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Pharmaceuticals pharmacovigilance system compliance: Are you ready for authorities inspection?

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Risk mitigation during medicinal products life cycle requires the marketing authorisation holders and the marketing authorisation applicant to have a compliant pharmacovigilance system in place. This necessitates effective monitoring of the pharmacovigilance quality management system. The pharmaceuticals` management strategy should ensure their readiness for authorities' inspection. The authorities' inspections metrics revealed that compliance rate needs to be optimised via incorporated standardised parameters and well identified compliance metrics for the conducted pharmacovigilance activities. This presentation will provide an overview of the major observations created during authorities` inspection, focusing on the key factors required to ensure effectiveness of the pharmacovigilance system. The pharmacovigilance strategies driven by pharmaceuticals require compliance rate improvement, aiming to minimise authorities' inspections critics.

Biography

Essam Ghanem is an experienced Physician and European Qualified Person for Pharmacovigilance (EU-QPPV). He has around 28 years of experience in clinical research and drug development in academic institutes, pharmaceutical industry and contractual research organisations. He has almost 8 years working experience as EUQPPV and International Speaker in the field of pharmacovigilance system compliance and risk mitigation. He is the Head of Pharmacovigilance and Chief Medical Officer at the pharmacovigilance consultation company VIGI-CARE.BVBA located in Belgium.

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