PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Department: Quality Assurance	**Date:**
Item/Process: Risk Management for Enterprise Resource Planning System post Implementation	**FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
1.0	**Server and Network Connectivity**								
1.1	Local network connectivity failure to ERP server.	• Total production activity will hamper. • Data Integrity. • Delay in release and dispatch. • Failure in Customer commitment.	3	• Issue with network switch or local network wire. • UPS power failure. • Improper arrangement of LAN cables.	1	• Manual controls for batch processing is in place. • Standby network switches is in place. • Second line UPS power backup is in place. • DG power backup is available. • All cable channelized in proper manner to the server. • Restricted access to server room. • Trained manpower for operations.	1	3	Current control measures are adequate.
1.2	Sever collapsed.	• Impact on Business. • Failure in Customer commitment.	2	• Natural Disaster like earthquake, flood, Lighting. • Fire incident.	1	• SOP for disaster management is in place. • Alternative/backup server is in place. • Fire extinguisher (B&C) is in place.	2	4	Procedure for retaining of data at HO to be implement.
1.3	Breakdown of ERP production server.	• All manufacturing activities will be hampered. • Effect on product quality and productivity. • Data Integrity. • Delay in release and dispatch.	3	• Software or hardware failure during operation. • Virus or malware effect. • UPS failure.	1	• Alternative server is available and be use while server downtime. • Preventive maintenance of server. • Manual controls for batch processing is in place. • Second line UPS power backup is in place.	1	3	Current control measures are adequate.

Department: Quality Assurance | **Date:**

Item/Process: Risk Management for Enterprise Resource Planning System post Implementation | **FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
		• Failure in Customer commitment.				• DG power backup is available. • Anti-Virus is in place to control Virus or malware effect.			
1.4	Data loss in server.	• Loss of master documents and generated data. • Regulatory observations.	3	• Server hard disk crashed. • Virus or malware effect.	2	• Backup database procedure is in place. • SOP for restoration process of data is in place.	1	6	Current control measures are adequate.
							RPN	**16**	
2.0	**Data Management**								
2.1	Data modification and deletion.	• Integrity of data which leads to GMP non-compliance. • Market complaint. • Product recall. • Loss of customer faith.	3	• Lack of control mechanism. • Untrained manpower. • System is not qualified/ validated.	1	• Administrative control of ERP system is in place. • Trained personnel. • Role based access control defined. • System is validated. • Any modification and /or deletion can be tracked in system.	1	3	Current control measures are adequate.

Department: Quality Assurance | **Date:**

Item/Process: Risk Management for Enterprise Resource Planning System post Implementation | **FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
2.2	Backdated or postdated entries by any end user.	• Violation of data Integrity. • GMP-noncompliance. • Market complaint. • Product recall. • Loss of customer faith.	3	• Lack of control mechanism on selection on date. • Untrained manpower.	1	• System qualified to control for date modification. • Administrative control of ERP system is in place. • Trained personnel.	1	3	Current control measures are adequate.
2.3	Transaction done by one user in another user login.	• Electronic signature violation. • Market complaint. • Product recall. • Loss of customer faith. • Regulatory observations.	3	• Sharing of password and PIN. • Wrong transaction identity.	1	• Users have their own User Id, password and PIN for access. • Procedure on password policy in place and training provided to all users. • SOP in place for controlling limited session expiration time.	2	6	Screen saver password policy to be applied.
2.4	Printer breakdown to take all ERP generated labels.	• Labeling activity will affect and finally traceability of material will not be possible.	2	• Software or hardware failure during operation. • UPS failure.	1	• Alternate printer available in other department which can be utilized. • Spare printer is maintained.	1	2	Current control measures are adequate.
							RPN	**14**	

Department: Quality Assurance | **Date:**

Item/Process: Risk Management for Enterprise Resource Planning System post Implementation | **FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
3.0	**Master data**								
3.1	Improper and wrong entry of Item master, UOM master, Item Type and Item Sub Type.	• Material Planning and procurement process will be wrong. • Wrong BOPP feeding. • Wrong Item conversion factor. • Product failure. • Wrong Item Identity. • Customer complaint.	3	• Lack of training and skills of users. • Lack of complete details while master data creation. • Lack of procedure.	1	• Training provided to all users. • Provision for training on demand available. • SOP for Item code logic is in place.	2	6	Procedures (SOP) for master data to be prepared.
3.2	Improper or wrong entry of Production Stage and activity, Equipment master and Bill of Process definition (BOPP).	• Material Planning and procurement process will be wrong. • Production activity will be hampered. • Product failure. • Customer complaint.	3	• Written procedures are not in place. • Lack of skills and training of user. • Master copies of BMR's and BPR's are not available for proper feeding. • BOPP approval procedure is not in place.	1	• Training provided to all users. • Provision for training on demand available. • Trained users for feeding of BOPP's. • Master copies of BMR's and BPR's are in place for proper BOPP feeding.	2	6	Procedure (SOP) for master data and BOPP approval to be prepared.

