one test step has a lifecycle status equal to 'Passed' and all other test steps have a lifecycle status equal to 'Skipped'.	Critical
FRS-8-20	Test Step Automation - Completion (Passed) - Action Log	The system shall insert an action into the action log for the parent test case when at least one test step has a lifecycle status equal to 'Passed' and all other test steps have a lifecycle status equal to 'Skipped'.	Critical
FRS-8-21	Test Step Automation - Completion (Passed with Limitations)	The system shall update the test case lifecycle status to Passed with Limitations when at least one test step has a lifecycle status equal to 'Passed with Limitations' and all other steps have a lifecycle status equal to 'Passed' or 'Skipped'	Critical
FRS-8-22	Test Step Automation - Completion (Passed with Limitations) - Action Log	The system shall log an action in the action log for the parent test case when at least one test step has a lifecycle status equal to 'Passed with Limitations' and all other steps have a lifecycle status equal to 'Passed' or 'Skipped'.	Critical
FRS-8-23	Test Step Automation - Fail	The system shall update the test case lifecycle status to Reviewing and the test case Result to Failed when at least one test step has a lifecycle status equal to 'Failed'	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-8-24	Test Case Automation - Start	The system shall update all test step lifecycle status to 'In Progress' when Test Case 'Start' action is executed.	Critical
FRS-8-25	Test Case Automation - Pass All	The system shall have the ability to Pass All test steps from the Test Case.	Critical
FRS-8-26	Test Case Execution - Approver Validation	The system shall have the ability to validate the current user against the Quality Representative approver assigned to the Test Case.	Critical
FRS-8-27	Test Cycle Creation	The system shall have the ability to create a test cycle from a select list of test cases.	Critical
FRS-11-1	File Upload	The system shall allow authorized users to upload files to records that are not in a locked state. This allows users to upload supporting information.	Critical
FRS-11-2	Prevent File Upload	The system shall enforce strict controls on file uploads for locked records, prohibiting any file attachments, uploads, or modifications when a record is in a locked state. This measure ensures high data integrity and safeguards against unauthorized changes to critical information.	Critical
FRS-11-3	Prevent File Delete	The system shall prevent the deletion of file attachments on locked records.	Critical
FRS-13-1	Audit Trail	The system shall capture and maintain a log of changes to data as defined by the system administrator.	Critical
FRS-15-1	Artifact - Versioning Unique Copy	The system shall retain a unique copy of each version of an artifact.	Critical
FRS-15-2	Artifact - Versioning Checkout	The system shall allow users to checkout artifacts that are in a Published status. Once checked out, the Artifact record shall become editable.	Critical
FRS-15-3	Artifact - Versioning Numbering	The system shall increment new artifact <u>versions</u> as 1, 2, 3 and so on.	Critical
FRS-15-4	Auto Versioning	The system shall provide the ability to auto version artifacts through the artifact lifecycle.	Critical
FRS-16-1	Record Locking	The system shall have the ability to lock records at a given workflow status.	Critical
FRS-16-2	Field Level Permissions	The system shall have the ability to assign read and edit permissions to fields.	Critical
FRS-16-5	Row Level Permissions	The system shall have the ability to assign/un-assign create, read, edit, and delete permissions to rows of data.	Critical
FRS-17-1	Project - Header	The system shall contain a highlights header for each project record to include: Project Id, Project Title, Project Manager, Project Status.	Other (non-regulated)
		<p>The system shall contain the following project details:</p> <p><u>Top Section</u></p> <p>Left Column:</p>	

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-17-2	Project - Detail	<ul style="list-style-type: none"> • Project Id • Project Title • Project Description <p>Right:</p> <ul style="list-style-type: none"> • Owner • Project Number • Project Manager <p>Status Section:</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Project Status • Schedule Status <p>Right Column:</p> <ul style="list-style-type: none"> • Budget Status • Resource Status • Issue Status <p>Schedule Section:</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Planned Start Date • Planned End Date <p>Right Column:</p> <ul style="list-style-type: none"> • Actual Start Date • Actual End Date • Go Live Date <p>Budget Section:</p> <p>Left Column:</p> <ul style="list-style-type: none"> • Budget • Spend <p>Right Column:</p> <ul style="list-style-type: none"> • Budget Remaining <p>System Information Section:</p> <p>Left Column</p> <ul style="list-style-type: none"> • Created By <p>Right Column:</p> <ul style="list-style-type: none"> • Last Modified By 	Other (non-regulated)

