

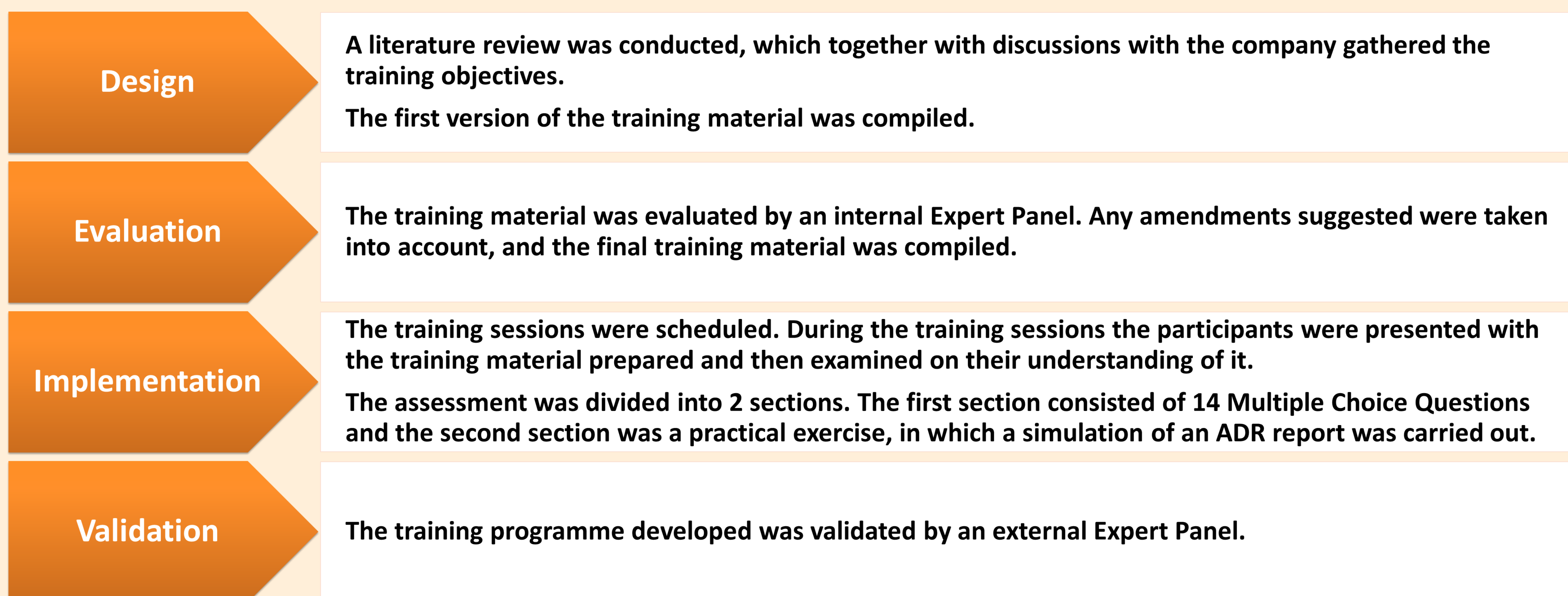
INTRODUCTION

Pharmacovigilance (PV) is a post-marketing surveillance strategy designed to capture Adverse Drug Reactions (ADRs). A Marketing Authorisation Holder requires a PV system in order to receive ADR reports.

AIM

To develop a training framework on PV for a Medical Oxygen producing company in Malta where a PV system was being established.

METHOD



RESULTS

The training material developed consists of:

- Training notes. Divided into 4 sections (Figure 1). Section 1 comprises an introduction to PV, which defines the key and types of ADRs. Section 2 introduces and explains thoroughly ADR reports. Section 3 describes the procedure to be followed in case of a cylinder or batch recall. Section 4 promotes the reporting of ADRs.
- Two ADR report collation forms. One for HealthCare Professionals and another for patients.
- A Standard Operation Procedures (SOP) matrix, where each SOP was linked to the relevant personnel to ensure that all personnel were aware and trained for all their responsibilities.