Department: Quality Assurance | **Date:**

Item/Process: Risk Management for Enterprise Resource Planning System post Implementation | **FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
3.3	Wrong MRP (Material Resource Planning) execution.	• Wrong material planning and procurement process. • Production activity will be hampered. • Delay in order execution. • Product failure. • Customer complaint.	3	• Item code wrong. • BOPP wrongly fed. • BOPP approval is missing. • Lack of skills and training of user.	1	• SOP for Item code logic is in place. • Trained users for feeding of BOPP entries.	1	3	Current control measures are adequate.
3.4	Approved Vendor list is not updated.	• Purchase Order cannot be issued to Vendor. • Delay in order execution. • Regulatory and customer observations. • Market starvation.	3	• Vendor documentation is not received on time. • Vendor qualification not performed.	1	• Defined Procedure is in place to update vendor on receipt of all relevant documentation.	1	3	Current control measures are adequate.
							RPN	**18**	

Department: Quality Assurance	**Date:**
Item/Process: Risk Management for Enterprise Resource Planning System post Implementation	**FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
4.0	**Inventory Module**								
4.1	Wrong material receipt at plant.	• Production activity will be hampered. • Business impact. • Improper material reconciliation. • Delay in order execution.	2	• Purchase Order creation without Purchase requisition. • Procedure for PO is not in place. • Wrong Vendor approval. • Wrong vendor site selection.	1	• System not allows doing Purchase Order without Purchase requisition. • System not allows doing GRN with purchase order. • While receipt of material, creation and verification access level are available for evaluation.	2	4	Procedure (SOP) for PO to be prepared.
4.2	Re-test or expiry material issue for production batches.	• Delay in order completion. • Product Failure. • Loss of customer faith. • Patient safety.	2	• Improper controls. • Wrong material release /rejected.	1	• System not allow to issue, re-test or expiry material for production batches. • Procedure is in place. • Trained personnel.	1	2	Current control measures are adequate.

Department: Quality Assurance	**Date:**
Item/Process: Risk Management for Enterprise Resource Planning System post Implementation	**FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
4.3	Wrong information on quarantine label.	• Cross contamination. • Product Failure.	3	• Wrong GRN prepared. • Lack of training. • Wrong information available on vendor COA.	1	• System control available to avoid future mfg. date and past expiry date. • Trained personnel. • Procedure for material receipt in place • While receipt of material, creation and verification access level are available for evaluation.	1	3	Current control measures are adequate.
4.4	Batch wise material traceability will be lost.	• Wrong batch execution. • Product Failure. • Market complaint. • Regulatory observations. • Patient safety.	3	• Same Batch No. generation for two different materials. • Lack of training.	1	• System control is in place to restrict duplicate batch number during GRN. • Trained personnel for operation.	1	3	Current control measures are adequate.
4.5	Wrong information on issue / dispensing slip for Production batches.	• Cross contamination. • Product Failure. • Regulatory observations. • Market complaint. • Patient safety.	3	• Lack of training. • Improper control. • Lack of procedure.	1	• System is qualified to restrict Item other than required for batch. • Trained personnel.	1	3	Defined procedure (SOP) for SRP to be prepared.
							RPN	**15**	

Department: Quality Assurance	**Date:**
Item/Process: Risk Management for Enterprise Resource Planning System post Implementation	**FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
5.0	**Quality Control**								
5.1	Wrong QC specification.	• Wrong material/production batch release. • Delay in order completion. • Product Failure. • Loss of customer faith. • Market complaint. • Patient safety.	3	• Procedure is not in place. • Improper master document. • Lack of training. • Lack of control.	1	• System having option for QC specification approval by QA. • Procedure for preparation of QC specification is in place. • Trained personnel.	2	6	Procedure (SOP) for QC specification to be Introduced.
5.2	On-test / bad stock material can be issued for production batches.	• Cross contamination. • Product Failure. • Market complaint. • Regulatory observations. • Patient safety.	4	• Improper control. • Wrong material release /rejected.	1	• SOP for material issuance is in place. • Status labels available on each container and material status can be identified easily. • System control available to issue only approved materials against respective QC specification. • System is qualified to restrict release if any tests failed.		4	Procedure (SOP) for releasing to be Introduced.
5.3-	Generation of sample label without AR No. allocation.	• Wrong QC sampling. • Effect on material stock.	3	• Improper control of system.	1	• System is controlled for auto generated AR number against respective GRN number /material batch number.	1	3	Current control measures are adequate.

