Understanding Risks in Pharmaceutical Processes

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INTRODUCTION

Risks associated with pharmaceutical processes are assessed, controlled, communicated and reviewed by the use of Quality Risk Management. The Quality Risk Management is a structured process to evaluate risks and the cause and effect of risks on quality. The publication of the International Conference of Harmonization (ICH) Q9 'Quality Risk Management' in 2005 had a large impact on the pharmaceutical industry.[1]

AIMS

- **To understand risks in different pharmaceutical processes relevant to the pharmaceutical industry and pharmaceutical wholesale dealers**
- **To develop, validate and conduct interviews with individuals working within the pharmaceutical industry and pharmaceutical wholesale dealers**

METHOD

Structured one-to-one interviews with pharmaceutical companies and wholesale dealers were conducted. Prior to conducting interviews, validation of interview questions was performed. This was done by development of an evaluation questionnaire through the recruitment by convenience sampling of four experts. The four experts responded to 11 questions, by using a 5-point Likert scale to assess the relevance of the interview questions. The scale ranged from 1 being not relevant to 5 being highly relevant.

Subsequently, a total of 12 pharmaceutical companies and 24 wholesale dealers were contacted in person, through email or by phone. The recruitment period began in November 2018 and ended in February 2019. The interview consisted of 13 structured questions and lasted approximately from a minimum of 15 minutes to a maximum of 45 minutes. Questions asked included the risks the entity faces, methods used for risk measurement and ranking and strategies used to conduct a risk assessment.

RESULTS

Twenty-one interviews were conducted; 15 from 12 pharmaceutical companies and 6 wholesale dealers.

When asked what risks the entity faced, 4 pharmaceutical companies mentioned risks related to routine manufacturing of the active pharmaceutical ingredient and another 3 mentioned quality risks, environmental risks and health and safety risks. All 6 wholesale dealers mentioned the risk of falsified medicines and temperature fluctuations.

Pharmaceutical companies and wholesale dealers answered questions related to measuring and ranking of risks, tools used for Quality Risk Management and frequency of updates to policies (Table 1).

Measuring and ranking of risks	Number of responses (n)
Through a risk assessment process	18
Risk Management tool	**Number of responses (n)**
FMEA	10
HAZOP and HACCP	2
Frequency of updates to policies	**Number of responses (n)**
Every three years	7
When implementing a new activity or if the previous procedure has failed	4
Every two years	3
Once a year	3

Table 1: Measuring and ranking of risks, tools used and frequency of updates to risk assessment policies (N=21)

CONCLUSION

Inferences from this study indicate that locally, both the pharmaceutical industry and wholesale dealers possess robust risk management strategies, with the Failure Mode and Effects Analysis being the most commonly used quality risk management tool. Establishing a robust quality risk management program is crucial not only to be compliant with regulatory requirements, but to ensure a high quality medicinal product reaches the patient.

REFERENCE

[1] 1CH Expert Working Group. International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use. ICH Tripartite Guidelines. Quality Risk Management (Q9). [Internet] 2005 Nov [Cited 2021 Apr 8]. Available from https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-3.pdf