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-17-3	Project - Child Artifacts	The system shall provide a list of artifacts for each project to include the Artifact Id, Artifact Number, and Title. The Artifact Id must contain a link to the artifact record.	Other (non-regulated)
FRS-17-4	Project - Child Milestones	The system shall provide a list of milestones for each project to include the Milestone Id, Milestone, Status, and Due Date. The Milestone Id must contain a link to the Milestone record.	Other (non-regulated)
FRS-17-5	Project - Workflow	The system shall contain a project workflow with the following steps. Initiation --> Start Planning --> Planning Planning --> Start Execution --> Execution Execution --> Start Closeout --> Closeout Closeout --> Close --> Closed	Other (non-regulated)
FRS-17-8	Code Review - Detail	<p>The system shall contain the following code review details: Top Section Left Column:</p> <ul style="list-style-type: none"> • Artifact Id • Artifact Number • Title • Project • Project Title <p>Right:</p> <ul style="list-style-type: none"> • Owner • Record Type • Application • Application Name <p>Details Section: Single Column:</p> <ul style="list-style-type: none"> • Introduction • Purpose 	Critical
FRS-18-1	Story - Header	The system shall contain a highlights header for each story record to include: Story Id, Record Type, REQ #, Subject, Lifecycle, Owner	Other (non-regulated)
FRS-18-1	Defect - Header	The system shall contain a highlights header for each defect record to include: Defect Id, Record Type, REQ #, Subject, Lifecycle, Owner	Critical
		<p>The system shall contain the following User Story details: Top Section: Left Column:</p> <ul style="list-style-type: none"> • Backlog Id • Record Type • Project Title • Application Name <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Sprint • Parent of User Story • Parent of User Story (Subject) <p>Artifact Section: Left Column:</p> <ul style="list-style-type: none"> • Artifact <p>Right Column:</p>	

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-18-2	Story - Detail (Backlog)	<ul style="list-style-type: none"> Artifact Title <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> Criticality Subject Description Acceptance Criteria <p>Sizing and Ranking Section:Left Column:</p> <ul style="list-style-type: none"> List Sequence Fibonacci Size WSJF <p>Right Column:</p> <ul style="list-style-type: none"> Business Value Time Criticality Risk Rating Cost of Delay <p>Team Section:Left Column:</p> <ul style="list-style-type: none"> Agile Team Product Owner Scrum Master <p>Right Column:</p> <ul style="list-style-type: none"> Developer QA Engineer <p>Gantt Information Section:Left Column:</p> <ul style="list-style-type: none"> Planned Start Date Planned End Date Planned Duration <p>Right Column:</p> <ul style="list-style-type: none"> Progress Gantt Sort Order 	Other (non-regulated)

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-18-2	Defect - Detail (Backlog)	<p>The system shall contain the following User Story details:Top Section: Left Column:</p> <ul style="list-style-type: none"> • Backlog Id • Record Type • Severity • Probability • Priority <p>Right Column:</p> <ul style="list-style-type: none"> • Owner • Sprint • Parent of Defect • Parent of Defect (Subject) <p>Where Found Section:Left Column:</p> <ul style="list-style-type: none"> • Release Detected • Application Detected <p>Right Column:</p> <ul style="list-style-type: none"> • Application Detected Name • Application Detected Version <p>Detail Section:Single Column:</p> <ul style="list-style-type: none"> • Subject • Description • Acceptance Criteria <p>Sizing and Ranking Section:Left Column:</p> <ul style="list-style-type: none"> • List Sequence • Fibonacci Size • WSJF <p>Right Column:</p> <ul style="list-style-type: none"> • Business Value • Time Criticality • Risk Rating • Cost of Delay <p>Team Section:Left Column:</p> <ul style="list-style-type: none"> • Agile Team • Product Owner • Scrum Master <p>Right Column:</p> <ul style="list-style-type: none"> • Developer • QA Engineer 	Critical
FRS-18-3	Story - Parent Functional Requirement	The system shall maintain the relationship between a story and its parent functional requirement.	Other (non-regulated)

