

GDP Information Day 2012 - Quality Risk Management Case Study

Example of a Poorly Executed Risk Assessment, using an FMEA-type tool

Severity 1-10	
1	No Patient impact
3	Minor Patient Impact
7	Significant Patient Impact
10	Life threatening

Probability of Occurrence 1-10	
1	Extremely unlikely to occur
3	May occur, but not often
7	Likely to occur sometimes
10	Very likely to occur everytime

Detection 1-10	
1	Detected every time
3	Detected sometimes, often
7	May be detected, but unlikely
10	No detection mechanism

Note: All RPNs > 100 require Risk Mitigation. RPNs < 100 are considered low risks and do not require Risk Mitigation.

	Function or Process Step	Failure Mode	Potential Impact	SEV	Potential Causes	OCC	Detection Mode	DET	RPN	Recomm ended Actions	Respon sibility	Target Date	SEV	OCC	DET	RPN
1	Returns Process	Damaged returned goods are put back into saleable stock	Packs of unknown quality might reach patients	6	Goods are not adequately checked after receipt	1	RP checks all returns and personally releases them to saleable stock	1	6	N/A	N/A	N/A	-	-	-	-
2	Returns Process	Recalled packs are inadvertently processed as returns and put back into saleable stock	Patients may receive defective medicines	10	Recall SOP not adequately followed	2	Internal Audits Training on recall SOP	3	60	N/A	N/A	N/A	-	-	-	-