

ROLE: DRUG SAFETY OFFICER SENIOR (DSOs)

JOB DESCRIPTION

1. Collection, management and processing data entry into the reference databases of drug adverse reactions from any source.
2. Transmission of ICSRs.
3. Quality Control.
4. Supporting the preparation of aggregate reports.
5. Supporting the Signal detection activity.
6. Supporting the preparation and the update of Safety Data Exchange Agreement (SDEA).
7. Medical literature monitoring.
8. Writing of Standard Operating procedures (SOPs) e Working Instructions (WI) and their updating.
9. Availability to cover activities of Deputy QPPV / QPPV / EudraVigilance QP / Local CPP.
10. Monitoring Authorities Websites to find out regulatory news or adjournments.