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# Example of Drug Safety Specialist Job Description

Our company is growing rapidly and is looking for a drug safety specialist. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

## Responsibilities for drug safety specialist

* Assumes responsibility of business owner for the Safety Query Tracking Tool
* Provide induction training on Safety Query Tracking Tool for new users
* Assumes responsibility for database searches on the DataMart for ad-hoc searches, DSURs, PBRERs, signal detection, audit- and inspection requests, metrics and any other search request
* Interacts with internal or external customers to define the criteria for a database search
* Leads projects or initiatives within Safety Analytics and Reporting, Safety Services or PDS and represents the Data Management Group in projects or initiatives beyond PDS
* General knowledge of medical scientific literature journal articles (e.g., function, types, use)
* Provides medical assessment on all cases for seriousness
* Contribute to, and provide subject matter expertise for PV templates for clinical trial protocols and non-interventional study protocols to ensure compliance with global PV regulations
* Review and advise on PV content of clinical trial protocols and non-interventional study protocols
* Participate in interdepartmental and interdivisional meetings in support of individual protocol reviews, input for PV requirements, and related processes

## Qualifications for drug safety specialist

* Awareness of the role of compliance in drug safety
* Maintains oversight of safety risk management and all other pharmacovigilance (PV) activities and ensures PV compliance and inspection readiness across all affiliate functions
* Experience in medical writing, strong interpersonal and communications skills, organizational and problem-solving skills required
* Strong knowledge of FDA regulatory reporting requirements and GMP GCP guidelines required
* 5+ Years of experience leading large global studies within Clinical Trial Safety required
* Experience writing Safety Management Plans required