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Role of pharma industries in the improvement of pharmacovigilance system

The public reputation of the pharma industry has been impacted by the many examples where PV systems have failed and companies have promoted unsafe indications and dosages of approved medicines, resulting in patient deaths and severe events. However, there are some examples where tragedies and failures such as thalidomide and the lack of a structured AE reporting system eventually result in some positive outcomes e.g. approved indications for thalidomide in leprosy and cancer-all managed under the umbrella of a comprehensive risk management system. Many drugs are launched and then prescribed and/or used outside of their authorized indication, and there remain significant challenges in controlling or influencing prescriber and patient behaviour to support safe use of the product. With the introduction of the FDAAA, PDUFA, and GVP, the pharma industry has seen seismic changes to PV requirements that focus on patient protection, proactive PV, and the need for PV quality systems. But does this mitigate the possibility for pharma company ineptitude and/or malpractice, and what should be done and what can be done by pharma to improve PV? Compliance is the minimum standard, not the gold standard. This presentation will look at some examples where the challenges of PV facing the pharma company can be proactively managed towards obtaining the right data, allow the right decisions to be made, and take the necessary actions toward safeguarding the patient.

Biography

Kieran O'Donnell has over 15 years of PV and since 2006 has been leading European and Global PV operations, gaining broad experience in PV QMS; Benefit-risk management; Signal Detection & Management; PSURs & DSURs; RSI development; ICSR and SUSAR submission; Inspection (MHRA GCP & PV and FDA PV inspections; ISO 9001:2000; and responsible roles such as the RP for EudraVigilance and Deputy QPPV for Pharmacovigilance. In addition to his PgC Pharmacovigilance, he has been a member of the RQA PV Committee since 2008 and is a Fellow of PIPA. He joined TMC *Pharma Services Ltd.*, UK in June 2014.

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