Drug Safety Specialist | Case Processing and Signal Detection

FIRSTNAME LASTNAME

Amsterdam, Netherlands | firstname.lastname@email.com
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Profile

Drug Safety Specialist with five years of pharmacovigilance experience at a marketing authorisation holder and a CRO. Processes individual case safety reports from clinical trials and post-marketing, codes in MedDRA and submits to EudraVigilance. Contributes to signal detection, PSURs and safety sections of risk management plans.

Career highlights

- Processed about 1,500 cases a year with 99 percent on-time regulatory submission.
- Ran monthly signal detection for six products and wrote two signal evaluation reports.
- Prepared the case processing part of an audit by the QPPV office with no findings.
- Moved case intake to a new safety database with zero lost cases.

Professional experience

Drug Safety Specialist **May 2022 to present**
Marketing authorisation holder (example) Amsterdam, Netherlands

- Process ICSRs in Argus Safety from intake to E2B(R3) submission to EudraVigilance and the FDA.
- Perform signal detection and contribute to PSURs and RMP updates.
- Reconcile safety data with clinical and medical information teams.

Pharmacovigilance Associate **September 2020 to April 2022**
Global CRO (example) Berlin, Germany

- Triage, data entry and MedDRA coding of clinical trial and spontaneous cases.
- Literature screening for three clients.
- Wrote case narratives.

Education

University of Münster. Master of Science in Pharmaceutical Sciences, 2020

Further training

EudraVigilance and E2B(R3) certificate (2021) | MedDRA coding best practice (2022) | GVP modules refresher (2025)

Languages

German (native) | English (business fluent) | Dutch (basic)

Core competencies

ICSR processing | MedDRA coding | EudraVigilance | E2B(R3) | Argus Safety | Signal detection | PSUR and PBRER | Risk management plans | GVP | Literature screening

Sample CV with invented content. Free Pharmacovigilance Specialist CV template by Andreas Schulz, MoreThanCareer.de: morethancareer.de/cv-templates/pharmacovigilance-cv-template.html