

Loveleen Arora

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Pitampura, Delhi 110034 Nationality: Indian

• **Drug Safety Professional**

- Competent and diligent M.Pharm professional offering a comprehensive experience of **02 years** in Pharmacovigilance/Drug safety.
- Possessing core competencies in Pharmacovigilance/Drug Safety, Drug Safety Databases (**ARGUS**).
- Professional Experience- Currently working as **Pharmacovigilance Associate** at **Wipro BPS, New Delhi** since **12Jan2018- Present**.

➤ As **Case Processor** and **ICH Case processor**:

- Initial receipt and triage of incoming cases (solicited, spontaneous, clinical trial and literature).
- Handling of Individual Case Safety Reports (ICSR) from various sources, review, verification, assessment and documentation of case related information: report type, validity, product coding [via CDD or WHO DD limitations], events selection and coding [via MedDRA limitation], seriousness criteria, causality, special scenarios and assessment of regulatory timelines. Processing of cases, performing MedDRA search for coding, labelling of adverse events, review and processing of Safety data. Also perform follow-up activities.
- Spearheading efforts across verifying overall consistency of cases, assessment of solicited or spontaneous serious and non-serious cases in Global Safety Database Argus (v 7.0.7)
- Discuss new scenarios, coding conventions, and ad-hoc queries.
- Other case processing related activities (e.g. case assignment, review of consistency checks, reconciliation, query management etc.).
- Coordinating with different functional team members, e.g. team leaders, and other health care professionals and QC's for completion of various cases with accurate consistency and proper validation.
- Other ad-hoc activities included maintaining defect tracker, sharing of ICSRs/CIOMS with licensing partners, case allocation to team, reconciliation report preparation of the cases from the licensing partners, conduct training on new updates etc.

• **Academic Qualification-**

- Post-Graduation: Masters in Pharmacy from (Al-Ameen College of Pharmacy) RGUHS, Bangalore.
- Graduation: Bachelor of Pharmacy from (Al-Ameen College of Pharmacy) RGUHS, Bangalore.

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• **Core Competence-**

▪ Pharmacovigilance, Extensive study of ICH guidelines, IND, NDA, ANDA and submission requirements such as eCTD, and sound knowledge of Drug development process, Clinical Research studies.

• **Technical Skills-**

▪ Computer Skills: Proficient in MS Office (Word, Excel, PowerPoint) applications.

▪ Coding: CDD, WHODD, MedDRA (V. 21.1).

▪ Database: Argus (7.0.7)

• **Skills and Attributes-**

▪ Sincere and dedicated towards work

▪ Hardworking

▪ Leadership Quality

▪ Flexible and Expressive communicator.

• **Extra-Curricular Activities-**

▪ Enjoys playing outdoor and indoor games like Basketball and Carom respectively and also interested in travelling, listening music, watching movies.

• **Declaration-**

▪ I hereby confirm that the information furnished above is correct to the best of my knowledge.

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