Risk Assessment

Presenter : Rahul Bhargava

Quality Risk Assessment – Packaging processes

Objective:.

Potential Failure Analysis

- Assures safe product package design (in early stages of development).
- Review of packaging material & design for potential risk and assigning risk factor as per severity.
- To predict consumer behavior on use of products in market place.

Scope:

The risk assessment covers the potential risk like few mentioned below

-Quality of Packaging material
-Process flow
-Environment condition
-Functionality of final package

Goal:

-Measuring the threshold of risk associated by the RPN (Risk priority number)
-Review and optimize QC parameters.

Guideline for Risk Rating

SEVERITY

Level	Patient Effect	Process Effect
10	Patient getting affected fatally.	Irreparable damage to batch/product. Product Quality Attributes are affected. Possible regulatory deficiency/customer query.
7	Patient is not affected fatally but deemed efficacy is not achieved. BUT the effect is not noticeable.	Reprocessing is possible but without affecting the quality attributes.
4	Patient is not affected fatally but deemed efficacy is not achieved. BUT the effect is noticeable and manageable.	Manufacturing related deviations not affecting the quality of the product.
1	No impact on patient.	No impact on Process and Quality.

PROBABILITY OF OCCURRENCE

Level	Design	Process
10	Certainty-Availability of prior knowledge/ Information/Reference that the phenomenon shall occur.	Certain chances.
7	Uncertainty- No information available with possibility of surprise/unexpected results	Fairly certain of the chances.
4	Uncertain-No information available but needs to be studied.	Remote possibility of chance.
1	Availability of prior information that the phenomenon shall NOT occur.	Almost uncertain no probability to happen.

DETECTION

Level	Process Control	Analytical Control
10	In-process checks/parameters/systems/ procedural controls are not available	No analytical technique/procedure is available
7	In-process parameters/procedural controls to be established	Qualitative detection technique.
4	In-process parameters/procedural controls to be established	Quantitative detection technique.
1	In-process test/Checks/Parameters/Systems are available	Multiple analytical tests support detection/measurement of required attributes.

Significance of Risk Priority Number (RPN = S x O x D)

Risk priority number	Nature of impact	Acceptance criteria	Mitigation (action/status)
1-100	No impact	Fine	No mitigation is required (It is a residual risk)
101-199	Indirect impact	Mediate	Mitigation shall be done
More than 200	Direct Impact	Cease	To be resolved with actions i.e risk mitigation

Example (a) **Risks involved in improper operation of pack for product dispensing resulting in failures.**

Use Step	Potential Failure Mode	Potential Effects of Failure	S	Potential Cause of Failure	O	RPN	Recommended Action(s)	Action Results				Action Results			
								Action Taken/	S	O	RPN	Conclusion remarks	S	O	RPN
Turn the cap clockwise until the end of rotation.	User does not turn the top chamber.	Cannot reconstitute drug.	4	User does not understand/follow instructions.	4	16		Clarified instructions in IFU.			0	IFU modified for clarity on instructions.	4	4	16
			4	Top Chamber says "Step 2 - Turn Clockwise" creating confusion with IFU, which says "Step 3" while box says "Step 2".	4	16		IFU steps are now A, B, C, etc.			0	No Change			0
	User does not turn the top chamber far enough.	Cannot reconstitute drug. Cannot remove top chamber in later step.	4	User does not understand/follow instructions.	4	16	Clarify how far to turn the chamber.	Images added to IFU showing start and end positions.	4	1	4	IFU modified for clarity on instructions.	4	4	16
			4	Lack of confirmation.	4	16	Clarify how far to turn the chamber.		4	1	4		4	4	16
	User turns too far.	User is frustrated.	1	Lack of confirmation.	4	4	Clarify how far to turn the chamber.	No change			0	We plan to improve interference of outer cap & plug for smooth functioning. IFU modified for clarity on instructions.	4	4	16
	The user has the chambers upside down and the liquid falls into the top chamber.	No affect. Bottom chamber liquid goes into top chamber when shaking.	1	User does not understand/follow instructions.	4	4	Explicitly state bottom chamber to stay upright.	User told to hold bottle upright.	4	1	4	No Change	4	1	4
	The user turns the wrong way.	Nothing happens. Due to design, top chamber does not disengage.	1	User does not understand/follow instructions.	4	4					0	We plan to improve interference outer cap & plug for smooth functioning.	4	4	16

Example Continuation By analyzing the risk factor, proper User Instruction to be created

Example (b) Probable risk for incoming packaging material

Sr. no.	Feature	Failure mode	Impacts	S (Severity rating)	Causes	O (Occurrence rating)	Current controls (Critical Process Parameters and Critical Quality Attributes)	D (Detection rating)	RPN (Risk priority number)		Actions	Target Date	Status (Open / Clos
1	Quality of Primary Packing Material	Packing Material is not of right quality	Product quality may be impacted	10	Packing process / control over process at vendor end.	10	Vendor are DMF sourced. Vendors are qualified. Each consignment is analyzed as per specification.	1	100	No mitigation required.			
		Improper storage condition for Primary Packing Material	Product quality may be impacted	10	Temperature & Humidity condition in warehouse is not mentioned	10	SOP exists for monitoring of temperature and humidity in warehouse Which states to store packaging material as per required environmental conditions. operators are trained.	1	100	No mitigation required.			

-On identifying all the potential risks and actions for control, we can assure that approved material is safe for use on shop floor.

Thank you