Information	
Name:	Project ordgp
Description:	Description of ordgp.
Version:	DEV
Date Created:	2022-01-21T10:15:30
Git Commit:	1e84b5100e09d9b6c5ea1b6c2ccee8957391beec
Git Tag:	ods-generated-v3.0-3.0-0b11-D
Git URL:	https://bitbucket-dev.biscrum.com/scm/ordgp/ordgp-releasemanager
OpenShift Cluster API URL:	https://openshift-sample
Created by Jenkins Job Name:	ordgp-cd/ORDGP-releasemanager
Created by Jenkins Build Number:	666

Risk Assessment for 'Project ordgp'

TABLE OF CONTENTS

8 DOCUMENT HISTORY

1 PURPOSE

This document is an assessment of risks associated with the usage of the Project ordgp. Risks are identified based on requirements and functions of the system and classified according to predefined rules. This will serve as a basis for risk management strategies and measures during the system life cycle.

2 BASE DOCUMENTS

The risk assessment is based on the following documents:

Reference Document	Version	Prefix for Ref. No.
Combined Specification Document	BI-IT-DEVSTACK / DEV-666	N/A All Ref. Numbers are unique
System and Software Design Specification	BI-IT-DEVSTACK / DEV-666	

3 ASSUMPTIONS

None

4 RISK ASSESSMENT PROCESS

Section 4.1 gives a high level description of the risk assessment table (see section 5). Details and classification rules, for the values in columns that need additional explanation, are given in section 4.2.

4.1 RISK ASSESSMENT TABLE DESCRIPTION

The risk assessment table in section 5 comprises the following columns:

Column	Description
Risk No.	Identifier of the risk for reference within other documents
Reference No.	Unambiguous reference to a specific requirement, function or a group of requirements in a reference document. The prefix indicates the referenced document
Requirement / Function	Short description of requirement or function
GxP	Relevance of the requirement or function for GxP or non-GxP (e.g. business). See section 4.2.1
Description of Risks/Failures (or reason for GxP = No)	Description of possible risks or failures associated with the requirement or function. More than one risk or failure may be associated with a requirement or function. If non-GxP risks are not evaluated, reason for classification as non-GxP is provided.
Prob. of Occurrence	Probability that the failure will occur.
Severity of Impact	Possible impact of the failure if it is not detected. See section 4.2.2
Prob. of Detection	Most probable point in time when the failure will be detected in routine operation of the system. See section 4.2.4
Risk Priority Number (RPN)	Product of the individual factors which determine the risk based on relevance, impact, probability of detection and Prob. of Occurrence (optional). See section 4.2.5

Risk Priority	Categorized risk which is derived from the risk priority number RPN. 1 identifies highest risk priority and 3 lowest risk priority.
Proposed Measures	Proposed measures (e.g. additional test requirements, design requirements, functional limitations, and organisational or procedural measures) for risk mitigation. This entry is mandatory for priority 1 GxP risks and optional for all other risk priorities
Comments	Comments as applicable (optional)

4.2 CLASSIFICATION RULES

4.2.1 GXP RELEVANCE

The requirement or function is evaluated to determine if it is related to GxP. If there are both GxP and non-GxP risks, GxP is documented as it is the more relevant risk. However, the associated non-GxP risk should also be taken into account.

GxP Relevance	Value	Option	Description
Yes	2	n/a	The requirement is directly related to GxP regulated activities. Failures could lead to incorrect data, loss of data, deterioration of product quality, or risk exposure for safety of patients or customers.
No	n/a	Non-GxP risks are not being evaluated	The requirement has no GxP relevance. However, the requirement may have an impact on business. Failures could lead to e.g. system downtime, delay of submission process, loss of corporate reputation etc.
	1	Non-GxP risks are evaluated lower than GxP risks	
	2	Non-GxP risks are evaluated the same as GxP risks	

For BI-IT-DEVSTACK	Non-GxP risks are not being evaluated

4.2.2 PROBABILITY OF OCCURRENCE

The probability that a possible failure does occur is classified according to the following table:

Probability Of Occurrence	Value	Description
Low	1	Frequency of the usage of the related function is <10 times per year.
Medium	2	Frequency of the usage of the related function is <10 times per week.
High	3	Frequency of the usage of the related function is >10 times per week.

