RISK ASSESSMENT

FOR

VENDOR APPROVAL & EVALUATION

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1.0 PRE APPROVAL

The Author's signature indicates that the document has been prepared in accordance with existing cGMP standards and adequately reflects the tasks and deliverables necessary for Risk Assessment of Process / System / Equipment / Instrument.

Prepared by/ Function	Designation	Signature	Date

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverables necessary for risk assessment of the Process / System / Equipment / Instrument and that the documentation and information included compiles with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head (Initiating Department)			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Approved By / Function	Designation	Signature	Date
Quality Assurance			

RISK ASSESSMENT FOR VENDOR APPROVAL & EVALUATION

2.0 OVERVIEW

2.1 Objective

The objective of the risk assessment is to identify different risks involved in the procedure of vendor approval and evaluation and to evaluate the impact of the risk on the quality product / patient, propose the corrective action and preventive action to mitigate / reduce the level of risk.

2.2 Scope

The scope of the risk assessment is restricted to vendor approval and evaluation.

3.0 REASON FOR RISK ASSESSMENT

The risk assessment shall be performed for following reason (√)

- New / Modification of Product / Process/ System / Equipment / Instrument

  Vendor Approval and Evaluation

- Inclusion of additional parameters in Risk assessment
- Others (Specify)

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4.0 TEAM MEMBERS

Following team members have been involved in the brain storming session of the risk management of this activity.

Date: _____ Time: _____ Venue: _____

Sr. No.	Name	Designation	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

The details of the discussion of the risk management of the activity, including the process flow of the activity, identification of the risks involved in the activity and corrective action and preventive action of the risk involved in the activity shall be recorded in section 5, 7 & 8.

After implementation of CAPA, the risk shall be recalculated and ensured to be at the acceptable level (Low).

Prepared By : _____ Date : _____

Reviewed By : _____ Date : _____

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5.0 ACTIVITY: (PROCESS / SYSTEM / EQUIPMENT / INSTRUMENT)

Specify the activities wherein the risk assessment is required. (Tick the appropriate box)

Process	
System	√
Equipment / Instrument	
Others: _____	

Description:

This Risk assessment is prepared to identify different risks involved in vendor approval and evaluation procedure and to evaluate the impact of the risk on the quality of product.
SOP Vendor Approval and Evaluation is available for approval and evaluation of vendors at ……...

Procedure covers the details related to following

1. **Qualification of vendors used for the R & D batches**
2. **Qualification of vendors for the commercial batches**
3. **Introduction of new vendors**
4. **Vendor Audit Checklist**
5. **Approved Manufacturer (Material Part Number {MPN functionality})**
6. **Exclusion of vendor**
7. **Periodic Evaluation of Vendor**

The qualification of vendors for commercial batches is based on the filled questionnaire, vendor audit (if applicable), analytical reports and stability data of the R & D batches.

The vendor is included in the vendor list for commercial manufacturing, if the evaluation is satisfactory. Periodic evaluation of vendor's performance is done as per procedure. The vendor shall be disqualified based on criteria's given in SOP. The information on exclusion of vendor shall be recorded by QA and Approved Manufacturer List shall be updated (BLOCKED) in SAP.

