visibility
intelligence
value

MobiVue PMMS System

Ajanta Pharma Ltd.

Functional Risk Assessment Document (WMS)

This user's guide includes the risk assessment protocols defined for the application functions.

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REVISION HISTORY

Revision Number	Date	Prepared By	Reviewed By	Comment
00	23-May-2023	Prateeksha	Sailendra Das	Risk Assessments defined for application function
01	02-09-2023	Leena P.	Sailendra Das	Risk Assessments defined for Implementation of Inward & Sampling Process

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PRE-APPROVAL

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1 INTRODUCTION

The purpose of this document is to list down all the possible risks related to system for **Mobivue PMMS system**. The document lists all the possible GxP and functional related risks with the implementation of the System. The risks are identified so as to ensure that appropriate mitigation actions are determined and addressed either in the system or outside the system to guarantee safe and appropriate usage of the application. The document also enumerates the mitigation actions identified for each of the risk.

2 OBJECTIVE

The purpose of this document is to detail the methodology used to identify the GxP and functional related risks associated with the implementation of the system. The activity of risk assessment is basically carried out to estimate the extent of validation effort that is required for the features and to ensure that the required external mitigation actions are in place for the risks before implementation of the features. It forms the basis for further qualification and other control activities.

The following are the considerations made for the risk assessment:

- Identification of critical operational parameters (e.g. critical sequence steps and critical functions that determine the quality of the product and data integration).
- Selection of the requirements that will be the focus of the design and the design reviews.
- Determination of the extent of validation.

3 SCOPE

The scope of this document is limited to the functional risk assessment of features provided in this document for the implementation of the Inward & Sampling Process.

4 DOCUMENT USAGE

This document is prepared initially with the basic risks identified during the user requirement specification stage of the project for the known risks related to the regulatory requirements and known functional requirements at that stage.

5 Risk Assessment Methodology

The methodology of risk assessment for the system consists of the activities such as identification of hazards in the functions, assessing the hazards, prioritizing the hazards based on the assessment and finally deciding on the mitigation actions for each of the hazard.

5.1 Identification of Hazards in The Functions

Hazards comprise of the problems that could arise if the system is implemented or what could go wrong with the system. This will include both the failures of the system as well as the failure of the users to use the system in the manner intended.

5.2 Evaluation of each of the Identified Hazard

Risk ranking and categorization:

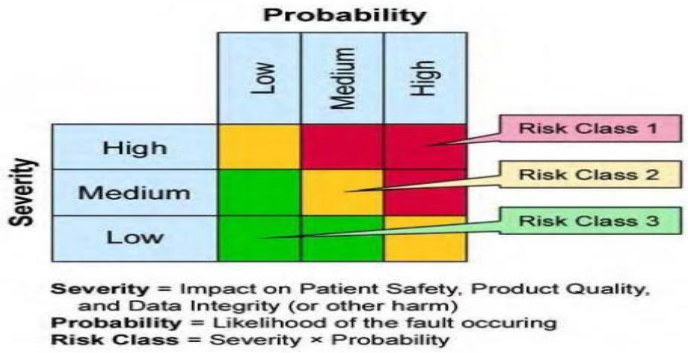
1. The criticality for each function shall be defined as below to derive the Risk Priority Number (RPN) scores.
2. Evaluate process/ functional parts to identify the risks involved in the process.
3. Identify the functional risks impact i.e. the impact on patient safety, product quality, data integrity, system security provide justification for being or not being the compliance risk as No Impact/ Indirect Impact/Direct Impact.
4. Assess the severity, probability and detectability of the risk. Refer following table to score severity, probability and detectability:

