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INTRODUCTION

The manufacturing and distribution process of medicinal products is targeted to guarantee a product that is safe and effective. Within every process of the pharmaceutical supply chain, there is the probability of an eventuality to occur.¹ Risk assessment provides the pharmaceutical industry with the ability to identify and mitigate risks. Risk assessment takes a proactive approach through the breakdown of three divisions; risk identification, analysis, and evaluation.

METHOD

This study was divided into three phases:

- i) Phase 1: Risk Identification through a literature review and semi-structured interviews with experts within a local pharmaceutical supply chain.
- ii) Phase 2: Risk Analysis through semi-structured interviews and discussions with relevant decision-makers within the supply chain.
- iii) Phase 3: Risk Evaluation through estimation and evaluation of risks against given risk criteria.

Data was gathered through the use of the FMEA tool. Potential failures were identified and classified according to probability of occurrence and severity of consequence. Probability and severity were defined quantitatively by giving a range from one (low) to three (high) using a 3x3 matrix. Detectability was analysed. A low detection score was ranked as three, medium as two, and high as one. The product of the three parameters, that are, probability of occurrence, severity of consequences, and detectability gave the overall RPN.

CONCLUSION

Minimising risks through a risk assessment exercise is essential for a safer medicinal product. This research provides an effective assessment of process quality risks within a pharmaceutical supply chain. The FMEA represents a positive methodology for improving the quality and reliability of batch release and distribution of finished goods by prioritizing the failure modes. Taking a proactive approach to risk management can assist in the prevention of future failure modes and results in an effective pharmaceutical supply chain.

AIMS

- i. Outlining the risk assessment of the supply chain processes at a Maltese pharmaceutical company, based on a Failure Mode and Effects Analysis (FMEA) approach
- ii. Recommending appropriate risk prioritization and mitigation strategies

RESULTS

Phase 1: The most critical factors that impacted the supply chain were noted. Decision-makers listed six factors that can affect the supply chain, with each factor being further divided into sub-categories. The main six factors were: materials, methods, environment, personnel, equipment and a miscellaneous category.

Phase 2 and 3: The FMEA tool identified 40 different potential failure modes, thirty-five of which had a low risk priority score. Ratings were provided for each failure mode based on the decision-maker's experience, literature review, and historical data of the company.

Serialisation was the process that obtained the highest RPN of 8. The process of serialisation classified as a high priority and the company should proceed with an instantaneous action. The recommended risk minimization strategy adopted in this scenario was to have quality assurance personnel review finished goods and report any deviations from compliance to serialisation and to provide adequate training to warehouse personnel (Table 1).

Table 1: Serialisation

Potential Failure Mode	S	P	D	RPN	Risk Priority	Action Taken
Pack not scanned by operator	2	2	2	8	High	Training to warehouse personnel

S = severity, P = probability of occurrence, D = detectability

REFERENCE

- [1] Breen, L.A. Preliminary examination of risk in the pharmaceutical supply chain in the National Health Service. *J Serv Sci & Manag.* 2008; 1(2), 193-9