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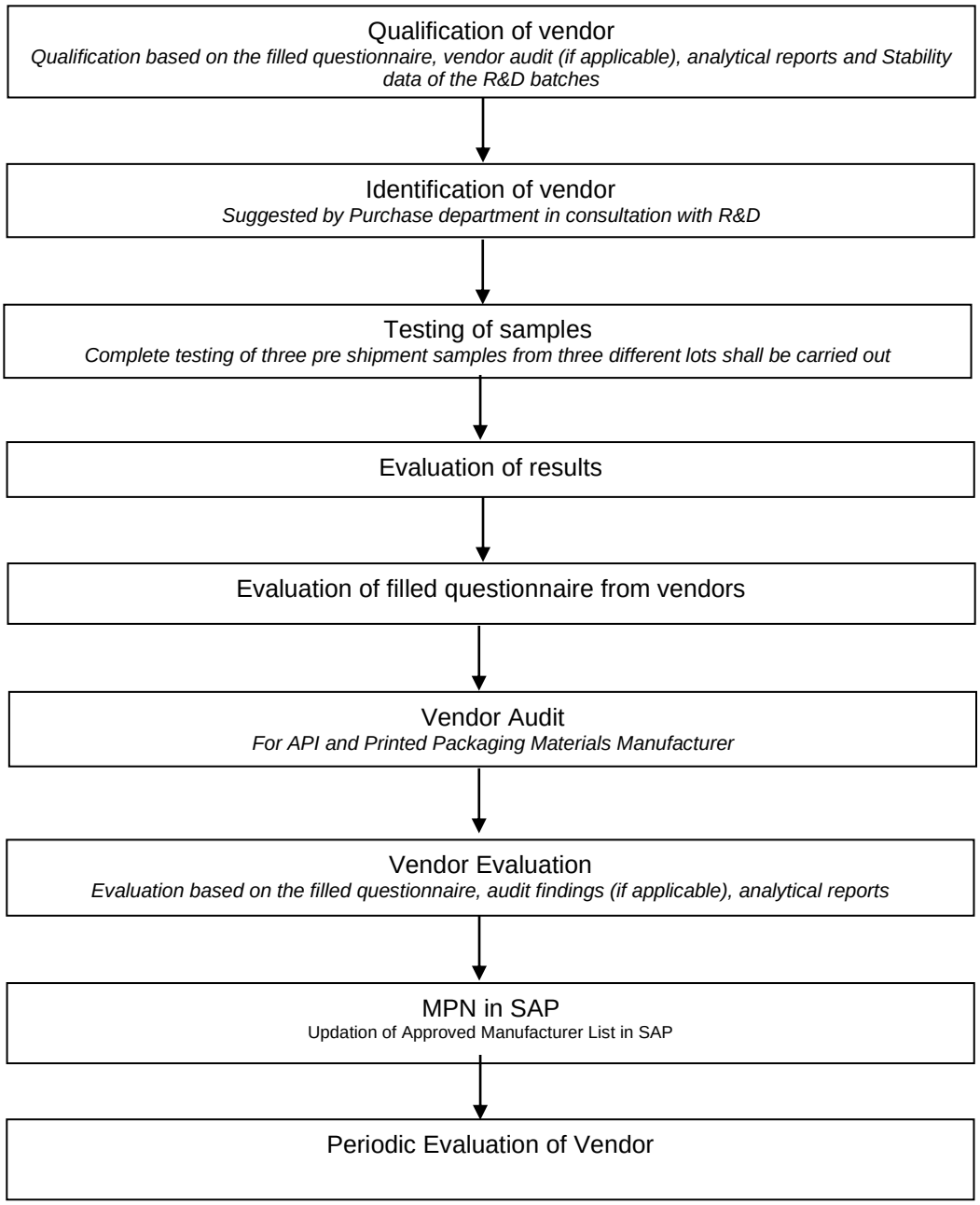
Process Flow:



6.0 DEFINITIONS AND METHODOLOGY

6.1 Severity of impact:

Identify the severity of impact of the risk on the quality of the product/service. Categorize the severity of impact of risk as Fundamental / High / Moderate / Minor / Insignificant as defined below and put score against each risk at section 7.0.

Category	Description	Score
Fundamental	Very significant and catastrophic impact	5
High	Significant losses and inefficiencies, necessitating timely adressal	4
Moderate	Loss of operating capability, deterioration of efficiency, management intervention required	3
Minor	Impact on operations and efficiency, but not pervasive	2
Insignificant	Limited or no impact on operations and quality of operational efficiency	1

6.2 Occurrence :

Identify the probability of occurrence of risk based on the occurrence frequency and put score against each risk at step 7.0.

Category	Probability of Occurrence	Description	Score
Almost certain	> 90 %	Is expected to occur in most circumstances	5
Likely	60-89 %	Will probably occur in most circumstances	4
Possible	25-59 %	Will probably occur at some time	3
Unlikely	10-24 %	Could occur at some time	2
Rare	< 10 %	May occur in exceptional circumstances	1

6.3 Detection:

Identify the level of detection of risk and give rating as below,

Category	Description	Score
Not aware/ No Control exists	Insufficient information to adequately assess and rate the control	5
Non existent / Very Little chance of detection	No procedural system in place, no risk reduction process procedure in place.	4
Not effective / Likely to be detected	Mitigation plans or risk reduction process & procedures though in place but do not ensure adequate control over risk occurrence / impact as the risk still exists over its acceptance level.	3
Effective / very likely to be detected	Approved Mitigation plans or risk reduction procedures, Checklists are laid down for early detection & immediate corrective actions are taken.	2
Very Effective / 100 % likelihood of detection	Mitigation plans or risk reduction process & procedures involve stringent approval and reporting norms with responsibility duly mapped to various management levels, minimizing possibility of occurrence / optimizing protection in the case of occurrence of the same at very early stage, controlling and reducing the risk.	1

