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Driven strategy for effective monitoring pharmacovigilance quality system – key points

Risk mitigation during medicinal products life cycle requires harmonization of pharmacovigilance activities handled by the involved stakeholders regarding their engagement strategy to ensure compliance. Pharmacovigilance system compliance necessitates the presence of effective quality system management. Real world data indicates that compliance rate needs to be optimized via incorporated standardized parameters and well identified compliance metrics. This presentation will provide an overview of the needed strategy for building up and monitoring of the quality system of pharmacovigilance. Such driven strategy for pharmacovigilance quality management will improves compliance rate and minimize authorities' inspections critics.

Biography

Essam Ghanem is an experienced physician and qualified person for Pharmacovigilance with almost 34 years of experience in clinical research and drug development in academic institutes, pharmaceutical industry and clinical research organizations. He has around eight years of working experience as EUQPPV and as Consultant Safety Physician in the Pharmaceutical Industry. At present, he is the chief executive officer of the Pharmacovigilance Consultation Company VIGI-CARE BVBA and working as the head of drug safety and Pharmacovigilance at Celyad Biopharmaceutical, Belgium. He is a member of European society of CRO Federation (EUCROF) Working Group (PVWG).

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