PRACHI UMESH RAUT

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OBJECTIVE

Seeking a challenging position in the field of Pharmacovigilance and strive for excellence - with passion towards work and fully utilize my skills for the fulfillment of organizational goals

Current Employment

Drug Safety Associate at **Tata Consultancy Services Ltd, Mumbai:**

Role: Pharmacovigilance scientist and Trainer/mentor for Team Members & Workflow Manager
Designation: Data Safety scientist /Process Trainer
Period: 23- May-2018 to 11-Dec-2020

Currently working as process trainer on E2B ICSRs case type since March 2020.
Majorly involved in Quality check of cases to ensure scientific rigor through accurate, complete and consistent data entry of adverse event reports from source documents (cases received from regulatory authorities, spontaneous and PMS Cases) with emphasis on timeliness and quality.

Skills & Competencies:

- Knowledge of drug safety & clinical development and ICH/GCP principles
- Good knowledge of Pharmacovigilance practices, Pharmacology and medical terminology.
- Good knowledge of USFDA, MHRA, EMEA, PMDA and CDSCO Pharmacovigilance regulatory requirements
- Good written and verbal communication skills and ability to present.
- Knowledge of Mailbox handling.

JOB DESCRIPTION:

- Review, extract and accurately enter AE data from marketed product, adverse event reports.
- Sending Med DRA requests as needed and discussing with operation physician regarding the amendment/split and raising queries regarding the events.
- Narrative writing as per regulatory format.
- Accountable for performing quality review for individual case safety reports of spontaneous, clinical, PMS and literature cases.
- Accountable for performing the appropriate clinical assessments (including the assessment of seriousness, company causality for each adverse event) adhering to SOPs/other controlled documents and regulatory requirements.
- Detailed knowledge of GCP & ICH guidelines with understanding of regulatory requirements.

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- Assuring and maintaining compliance with regulatory and local/global SOP timelines using proactive workflow management.

- Developing and maintaining knowledge of the appropriate disease biology areas and associated client's product knowledge.

- Demonstrated knowledge of safety concepts, global regulatory reporting obligations, relevant Pharmacovigilance drug safety online (PDSO) SOPs, Pharmacovigilance Agreements and Safety Data Exchange Agreements.

- Raising queries to Safety Responsible personnel for missing information. Adhering to productivity, timeline compliance and quality of cases.

Process Trainer:

Training and mentoring of the new associates and mentoring of the all team member with respect to training on all new updates in the process.

- To resolve day-to-day technical queries and various grievances of team members
- Weekly meeting-training to all team members on query resolution sessions or new updates.
- • Liaise with clients for case specific queries and compliance.
- Involved in process improvement plans.
- Coordinate with the team members to ensure efficient case processing and assessment
- Ensure that team follows workflow procedures, SOPs and case processing guidelines
- Data collaboration of all identified Critical and Non critical errors which required to share with the clients, accordingly monthly/weekly training to all team members to minimize error accuracy within the team. • Maintenance and tracking of all queries and queries resolution record which has been raised to clients (external)/internally –which contributes in easy going in future prospective situations to tackle same kind of queries with minimal time.

Workflow Manager:

Also has worked as back-**up of Team lead** with following Additional Activities:

- Daily work allocation within the team
- Manage the receipt, assignment and processing of all serious-non serious reports.
- Participate in client meetings and project specific updates.
- Meeting timelines and quality standards for deliverables. Identify the priority cases which were at TCS end
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Reporting to the team lead for daily processed-unprocessed cases • Calibration Qcers

Experience on Tool

1. Working on Argus software (PV database)
2. Med DRA 20.1
3. Good at using MS Word, Excel, PowerPoint and Email writing
4. Completed certification course on SAS, C++, JAVA

ACHIEVEMENTS:

Awarded as **"Star performer and Best Team Award" 2019 by TCS.**

Awarded as **"Valuable contribution in GSK Pharma PV – E2B Process" in 2020 by GSK.**

KEY STRENGTHS:

- People development
- People Management
- Self-motivated, efficient team player
- Disciplined and hardworking

EDUCATIONAL QUALIFICATION :

Qualification	Institution	Board/ University	Year of passing	Percentage / CGPA
Master of Pharmacy	SKBCOP, Kamptee	RTMNU Nagpur University	2018	CGPA 8.35
Bachelor of Pharmacy	SKBCOP, Kamptee	RTMNU Nagpur University	2016	70.29%
Diploma in Pharmacy	SSDIPD, Kamptee	RTMNU Nagpur University	2011	81.60%

M Pharm Project Work:

"β Amyloid Induced Memory Impairment in mice: Modulation by Agmatinergic System."

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- **PRESENTATIONS**

  - Presentedposter entitled **"Interaction** between **Amative and NYPergic system within Central Nucleus of amygdala in post – traumatic stress induced anxiety in mice" on 'NATIONAL SCIENCE DAY',** held on February 2017, at SKB College of Pharmacy, Kamptee, Nagpur.

  - Presented poster entitled **"Characterization of Agmatinergic Signaling In β-Amyloid Induced Impaired Learning and Memory."** at "**69th Indian Pharmaceutical Congress 2017"** Chitkara University, Chandigarh from 22-24 December, 2017.

  - Participated in **Innovation** & **Research in Pharmaceutical Sciences,** RESEARCH PRESENTATION COMPETITION**,on 'NATIONAL SCIENCE DAY',** held on 28 February, 2017, at SKB College of Pharmacy, Kamptee, Nagpur.

Paper published:

- Neuroprotective effect of agmatine in mouse spinal cord injury model: Modulation by imidazole receptors
- Evidences for agmatine alterations in Aβ 1-42 induced memory impairment in mice

Conferences/ Workshop Attended:

- XXXXV Annual Conference of Indian Pharmacological Society & International Conference on "Navigating Pharmacology towards safe and effective therapy", held at Nagpur from 5^{th} – 7^{th} ^{Jan} 2013. Smt. Kishoritai Bhoyar College of Pharmacy, Kamptee.

  Attended three days National Conference on "Neurodegenerative **Diseases: Strategies of Drug Discovery and Delivery to the Brain**" at SVKM's Dr. Bhanuben Nanavati College of Pharmacy, Mumbai on 27-29 July 2017.

PERSONAL DETAILS:

Date of Birth	21st June 1991
Address	Villa no 42, Al sameeh street Near shaikha Mouza mosque, Al rahba Abu Dhabi UAE
Gender	Female
Marital Status	Single
Nationality	Indian

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Languages Known	English, Hindi and Marathi
Passport Number	U3326307

DECLARATION: I do hereby confirm that the information given above is true to do the best of my knowledge and belief. Place: Date:

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