Risk Assessment Document of Product Transfer

Risk Assessment for Transfer of Product Transfer

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1.0 Approval Signature

This document is prepared by the Quality Assurance team of .....

PREPARED BY		
NAME	**DESIGNATION**	**SIGNATURE /DATE**

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2.0 Introduction:

According to the definition, given in Annex 15, 20 of the EU-GMP-Guide and ICH Q9, a risk assessment is a method to assess and characterise the critical parameters in the functionality of an equipment or process. Therefore, risk assessment is a key element in the qualification and validation approach.

In the project context, risk analyses are performed as basic GMP/EHS-Risk assessment, which shall help to identify important GMP/EHS-requirements.

3.0 Aim of the Risk Analysis:

At the very basic stage of design the risk assessment is to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment.

During study all GMP and EHS parameters will be identified and assessed for the risk if not considered in the design or requirements.

The Risk assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP and EHS risks.

4.0 Reference Documents:

S.No.	Document Title	Document Number
1.	Validation master plan	
2.	Project validation plan	

5.0 Participants

Name	Function	Signature

6.0 Risk Management Process

A typical Risk management process consists of following steps:

- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation

- Risk Control
  - Risk Reduction
  - Risk Acceptance

- Result of Risk management processes
- Risk Review

- **Risk Assessment:**

  It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
  Risk identification is a systematic use of information to identify hazards referring to the risk question or problem description.
  Risk analysis is the estimation of the risk associated with the identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harm.
  Risk evaluation compares the identified and analyzed risk against given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.
  The output of a risk assessment is either a quantitative estimate of risk or a qualitative description of range of risk. In case of qualitative description the risk is expressed using descriptors such as “high”, “medium” or “low”.

- **Risk control:**

  It includes decision making to reduce and/ or accept risks. The purpose of risk control is to reduce the risk to an acceptable level. The amount of effort used of risk control should be proportional to the significance of the risk.
  Risk reduction focuses on processes for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Risk reduction might include actions taken to mitigate the severity and probability of harm.
  Risk acceptance is a decision to accept risk. Risk acceptance can be a formal decision to accept the residual risk or it can be a passive decision in which residual risks are not specified.
- The output/ result of the quality risk management process should be appropriately communicated and documented.
- Risk management should be an ongoing part of the quality management process. A mechanism to review or monitor events should be implemented.
  The output/ results of the risk management process should be reviewed to take into account new knowledge and experience.

This document applies the risk management principles to identify the risks associated with the design, construction and operational features of any equipment, which is going to be procured and installed in the facility.

7.1 Identifying GMP risk

Identification of Risk associated with the equipment, is generally based on prior experience and the concerns of the participants of risk assessment document.

The risks identified are categorized as "GMP risk" or "Non-GMP risk".
GMP is defined as "the practices which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization."
Thus, GMP covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures have been taken; full traceability of a product through batch records and distribution records; and systems for recall and investigation of complaints.

Thus those risks which might have a direct or indirect impact on the quality of the product are classified as "GMP risk". Also, those risks which might result in regulatory guidelines non-compliance are also classified as "GMP risk".
For example: The MOC of the product contact part has a direct impact on the quality of the product. Thus, it is classified as GMP risk.
The "Non GMP" risks include risks related to EHS, operational and other non-critical hazards.

Following types of risks are mainly identified during risk assessment process:

- Risk related to product contact materials for equipment and containers (eg. Selection of SS grade, gaskets, lubricants etc.)
- Risks related to appropriate utilities and their control (eg. Steam, gases, power source, compressed air etc.)
- Risks related to Calibration/Preventive maintenance
- Risks related to protection the environment and health & safety of personnel.
- Risks related to Cleaning & Sterilization
- Risks related to control system of the equipment
- Risks related to product loss

7.2 Risk Analysis & Evaluation

The risk analysis is performed using a qualitative basis of approach.
Qualitative analysis uses word form or descriptive scales to describe the magnitude of potential consequences/ impact and the likelihood that those consequences will occur.
The qualitative measures of likelihood includes descriptors like "Unlikely", "Possible" and "Likely", whereas the qualitative measures of consequence/ impact includes descriptors like "Minor", "Moderate" and "Major".

Qualitative measures of likelihood

Level	Descriptor	Example detail description
1	Unlikely	May occur at some time
2	Possible	Might occur at some time
3	Likely	Will probably occur in most circumstances

Qualitative measures of consequence/ impact

Level	Descriptor	Example detail description
1	Minor	• No impact on the product quality or outcome of the equipment. • Features required for easing equipment operation.
2	Moderate	• No direct impact on product quality/ outcome of equipment. However may indirectly affect the product quality. • Minor effect on personnel health • Used in the initial stage of operation, however it may affect the final output but those are not used for final release of output. • Effect on environment such as clean room.
3	Major	• Features having direct impact on product quality/ outcome of equipment like contact parts MOC, Surface finish, Control system, Process air quality etc. • Failure could lead to regulatory non-compliance. • Loss/ damage to equipment or its critical sub-components • Critical instruments not calibrated or not of desired range or accuracy. • Proper supporting documentation not provided. • Major effect on personnel health

Based on the above parameters of likelihood and consequence a qualitative risk analysis matrix is prepared to identify the overall Level of Risk, as mentioned in table below.