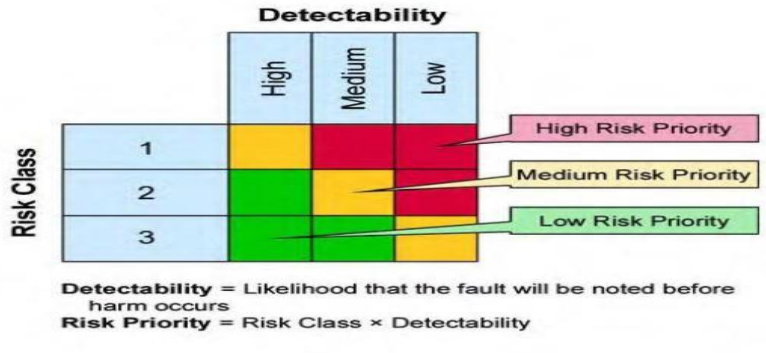
Value	(S) Severity of impact (Consequence)	Value	(P) Probability of failure (Likelihood of adverse event occurring)	Value	(D) Level of detection
3	High (H): Can cause serious adverse health consequences, which can threaten the life of patient or even death. Direct and significant impact on product quality/data security/integrity	3	High (H) frequency or probability of failure: Often	1	High (H): The risk can be detected through deployed control measure/system and the detection system is automated.
2	Medium (M): Temporary or reversible adverse health consequences but the life of the patient is not threatened. Indirect and significant impact on product quality/data security/integrity	2	Medium (M) frequency or probability of failure: Periodic	2	Medium (M): The risk can be detected later through deployed control measure/system and the detection is through manual method.
1	Low (L): No effect/Impact for patients. Insignificant impact on product quality/data security/integrity/GxP requirements.	1	Low (L) frequency or probability of failure: Seldom	3	Low (L): The risk cannot be detected through deployed control measure/system the detection is possible after longer period/interval.

Calculate Risk Priority Number (the level of overall risk) by multiplying Severity, Probability and Detectability. RPN = (S) x (P) x (D). Following table defines the Risk Priority Number:

Risk Score	Risk Class	Action to be taken
9 to 27	Critical	Implementation of mitigation actions for this category of risks have to be ensured before release of the system. Intensive testing is required.
6 and 8	Major	Mitigation actions for this category of risks have to be ensured before release of the system. Extension may be permitted with appropriate justification and alternate mitigation action. Normal testing is required.
1 to 4	Minor	Risk is acceptable; procedural control may be required to manage risk. Verification may be required.

1. Provide mitigation action to manage the risk.
   i. If the RPN is above 6 the current control measures shall be reviewed to determine the need to take further corrective action. Risk reduction shall be done by reviewing against current control measure and / or by employing additional risk control measure (corrective action).
   ii. If the risk is reduced to Equal or below 6 RPN it shall be accepted.
2. Assess residual risk level to ensure risk mitigation to acceptable level.





3. If the risk mitigation not acceptable, such risks are re-assessed / evaluated. They all shall be treated as open and shall undergo once again complete quality risk management process
4. Provide verification measure(s) to ensure mitigation actions are established.
5. Communicate the risks, Mitigation Period, Responsibility & target date to risk owners and/or responsible persons/ stake holders.

5.3 TABLE FOR RISK IDENTIFICATION, RISK ASSESSMENT AND RISK CONTROL

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
User & Role Management :-															
User IDs is not unique.	• Breach of data integrity • No tracking of changes done by person • Process disturbance.	Indirect	Indirect	Direct	3	3	3	27	• The system should not allow creation of duplicate User Ids. • The user Id should be unique.	• The system will not allow creation of duplicate User Ids. • Duplicate User Ids verification to be verified during Qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System & record access is not limited to authorize users only	• Breach of data integrity • No tracking of changes. • Process disturbance.	Indirect	Indirect	Direct	3	3	3	27	• System should be design as per the User Management & Role Management concept. • Provision should be available to provide module wise authorization.	System & record access will be limited to authorize users only. The same will be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Guest accounts available or active in the system	• System can be accessed by un-authorized persons • Loss of data integrity • No tracking of changes. • Process disturbance.	Indirect	Indirect	Direct	3	**3**	**3**	**27**	• User creation provision should be available in authorized user ID only. • Guest account should not be available in system.	Guest account will not be available in system. The same to be verified during qualification.					

