RISK IDENTIFICATION,ASSESSMENT & MITIGATION TEMPLATE

Mr. R.M. Gupta (M. Pharm.), is a free lancer consultant for US DMF, COS, ANDA, ACTD, CTD, eCTD and other regulatory submissions.
guptarmg1952@gmail.com

He is associated with Perfect Pharmaceutical Consultants Pvt. Limited and Global Institute of Regulatory affairs (Pune, India)
Providing - Regulatory Affairs Courses ,

Abstract: The risk involved in pharmaceutical manufacturing is largely associated with:

1. Poorly written SOP, incomplete knowledge of the process/machines/materials /areas/services
2. Unauthorized changes in process, incomplete vendor audits, changes in source of raw materials
3. Incomplelete specifications of Raw materials/Finished Goods,
4. unwarranted procedures
5. Unknown personnel disabilities
6. Improper training, system failures,
7. Lack of validation activities, Lack of organizational harmony
8. Job dissatisfaction, poor maintenance, interference of the management with critical functions such as quality assurance, quality control, purchase and production,
9. Faulty organization structure, lack of management commitment for quality,
10. Poor man and material flow, Poor environmental control
11. Poor control on process water
12. Inappropriate cleaning procedures for the equipments,
13. Lack of sanitation and hygiene
14. Poor control on rodents/insect/worming and birds, undue filth and microbial contamination, undue cross contamination.

Risk Control involves proper identification, classification, mitigation and prevention of root cause of the probable errors. The present protocol is a very basic version. The same may be customized as per specific requirements. The readers are invited to post their queries at guptarmg1952@gmail.com

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1.0 RESPONSIBILITIES:

Sector	Responsibilities
Risk Assessment Officer	To identify the risk
Manufacturing In charge	To report all deviations and unwarranted results in production
Maintenance In charge	To report equipment limitations and deficiencies
Quality Control In charge	To test the products
Quality Assurance	To control the entire process and to mitigate the situation

2.0 OBJECTIVE: This is applicable to all functional areas including RM and FP Storage, Manufacturing, Packaging, Maintenance procedures, Cleaning Procedures, receipt, storage and release or approval of the materials. It is applicable to entire procedures as well as their subparts.

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3.0 SCOPE:

To provide procedure for identification, classification, mitigation and prevention of risk during manufacturing of ……..at …….

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Risk Control involves proper identification, classification, mitigation and prevention of root cause of the probable errors.

4. RISK IDENTIFICATION:

	Elements	**Description**	**Observations**
4.1	Identify the SOP associated with risk	Provide SOP Title and Clause No which is to be assessed for risk	
4.2	State Likelihood of Risk Occurrence	State the probability of the event occurring as most likely, some times, Rarely.	
4.3	Provide details on Raw Data Collected for risk analysis	Collect the raw data which is to be analyzed for risk assessment	
4.4	Identify Major System / Component / Functional Area / Subsystem affected	Identify the major system / component and the pertinent subsystem or component based on the process in which the risk event has occurred.	
4.5	Rate the severity of Risk	Rate the risk as High, Medium or Low, derived from likelihood and severity (Very Critical, Critical, Minor)	
4.6	Assign the priority	QA Manager/Production ,Manager/Regulatory Manager/Marketing Manager to assign priority to the risk	
4.7	(Category)	Identify the risk as: Gross cGMP Violation/Minor GMP Violation.	
4.8	Assign Specific ID	Assign specific ID to each risk	

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5. **RISK ASSESSMENT AND INVESTIGATION**.

5.1	Define the Risk	Gives detailed statement of the risk involved with the procedure	
5.2	Define the Impact of risk	Sates the consequence of the event on quality and yield of the product. You may also describe average and worse case consequences.	
5.3	State the Major Products affected	Provide Name of the Products with batch No	
5.4	Analyze the impact of risk on quality and efficacy of the product	Briefly describes the impact on chemical/physical/microbiological properties of the drug/product. If required identify the impact on impurity profiling , assay and stability of the product	
5.5	Stare Time Sensitivity of the risk	Estimates the relative urgency for identification and management of risk involved.	
5.6	State Severity of risk control	State the severity or the potential impact of the risk. on product quality, yield and on timelines .	
5.7	Identify the Other Affected Areas	Identify any other subsystem or subsequent processing steps which may get affected by the risk.	

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6. RISK MITIGATION AND PREVENTION

6.1	Define the Variation to be done in SOP	Describe what variations will be required in the process to minimize the risk	
6.2	State Risk Handling Plans	Briefly describes plans to nullify the risk. .	
6.3	State Risk Monitoring Activity	Describe the plan/in process tests to monitor the risk	
6.4	Risk Control Review	Review the few batches for efficacy of risk control measures	
6.5	Specify the Periodic Review program for risk control	Provide the frequency or exact dates for reviewing the risk control activities	
6.6	Risk Reported By	Records name and phone number of individual who reported the risk.	
6.7	Risk Closing Rationale	Reason for closing the risk.	

7. SUMMARY AND CONCLUSIONS:

Risk Assessment Authorization Page

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