Pharma IT

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Drug Safety & Pharmacovigilance Team Profiles

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Selected Profiles for Drug Safety & Pharmacovigilance

Sukhjit Gill
Director of Drug Safety & Pharmacovigilance at Pharma IT. Holds more than 15 years of experience from pharmaceutical companies and 3+ years of experience within the medical device industry. Solid experience with various pharmacovigilance tasks within development and post-marketing, preparing high-quality aggregate reports (DSUR, PSUR/PBRER, etc.), SOP writing, ICSR case scientific review and reporting to authorities, safety surveillance, signal detection, literature review, MedDRA coding, SAE handling from clinical trials, SAE reconciliation and unblinding. Furthermore, experience with device vigilance handling, SAE/SADE monitoring and reporting to NA/EC, evaluation of serious incidents, IMDRF coding, MIR reporting and communication with Regulatory Authorities/Notified Bodies, execution of Recalls/FSCA and implementation of new MDR regulations.

Sanne Strange
Principal Pharmacovigilance Physician with over 20 years of experience in the pharma- ceutical and biotech industries, as well as 5 years of experience in the hospital setting. Educated MD with full registration of physician and Diploma in Pharmaceutical Medicine. Subject matter expert in the medical review of adverse events, preparation & evaluation of safety-related clinical study documents, monitoring, and signal generation & handling. Hands-on experience chairing and preparing safety management teams, safety committee meetings, and data monitoring committee meetings. Experience responding to internal and external requests from Regulatory Agencies and Health Authorities, coding consistency, & reconciliation.

Kristine Kornø
Principal Pharmacovigilance Consultant with over 10 years of experience as Global Safety Advisor working with clinical trials and post-marketing (incl. drug-device combination products). Subject matter expert in handling of clinical trials (phase I-IV, PASS, NIS, and IIS). Extensive experience as Product Responsible person for marketed and developing products; Medical assessment of solicited and spontaneous ICSRs; Writing aggregated safety reports (DSUR, PSUR, PADER) and Signal detection and Management.

Mie Altermann Sørensen
Senior Pharma Consultant with 9 years of experience in the pharma industry, including work in medical information and pharmacovigilance related to surveillance activities such as signal detections, PSURs, literature monitoring, batch trending, and HHEs. Drug safety experience from having worked in headquarters and affiliates. Solid experience with scientific review and writing of company comments. Further experience includes 2 years of experience with medical information.

Rikke Engel
Pharmacovigilance consultant with over 5 years of experience in the pharmaceutical and medical device industry both within clinical trials and post-marketing. Extensive expertise covering various aspects of vigilance, including: Case handling and submissions to Regulatory Authorities; analysis of regulatory intelligence; preparation of aggregate reports (Annual Reports and DSURs); creation and negotiation of Pharmacovigilance Agreements; authoring Standard Operating Procedures (SOPs); providing training on procedures and within pharmacovigilance; and active participation in audits and inspections.

Emma Rovsing Kristiansen
M.Sc. in Pharmacy and Associate Consultant with 3 years of experience in pharmacovigilance - in the past as a student assistant, now as a consultant. Experience with safety mailbox monitoring and case processing including triage, book in, data entry, QC, and scientific review of spontaneous and study cases in Argus Safety Database. Experience with distribution and submission of study cases. Furthermore, Emma has successfully completed the EudraVigilance electronic reporting of ICSRs knowledge evaluation and is experienced in download and assessment of ICSR and MLM from EudraVigilance.

Kirstine Bækgaard Andersen
Associate Consultant with more than 2 years of experience with pharmacovigilance working with safety mailbox monitoring, book-in, data entry, QC and scientific review of safety data from both clinical trials and post-marketing, and ICSR reporting for clinical trials. Experience with maintenance and change management of the Argus Safety Database. Successful completion of EudraVigilance ICSR knowledge evaluation, and experience with registration of organisations in EudraVigilance. Worked with Regulatory Affairs in a biotech company for 2 years.

Nina Lyck
Associate Consultant with a M.Sc. in Pharmacy from the University of Copenhagen (2022). During her studies, Nina worked with pharmacovigilance for two years and has experience with handling of safety data from both clinical trials and post-marketing including book-in, data entry, and coding in the safety databases Argus and Veeva, as well as reconciliation.

Sidsel Levring Madsen
Associate Consultant with a M.Sc. in Pharmacy (2022) with experience in pharmacovigilance working with book-in, data entry, and quality control of safety data from both clinical trials and post-marketing in both Veeva Safety and Argus Safety Database. Experience with periodic system review of Argus Safety Database as well as maintenance and preparation and execution of test cases within Argus Safety Database. Holds an Essential GCP for Sponsors Certification from Brookwood and has completed training in GAMP5 & Computer System Validation as well as Clinical Development and Applied Good Clinical Practice (GCP). Gained 2.5 years of experience during her studies within Global Pharmacovigilance in a pharmaceutical company.

Safety System Support Team

Maria Skov Andersen
Vice President of Veeva Services at Pharma IT. Consultant with 7 years of experience in the pharmaceutical industry. This includes 3 years of experience during her studies. Experienced with handling adverse event reports including case processing, scientific review, reconciliation, and MedDRA coding of spontaneous and study cases into the safety databases Argus and Empirica. Completed all modules within the Master of Pharmacovigilance program at the University of Hertford- shire, UK. Successful completion of EMA's XEVMPD knowledge evaluation. EDMS system expert with advanced Veeva system administrator certification and experience with Veeva implementation. Experienced with compliance tasks such as system validation within the drug safety area.

Linda Dang
Associate Consultant with two years of experience in the pharmaceutical industry. Experience with system administration of the PV safety databases including Veeva, Argus, and HALOPV. This includes supporting end-users and handling change management and user administration. Experienced in supporting the validation of DocuSign and system administration of this system. Linda holds a MSC in Pharmacy and is a certified Veeva Vault Platform Associate Administrator.

Alexander Malling
Associate Pharma Consultant with 3 years of experience within Regulatory Affairs, including, data entry into Regulatory Information Management System (RIMS), and compilation of eSubmissions. Experienced Veeva Vault system administrator within RIM, Quality and Safety with experience in change management, end user support and IT validation. Experience in administrator role for non-Veeva safety applications (Argus, HALOPV). Alexander holds a Master of Science in Bioinformatics and is Veeva Vault Platform Associate Administrator.

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Want to learn more about how our team can assist you?

Reach out to **Sukhjit Gill**
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