System have not provision to auto log off the user session after specified number of minutes of inactivity, by requiring that the user re-enter their User ID and password to continue the user session (Preferable 05 min.)	• System can be accessed by un-authorized persons • Loss of data integrity • No tracking of changes. • Process disturbance.	Indirect	Indirect	Direct	3	3	2	18	System should have provision for auto log off after predefined time period	Provision will be available in system for auto log off after predefined time period. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System shall not enforce password complexity (special character, numeric and uppercase).	• Password can be miss use & shared • Loss of data integrity • No tracking of changes. • Process disturbance.	Indirect	Indirect	Direct	3	3	3	27	System should have the facility for password complexity	Facility for password complexity will be available in system. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System shall not enforce minimum password length (Minimum 8 Character)	• Password can be miss use & shared • Loss of data integrity • No tracking of changes.	None	Indirect	Direct	3	3	3	27	System should provide for restriction of password acceptance if it does not meet the required length criteria.	In system, provision will be available to accept minimum password length of 8 characters. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
The system permit passwords to be picked from previous 3 passwords used	• Password can be miss use • Loss of data integrity • No tracking of changes.	None	None	Direct	3	3	3	27	System should restrict the last 03 used password and prevent of re-use	System will not allow last 03 used password. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Password not masked.	• Password can be miss use • Loss of data integrity • No tracking of changes in system • Process disturbance.	None	None	Direct	3	3	3	27	System should have provision to mask the password	Provision will be available in system for mask the password during enter. The same to be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
The system not lock out users when their passwords have expired (After 90 days)	• Password can be miss use & shared • Loss of data integrity • No tracking of changes in system	None	None	Direct	3	3	3	27	The system should provide for setting up of option to mandatory change the password in a defined frequency. The system should prompt the user to change the password well in advance of the expiry.	Provision will be available in System to lock password after 90 days if not changed before expiry. The same to be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
The system is not lock User IDs after consecutive invalid login attempts to the system (03 invalid attempts)	• Unauthorized person may be access the system	None	None	Indirect	2	3	3	18	The system should lock User IDs after consecutive invalid login attempts to the system (03 invalid attempts)	The system will be lock User IDs after consecutive invalid login attempts to the system (03 invalid attempts). The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
The system not enforce to change the password for the first time user login.	• Unauthorized person may be access the system • Data integrity	None	None	Direct	3	3	3	27	The system should enforce to change the password for the first time user login.	Provision to change password for the first time user login will be available in system. The same to be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
The system allows to reset a password by unauthorized person	• System can be accessed by un-authorized persons • Loss of data integrity • No tracking of changes. • Process disturbance.	Indirect	None	Direct	3	3	3	27	The system should restrict to reset a password by unauthorized person	Only authorized person will be able to re-set the password. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Role-Wise User Privileges facilitates not available	• Unauthorized activity may be happened in system • No tracking of changes • Process disturbance	None	None	Direct	3	3	3	27	Role-Wise User Privileges facilitates should be available in the system.	Role wise user privilege facilities will be available in system. The same to be verified during qualification.					

Role-Wise User Privileges facilitates not under control by authorized function	• There will be no control on system • Uneven role will be assigned • Process disturbance	Indirect	None	None	2	3	3	18	Role-wise user privileges provision should be control by authorized function	Provision will be available in system for Role-wise user privileges creation & it can be under control by authorized function. The same to be verified during qualification.					
Audit Trail Requirements:															

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Audit trail not available in the System	• No traceability. • Data manipulation or falsifying data/records • Accidental or intentional change in GxP records	Indirect	None	Direct	3	3	3	27	The system should have provision for Audit trial facility to track the changes/activity in system.	Audit trial facility will be available in the system. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Audit trail records not secured and protected from intentional or accidental modification (read-only access).	• No traceability. • Data manipulation or falsifying data/records • Accidental or intentional change in GxP records	Indirect	Indirect	Direct	3	3	3	27	Audit trail records should secure and protected from intentional or accidental modification (read-only access).	Audit trail records will be secured & Read only form in system. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
In Audit trail records provision for date/time stamp not available.	• No traceability • Data manipulation or falsifying data/records	None	None	Direct	3	3	3	27	The date & time recording provision in Audit trail should be available in system.	The date & time recording provision in Audit trail will be available in system. The same to be verified during qualification.					
Enabling /Disabling audit trail option is available with any level of user.	• No traceability. • Data manipulation or falsifying data/records	None	None	Direct	3	3	3	27	Enabling /Disabling provision for audit trail should not be available in system.	Audit trial enable /disable option will not be available in the system. The same to be verified during qualification.					