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-18-3	Defect - Tasks	The system shall have the ability to create child tasks for a defect and assign a due date and user.	Critical
FRS-18-4	Defect - Parent Functional Requirement	The system shall maintain the relationship between a defect and it's parent functional requirement.	Critical
FRS-18-4	Story - Tasks	The system shall have the ability to create child tasks for a user story and assign a due date and user.	Other (non-regulated)
FRS-18-5	Functional Requirement - Child Defects	The system shall provide a list of Defects for each functional requirement to include the Backlog Id, Subject, Lifecycle, Lifecycle Date, and Record Type. The Backlog Id must contain a link to the defect record.	Critical
FRS-19-1	Collaboration	The system shall provide the ability to post and share comments on a record.	Other (non-regulated)
FRS-20-1	Installation	The system shall provide an installation URL.	Other (non-regulated)
FRS-21-1	Project Navigator - Artifact Tab	<p>The system shall provide the ability to navigate artifacts by project and lifecycle.</p> <ul style="list-style-type: none"> ARTIFACTS <ul style="list-style-type: none"> Specifications Qualifications Planning Risk 	Other (non-regulated)
FRS-21-2	Project Navigator - Artifact Preview	The system shall provide the ability to preview in progress artifacts from within the project navigator.	Other (non-regulated)
FRS-21-3	Project Navigator - Artifact Approval	The system shall provide the ability to review and approve artifacts from within the project navigator	Other (non-regulated)
FRS-21-4	Project Navigator - Assurance Tab	The system shall provide an area to navigate testing: Results, Cycle Management, Trace Management.	Other (non-regulated)
FRS-21-5	Project Navigator - Assurance - Test Case Section	<p>The system shall provide an area to view project user stories. <u>Dynamic Search</u></p> <ul style="list-style-type: none"> Test Case Id Topic Author Product Owner Quality Representative Lifecycle Start Date End Date <p><u>Defect</u></p> <ul style="list-style-type: none"> Id Topic Author Product Owner Quality Representative Lifecycle Lifecycle Date 	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-21-5	Project Navigator - Assurance - Results	<p>The system shall provide an area to navigate testing results by project, artifact, and test cycle.</p> <ul style="list-style-type: none"> • Select Project, Qualification, and Test Cycle • Display Test Result Doughnut Chart. • Display total number of test cases by test result (Not Started, In Progress, Passed, Failed) • Clicking on a test result total display a list of test cases <ul style="list-style-type: none"> • Test Case No • Name • Result • Lifecycle • Lifecycle Date 	Other (non-regulated)
FRS-21-7	Project Navigator - Assurance - Test Case Create	The system shall enable an authorized user to click ,ÄòNew,Äô to create a new Test Case from the Test Case section within the Assurance tab.	Critical
FRS-21-8	Project Navigator - Assurance - Test Case Edit	The system shall enable an authorized to ,ÄòEdit,Äô existing Test Cases from the Test Case section within the Assurance tab.	Critical
FRS-21-9	Project Navigator - Assurance - Cycle Management	The system shall provide the ability to add a set of existing test cases to a test cycle.	Other (non-regulated)
FRS-21-10	Project Navigator - Assurance - Trace Management	The system shall provide the ability to automatically generate or view a trace matrix for a qualification document.	Other (non-regulated)
FRS-21-11	Project Navigator - Work Tab	The system shall provide an area to navigate work such as projects, user requirements, functional requirements, stories, and defects.	Other (non-regulated)
FRS-21-12	Project Navigator - Work - User Requirement Section	<p>The system shall provide an area to view a list of project user requirements.</p> <p><u>Dynamic Search</u></p> <ul style="list-style-type: none"> • REQ # • Subject • Criticality • Test Case Id • Lifecycle • Lifecycle Start • Lifecycle End <p><u>User Story List</u></p> <ul style="list-style-type: none"> • Id • REQ# • Subject • Criticality • Test Case Id • Lifecycle • Lifecycle Date 	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-21-13	Project Navigator - Work - User Requirement Create	The system shall enable an authorized user to click „New“ to create a new User Requirement from the User Requirements section within the Work tab.	Critical
FRS-21-14	Project Navigator - Work - User Requirement Edit	The system shall enable an authorized user to Edit an existing User Requirement from the User Requirements section within the Work tab.	Critical
FRS-21-15	Project Navigator - Work - Functional Requirement Section	<p>The system shall provide an area to view a list of project functional requirements.<u>Dynamic Search</u></p> <ul style="list-style-type: none"> • REQ # • Subject • Parent of FR (Subject) • Criticality • Test Case Id • Lifecycle • Lifecycle Start • Lifecycle End <p><u>User Story List</u></p> <ul style="list-style-type: none"> • Id • REQ# • Subject • Parent • Criticality • Test Case Id • Lifecycle • Lifecycle Date 	Critical
FRS-21-16	Project Navigator - Work - Functional Requirement Create	The system shall enable an authorized user to click „New“ to create a new Functional Requirement from the Functional Requirements section within the Work tab.	Critical
FRS-21-17	Project Navigator - Work - Functional Requirement Edit	The system shall enable an authorized user to Edit an existing Functional Requirement from the User Requirements section within the Work tab.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie


REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-21-18	Project Navigator - Work - User Stories Section	<p>The system shall provide an area to view project user stories.<u>Dynamic Search</u></p> <ul style="list-style-type: none"> • Subject • Sprint • Priority • Developer • Product Owner • QA Engineer • Lifecycle • Lifecycle Start • Lifecycle End <p><u>User Story List</u></p> <ul style="list-style-type: none"> • Id • Subject • Sprint • Priority • Developer • Product Owner • QA Engineer • Lifecycle • Lifecycle Date 	Other (non-regulated)
FRS-21-19	Project Navigator - Work - User Stories Create	The system shall enable an authorized user to create a new User Story from the User Story section within the Work tab.	Critical
FRS-21-20	Project Navigator - Work - User Stories Edit	The system shall enable an authorized user to 'Edit' existing User Stories from the User Stories section within the Work tab.	Critical
FRS-21-21	Project Navigator - Work - Defects Section	<p>The system shall provide an area to view project user stories.<u>Dynamic Search</u></p> <ul style="list-style-type: none"> • Subject • Sprint • Priority • Developer • Product Owner • QA Engineer • Lifecycle • Lifecycle Start • Lifecycle End <p><u>Defect</u></p> <ul style="list-style-type: none"> • Id • Subject • Sprint • Priority • Developer • Product Owner • QA Engineer • Lifecycle • Lifecycle Date 	Other (non-regulated)
FRS-21-22	Project Navigator - Work - Defect Create	The system shall enable an authorized user to click „New“ to create a new Defect from the Defect section within the Work tab.	Critical

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie

REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-21-23	Project Navigator - Work - Project Section	<p>The system shall provide an area to view project status, milestones, and spend. <u>Project Status List</u></p> <ul style="list-style-type: none"> • Project Name • Project Id Link • Project Number • Project Description • Project Lifecycle • Project Status • Schedule Status • Budget Status • Issue Status • Resource Status <p><u>Milestone List</u></p> <ul style="list-style-type: none"> • Milestone Id Link • Milestone • Date Due • Status Indicator <p><u>Spend Chart</u></p> <ul style="list-style-type: none"> • x-axis = milestone • y-axis = spend 	Other (non-regulated)
FRS-21-23	Project Navigator - Work - Defect Edit	The system shall enable an authorized user to Edit an existing Defect from the Defect section within the Work tab.	Critical
FRS-21-24	Project Navigator - Work - General - Refresh	The system shall provide the ability to refresh the data table with changes.	Other (non-regulated)
FRS-21-25	Project Navigator - Work - General - Pagination	The system shall have the ability to display work listed on multiple pages.	Other (non-regulated)
FRS-21-26	Project Navigator - Work - General - Filter Toggle	The system shall provide a feature to toggle the visibility of the filters section on the screen, allowing users to either display or conceal this section as per their need.	Other (non-regulated)
FRS-21-27	Project Navigator - Work - General - Delete Multiple Rows	This system shall provide the ability to delete multiple rows.	Other (non-regulated)
FRS-21-28	Project Navigator - Work - General - Filter	The system shall provide the ability to filter work records by displayed fields.	Other (non-regulated)
FRS-21-29	Project Navigator - Work - Project Edit	The system must enable authorized users to modify and update project records efficiently, ensuring data integrity and alignment with ongoing project needs.	Other (non-regulated)
FRS-21-30	Project Navigator - Work - Project Create	The system shall have the ability to create project records.	Other (non-regulated)

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie

REQ#	SUBJECT	DESCRIPTION	CRITICALITY
FRS-21-31	Project Navigator - Home	The system shall have a Home Page from which the user can navigate to features within the application.	Other (non-regulated)

	Document Name:	GxP Genie Functional Requirements Specification	Status:	Pending Review
	Document Number:	GxP-FRS-01	Status Date:	July 6, 2024
	Version:	1.00	Project:	GxP-1001 - GxPGenie

8. APPROVAL HISTORY

END STAGE	ACTION	ACTION DATE	USER	TITLE
-----------	--------	-------------	------	-------