Senior Pharmacovigilant Professional

SAURAV BHATTACHARJEE

9886062633 saurav_tez@yahoo.co.in

A manager in Digital and Pharmaceutical operations, Drug Safety Scientist offering over 6.7 years of expertise in Pharmacovigilance, and Safety Reporting and 9 years in medical transcription in the American Healthcare sector. Saurav extends expertise in Complaint Management in Medical Device, Global Safety Assessment of investigational and marketed products throughout their lifecycle. This includes all Pre and Post-Marketing Safety, Pharmacovigilance (PV) and Risk Management activities. Working together with the senior management from the Drug Safety and Pharmacovigilance (DSPV) departments, he manages the safety assessment of products.

Demonstrative experience in literature review, complaint handling, preparing safety reports and communicating changes in the product risk profile to internal and external stakeholders. Saurav remains responsible for identifying, reporting and following up on adverse effects of drugs, pharmacovigilance agreements with keen focus on clinical trials, effects of drugs, and ensuring that products which are released are safe for the public. Recognized as a Subject Matter Expert in Pharmacovigilance with specific drugs; including knowledge of applicable clinical trial safety regulations and post-marketing safety regulations. Includes knowledge of case processing, expedited reporting rules, and safety database concepts. Demonstrates ability to mentor and lead PV Scientists.

Exhibiting the ability to work in a dynamic, changing environment to meet corporate and patient needs, Saurav is looking forward to a challenging role in the ITES Healthcare domain.

Career Timeline

Jul 2003 to Nov 2012
Nuance Transcription Services India Private Limited, Bangalore
QA Editor / Medical Transcriptionist

Dec 2012 to Jul 2019
Quintiles India Private Limited
Senior Drug Safety Associate
(Operations specialist)

Recognized For

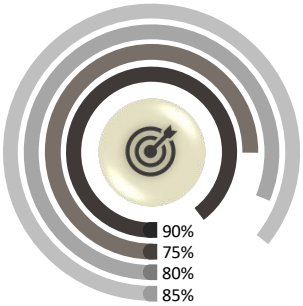
- Managing a team of 14 people with 2 leads under me for complaint handling and management for medical devices .
- Managing and mentoring overseeing and managing Pharmacovigilance (PV) activities for a group of products, including regulatory responses and literature review / management for safety findings for an assigned group of products.
- Stakeholder management. Improving quality of editing in narrative writing.
- Initiatives for process improvement and improving efficiency and leading consistent work processes across assigned product groups considering cross-program practices.

Critical Areas of Focus

- Steers medical device complaint management team for quality and productivity.
- Steers Safety Management Team (SMT) for assigned products. Reading pharmacovigilance agreements and clearing knowledge tests regarding the same. Training a team of 6 people and a total of 4 batches, priming them up for production floor.
- Quality improvement plan both for pharmacovigilance support team, creating special huddles and projects for the same. Working on a quality improvement project to help with quality improvement in ICSRs.
- Participates in individual case safety report (ICSR) case management to ensure timely and accurate reporting of ICSRs.
- Demonstrates expert level knowledge and ensures compliance with current and applicable global PV regulations and guidelines (e.g., CIOMS, EMA, FDA, ICH, etc.), SOPs and quality standards.

Signature Skills

- American Health Care System
- Regulatory Compliance
- Risk Profile Management
- Clinical Trial Cases



Safety Compliance

HIPPA Compliance

Academics

Post graduate diploma in Pharmacovigilance and clinical research

Bachelor of Pharmacy, 61% (2002)

Certifications

Certification course in Project Management (IIT Delhi)

Certification in Business Analytics and Technical Writing from Manipal ProLearn (Manipal University)

- Contributes to vendor governance activities and key performance indicators to ensure DSPV excellence.
- Remains abreast, acting as the thought leader across new PV/safety regulations and guidance from the regulatory authorities.

Work Experience

IQVIA (previously Quintiles India Private Limited)
Senior Drug Safety Associate (Operations specialist)

Significant Contributions

- Risk management identification with adverse events serious or nonserious of ICSRs, literature reports, solicited reports, etc. Identifying ICH dates, FDA regulatory submissions
- Assessed the risk assessment profile of various drugs with regards to drugs of various multinational companies.
- Led discussions with pharmacovigilance physicians regarding attributions and clinical aspects of the cases.
- Filed deviations memos regarding processes to the regulatory authorities.
- Spearheaded the implementation of Pharmacovigilance profile testing software.
- Worked in pharmacovigilance automation project to check if the system is able to calculate the age and do automatic duplicate search in ArisG..
- Reviewed existing policies and processes, deftly suggesting improvements and procedural enhancements to increase efficiency.
- Played a critical role during inspections and audits, and for acquiring GCP certifications.
- Recognized for processing cases with SUSAR and SUA.
- Supported pharmacovigilance systems and creating tickets and solving PV system issues, whilst coordinating and liaising across cross functional departmental of pharmacovigilance units, for issues raised, and resolving escalations by extending appropriate solutions.
- Remained as the thought leader for trainees and new members on the team.
- Resolving pharmacovigilance admin issues as part of support desk.
- Contributes to vendor governance activities and key performance indicators to ensure DSPV excellence. • Remains abreast, acting as the thought leader across new PV/safety regulations and guidance from the regulatory authorities.

A Day at Work

30%

Demonstrates leadership and interacts collaboratively and effectively in a team environment (including Safety, Clinical Development, Clinical Operations,), as well as with external colleagues.

25%

Applies clinical judgment to interpret case information, helps guide staff on clinical judgment and interpretation of case information.

20%

Understands, interprets, analyzes, and clearly presents scientific and medical data in verbal and written format (including intermediate understanding and application of medical concepts and terminology).

30%

Mentors others to develop these skills and serves as a leader within the PV Scientist team.

Awards

- Bravo awards - 2015

Nuance Transcription Services India Private Limited, Bangalore
QA Editor / Medical Transcriptionist

Significant Contributions

- Recognized for systematically checking and ensuring all doctor’s transcripts were well within HIPPA guidelines.
- Ensured drug dosage and medicinal errors that could arise in transcripts were checked and corrected.
- Guiding a team through initial project guidance

Awards

- Best team performer award for the month of December 2011, 2010
- Best achiever award 2005-2006
- Working nonstop without any off for 1 continuous month