

Shubham Purushottam Jaybhaye

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PROFILE SUMMARY

Enthusiastic and extensively trained Master of Pharmacy graduate with a strong background in pharmaceutical sciences, actively seeking a dynamic role in clinical research, data management, pharmacovigilance, and regulatory affairs. Proficient in pharmacology and skilled in drug development, with proven capabilities in cross-functional collaboration and maintaining compliance with regulatory standards. Committed to enhancing healthcare outcomes within a challenging professional setting.

INTERNSHIP

Trainee Clinical Research Coordinator <i>VSG Life Science, Nashik</i>	Dec 2023 – June 2024 Nashik, India
<ul style="list-style-type: none">Collaborated with monitors across site phases (selection, initiation, monitoring, closeout) for smooth study progression.Supported PIs, Sub-Is, and site personnel in executing trial activities while strictly adhering to ICH-GCP guidelines.Coordinated and managed on-site clinical trial activities, ensuring protocol, GCP, and local regulation compliance.Communicated effectively with Sponsors, CRAs, Laboratories, Investigators, Monitors, and site team members for study execution.Managed Informed Consent Process, screening, and subject randomization, promoting ethical research.Documented and transcribed clinical data into EDC systems, resolving queries for data accuracy.Handled source documentation, CRF entries, query resolution, safety reporting, feasibility assessments, and EC submissions expertly.	

EDUCATION

Master of Pharmacy (Pharmacology) <i>Savitribai Phule Pune University</i> 8.62 (CGPA)	Dec 2022 – July 2023 Nashik, India
Bachelor of Pharmacy <i>Savitribai Phule Pune University</i> 6.98 (CGPA)	Jan 2020 – Jul 2022 Malkapur, India
Diploma in Pharmacy <i>Directorate of Technical Education, Maharashtra State, Mumbai</i>	Aug 2018- May 2020 Nagpur, India
Higher Secondary Certificate (HSC) <i>Maharashtra State Board of Secondary and Higher Secondary Education</i> 80.46%	2016 – 2017 Risod, India
Secondary School Certificate (SSC) <i>Maharashtra State Board of Secondary and Higher Secondary Education</i> 84.60%	2014 – 2015 Risod, India

PUBLICATIONS

Research Article

International Journal of Pharmacy & Pharmaceutical Research

Formulation and evaluation of Novel Herbal Mouth Gel of Aloe Barbadensis,

Azadirachta indica and Curcuma Longa for Healing of Mouth Ulcer

PROJECT

Post Graduation Dissertation

Evaluation of Safety and Efficacy of Subcutaneous Injection Denosumab (Test) with Reference Medicinal product Denosumab (Reference) with the Patient of Bone metastases from the Solid tumor under the guidance of Dr. Aman Uganlawar, Associate Professor of S.N.J.B's S.S.D.J College of Pharmacy, Chandwad, Nashik.

TRAININGS

- Uppsala Monitoring Centre - **Essentials of pharmacovigilance communications** (2023)
- Uppsala Monitoring Centre - **Introduction to pharmacovigilance** (2023)
- Web-based training on **Good Clinical Practice (NIDA)** (2023)

CURRICULAR ACTIVITY

- Completed online **Good Clinical Practice (GCP)** training provided by NIDA Clinical Trial Networks on March 28, 2023.
- Successfully completed a workshop on "**Clinical Research Coordinator (CRC) & GCP**" organized by the **Indian Society for Clinical Research (ISCR)** on January 7, 2023.
- Attend the **DCGI** Audit.
- Attend Sponsor Audit and successfully completed.

SKILLS

Study Protocol Adherence

Informed Consent Process

Patient Recruitment and Screening

Data Collection and Management

Source Documentation

Regulatory Documentation

Electronic Data Capture

AE & SAE Reporting

Adaptability

Problem-Solving

Communication

Time Management

Teamwork

LANGUAGES

English

Hindi

Marathi

AREAS OF INTEREST

Clinical Research

Pharmacovigilance

Clinical Data Management

Regulatory Affairs