Audit trail records have not the time/date of user entries and actions that create, modify, or delete electronic records.	• No traceability • Data manipulation or falsifying data/records	Indirect	None	Direct	3	3	3	27	Audit trail records should have the time/date of user entries and actions that create, modify, or delete electronic records.	In Audit trial, contains will be available as time/date of user entries and actions that create, modify, or delete electronic records. The same to be verified during qualification.					
Backup, Restoration, Archival and Communication failure :-															
Provision for data backup , restoration and archival facility	Data loss	Indirect	None	Direct	3	3	3	27	Provision for data backup, restoration and archival facility should be available on respective server.	Data backup & restore Data backup, restore and archival provision will be available on server. The same to be					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
not available on required server										verified during qualification.					
Sufficient storage space is not available on data base server.	• Data may not be stored in data base server. • Loss of critical data/records	Direct	None	Indirect	3	**3**	**3**	**27**	Sufficient storage space should be available on data base server.	Sufficient storage space will be available on data base server. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Failure of system due to natural disaster.	• System breaks down. • No business operations. • Data loss.	Indirect	None	Indirect	2	3	3	18	Disaster management procedure should be available at software installation site.	Disaster management procedure will be available at software installation site. The same to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Data miss match during legacy data upload	• Data miss match with original data • Business loss • Data integrity	Indirect	None	Direct	3	3	3	27	Data should not be miss match during legacy data upload.	• Data will be uploaded by trained person • Data verification will be carried out as per the approved qualification protocol.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Communication failure between BCI System to server and vice versa	• Error in data communication • Data Loss	Direct	None	None	3	3	3	27	System should not push/pull data during communication failure between BCI to system.	• System will not push/pull data during communication failure between BCI to server and vice versa. The same shall be verified during qualification. • System connectivity test between system to BCI & BCI to system to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Communication failure between BCI System to SAP and vice versa	• Error in data communication • Data loss • Business impact	Indirect	None	None	2	3	3	18	System should not push/pull data during communication failure between BCI to SAP system.	• System will not push/pull data during communication failure between BCI system to SAP and vice versa. The same shall be verified during qualification. • System connectivity test between BCI to SAP to be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Master , Inward and Sampling Module :-															
Master data can be changed without proper authorization.	• No accountability of changes. • Falsification of the data	Indirect	None	Direct	3	3	3	27	Master Maintenance access should be restricting to limited Authorized Users.	Master Maintenance access will be restricting to limited Authorized Users. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Users of all levels have the right to modify the master data.	• Loss of data integrity. • Inefficient operations. • Data manipulation	Indirect	None	Direct	3	3	3	27	Users of all levels should not have the right to modify the master data. Only authorized levels should have the right to modify the master data.	Users of all levels will not have the right to modify the master data. The same shall be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Unauthorized User is able to access in device of the respective Modules/ Sub-modules	• No control over generation of data. • Inefficient business operations. • Data manipulation • Data integrity.	Indirect	None	Direct	3	3	3	27	Only Authorized User should be able to access in device of the respective Modules/ Sub-modules.	Only Authorized User will be able to access in device of the respective Modules/ Sub-modules. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System accept the invalid or duplicate data during scanning (Gate entry no., Purchase order no, GRN no. etc.)	• No control over generation of data. • Inefficient business operations. Data mismatch • Data integrity.	Direct	Indirect	Direct	3	3	3	27	System should not accept the invalid or duplicate data during scanning (Gate entry no., Purchase order no, GRN no. etc.)	System will be restricting in case of invalid or duplicate data during scanning. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allows confirming transaction without filling all mandatory fields.	• Incomplete records • Loss of operation efficiency	Indirect	None	Direct	3	3	3	27	System should not allows confirming transaction without filling all mandatory fields.	System will not allow to proceed further without updating all the mandatory fields. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Unauthorized User is able to Print / Reprint Label.	• No control over generation of data. • Data-integrity	None	None	Direct	3	3	3	27	Only authorized User should able to Print / Reprint Label by the system.	Unauthorized User will not able to Print / Reprint Label. The same shall be verified during qualification.					
System will allow duplicate invoice number	• Data mismatch • Loss of critical process flow • Business impact	None	None	Direct	3	**3**	**3**	**27**	System should not allow duplicate invoice number	System will not allow duplicate invoice number. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow vehicle inspection of the inactive gate entry number	• Data mismatch • Loss of critical process flow	Indirect	None	Direct	3	3	3	27	System should not allow vehicle inspection of the inactive gate entry	System will not allow vehicle inspection of the inactive gate entry. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to proceed next step if any non-conformance observed, hold, Rejected in vehicle entry	• Data mismatch • Loss of critical data • Unaccepted material proceed for the next step	Indirect	Indirect	Direct	3	3	3	27	System should not allow to proceed next step if any non-conformance observed, Hold, Rejected entry in the vehicle inspection.	System will not allow to proceed next step if any non-conformance observed, Hold, Rejected entry in the vehicle inspection. