L-Università ta' Malta
Faculty of Medicine & Surgery
Department of Pharmacy

GOOD DISTRIBUTION PRACTICE TRAINING FOR MEDICAL DEVICE INDUSTRY

Louise Grech, Julian Fearne, Karen Farrugia, Elaine Gatt Baldacchino, Anthony Serracino Inglott

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

email: louise.grech@um.edu.mt

INTRODUCTION

In 2017 the European Parliament initiated the process towards a safer regulatory framework for medical devices with the change from Directives to Regulations. The EU Medical Device Regulation 2017/745 came into force into 2020 and In-Vitro Diagnostic Regulation 2017/746 and is coming into force within 2022.

AIM

To devise a training programme on good distribution practices based on the new medical devices regulations.

METHOD

Feedback from medical device industry stakeholders was compiled to assess training needs. A 6 hours online training programme was developed. The training programme was validated by an expert panel consisting of 3 professionals working at different scenarios within the medical device industry. The training was delivered on two mornings. Topics were divided into 5 sessions consisting of 1) an introductory session focusing on regulations and medical devices classifications; 2) quality and safety of medical devices; 3) case-studies of challenges experienced by stakeholders; 4) CE markings and 5) vigilance of medical devices. The online delivery method adopted an interactive approach with intermittent quizzes and discussion platforms. The programme was validated by the participants through the online distribution of a validated questionnaire.

RESULTS

- The expert panel (n=3) agreed that the training programme developed was feasible to implement, met the outlined learning objectives and outcomes and addressed the current the needs of the stakeholders feedback. The delivery method and duration of the sessions were well planned.
- Out of the 53 participants who completed the training, 18 were pharmacists.
- A total of 29 participants completed the evaluation form of the training.
- All the respondents (n=29) indicated that the course was very useful for their line of practice with 28 participants strongly agreeing that training content was well delivered, and assisted them to adapt to the new medical device regulations.
- The majority of the participants (n=20) opted for an online delivery mode, 4 participants indicated hybrid while 5 preferred a face to face delivery mode.
- The main reason given for online/hybrid choice was because this mode fitted well with work demands.

CONCLUSION

The training programme developed provided a platform where experts and users come together to learn the required knowledge whilst encourage sharing of experiences and approaches to overcome challenges presented with the transition to the new MDR regulations whilst continuously ensuring patient safety. The training highlighted the need to further educational seminars targeting various aspects related to patient safety medical devices including the need to enhance expertise in Notified Bodies, good management practices and digitalisation in relation to medical devices and in-vitro diagnostics.

Acknowledgements: Malta Laboratories Network