4.2.3 SEVERITY OF IMPACT

The severity of the impact of a possible failure is evaluated according to the following classes:

Severity of Impact	Value	GxP Impact	Non-GxP Impact (e.g. to cover business risks)
Low	1	No impact on product quality, patient safety, or data quality; no impact on data integrity is expected: no deviation from regulatory obligations or predicate rules	Low cost risk; no delay of regulatory processes
Medium	2	Product quality, patient safety, or data quality could be impacted; correctable impact on data integrity; potential; probability of a deviation from regulatory obligations or predicate rule	Medium cost risk; short delay of regulatory processes
High	3	Product quality, patient safety, or data quality will probably be impacted; uncorrectable impact on data integrity; deviation from regulatory obligations or predicate rules	High cost risk; significant delay of regulatory processes

4.2.4 PROBABILITY OF DETECTION

The most probable point in time when a possible failure is detected is classified according to the following table:

Probability of Detection	Value	Description
Inmediate	1	The failure is detected immediately when it occurs. The user is able to take immediate measures to correct the failure before any impact can occur.
Before Impact	2	The failure is not detected immediately by the user but later before it may have any impact. The effect of the failure may still be corrected or minimized by appropriate corrective actions.
After Impact	3	The failure will most probably not be detected before the expected impact occurs.

4.2.5 RISK PRIORITY NUMBER AND RISK PRIORITY

Calculate a risk priority number RPN by multiplying the values of the individual factors:

RPN = Value(GxP Relevance) * Value(Prob. of Occurrence) * Value(Severity of Impact) * Value(Prob. of Detection)

Assign the risk priority for the risk according to the following table:

RPN	Risk Priority
1-4	3
6-16	2
>16	1

A risk considered as non-GxP and not being evaluated will lead to a RPN = 0 and Risk Priority = 0.

4.2.6 PROPOSED MEASURE

Depending on the risk priority risk mitigating measures must be defined according to the following table. The System Owner must ensure that the defined measures are being implemented.

Risk Priority	**Requirements for mitigating measures**
1	Measures in addition to functional or requirements testing need to be defined, whenever feasible. Measures can be procedural measures (e.g. additional checks, four eyes principle, typically defined in a WI or SOP) or technical measures (e.g. additional technical checks, technical security measures).
2	Measures need only to be defined if the underlying functionality cannot be tested, or cannot be tested on an appropriate level.
3	In general no risk mitigating measures need to be defined.

5 RISK ASSESSMENT TABLE

Risk No.	Ref No.	Requirement/ Function	GxP (see 4.2.1)	Description of risks/failures (or reason for GxP = No)	Prob. Occur.	Severity Impact	Prob. Detect.	RPN	Risk Prio.	Proposed Measures	Comments
ORDGP-136	ORDGP-125	Story 1	N1	Summary:RA 1. Suspendisse potenti. Cras ante quam, hendrerit vel massa quis, ultricies pellentesque mauris. Pellentesque eu odio dictum, luctus massa vitae, dignissim enim.	L	M	B	4	3	Mitigations: ORDGP-140 Tests: ORDGP-137, ORDGP-138, ORDGP-139	N/A
				Summary:RA 2. Suspendisse potenti. Cras ante quam, hendrerit vel							

ORDGP-141	ORDGP-126	Story 2	R2	massa quis, ultricies pellentesque mauris. Pellentesque eu odio dictum, luctus massa vitae, dignissim enim. Morbi pretium massa quis nunc pharetra, id faucibus purus condimentum. Sed augue lacus, faucibus in erat non, rutrum rhoncus dolor. Proin ornare rutrum tristique. In dictum purus sit amet justo dignissim tristique. Sed ligula ante, tempus non turpis eget, iaculis consequat	H	H	I	18	1	Mitigations: None Tests: None	N/A

				dui. Aenean orci tortor, interdum at magna vitae, euismod lacinia odio. Nullam ac ante orci. Quisque in mattis purus. Maecenas volutpat bibendum felis, in porttitor dui imperdiet et. Mauris ac feugiat lacus. Interdum et malesuada fames ac ante ipsum primis in faucibus. Maecenas feugiat, turpis nec finibus pellentesque, lectus arcu pellentesque ex, in tempus metus velit sit amet purus. Phasellus ut volutpat orci.							