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to enter the expiry date before the manufacturing date	• Data mismatch • Unaccepted material proceed for the next step • Business loss	None	None	Direct	3	3	3	27	System should not allow to enter the expiry date before the manufacturing date	System will show error message and restrict to proceed for next step. The same shall be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to complete material inspection before all material inspection completion	• Data mismatch • Missed of critical data verification • Missed to material identification and unidentified material proceed for next step	Indirect	None	Direct	3	3	3	27	System should not allow to complete material inspection before all material inspection completion.	System will not allow to complete material inspection before all material inspection completion. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to proceed next step if any non-conformance observed, hold or Rejected materials in Material Inspection	• Data mismatch • Loss of critical data • Unaccepted material proceed for the next step	Direct	Indirect	Direct	3	3	3	27	System should not allow to proceed next step if any non-conformance observed, Hold or Rejected materials in the Material inspection.	System will not allow to proceed next step if any non-conformance observed, Hold or Rejected materials in the Material inspection. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to use non calibrated balance	• Data mismatch • Data integrity	Indirect	None	Direct	3	3	3	27	System should not allow to use non calibrated balance.	System will show alert message if the balance is not calibrated. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Material showing in GRN posting without weight /quantity verification	• Quantity miss match • Data integrity	None	None	Direct	3	3	3	27	Material should not showing in GRN posting without weight /quantity verification	System will show materials for the GRN posting of which the weight /quantity verification done. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
GRN number not created in system	• Productivity loss • Operation failure	None	None	None	1	3	3	9	Response from SAP should be available during GRN number activity.	System will give alert message in case GRN number not created. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System accepted invalid and duplicate Material barcode	• Data mismatch • Impact on critical data • Wrong material proceed for next process	Indirect	Indirect	Direct	3	3	3	27	System should not accept invalid and duplicate Material barcode	System will give alert message in case of invalid and duplicate material barcode scanning. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System accepted invalid and duplicate pallet barcode	• Data mismatch • Impact on critical data • Wrong material proceed for next process • Data integrity	Indirect	None	Direct	3	3	3	27	System should not accept invalid and duplicate pallet barcode	System will give alert message in case of invalid and duplicate pallet barcode scanning. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System accepted invalid master data (Cubicle, Equipment, pallet, balance, weight box etc.)	• Data mismatch • impact on critical data • Wrong material proceed for next process • Data integrity	Indirect	None	Direct	3	3	3	27	System should not accept invalid master data (Cubicle, Equipment, pallet, balance, weight box etc.)	System will give alert message in case of invalid data enter. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to start calibration, use balance without setting initial zero reading	• Incorrect data entry	Direct	Indirect	Direct	3	3	3	27	System should not allow to start calibration, use balance without setting initial zero reading	System will give alert message in case of balance initial reading not set to zero. The same shall be verified during qualification					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System accept invalid data against the SAP data in case of the data received from SAP (Material code, Purchase order etc.)	• Data mismatch • Impact on critical data • Data falsification.	Direct	Indirect	Direct	3	3	3	27	System should not accept invalid data against the SAP data in case of the data received from SAP (Material code, Purchase order etc.)	System will validate the data which are received from SAP & will not accept invalid data against the SAP data. The same shall be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Sequential cleaning procedure not followed i.e. Cleaning start, cleaning stop, cleaning verification	• Data mismatch • Impact on system operation.	None	None	Direct	3	3	3	27	System should proceed as per sequence for cleaning.	Sequential cleaning will be followed by system. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System accepted if different cleaning types selected during verification	• Data mismatch • Impact on system operation.	Direct	None	Direct	3	3	3	27	System should not accept if different cleaning types selected during verification	System will provide alert message. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow line clearance for the un-cleaned area /Equipment	• Data integrity • Contamination/cross contamination • Business loss	Direct	Indirect	Direct	3	3	3	27	System should not allow line clearance for the un-cleaned area /Equipment	System will not allow line clearance for the uncleansed cubicle/equipment. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System show unpicked materials in pre-staging	• Process violation • Data mismatch • Impact on critical data • Wrong material proceed for next process	Indirect	None	Direct	3	**3**	**3**	**27**	System should not show unpicked materials in pre-staging	In pre-staging system will show only the picked material. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow Raw material to proceed further step without line clearance	• Data mismatch • impact on critical data • Wrong material proceed for next process	Direct	Indirect	Direct	3	3	3	27	System should not allow Raw material to proceed further step without line clearance	System will not allow to proceed raw material to proceed further activities without line clearance. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
MobiVue PMMS stock not updated as per the SAP stock update i.e. after Material return to vendor and Material destruction	• Data mismatch • Impact on critical data • Impact on material stock	None	None	Direct	3	3	3	27	MobiVue PMMS System should have provision to update the stock quantity manually by the Physical stock adjustment module	System will allow to update the stock quantity manually. The same shall be verified during qualification.					