Risk Ranking: Calculate the total score for the particular risk by multiplying the scores of Severity of impact, Occurrence and Detection

Categorize the risk as Low risk, Medium risk or high risk, as follow

RISK LEVEL	OBTAINED SCORE
HIGH RISK	125 to 64
MEDIUM RISK	Below 64 to 27
LOW RISK	Below 27

Upon evaluation of the risk, elaborate the methodology for notification of the risk, responsibility for the handling of risk and Corrective action, Preventive action (CAPA) plan for the identified risk.

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Note: In addition to RPN No. calculation.

a. If any parameter is having severity as 'Fundamental or High' (i.e. 4 or 5 scale number) then final risk level should be decided as 'High' irrespective of RPN number.
b. If any parameter is having severity as 'Moderate' (i.e. 3 scale number) then final risk level should be decided as at least 'Medium' unless and otherwise the risk is classified as High with RPN greater than 64.

- Criteria 'a' & 'b' are applicable at the stage of identification of risk whereas after mitigation control the final risk level should be confirmed on the basis of RPN number only irrespective of individual severity scale.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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7.0 IDENTIFICATION OF RISK INVOLVED

S. No.	Description of Risk	Risk Involved	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Remarks
1								
2								
3								
4								
5								
6								
7								

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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8.0 NOTIFICATION AND CAPA

8.1 NOTIFICATION AND CAPA OF HIGH RISK*:*

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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8.2 NOTIFICATION AND CAPA OF MEDIUM RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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8.3 NOTIFICATION AND CAPA OF LOW RISK:

Risk	Risk Involved	Total Score	Incidence Notification	Corrective action	Preventive action	Responsibility	Remarks

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

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8.4 MITIGATION CONYROL& RE-EVALUATION OF IDENTIFIED RISKS AFTER IMPLEMEMNTATION OF CAPA:

S. No.	Description of Risk	Mitigation Control Reference Documents	Severity of the impact (S)	Occurrence (O)	Detection (D)	Risk Priority No. (S x O x D)	Risk Category	Verified By (Sign & Date)
1								
2								
3								
4								
5								
6								
7								

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9.0 TRAINING AND EVALUATION RECORD

Date :	Timing : From _____ to_____
Venue :	Name of Trainer :
Title : Risk Assessment	Method of training:

Sr. No.	Name of Employee	Employee Code	Evaluation Details	
			Signature of Trainee	Remarks

Signature of Trainer (Sign/Date): _____

Comments:

_____

_____

_____

Verified By: _____ Date : _____

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10.0 SUMMARY AND CONCLUSION:

10.1 Evaluation of Data :

10.2 Mitigation Plan :

10.3 Evaluation of Risk Involved after Mitigation Control :

10.4 Summary :

10.5 : Conclusion

Prepared By : _____ **Date** : _____

Reviewed By : _____ **Date** : _____

11.0 REFERENCE DOCUMENTS:

S.No.	Title

Reviewed By : _____ Date : _____

12.0 ABBREVIATION:

S.No.	Abbreviation	Description

Reviewed By : _____ Date : _____

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13.0 ATTACHMENTS:

S.No.	Description

Reviewed By : _____ Date : _____

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14.0 COMPLIANCE VERIFICATION:

S.No.	DESCRIPTION	COMPLIANCE (Y/N)	VERIFIED BY

Reviewed By : _____ Date : _____

15.0 POST APPROVAL:

This is hereby certified by the following functionaries, that the risk assessment of the activity in the department stands qualified for its intended purpose.

The reviewer's signature indicates that, this document has been reviewed and it accurately and completely reflects the tasks and deliverable necessary for risk management and all associated equipment/instruments and systems and that the documentation and information included complies with applicable regulatory / departmental requirements and current Good Manufacturing Practices.

Reviewed By/ Function	Designation	Signature	Date
Department Head (Initiating Department)			
Regulatory Affairs			
Quality Assurance			

The approver's signature indicates that the documentation and information contained herein complies with applicable regulatory/departmental requirements and current Good Manufacturing Practices.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			