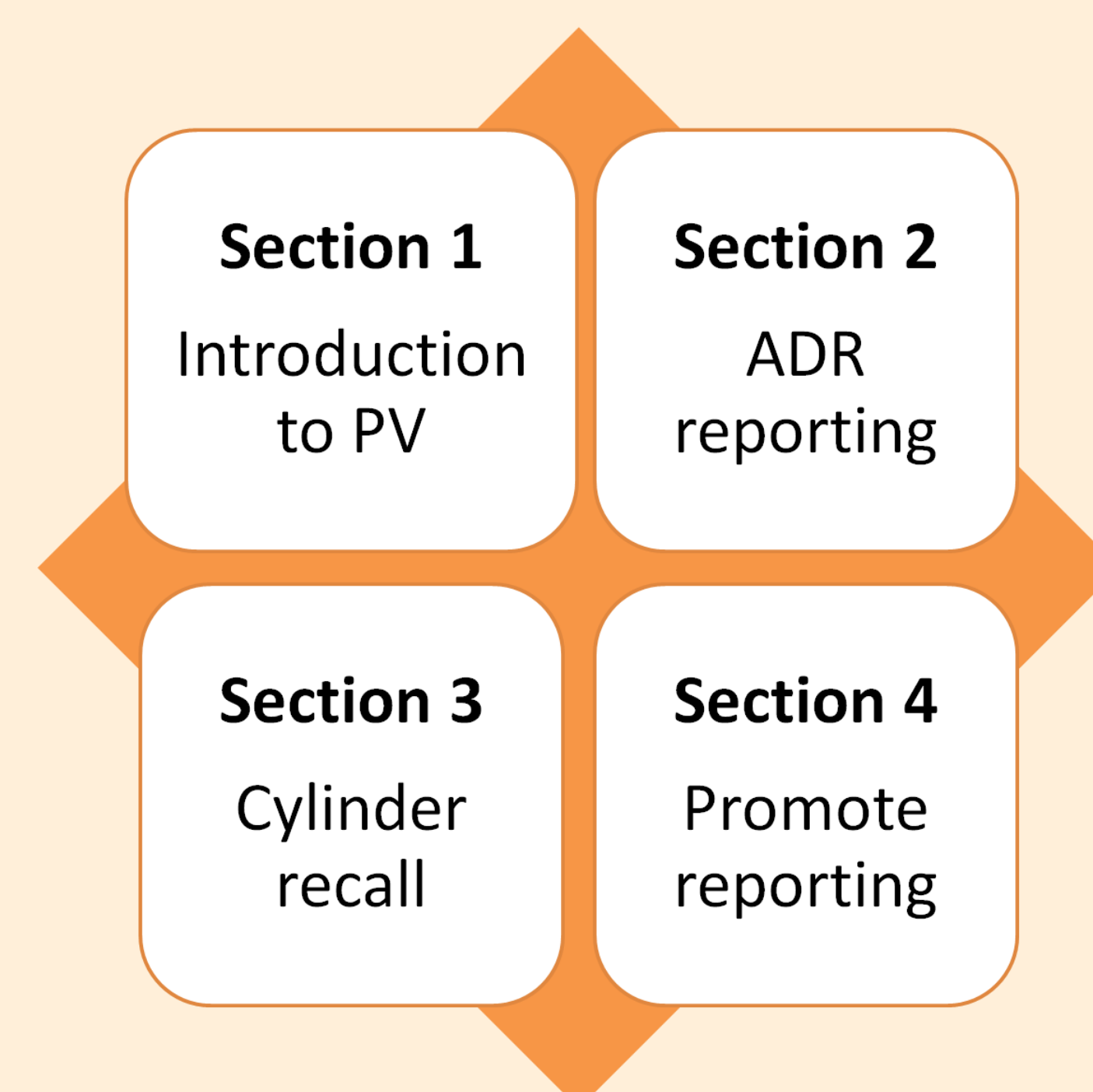


Figure 1 - Training sections

Training examination results show that all 7 participants scored 100% on their MCQs and performed successfully in the practical exercise, thus completing their training.

The validation of the training process found the training material easy to follow and adequately presented. The ADR report collation forms were found to be effective at gathering all the data necessary to process ADR reports, and that a practical exercise is most important to assess the understanding of the employees on how to handle ADR reports.

CONCLUSION

The training material prepared sought to appropriately train staff in order to set up a PV system. The material prepared was found effective in: introducing personnel to PV, explaining the different types of ADRs and in receiving and processing ADR reports with the help of the collation forms prepared, and giving the appropriate training according to the job description with the help of the SOP matrix.