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Medical device vigilance in EU

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Medical device vigilance is the monitoring of the safety profile of medical devices, from the processing and reporting of single adverse incidents through to the removal of products from the market as part of a Field Safety Corrective Action. This to ensure that patient's and healthcare professional's safety is monitored and action taken as soon as a safety concern with a medical device arises. Manufacturers are obliged to maintain robust medical device vigilance and post marketing surveillance systems in order to attain and maintain their CE certificate. This session will focus on requirements for a robust medical device vigilance system in EU and how to achieve a strong QMS.

Biography

Parminder Kaur is a regulatory expert and a QPPV having 19 years of recognised global expertise in a broad range of therapy areas. She has also played a major role in setting the in-house RA and PV systems in compliance with the European regulations at various companies; assisted various companies during Inspections and Audits conducted by EU Regulatory Authorities. Parminder was awarded Sikh Business Women of the year award in 2014. In 2011, she led an IMI Project on combination therapy at EFPIA, in close collaboration with Research & Development Group (RDG) at European Commission. In March 2007, Mrs. Kaur 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. Parminder had also been a speaker, panellist and Masterclass provider at various National and international Conferences. Parminder is currently running her own regulatory affairs and pharmacovigilance consultancy, RegPak BioPharma Consulting based in Amsterdam.

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