RISK ASSESSMENT AND IMPACT ANALYSIS OF PLC SYSTEM FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE

System Name	**Automatic Vertical Round Bottle Sticker Labelling Machine**
System ID	**……**
Location	**Dry Syrup**
Effective Date	

CONTENTS

1.0.0 PRE APPROVAL SIGNATURES:

The signatures below indicate approval of this Risk assessment of PLC system of Automatic Vertical Round Bottle Sticker Labelling Machine indicates that it is ready for execution.

RISK ASSESSMENT PRE-APPROVAL

Function	Name	Department	Designation	Signature/Date
Prepared by		**Engineering**		
Reviewed by		**Engineering**		
Reviewed by		**Production**		
Reviewed by		**Quality Assurance**		

Final Approval: Final approval has been given by the following

Function	Name	Designation	Signature/Date
Approved by		**Head Quality Assurance**	

2.0.0 GENERAL:

2.1.0 PURPOSE:

A principal purpose of this document is to identify and evaluate the risk factor of PLC system of Automatic Vertical Round Bottle Sticker Labelling Machine and also provides its mitigations. The purpose of the risk assessment is to minimize affect the safety, quality, reliability or durability of a product and to get maximum benefits of CGMP from PLC system of Automatic Vertical Round Bottle Sticker Labelling Machine. This document identifies the functions which may impact on patient safety, data integrity and product quality.

2.2.0 SCOPE:

The scope of this document is to identify the Risk of PLC Automatic Vertical Round Bottle Sticker Labelling Machine. Risk Assessment process has following points.

- Identify Risk
- Individual function risk scenario
- Identify and verify appropriate controls
- Mitigation for function risk scenario

2.3.0 BACKGROUND:

The **"Automatic Vertical Round Bottle Sticker Labelling Machine"** is a new system purchase specifically for use at ……

2.4.0 REVISION HISTORY:

Version No.	Effective Date	Reason for Change
00		New Document

2.5.0 REFERENCES:

The test and execution procedure within the scope of the Risk assessment document are consistence with the following reference.

Guideline	Details
GAMP-5	Good Automated Manufacturing Practices
21 CFR Part 210	Code of Federal Regulations, Current Good Manufacturing Practices in Manufacturing Processing, Packing.
21 CFR Part 211	Code of Federal Regulations, Current Good Manufacturing Practices for finished Pharmaceuticals.
EU GMP Annex-11	European Union Good Manufacturing Practices Annexure-11

2.6.0 RESPONSIBILITY:

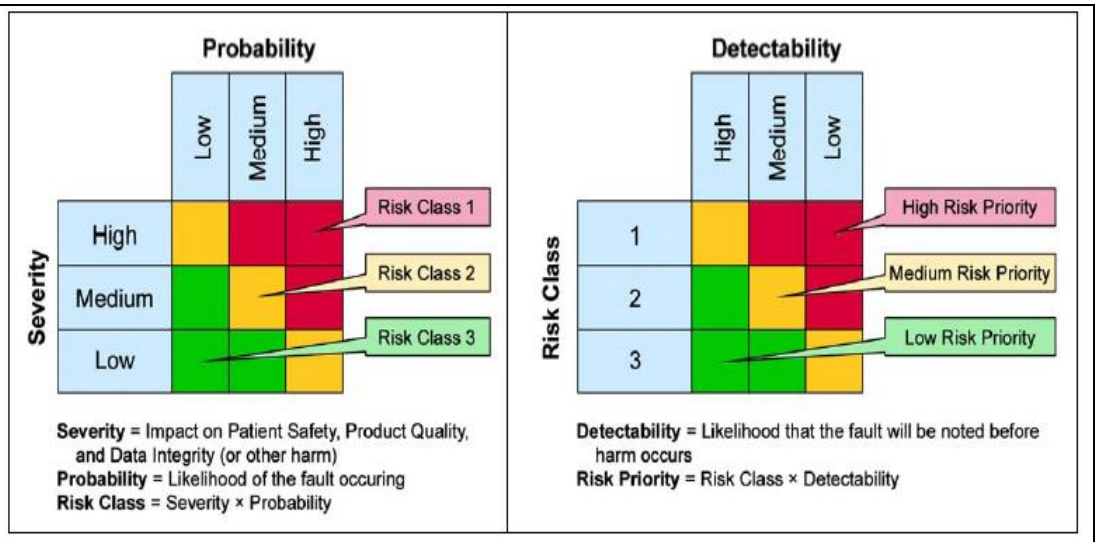
- Collect all manuals, electrical wiring diagram and documentary or any other data necessary for the preparation, execution of Risk Assessment document from M/S. ……..
- Preparation and execution of Risk Assessment document.
- Initiate risk assessment study in coordination with Production, Quality Assurance and Engineering.
- Provide training to the persons, who present during execution, of this study.

