Considerations for promoting pharmacovigilance excellence within biopharma

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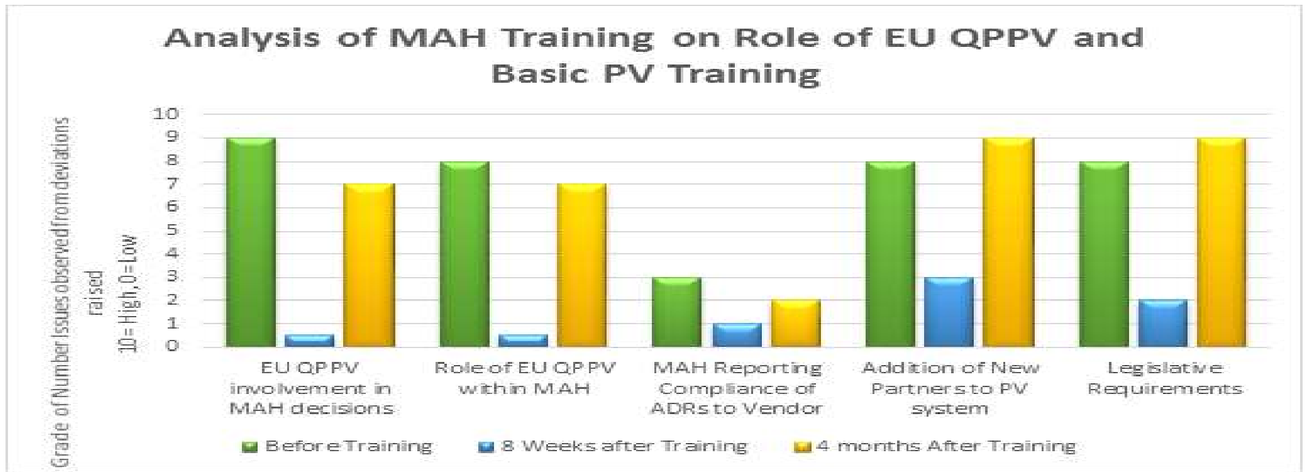
Objectives

To highlight the challenges that may arise with improving compliance at a senior level and the methods for improving organizational effectiveness and promoting pharmacovigilance excellence within biopharma when the role of the EU QPPV is outsourced to vendor.

Method

We provided initial pharmacovigilance training to key Marketing Authorization Holder (MAH) staff on the role of EU QPPV and basic PV training. Over a 6-month period, we monitored the effectiveness of the training by measuring the deviations that occurred following the training on the role of the EU QPPV and basic PV training.

Results



Training was provided to MAH senior management with the aim of enhancing the pharmacovigilance system, enhancing QPPV oversight, and promoting compliance in the organization. The training focused on areas of the legislative requirements, responsibilities of the MAH in relation to EU QPPV, responsibilities of EU QPPV, the requirements of adding new partners to the PV system, how to report safety information to the pharmacovigilance department. A key element of the training was making the MAH aware of their responsibilities towards the EU QPPV and ensuring that the MAH was aware that any business changes can have the potential to affect the PV system. Training was received well and over the course of 8 weeks, outsourced EU QPPV started to see improvements. Improvements noted included more involvement in the QMS, improved MAH reporting compliance of ADRs and notification of changes that had the potential to change the PV system for the MAH. However, after 4 months, the EU QPPV started to experience situations where there was a failure of the MAH to facilitate QPPV pharmacovigilance system oversight with the QPPV being omitted from critical processes that would have an impact on the pharmacovigilance system i.e. product acquisitions/ product divestments.

Conclusion

Based on the case study, results demonstrate the EU QPPV and the MAH Senior Management need to work in partnership to ensure that the PV system & QMS are robust to ensure that Patient Safety is protected. Challenges noted for the EU QPPV from the case study are mainly around contracts between third party vendor and MAH with the level of work required vs what is required per EU legislation, input into QMS and the level of detail required for PV at the MAH and having the oversight of the MAH. In order, to mitigate the results presented in this case study and to enhance working relations between the EU QPPV and MAH Senior Management annual refresher training on the MAH responsibilities to the EU QPPV and the responsibilities of the EU QPPV are added to the MAH Senior Management training plan. Furthermore, the MAH responsibilities to the EU QPPV could be described within Senior Management Job Descriptions to achieve harmonization.