Akshata Praveen Deshpande

9766412833 | deshpandeakshata98@gmail.com | Pune, Maharashtra |
www.linkedin.com/in/akshata-deshpande- 73211b1b9 |

PROFESSIONAL SUMMAY

Dedicated and detail-oriented professional with 3 years of experience in biopharmaceutical manufacturing, currently working at Lupin Ltd. (Biotech Division) and leading Quality Management System activities. Responsible for the planning, execution, and oversight of Quality Assurance Management System (QAMS) for both upstream and downstream manufacturing batches, working closely with cross functional teams (CFTs) to ensure compliance with industry standards in a highly regulated environment.

SKILLS

- Caliber QAMS
- EDMS
- E-log
- DMS
- Microsoft Office

PROFESSIONAL EXPERIENCE

Officer **05/2023 - Present**
Lupin LTD. (Biotech Division), Pune

- Accountable for overseeing and implementing key biopharmaceutical principles, including **Change Control, Corrective and Preventive Actions (CAPA)**, and **Qualification processes (IQ, OQ, PQ)**, in alignment with **ALCOA/ALCOA++** principles, **data integrity standards**, and **Good Documentation Practices (GDP)**.
- Proficient in utilizing **TrackWise system (Caliber QAMS)** with hands-on experience.
- Experienced in preparing and revising controlled documentation, such as **Standard Operating Procedures (SOPs)** and **Equipment Operating Procedures (EOPs)** within **Electronic Document Management Systems (EDMS)**.
- Experienced in developing and executing validation documentation, including **Installation Qualification (IQ) protocols**, **Operational Qualification (OQ) protocols, Performance Qualification (PQ) protocols, addendum protocols**, **study protocols**, and **assessment reports**.
- Experienced in monitoring and evaluating the effectiveness of CCP, CCT, and CAPAs, using the Caliber QAMS system.
- Responsible for the **annual Performance Verification (PV)** of GMP equipment (e.g., **steam sterilizers, walk-in cold rooms, CO_2 incubators, LAFUs/BSCs, dynamic pass boxes**), including **report compilation**.
- Developing knowledge of **regulatory compliance** frameworks, including **21 CFR Part 11**, **EU Annex 11**, **GxP**, **GAMP categories**, and **Data Integrity principles**.
- Support the execution of **periodic reviews for software-based systems** using the **EDC-OQ-BT-003 checklist**, ensuring lifecycle compliance.
- Reviewed **electronic batch process data** at scheduled intervals using established checklists to ensure compliance, data integrity, and procedural accuracy**.**

Junior Trainee **05/2022 - 05/2023**
Lupin LTD. (Biotech Division), Pune

- Performed regular **facility rounds** to ensure compliance with cGMP requirements; reviewed **logbooks, Batch Production Records (BPRs)**, and related documents to maintain **Good Documentation Practices (GDP)**.
- Managed **departmental training** through **SABA Learning Management System (LMS)**; **coordinated Instructor-Led Training (ILT)**, **Web-Based Training (WBT)**, and **blended learning**, including **CAPA-driven refresher training.**

EDUCATION

Master of Science in Biotechnology **2019 – 2021**
Vidya Pratishthan's College of Arts, science and Commerce, Savitribai Phule Pune University (SPPU)
CGPA: 8.50/10.0

ADDITIONAL INFORMATION

- Gender: Female
- DOB: 11.03.1998
- Nationality: Indian
- Languages: English, Hindi, Marathi