Engineering	Production	Quality Assurance
➢ Co-ordinate during execution of Risk Assessment. ➢ To provide utilities for Risk Assessment. ➢ To check the Risk Assessment document.	➢ Co-ordinate during execution of Risk Assessment activities. ➢ Provide personnel for facilitating the execution of Risk Assessment activity. ➢ Check that test requirements are completed. ➢ To check the Risk Assessment document.	➢ Co-ordinate during execution of Risk Assessment activities. ➢ To check and approve the Risk Assessment document.

3.0.0 **RISK ASSESSMENT:**

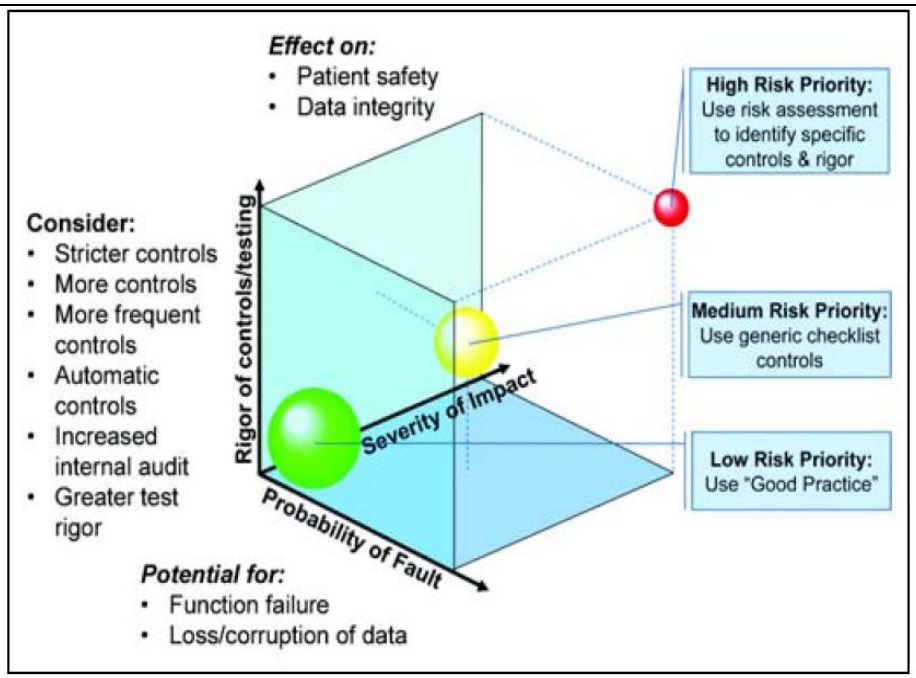
- Risk is the combination of the probability of occurrence of harm & the severity of that harm. Risk assessment shall be done to determine the criticality of the system to the process (with respect to product efficacy or patient safety.
- Risk assessment together shall help to determine the strategy & priority in which each system should be addressed for remedial action. High criticality systems with poor compliance shall result in a high priority for remedial action, whereas, low criticality systems with poor compliance may fall below the threshold for remedial action.

Risk Assessment Method



- **Risk Severity (Impact or Significance):**
  - Risk assessment requires not only the identification of the immediate effects of the risk but also the long term and widespread impact of those effects. These effects must take into account a wide variety of issues including impact on regulatory compliance. Impact on Patient safety, product quality and data integrity (or other harm) may be considered. A suggested method of representing this is as per as Low (L), Medium (M) or High (H).
  - **Low**: Expected to have a minor negative impact. The damage would not be expected to have a long term detrimental effect.
  - **Medium**: Expected to have a moderate impact. The impact could be expected to have short to medium term detrimental effects.
  - **High**: Expected to have a very significant negative impact. The impact could be expected to have significant long-term effects and potentially catastrophic short-term effects.
- **Risk Classification (Risk Class):**
  - Based on the Risk Likelihood & Severity of risk, identify the risk class. It may be mentioned as Class 1, Class 2 or Class 3 as per Table.
- **Probability of Detection (Detectability):**
  - The purpose of this stage in the assessment process is to identify if the risk event is recognized or detected by other means in the system. Hence a Class 1 risk, if it has a high probability of detection may not pose such a serious threat because it can be recognized quickly and suitable corrective actions can be taken to mitigate its impact. Conversely, if the same fault has low probability of detection then one needs to seriously consider review of the design or the implementation of alternate procedures to avoid the event. It may be mentioned as Low (L), Medium (M) or High (H).
  - **Low**: Detection of the fault condition is perceived to be unlikely.
  - **Medium**: Detection of the fault condition is perceived to be reasonably likely.
  - **High**: Detection of the fault condition is perceived to be highly likely.

