

SUSHANT KAILAS AMALE

Total Exp.: 04 Year

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PERMANENT ADDRESS: 25, datt colony college road, kannad. Dist:- Aurangabad 431103

PROFESSIONAL SUMMARY

- **Production Executive with 3.2 years in Sanofi India Ltd.**
- **Production officer at Harman Finochem 10 months .**
- **Completed lean six sigma green belt certified course**

WORK EXPERIENCE

- Preparation and updation of Batch records considering the regulatory requirements.
- Involve in Process improvement in manufacturing process like OEE(overall equipment efficiency)
- Expriance in handling blister packing ,bottle packing machines like IMA IC150, CAM , strip packing , C 350, PG express ,230XTS ,bottle CVC ,bottle IMA ,case packer , uhlmann packing machine,
- Perform validation and qualifications.
- Assisted in planning, scale up ,exhibit,, commercial and tech transfer activities in new Product transfer and validation
- To monitor and assist during execution of validation batches of new products
- Identify issues in efficiency and suggest improvements.
- Setting of Track and Trace system (Sterilization, Aggregation, Pallatization) for new product.
- SAP (System Accounting & Processing) - material Requisition, Posting Of finished Goods and consumed material for batch, Bulk Posting, Maintenance intimation, Generation Of new recipe and BOM related activity
- Coordinates with the team members, interdepartmental and supervise the activities and Manpower management
- Cgmp and SOP training and evaluation of newly joined employees

JOB RESPONSIBILITIES

- Responsible for Preparation of batch records, MFR ,BPR, validation and qualification protocol
- Responsible for quality, safety, strength, identity & purity of Product as per cGMP norms.
- Monitor operator's productivity and provide constructive feedback and coaching.
- Responsible for remove stability, consignment samples from in process of packaging
- Involved in process improvement in manufacturing process.
- To ensure timely Preventive / Breakdown Maintenance of equipment.
- Supervise cleaning and sanitization of processing area machine and equipment's.
- Co-ordination with QA, QC, Warehouse and Engineering for related activities.
- Handling of QMS related documents, Market complaint investigation.
- To perform sampling of finished products, bulk samples.
- To co-ordinate during process validation, cleaning validation & hold time study.
- Handling of QMS related documents like Change Control, Deviation, Risk Assessment, Market complaintinvestigation.
- Prepare and Execution of new equipments qualification/requalification process (URS, IQ, OQ and PQ) protocol andreports.
- To perform in-process control checks during manufacturing and packing process.

SKILL SET

TECHNICAL	PROFESSIONAL
Instruments Handled: leak test apparatus, Axicon Barcode verifier, weighing balance with printer, CAM Cartonator and Blister Packing machine , Track and Trace , Aggregation Machine.	Initiative & Enthusiastic.
Computer knowledge (SAP, Geode+, Phenix, MS Word, MS PowerPoint, MS Excel)	Good Team-Player.
Academic Knowledge of Medicines and Drugs.	Quick-learner.

AUDIT FACED

FDA
MHRA
GQA (Globe quality Audit)
USFDA

ACADMIC QUALIFICATIONS:

DEGREE/ COURSE	COLLEGE/SCHOOL	UNIVERSITY/BOARD	YEAR	PERCENTAGE/ C GPA
M. PHARM (Pharmaceutics)	AISSMS College of Pharmacy, Pune	Savitribai Phule PuneUniversity	2018- 2019	8.5 A+
B. PHARM FINAL YEAR	R C Patel College of Pharmacy ,Shirpur	North Maharashtra university	2016- 2017	60.03
H.S.C.	J B College ,Garada	Aurangabad Divisional Board	2012- 2013	62.33
S.S.C.	Sane Guruji Vidhyalaya ,kannad	Aurangabad Divisional Board	2010- 2011	70.33

ACDEMIC PROJECT WORK:

M. Pharm: Formulation , development and evaluation of nasal transmucosal solid lipid nanoparticle.
Under Dr.Ahwini Madgulkar

PERSONAL DETAILS:

Name : Sushant Kailas Amale
Date of birth:02/01/1996
Gender : Male
Nationality : Indian
Marital Status: Single
Languages : English. Hindi, Marathi
Address : 25,Datt Colony College Road, Kannad. Dist:- Aurangabad 431103
Hobbies : Trekking, Reading

DECLARATION:

I hereby declare that all the details furnished above are true to the best of my knowledge.

SUSHANT AMALE