ORDGP-142	ORDGP-126	Story 2	N0	Summary:RA 3. Suspendisse potenti. Cras ante quam, hendrerit vel massa quis, ultricies pellentesque mauris.	L	L	A	N/A	0	Mitigations: None Tests: None	N/A

The following table contains more information about the proposed mitigations:

Mit. No	Type	Mitigation description	Risk No.
ORDGP-137	test	Unit Test 1 Suspendisse potenti. Cras ante quam, hendrerit vel massa quis, ultricies pellentesque mauris. Pellentesque eu odio dictum, luctus massa vitae, dignissim enim. Morbi pretium massa quis nunc pharetra, id faucibus purus condimentum. Sed augue lacus, faucibus in erat non, rutrum rhoncus dolor. Proin ornare rutrum tristique. In dictum purus sit amet justo dignissim tristique. Sed ligula ante, tempus non turpis eget, iaculis consequat dui	ORDGP-136
ORDGP-138	test	Unit Test 2 Suspendisse potenti. Cras ante quam, hendrerit vel massa quis, ultricies pellentesque mauris. Pellentesque eu odio dictum, luctus massa vitae, dignissim enim. Morbi pretium massa quis nunc pharetra, id faucibus purus condimentum. Sed augue lacus, faucibus in erat non, rutrum rhoncus dolor. Proin ornare rutrum tristique. In dictum purus sit amet justo dignissim tristique. Sed ligula ante, tempus non turpis eget, iaculis consequat dui	ORDGP-136

ORDGP-139	test	Unit Test 3 Suspendisse potenti. Cras ante quam, hendrerit vel massa quis, ultricies pellentesque mauris. Pellentesque eu odio dictum, luctus massa vitae, dignissim enim. Morbi pretium massa quis nunc pharetra, id faucibus purus condimentum. Sed augue lacus, faucibus in erat non, rutrum rhoncus dolor. Proin ornare rutrum tristique. In dictum purus sit amet justo dignissim tristique. Sed ligula ante, tempus non turpis eget, iaculis consequat dui	ORDGP-136
ORDGP-140	mitigation	Mitigation 1 Suspendisse potenti. Cras ante quam, hendrerit vel massa quis, ultricies pellentesque mauris. Pellentesque eu odio dictum, luctus massa vitae, dignissim enim. Morbi pretium massa quis nunc pharetra, id faucibus purus condimentum. Sed augue lacus, faucibus in erat non, rutrum rhoncus dolor. Proin ornare rutrum tristique. In dictum purus sit amet justo dignissim tristique. Sed ligula ante, tempus non turpis eget, iaculis consequat dui. Aenean orci tortor, interdum at magna vitae, euismod lacinia odio. Nullam ac ante orci. Quisque in mattis purus. Maecenas volutpat bibendum felis, in porttitor dui imperdiet et. Mauris ac feugiat lacus. Interdum et malesuada fames ac ante ipsum primis in faucibus. Maecenas feugiat, turpis nec finibus pellentesque, lectus arcu pellentesque ex, in tempus metus velit sit amet purus. Phasellus ut volutpat orci.	ORDGP-136

6 DEFINITIONS AND ABBREVIATIONS

6.1 DEFINITIONS

Term	Definition
Jenkins	Build engine supplied by cloudbees - part of OpenDevStack (BI-IT-DEVSTACK)
xUnit	Unit testing framework, aggregaults across multiple languages

6.2 ABBREVIATIONS

Abbreviation	Meaning
ODS	OpenDevStack
EDP	Enterprise Development Platform

7 REFERENCE DOCUMENTS

- Combined Specification Document (version BI-IT-DEVSTACK / DEV-666)
- System and Software Design Specification including Source Code Review Plan (version BI-IT-DEVSTACK / DEV-666)
- Functional and Requirements Testing Plan (version BI-IT-DEVSTACK / DEV-666)

No further reference documents

8 DOCUMENT HISTORY

The following table provides the history of the document.

Version	Date	Author	Change Reference
1	See Summary of electronic document or signature page of printout.		Initial document version.

The following table provides extra history of the document.

Version	Date	Author	Reference
	See summary of electronic document or signature page of printout.		