- **Risk Priority:**
  - By combining the Risk Classification with the Probability of Detection, it is possible to prioritize, which determines how urgent and important it is to mitigate a particular risk.
  - Once these priorities have been determined the team can proceed to define and document the appropriate measure(s) to mitigate the adverse event that poses the risk. Risk Priority may be mentioned as High Priority, Medium Priority or Low Priority. Table below provides the guidance to arriving at the Risk Priority.
- Risk assessment together shall help to determine the strategy & priority in which each system should be addressed for remedial action. High criticality systems with poor compliance shall result in a high priority for remedial action, whereas, low criticality systems with poor compliance may fall below the threshold for remedial action.

Relationship of Risk, Severity and Control	

- **Five step approach to risk management:**

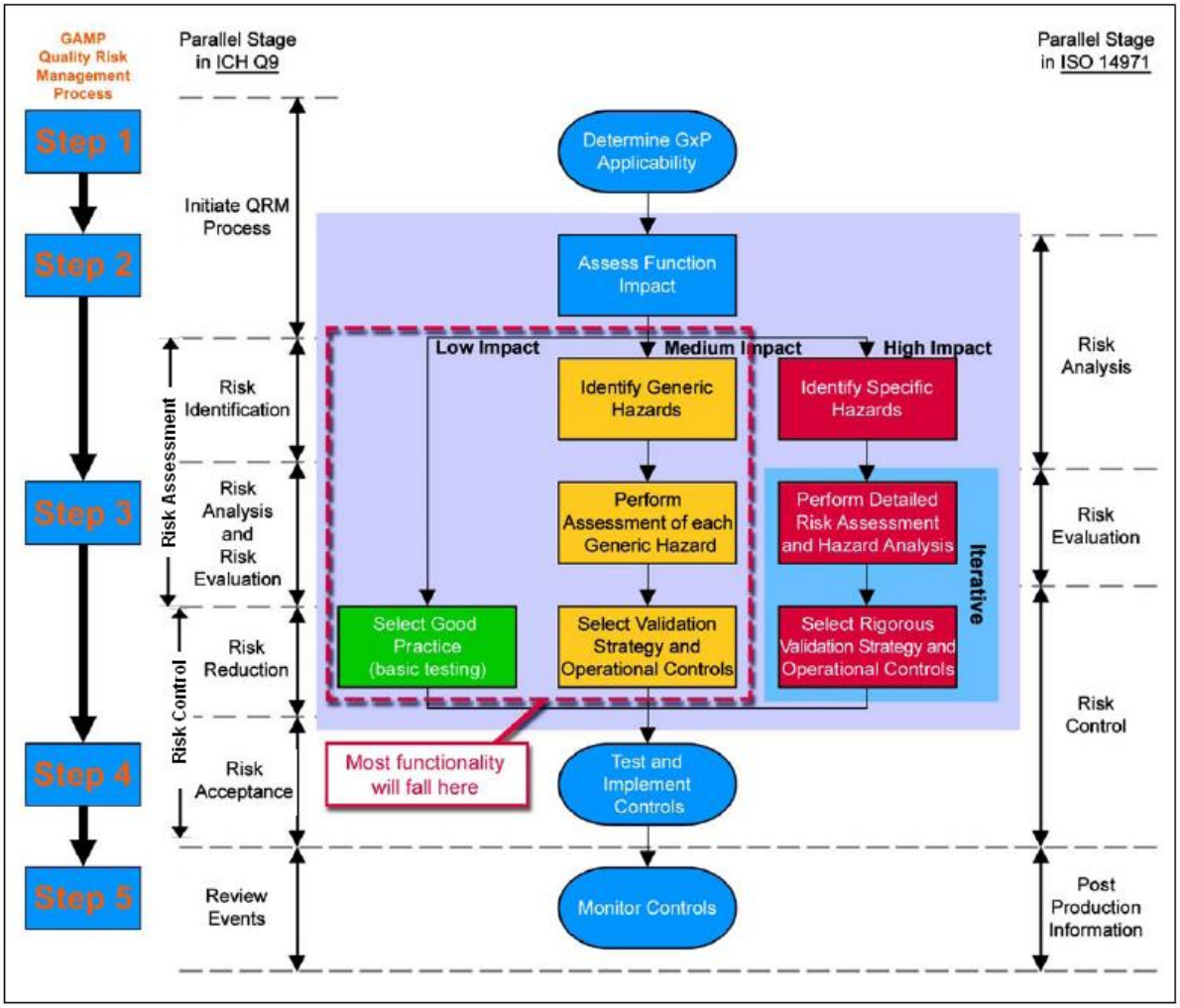
Step 1: Initial Assessment

Step 2: Identify functions with impact on patient safety, product quality & data integrity

Step 3: Perform functional risk assessments & identify controls

Step 4: Implement & verify appropriate testing & controls

Step 5: Review risks & monitor controls



- Risk scenario & mitigation approaches are evaluated module wise.

