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TITLE: QUALITY RISK MANAGEMENT				

1.0 PURPOSE:

To lay down the Procedure to identify the hazards (sources of quality risk/ hazards) associated with the manufacture and delivery of the Intermediates and APIs.

2.0 SCOPE:

This SOP shall cover overall management of risks that arise from the manufacture and delivery of the Intermediates and APIs at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

- 3.1 Head of the department shall be responsible to identify and assess the different risks involved within their respective work areas together with any additional controls, corrective and preventive actions as required and appropriate to the risk identified.
- 3.2 The concerned department in-charge or designee shall prepare the risk assessment document.
- 3.3 Head-QA shall be responsible for approval the risk assessment document.
- 3.4 Risk Management Team shall be responsible for the overall Risk Management Program, its review and closure.

4.0 DEFINITIONS:


- 4.1 **Risk:** The combination of the probability of occurrence of harm and the severity of that harm.
- 4.2 **Severity:** A measure of the possible consequences of a hazard.

5.0 PROCEDURE:

5.1 General Aspects of Risks management:

- 5.1.1 Quality risks management team shall be formed by the Head-QA/Designee.
- 5.1.2 The members shall comprise of the personnel having technical knowledge and working experience with the process.

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5.1.3 The members shall be trained in the details of the procedure on Quality risks assessment.

5.1.4 Briefing shall be provided by the Head-QA to the Risk management team members and the necessary procedures on Quality risks assessment.

5.1.5 While doing quality risks analysis a consensus shall be arrived on the nature and magnitude of the quality risks.

5.1.6 Quality risks shall be established keeping in mind the regulatory requirements and ultimate end user applications the interests of the immediate customers and end use customers.

5.1.7 Democratic and peaceful means shall be followed while doing quality risks analysis. An element of bias/ over estimations/ under estimations/ suppression of data/ information/ risks shall be avoided.

5.1.8 While doing risks analysis the focus shall be on to determine the probability of occurrence of harm (that how often the harm may occur) and if the harm happens what shall be the consequence of that harm (that is how severe the harm may be/ may happen). Facts and figures shall be used for estimation of the quality risks. The historical experience and technical and technological judgments shall be applied. The process of quality risks estimation should be a formal process. This one should be in a systematic manner; as per this procedure and any causal element should be avoided.

5.1.9 The quality risks documentation shall involve the following:


5.1.9.1 A description of the product or process.

5.1.9.2 A list of the responsible persons or owners.

5.2 Do the Risks Analysis :

5.2.1 Identify the key process stages.

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5.2.2 Identify the hazards.

5.2.3 Estimate the risks to the quality Evaluation of the Risks.

5.2.4 Apply criteria for decisions on acceptability of the risks within in acceptable levels.

If the risks are beyond the level of acceptance ensure necessary corrective and preventive actions to bring the quality risks within the acceptable levels. Follow corrective and preventive action procedures for this purpose.

5.3 Risk Evaluation:

5.3.1 Evaluation of risk can be performed by using Risk Priority Number (RPN), as follows:

5.3.1.1 **Risk Priority Number (RPN) is calculated by using the formula:**

$$\text{RPN} = \text{Severity (S)} \times \text{Occurrence (O)} \times \text{Detect ability (D)}$$

5.3.1.2 **Severity (S):**

Severity (S) refers to an assessment of the seriousness of the risk effect or the discrepancy or deviation or failure as it affects the end-user.


Higher rating is necessary because of quality failure or introduction of contamination during these steps will result in a higher risk to the product safety and end-user. The lower the severity the lower the risk involved. The rating for determining severity is given in the following Table.

1	2	3	4	5
No effect	Minor	Moderate	High	Critical

5.3.1.3 **Occurrence (O):**

Occurrence (O) refers to an assessment of the probability of the incident of a risk effect or discrepancy or failure. A higher probability of occurrence may be possible if the equipment or system or process is poorly designed.

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The lower the probability of occurrence, the lower is the risk involved. The rating scale for determining the probability of occurrence is given in the following Table.

1	2	3	4	5
No Known occurrences	Low (Less than 25 reported cases till date/less than)	Moderate (More than 25 reported cases till date /between 26 and 75 % probability of occurrence)	High (between 1 and 10 reported cases per month)	Very High (more than 10 reported cases per month)

5.3.1.4 Detection (D)


Detection is the ability to detect a risk or an incident of defect, discrepancy, deviation or a failure as it affects the end-user. The ability of detection depends on the system, equipment or operation.

Lower the ability to detect the defect, higher is the risk.

1	2	3	4	5
Certain (fault will be detected during in-process/routine checks)	Almost certain (> 90% probability detection)	High (75-89% probability detection)	Moderate (35-74% probability detection)	Low (< 34% probability detection)

The risks shall be categorized as Extreme(Critical), Major, Moderate, Minor and Lower depending on the product of probability of occurrence, degree of severity and ability of detection as the Risk Priority Number (RPN) value.

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5.4 Risk Controls:

- 5.4.1 Take corrective and preventive actions to minimize the risks.
- 5.4.2 Analyze the options. Implement the actions which reduced the maximum risks and at the same time user friendly and economic.
- 5.4.3 In general Lower and Minor type of consequences are considered acceptable.
- 5.4.4 Mitigation actions shall be taken for moderate, major and extreme consequences based on the concerned nature of risk.


5.5 Risk Control Strategy:

Failure ↓	Consequence based on RPN number				
	1-25	26-50	51-75	76-100	101-125
1	Lower	Minor	Moderate	Major	Extreme(critical)
2					
3					

5.6 Risks Reduction:

- 5.6.1 Propose the change control.
- 5.6.2 Evaluate the quality risks of the proposed change.
- 5.6.3 Proposed change should end up in reducing the quality risks.
- 5.6.4 Implement the quality risks reduction management programmes as per documented procedures, Change control management, Qualification, validation of the equipments and processes, amendments in the existing systems. Training and competence and other elements of the quality management system.
- 5.6.5 Monitor for the effectiveness of the proposed corrective actions and preventive actions through change controls supervision and audits/ verifications.

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5.6.6 Evaluate the residual risks after implementing the proposed changes.

5.6.7 Determine whether the overall residual risks are acceptable or not.

5.7 Review of the Quality risks management process:

5.7.1 This must be done post implementation of the quality risks reduction management programmers.

5.7.2 Ensure that the required changes are reflected in the documented procedures.

5.7.3 Ensure internal and external customer feedbacks that the quality risks have been reduced.

5.7.4 Through audits ensure the continued reduced levels of quality risk.

5.8 Risk Assessment Report on Manufacturing process Numbering System:

RAR/XXXX/NNN/RR

RAR Indicates : Risk Assessment Report,

XXXX Indicates : Product Code,

NNN Indicates : Serial Number of the respective Product,

RR Indicates : Revision No.

Ex: RAR/DAH-II/001/00, RAR/MRA-II/001/00

6.0 FORMATS / ANNEXURE(S):

Nil

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.08.2016	New SOP is introduced	--
01	01.04.2017	1. SOP format changed make to inline with SOP-QA-001-04.	QA-CRF-014/16
02		SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/17028

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