

# Pranali Vinayak Mane

✉ manepuranali1226@gmail.com

☎ 7021447171

📍 B-03 Anand Mangal CHS, Sector 16, New Panvel (Navi Mumbai)

📅 26/12/1993

## 🔗 Profile Summary

- **Insightful experience of nearly 5+ years** in Clinical and Pharmacovigilance domain includes- Case processing, Case review and Case submission.
- Proactively oversees creation and **continuous improvement** of adverse event reporting and management processes on a global scale, including the oversight of the case management and regulatory submissions activities
- Excellence in monitoring **quality and efficiency** across functions to identify trends and opportunities for improvements for effective team utilization and productivity.
- Processed safety information in safety databases like ARGUS for spontaneous, clinical trial, PMS studies (Social Media Program, Patient Oriented Program, Patient Support Program, Market Research Program and Registries), literature cases
- Assisted to ensure that any change Oracle - Argus Implementation/ Configuration/ Upgrade/ Maintenance of Drug Safety Application is implemented by the business in time.

## 🎓 Education

### Master in Pharmacy

Dr. D. Y. Patil, IPSR, Pimpri, Pune

08/2015 - 09/2017

### Bachelor of Pharmacy

Dr. D. Y. Patil, IPSR, Pimpri, Pune

07/2011 - 06/2015

## 📁 Professional Experience

### Medical Writer

LMT Glocal Service

03/2023 - 12/2023 | Thane

- Drafting medical summarization.
- Conducted weekly meetings when required for all the operational/ functional activities with proper documentation into Minutes of Meeting.
- Accurate, complete and consistent summarize report from source documents with emphasis on timeline and quality.

### Senior Process Executive

Tata Consultancy Services

04/2021 - 03/2023 | Thane

- Responsible for Data Entry of Individual case safety reports into the safety data base.
- Managed and supported audits and inspections and ensured that projects are audited and inspected at all times in adherence to the laid processes, compliances and documentation (good documentation practice). Steered investigation, RCA, impact assessment & CAPA, effectiveness check, tracking until closure.
- Serve as the global lead for aggregate reporting, signal management, and literature surveillance projects.
- Acted as the literature lead, conducting ongoing literature safety surveillance for both marketed and investigational products.
- Identified and evaluated ICSRs from literature sources and assessed event of special interest.
- Executed: ICSRs expedited and non-expedited submission to US FDA, EMA and MHRA.

**Cognizant Technology Solution**

- Received information on adverse events (spontaneous and clinical), performed initial checks, searched data-bases to prevent duplicate entries, created case file and received drug safety reports in the tracking tool and /or safety database (ARGUS).
- Ascertained scientific rigor through accurate, complete and consistent data entry of adverse event report from source documents with emphasis on timeline and quality.
- Performed accurate and consistent coding of all events and medicine for serious and non-serious cases entered in the ARGUS with the use of MedDRA, CCDS and WHO-DD.
- Interacted with internal or external contacts to resolve issues related to the processing of cases and PQCs.
- Provided training to new joiner and mentored for preparation of ICSR in ARGUS database.
- Led monthly accuracy of data, error trend with improvements, impact analysis was shared and the team was re-iterated, queries resolved and updates shared during the sessions.
- Also worked on E2B validation.

 **Projects****Anti-inflammatory and Analgesic Activity of Herbal Drug on Experimental Animals**

2017

 **Courses****Conference**

- Attended one day state level seminar on “Overview of Animal Pathology, Demonstration of Organ Collection and Preservation” held in Pimpri, Pune.
- Attended 68th IPC held in Andhra University, Vishakhapatnam.

 **Awards****NOTABLE ACCOMPLISHMENTS/AWARDS/RECOGNITION:**

- Recognized by client for consistent performance for E2b Validations and Argus J prioritization of cases
- Recognized by senior leadership for zero miss in compliance and submission of cases
- A Spotlight Award is a monetary award designed to acknowledge the contributions of employees who go above and beyond the everyday scope of their responsibilities, or those who have particularly excelled in the execution of a job duty.
- Rookie of the Year is an award given to a new employee judged most accomplished in the first year.

 **IT Skill**

- MS Office (Word, Excel, PowerPoint)

 **Declaration**

I hereby declare that the forgoing information is correct complete to the best of my knowledge and belief.

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**Pranali Vinayak Mane**  
New Panvel