Department: Quality Assurance | **Date:**

Item/Process: Risk Management for Enterprise Resource Planning System post Implementation | **FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
5.4	Generation of Approved label without releasing of material/ production batches.	• Wrong QC sampling. • Effect on material stock. • Cross contamination. • Product Failure. • Market complaint. • Regulatory observations. • Patient safety.	3	• Improper control of system. • Lack of training.	1	• System is controlled to restrict Approved labels with AR no. authorization. • Trained personnel.	1	3	Current control measures are adequate.
								16	
6.0	**Production Module**								
6.1	Wrong Production batch order creation.	• Production activity will be hampered. • Wrong materials issue. • Wrong brand selection at • Finish Goods stage. • Market complaint.	3	• Improper control of system. • Wrong BOPP, batch size, Mfg. date and Exp. date selection. • Lack of training.	1	• System control is in place. • Master copies of BMR's and BPR's are place for proper feeding. • Trained personnel.	1	3	Procedure (SOP) for batch order creation to be prepared
6.2	Production batch number generation is wrong or not in proper order.	• Effect on production activity. • Loss of customer faith.	3	• Product batch no. prefix is wrong mentioned in BOPP.	1	• Trained person available for Product batch no. prefix while feeding BOPP.	1	3	Procedure (SOP) for batch numbering to be introduced.

Department: Quality Assurance | **Date:**

Item/Process: Risk Management for Enterprise Resource Planning System post Implementation | **FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
6.3	Wrong Store Requisition for production (SRP) batches.	• Production activity will be hampered. • Cross contamination. • Product Failure. • Market complaint. • Regulatory observations.		• Improper control of system. Lack of training. • Wrong production batch order.	1	• System control is in place. • Trained personnel. • Verification done by Quality Assurance department.	1	3	Current control measures are adequate.
6.4	While batch production activity log, wrong selection of date, stage, machine and value.	• Effect on production activity. • Violation of data Integrity.	3	• Improper control of system. • Lack of training.	1	• System is qualified to not accept date, less than production start date and greater than current date. • Trained personnel.	1	3	Current control measures are adequate.
6.5	Improper feeding of extra material return from production.	• Mix-up chances. • Improper material reconciliation. • Market complaint. • Product Failure. • Loss of customer faith. • Patient safety.	3	• Wrong selection of product, batch no., issue note, item and return quantity. • Lack of training.	1	• Procedure is in place. • System is qualified to control if any mismatching found while doing transaction. • Trained personnel.	1	3	Current control measures are adequate.

Department: Quality Assurance	**Date:**
Item/Process: Risk Management for Enterprise Resource Planning System post Implementation	**FMEA No.:**

S. No	Potential failure mode	Potential effects (process/ end users) or consequence	S	Contributory Factor	O	Current control Measures	D	RPN (SxOxD)	RPN Rank
6.6	Inappropriate control while releasing batch by QA.	• Delay in sale Invoicing /dispatch. • Market complaint. • Product Failure. • Loss of customer faith. • Patient safety.	3	• Uncontrolled access right for batch releasing. • Procedure unavailable. • Lack of training.	1	• Specific users and their role define in system for Product batch release by QA. • Procedure is in place. • Listed trained persons available.	1	3	Current control measures are adequate.
							RPN	**18**	
7.0	**Sales Module**								
7.1	Sales invoice performed without batch release by QA	• Market Complaint • Product recall • Patient safety.	4	• Uncontrolled access right for batch releasing. • System is not validated.	1	• System is qualified to control Sales Invoice if batch is not released by QA. • Specific users and their role define in system for Product batch release by QA. • Trained Personnel. .	1	4	Current control measures are adequate
							RPN	**4**	

S- Severity, O- Occurrence rating, D-Detection rating, RPN Risk Priority Number

<u>Conclusion</u>- On the basis of risk rating calculation (RPN) and evaluation of risk assessment; it has been concluded that each potential failure mode of Risk Management for Enterprise Resource Planning System post Implementation is in the minor category and RPN is within acceptance limit. As per above risk assessment there is no impact on product quality.