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Good pharmacovigilance practice
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Effective pharmacovigilance requires a set of rules, operating procedures, and practices that must be followed to ensure the quality and integrity of marketed product. Good Pharmacovigilance Practice (GVP) is a quality standard for monitoring the safety of medicines and if necessary, taking action to reduce the risks and increase the benefits of medicines. It ensures the detection, collection, assessment, understanding, and prevention of adverse effects with medicinal products. As per GVP, every Marketing Authorization Holder (MAH) must ensure that they have an adequate and effective quality system for monitoring the medicines they have license for. It is expected that MAH: maintains a pharmacovigilance system; document all actions they take concerning safety reporting and signal detection and; have enough competent, appropriately qualified and trained staff to work the system. In order to gain a greater understanding of GVP requirements, this session will cover GVP modules I to XVI covering major pharmacovigilance processes which should be implemented by the pharma companies doing business in EU.

Biography
Parminder Kaur is a regulatory affairs and PV expert with 19 years of recognized global expertise in a broad range of therapy areas. She has played a major role in setting the in-house RA and PV systems in compliance with the European regulations at various companies. She has provided strategic input for regulatory matters regarding product development aimed for EU launch, ranging from innovative product development incl. gene therapies, biologicals and biosimilars, vaccine and generic product approval as well as orphan designations and early access to unapproved medicines. She has also been highly involved in the pharmacovigilance set-up at various companies. She has played a major role in setting the QA systems in compliance with the European legislation at various companies; assisted various companies during inspections and audits conducted by EU Regulatory Authorities. She is acting as EU-QPPV and deputy QPPV for some companies. Currently, she is running her own consulting firm - RegPak BioPharma Consulting, Netherlands.

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