Risk Identification	Risk Assessment							Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
MobiVue PMMS stock not updated as per the SAP stock update i.e. After Material return from the Production	• Data mismatch • Impact on critical data • Impact on material stock	None	None	Direct	3	3	3	27	MobiVue PMMS System should have provision to update the stock quantity by using the Material return module	System will allow to update the stock quantity. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Data push & pull between SAP and BCI system not matched	• Data miss match • Business loss • Productivity loss	Indirect	None	Direct	3	3	3	27	Data push & pull between SAP and BCI system should be matched.	Data pushed/pulled between SAP and BCI system will match with each other. The same shall be verified during qualification.					
GRN cancellation and reposting details not updated in SAP	• Data miss match • Business loss • Productivity loss	Indirect	None	Direct	3	3	3	27	GRN cancellation and reposting details should be updated in SAP.	GRN cancellation & re-posting details will be updated in SAP. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control							
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
System allow to complete sampling procedure before completion of all picked container sampling	• Data miss match	Indirect	None	Direct	3	3	3	27	System should not allow to complete sampling before completion of sampling all picked containers.	System will not allow to complete sampling before completion of sampling all picked containers. The same shall be verified during qualification.					

Risk Identification	Risk Assessment								Risk Control						
Risk description	Justification with relevant cause/s	Impact (Direct/ Indirect/ None)			S	P	D	RPN	Mitigation actions	Current control/Test coverage	Test/ Document No. (Step No.)	Residual risk			
		Product Quality	Patient Safety	Data Integrity								S	P	D	RPN
Sample quantity not debited from the BCI stock	• Data miss match	None	None	Direct	3	3	3	27	Sample quantity should be debited from the BCI stock.	Sample quantity will be debited from the BCI stock. The same shall be verified during qualification.					

Conclusion: - In the above functional risk assessment all the Risk Scenario considered for the system, based on that the severity (S), Probability (P) and Detectability (D) numbering done & identify current control & mitigation Action.

As per identified test coverage, all test shall be verified during qualification & after evaluation of all test coverage, residual risk Scenario shall be evaluated. Based on the residual risk result further action plan will be define if applicable. After that post approval to be ensured.

6 POST-QUALIFICATION REMARK

7 Post Qualification Signatures

Ajanta Pharma Ltd :-

--	Name	Department	Designation	Sign & Date
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				