Qualitative risk analysis matrix – level of risk

Likelihood	Consequences/ Impact		
	1 – Minor	2 – Moderate	3 – Major
1 (Unlikely)	Low	Medium	High
2 (Possible)	Low	Medium	High
3 (Likely)	Medium	High	High

The final Risk level shall thus be described using descriptors such as “Low”, “Medium” & “High”, where each descriptor implies the following meaning:

Low Risk can be accepted or ignored. These do not affect the final quality of the equipment/ system and it can be managed by routine procedures and are unlikely to need specific application of resources.

Medium Risk required ongoing monitoring and review, to ensure level of risk does not increase. Otherwise managed by routine procedures.

High Action plans must be developed, with clear assignments of individual responsibilities and timeframes.

7.0 RISK ASSESMENT

In the following section a table is produced for the risk analysis. The significance or instruction for each column is described in the following paragraph.

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Column 1:	**Serial number** of Risk analysis item
Column 2:	**Process step/Component**: Identify the process step or component associated with the risk.
Column 3:	**Risks**: Identify the type of risk associated with the process or component.
Column 4:	Verify that whether risk have **GMP impact.**
Column 5:	**Justification**: Provide justification for declaring both yes/no for GMP Impact in column 3.
Column 6:	For the risk **other than of GMP impact,** write what is the type of risks e.g. EHS, Operational.
Column 7:	**Justification**: Provide justification for considering any risk.
Column 8:	**Risk level** Determine the Risk level as High, Medium or low based on the impact.
Column 9:	**Risk Control:** It is further divided into following three sections
Column 9a:	**Mitigation Method**: Write the risk mitigation strategy as considered in design.
Column 9b:	**Residual risk level**: After the risk mitigation what is the residual risk level, whether it is acceptable, low or Medium
Column 9c:	**Verification:** Write the test point where the risk mitigation strategy will be verified.

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
General Design of Equipment/Components:										
Equipment and Area:										
1.	Suitability of Equipment / Instrument	Equipment Capacity Change , Changing of batch Size from current batch size	Yes	Qualification of Equipment According the required Batch size	No	NA	Low	Prepare Comparison Sheet of Equipment and area between current facility and new facility.	Acceptable	Comparison Sheet
2.	Verification of area	Increase the chance of Contamination	yes	Daily Environmental monitoring carried out	Contamination of area	Verification of Non viable	Medium	Prepare Comparison Sheet of area as per validation and Process requirement	Acceptable	Comparison Sheet
Cleaning:										
3.	Cleaning Validation	Contamination of product	Yes	Revalidate the cleaning validation including new product	No	NA	High	Execute the cleaning validation with new product	Acceptable	Cleaning Validation
Process:										
4.	Verification of Process and critical parameter	Chance of OOS result of finish product	Yes	Three process validation batches taken	No	NA	Major	Review of process validation report	Acceptable	Validation Report

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S. No	Process steps/ component	Risk	GMP Risk Yes/No	Justification	Other Risk type	Justification	Risk Level	Risk Control		
								Mitigation Method	Residual risk level	Verification
5.	Filtration	Chance of Contamination	Yes	Filter validation is carried out with all new product	No	NA	Major	Review the validation report		
Training :										
6.	Training	Increase the chance of Human error	Yes	Provide Training all concern person	No	NA	Major	Provide Training all concern person which is involve in the production activity and analytical activity	Acceptable	

8.0 Summary and Conclusion

- The Risk analysis is performed to establish the design parameters of the equipment so as to meet the desired performance of the equipment i.e. Ampoule filling and sealing machine
- The critical risks pertaining to GMP and other than GMP were analyzed with justification and mitigation procedures.
- For each recognized GMP-risk and other than GMP risks necessary measures are defined. Organizational measures, like SOPs, are also possible measures for special GMP-risks. The availability of these SOPs will be checked during the performance of the OQ.
- The risks where conceptual procedures shall be employed, standard operating procedures (SOPs), Preventive maintenance schedules, Certificates and related documents indicated as mitigation procedures shall be ensured at respective test points.

*"It is concluded that the **Risk analysis** performed for the equipment will prevent the risk of failures of critical parameters during design, commissioning, installation, operation and performance of the equipment".*

9.0 Abbreviations

Acronym	Definition
cGMP	Current Good Manufacturing Practice
RAD	Risk Assessment Document
QA	Quality Assurance
EU-GMP	European – Good Manufacturing Practice
ICH	International Committee for Harmonization
EHS	Environmental Health and Safety
GMP	Good Manufacturing Practices
MOC	Material Of Construction
SS	Stainless Steel
P&ID	Process & Instrumentation Diagram
PTFE	Poly Tetra Fluor ethylene
db	Decibel
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
Ra	Roughness average
GA	General Arrangement
GAMP	Good Automated Manufacturing Practices
SOP	Standard Operating Procedures
HEPA	High efficiency particulate air
MMI	Man Machine Interface
PLC	Programmable Logic Controller
O & M	Operation and Maintenance Manual
CFR	Code for Federal regulations