

Curriculum Vitae

SHRUTIKA SHAMRAO GAIKWAD

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PROFILE SUMMARY

Experienced Pharmaceutical Professional with 3 years at Glenmark Pharmaceuticals, BLISS GVS and INDOCO remedies adept in Quality Management System, Experienced compliance team member work on 21 CFR, EU Ann 11 and GAMP 5 in computerized system validation and Validation framework. Proficient in QMS, Change Control, CAPA, Agile SDLC, Deviation, Incident, OOS, OOT, inventory control, personal training, and handling market complaints. Skilled in JIRA, HP ALM, Q test, ServiceNow, Val genesis, Veeva, SAP (ECC, PP, QM), SAP S/4 HANA, LIMS, Track wise, LMS, MSB Doc Microsoft. Ensuring efficient operations and adherence to regulatory standards. Validation of Empower and Chromeleon. Areas of interest include CSV, Production, QMS, IPQA, QA, and Analytical QA.

EMPLOYMENT HISTORY

<u>Company:</u> INDOCO Remedies Chhatrapati Sambhajnagar	<u>Designation:</u> Officer- QA (CSV Team Member)	<u>Duration:</u> Jan-2025 to Mar-25
<u>Company:</u> Bliss GSV Palghar	<u>Designation:</u> Officer- Production (Validation Team Member)	<u>Duration:</u> Oct-2024 to Jan-2025
<u>Company:</u> Glenmark Pharmaceuticals Ltd. Chhatrapati Sambhajnagar	<u>Designation:</u> Officer- Production (Validation Team Member)	<u>Duration:</u> Aug-2022 to Sep-2024

Job profile & Responsibilities:

- ❖ **Ensures Quality Output:**
 - Participates in CSV validation for consistent quality. Develops and maintains clear, accurate production documents (SOPs, work instructions) for compliance.
 - Implements and monitors QMS practices to identify and address quality deviations. Initiation of Change Control, OOS, OOT, Incident, Deviation through Track wise. Training Management through LMS (Aspire).

❖ **Qualification and Validation:**

- With hands-on experience in preparing and reviewing various documents and test scripts, including User Requirement Specifications (URS), Functional Risk Assessments (FRA), Design Specifications (DS), Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), Periodic review, Audit trial.

❖ **Optimizes Production & Inventory:**

- Collaborates with planning to schedule efficient production runs. Manages inventory levels to minimize stockouts and overstocking.

❖ **Drives Improvement & Efficiency:**

- Continuously develops skills through training and mentors colleagues.
- Contributes to CAPA by investigating production issues and developing corrective actions. Manages and documents changes (Change Control). Participates in BPR reviews to identify process improvements.
- Leads SOP implementation and trains colleagues for consistent execution.

❖ **Market Complaints:**

- Assists with investigating and resolving market complaints related to product quality.

Technical Skills:

- ❖ SAP (ECC, PP, S/4 HANA)
- ❖ LIMS
- ❖ Quality Management Systems (QMS)
- ❖ Computerized System Validation
- ❖ Production documentation (SOPs, work instructions)
- ❖ Production planning and inventory control
- ❖ CAPA (Corrective and Preventive Action)
- ❖ Change Control, Incident, OOS, OOT, Deviation
- ❖ BPR, BMR Preparation
- ❖ E-BMR
- ❖ TrackWise
- ❖ MSBDoc
- ❖ LMS (Aspire)
- ❖ JIRA, Q test, Veeva
- ❖ Periodic Review, Audit trial

PERSONAL INFORMATION

Name:	Mrs. Shrutika Shamrao Gaikwad
DOB:	12-June-2001
Sex:	Female
Address:	Ravet, Pimpri Chinchwad, Pune, 412101.
Marital Status:	Married
Nationality:	Indian
Languages:	English, Hindi, Marathi,

CERTIFICATIONS

- ❖ MSCIT Certified.
- ❖ SAP S/4HANA Certified.

EDUCATIONAL QUALIFICATION

Course	Institute/College	University/Board	Year of Passing
M Pharmacy (Pharmaceutics)	Pravara Rural College of Pharmacy, Pravaranagar	Pune	2024
B. Pharmacy	Pravara Rural Women's College, Sinnar	Pune	2022

DECLARATION

I assess myself as a hardworking, sincere, confident and enthusiastic person. I have strong Willpower & I am ready to learn new things. I believe highly in teamwork and adopt myself to any environment with ease. The above information is true with best of my knowledge.

Date:

Place:

Yours's faithfully,
Gaikwad Shrutika Shamrao.