

PHARMACEUTICAL RISK MANAGEMENT EDUCATION

Matthew Borg, Maresca Attard Pizzuto, Lilian M. Azzopardi

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

email: matthew.borg.21@um.edu.mt

INTRODUCTION

Risk management helps in the decision-making process within a pharmaceutical environment by highlighting risks involved and providing strategies to minimise them. Professionals need to have the knowledge, skills and behaviours to meet the demands of an increasingly complex and challenging pharmaceutical landscape.

AIMS

To assess competences acquired by post-graduate pharmacy students with respect to risk management.

METHOD

- Students following the Master of Science in Pharmaceutical and Regulatory Sciences acquire skills of estimating and managing risk in pharmaceutical processes.
- Course contents cover risk assessment, problem identification, probability determination, risk control and strategies to mitigate risk and applications of risk management principles in pharmaceutical processes.
- As part of the course fulfilments, students carry out a dissertation with a topic of choice and a case study of the application of competence by a student in risk management principles in industry is presented.

CASE STUDY

- A literature review to understand the current state of research on risk assessment within a pharmaceutical environment was undertaken.
- A risk assessment tool was developed and validated based on two change controls carried out by a local pharmaceutical industry.
- Risks associated with the identified change controls were assessed through a focus group.
- Failure Mode and Effects Analysis was used as a risk assessment tool.

RESULTS

- Out of a total of 831 change controls issued between January and November 2023, two change controls, 'Update of dissolution method' and 'Update of product carton artwork' were identified by means of a frequency count.
- Twenty-one and 8 risks were identified for the two change controls respectively.
- The skills acquired in the programme were applied and the identified risks were illustrated onto two Fishbone diagrams and risk mitigation strategies were put forward (Table 1).
- Risks were quantified, using 5-point Likert scales from 1-5 anchored by 1 being the lowest score, for probability of occurrence and severity of consequences.

Table 1: Risk mitigation strategies put forward for the identified risks

Change control	Proposed mitigation strategy
Update of dissolution method	1) Perform accelerated stability study. 2) Test batches at end of shelf life.
Update of product carton artwork	1) Artwork required by client must be included with batch purchase order.

CONCLUSION

The case study served to indicate an example of application of learning from the pharmaceutical risk management study unit. The competences acquired through the incorporation of pharmaceutical risk management in pharmaceutical processes in the post-graduate programme, help students to merge practical occurrences with scientific risk management principles to be applied with confidence in today's dynamic pharmaceutical environments.