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Detection and evaluation of drug safety signals

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Early identification of the hazards associated with drugs is the main goal of those involved in pharmacovigilance. 'Signal detection', 'signal generation' or 'signalling' refers to a process that aims to find, as soon as possible, any indication of an unexpected drug safety problem which may be either new ADRs or a change of the frequency of ADRs that are already known to be associated with the drugs involved. The results of this surveillance exercise tend to arouse suspicions and should always be followed up by in-depth investigations. Spontaneous reporting systems for suspected adverse drug reactions (ADRs) remain a cornerstone of pharmacovigilance. The requirement for companies to perform signal detection is mandatory in Europe and highly recommended in the U.S. This session will describe how to implement signal detection as part of company's pharmacovigilance operations thus will cover signal assessment, timing and frequency of signal detection, triage, and data mining runs.

Biography

Parminder Kaur is a Regulatory Affairs and Pharmacovigilance professional with EU expertise and has been working in the field more than 17 years. She has provided strategic input for regulatory matters regarding product development aimed for EU launch. She has provided Pharmacovigilance as well as QA set-up at various companies; assisted various companies during Inspections and Audits conducted by EU Regulatory Authorities. In March 2007, she had been selected by the European Federation of Pharmaceutical Industries and Association (EFPIA) for her global expertise and also had an honour to be the Scientific Representative from India for the year 2000-2001, duly sponsored by UNESCO. She has led an IMI Project on combination therapy at EFPIA, in close collaboration with Research & Development Group (RDG) at European Commission. She is currently having her own regulatory consulting firm by the name of RegPak BioPharma Consulting and is based in Amsterdam, The Netherlands.

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