main&mission	Document Name:	GxP Genie User Requirements	Status:	Effective
	Document Number:	GxP-URS-01	Status Date:	September 25, 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 software assurance (CSA).

2. PURPOSE

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

3. REVISION CHANGE SUMMARY

VERSION	CHANGED BY	CHANGED DATE	DESCRIPTION
1.00	Cosmo Politan	Wed Sep 25 17:56:26 GMT 2024	Initial Version

4. RELATED DOCUMENTS

DOCUMENT #	TITLE
GxP-FRS-01	GxP Genie Functional Requirements Specification

5. DEFINITIONS

TERM	DESCRIPTION
CSV	Computer Systems Validation
CSA	Computer Software Assurance
OQ	Operational Qualification
IQ	Installation Qualification

6. ROLES AND RESPONSIBILITIES

FUNCTIONAL ROLE	RESPONSIBILITY	INDIVIDUAL
Project Manager	Manage project timeline, cost, and budget.	Margo Rita
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
URS-1	Artifact - Validation Plans	The system shall provide the ability to manage validation planning including the creation and management of validation master plans and validation summary reports.	Critical
URS-2	Artifact - Requirements Specifications	The system shall provide the ability to create and manage user and functional specifications.	Critical

REQ#	SUBJECT	DESCRIPTION	CRITICALITY
URS-3	Artifact - Technical Specifications	The system shall provide the ability to create and manage design specifications and code reviews.	Critical
URS-4	Artifact - Risk Assessments	The system shall provide the ability to create and manage system and functional risk assessments.	Critical
URS-5	Artifact - Protocols	The system shall provide the ability to create and manage installation, operational, and performance qualifications.	Critical
URS-6	Artifact - General	The system shall have the ability to create and manage validation artifacts. • User Requirement Specification • Functional Requirement Specification • Design Specification • Code Review • Installation Qualification • Operational Qualification • Performance Qualification • System Risk Assessment • Functional Risk Assessment • Validation Master Plan • Validation Summary Report • Requirements Trace Matrix	Critical
URS-7	Process Workflow Exection	The system shall provide the ability to execute process workflow.	Critical
URS-8	Test Management	The system shall provide the ability to plan, manage and monitor computer system testing.	Critical
URS-9	Inventory/System Management	The system shall provide the ability manage information about systems including their location.	Critical
URS-10	Process Workflow Adminstration	The system shall provide the ability to configure and administer process workflow.	Critical
URS-11	File Management	The system shall provide the ability to manage file attachments.	Critical
URS-12	Electronic Signatures	The system shall provide the ability to capture electronic signatures in accordance with 21 CRF Part 11.	Critical
URS-13	Electronic Records Management	The system shall provide the ability to manage electronic records in accordance with 21 CRF Part 11.	Critical

REQ#	SUBJECT	DESCRIPTION	CRITICALITY
URS-14	Reports and Dashboard	The system shall provide out of the box reporting capability.	Critical
URS-15	Version Control	The system shall provide the ability to manage artifact versions.	Critical
URS-16	Security and Access Control	The system shall provide the ability to manage and control user/group permissions to application functionality and data.	Critical
URS-17	Project Management	The system shall provide the ability to manage a project.	Other (non-regulated)
URS-18	Work Management	The system shall provide the ability to manage and monitor work performed to build, validate, and maintain computer systems (.e.g. users stories, defects)	Other (non-regulated)
URS-19	Collaboration	The system shall provide the ability to collaborate between users.	Other (non-regulated)
URS-20	Application Installation	The system shall provide the ability to install remotely.	Other (non-regulated)
URS-21	User Friendly Navigation	The system shall provide the ability to easily navigate to a General (Home), Validation Life Cycle, System Life Cycle (SLC), and Test Cycle information for a project.	Other (non-regulated)

8. APPROVAL HISTORY

END STAGE	ACTION	ACTION DATE	USER	TITLE
Effective	Publish	September 25, 2024	Cosmo Politan	
Pending Release	Approve	September 24, 2024	Lavan Lella	
Pending Release	Approve	September 4, 2024	Cosmo Politan	
Pending Release	Approve	June 24, 2024	Cosmo Politan	