- **Risk assessment should be performed considering the risk related to:**
  - Safety of product, personnel & environment
  - PLC system hardware (component & sub component) & software.
  - **Personnel**: All personnel should have appropriate qualifications, level of access and defined responsibility to carry out their assigned duties.
  - **Change and configuration Management**: Any changes to a PLC system including system configurations, hardware and software, should only be made in a controlled manner in accordance with a standard procedure.
  - **Periodic Evaluation**: PLC systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP.
  - **Security and authorization**: Physical and/or logical controls should be in place to restrict access to PLC system to authorized persons. Suitable methods of preventing unauthorized entry to the system may include the use of keys, passwords, restricted access to computer equipment and data storage areas.
  - **Business Continuity**: For the availability of PLC system of supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system break down. The time required to bring the alternative arrangements into use should be based on risk and appropriate for a particular system and the business process it supports. These arrangements should be adequately documented and tested.

- Interlocks are measures that are put in place to reduce risk to an acceptable level. Interlocks are aimed at:

- Eliminating risk through process or system re-design: If any abnormality is observed during qualification the risk is mitigated through redesign the system.
- Reducing risk by reducing the probability of a failure occurring.

Reducing risk by increasing the in process detectability of failure (Emergency stop, limit switches, Sensors etc.).

4.0.0 RISK ASSESSMENT

Risk assessment and control							
Risk Area	**Risk Identification**	**Likelihood**	**Severity**	**Risk Class**	**Detectability**	**Risk Priority**	**Measures and control (Risk mitigation)**
Equipment Risk	Unstable power supply may damage the PLC and HMI system	High	Medium	1	Low	High	Stable Mode power supply (SMPS) should connect to equipment for prevention of PLC and HMI system.

Risk Assessment Post Mitigation						
Likelihood	**Severity**	**Risk Class**	**Detectability**	**Risk Priority**	**Residual Risk (Post Mitigation)**	**Risk Eliminated & Accepted/ Risk Reduced & Accepted**
Low	Medium	Risk Class-3	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ Verified By (QA) Sign / Date: _____Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Business and GMP Risk	Untrained person may try to operate the system	Low	Medium	3	High	Low	Training should be available for equipment operation

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ Verified By (QA) Sign / Date: _____Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
System and GMP Risk	Any Change or configuration in the system hardware/software may impact its functionality.	Medium	Medium	2	Medium	Medium	Any change to a PLC system should be done in accordance with a standard procedure. Major modifications/ changes shall be followed by re-validation.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	Medium	3	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ Verified By (QA) Sign / Date: _____

Risk assessment and control

Risk Area	Risk Identification	Likelihood	Severity	Risk Class	Detectability	Risk Priority	Measures and control (Risk mitigation)
Process, personnel And equipment risk	Machine may not be stopped in case of emergency	Medium	High	1	High	Medium	Emergency Switch Operated alarm and Interlock should be available in the System.

Risk Assessment Post Mitigation

Likelihood	Severity	Risk Class	Detectability	Risk Priority	Residual Risk (Post Mitigation)	Risk Eliminated & Accepted/ Risk Reduced & Accepted
Low	High	2	High	Low	Negligible	

Remarks: _____

Done By Sign / Date: _____ **Verified By (QA) Sign / Date:** _____

5.0.0 SUMMARY REPORT

_____

_____

_____

_____

_____

_____

_____

Function	Name	Department	Sign. & Date
Done by		Validation Engineering	
Verified by		QA	

6.0.0 LIST OF ABBREVIATIONS

Acronym		Description
cGMP	→	**C**urrent **G**ood **M**anufacturing **P**ractices
GAMP	→	**G**ood **A**utomated **M**anufacturing **P**ractices
GMP	→	**G**ood **M**anufacturing **P**ractices
ID	→	**Id**entification Number
IO	→	**I**nput **O**utput
IQ	→	**I**nstallation **Q**ualification
PLC	→	**P**rogrammable **L**ogic **C**ontroller
CFR	→	**C**ode of **F**ederal **R**egulation
HMI	→	**H**uman **M**achine **I**nterface
RA	→	**R**isk **A**ssessment

7.0.0 POST APPROVAL SIGNATURES

This is specific Risk Assessment of the PLC system of Automatic Vertical Round Bottle Sticker Labelling Machine. This Document is Checked and approved by the following.

RISK ASSESSMENT POST APPROVAL

Function	Name	Department	Designation	Signature/Date
Checked by		**Engineering**		
Reviewed by		**Engineering**		
Reviewed by		**Production**		
Reviewed by		**Quality Assurance**		

Final Approval: Final approval has been given by the following

Function	Name	Designation	Signature/Date
Approved by		**Head Quality Assurance**	