**CURRICULUM VITAE**

MALLI

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**SUMMARY:**

Profile : Male,33.Married

Nationality : Indian

Current Location : Dubai,UAE

Current Position : Sr.Executive

Company : Aurobin.do Pharma Ltd,.

Preferred Locations : INDIA,UAE,OMAN and SAUDI ARABIA.

Salary Expectation : Negotiable

**PROFESSIONAL EXPERIENCE:**

Having 9Years and above experience in Parenterals formulation in QA and QCdepartment.

Presently working in AUROBINDO PHARMA LIMITED, UNIT-12, Bachupally, Hyderabad from Dec 2013 to till date as a Sr. Executive(E3).

Previously worked in Gland PharmaLimited, HyderabadParenterals Division from July 2011 to Nov 2013. Gland Pharma Limited is a USFDA approved and ISO 9001 certified company where we manufacture SVP’S like ampoules, vials, Prefilled Syringes & Biotech products. Gland Pharma Limited is pioneered in Heparin Technology and having tech support from Vetter Group Germany. USIFROID state of art lyophilizer is hallmark of Gland Pharma with wide range of export to more than 20 countries all over the world.

Monitoring of Eli Lilly project for insulin manufacturing, filling and Packing (Huminsulin30/70, Huminsulin50/50, Huminsulin R, Huminsulin N)

Previously worked in CELON LABORATORIES LIMITED, Hyderabad from March 2010 to June 2011.

Previously worked in SARVOTHAM CARE LIMITED, Baddi, Himachal Pradesh from Feb 2009 to Feb 2010.

**JOB PROFILE:**

**DEC 2013 TO PRESENT AUROBINDO PHARMA LTD, UNIT-XII, HYDERABAD, INDIA.**

**Documentation:**

* Preparation and reviewing of SOP’s.
* Review of Analytical and Environmental monitoring reports of the batch.
* QMS and DMS activities and Investigations of Deviations and change controls
* Creation, issuance and control of documents through DMS.
* Preparation, issuance and control of BPRR’s and BPAR’s.
* Storage retrieval and destruction of Batch record**s.**
* Maintaining and reviewing of control samples

**Reporting to manager of Quality control:**

* Investigation of Out of Specifications, OOT and Invalidities.
* Handling of Change controls of different changes related to facilities, equipment’s and

process.

* Review of Stability Protocols & summary reports.
* Method validation documents review.
* Review of Analytical transfer documents.
* Preparation and review of finished product Annual Product Quality review.
* Review of documents like SOP’s, STP’s related Quality control & Quality assurance documents as per Pharmacopeia requirements, cGMP, GLP and regulatory requirements.
* Handling of Deviations of facilities, equipment’s and during regular production.
* Investigation of deviations and failures through various assessment tools.
* Implementation and execution of sterility assurance concepts.
* Support to Regulatory Affairs in preparation of dossiers for various regulated markets
* Investigation of Environmental monitoring excursions.
* Ensuring Quality control compliance with regulatory requirements.
* Monitoring of Microbiology Laboratory and quality control to ensure GMP compliance.
* Identification, Implementation and Closure of CAPAs.
* Participation in conducting Internal Quality Audit.
* Release of bulk antigen for blending by review of all documents relating to
* Manufacturing & Certificate of analysis and ensure that are complete, accurate in

compliance with established procedures

**In-process Quality Assurance:**

* Core production area of Dry powder injectables and Lyophilized injectables covering all activities from Raw material dispensing to packing.
* Executions of Aseptic media fill validations in DPI and Lyo areas.
* Involving in validation of Tunnel sterilizer, Autoclave, Vial washing machine and HVAC system.
* Execution of Process Validations.
* Monitoring and Training of personnel working in Aseptic area.
* Maintaining track records of gowning qualification for personnel working in aseptic area.
* Review of microbiological Environmental and Personnel monitoring reports.
* Coordination with stores, QC, Validation and Engineering teams for timely implementation of production quality.
* In process good manufacturing practices in the production area.
* Preparation and review of SOP’s and formats.
* Batch transactions through ERP.
* Review of Batch records and GMP records.
* Preparation and compliance to various regulatory audits.
* Execution of re-validations as per Validation master plan schedule.

**Dispensing:**

* Monitoring the cleanlineness of area & environmental conditions.
* Verifying the approved status, retest status of the drug.
* Verifying the logbooks related to all activities in stores.
* Monitoring the calibration status of weighing balances & validation of dispensing booth LAF are implementing in time.
* Giving the clearance for dispensing & sampling.
* Monitoring the total dispensing activity.

**PROCESSING:**

**DPI:**

* Monitoring the sanitization of canisters and transferring in to sterile area.
* Verification of autoclave loads & validation loads.
* Monitoring the calibration and validation status of all equipment’s.
* Monitoring the settle plate exposures, air sampling and personnel monitoring of all personnel who enters in sterile area.
* Verifying the all logbooks which are related to all activities going inside the presterile & sterile area
* Giving the clearance for decartoning, washing, depyrogenation, filling, sealing, inspection and packing operations.
* Doing the in process checks in washing area, filling area, sealing area, inspection area and packing area.

**LYO:**

* monitoring the compounding activities with checking the weights of all raw materials.
* Verifying the log books of compounding & filling area and cleanlineness in compounding room & filling room.
* Monitoring the solution preparation and doing the in process checks like temperature, pH of the solutions at stages & collecting the samples online and sending to QC
* Giving the clearance for washing, depyrogenation, filling, loading, unloading, sealing, inspection and packing activities.
* Doing the in process checks in washing, filling area and sealing area.
* Participation in media fills & process validations

**PACKING:**

* Verifying the log books, area cleanliness and environmental conditions.
* Doing the in process checks during the Labeling and packing operations.
* Collection of sterility identification analysis and control samples sending to QC in time.
* Reviewing the BPRR & BPAR after completion of the entire packing activity.
* Implementation of track and trace system for all the markets
* Preparation and approval of all art works of the packing

**JULY 2011 TO NOV 2013 AT GLAND PHARMA LTD, HYDERABAD, INDIA.**

* Giving line clearances for Dispensing, Compounding, filling and packing
* In process checks, online documentation, Monitoring of Clean rooms.
* Execution of Media fills for validation of aseptic area.
* Responsible for routine inspection for various departments to maintain GMP compliance at all levels.
* Involve in visual inspection of cleaned manufacturing equipments for giving line clearance during the product change over.
* Verify and checking calibrations status of instruments, validation status of equipments and planning to calibrate and validate the equipments & instruments before due dates.
* Performing In process QA activities in Dispensing, Compounding, Filling, sealing, optical testing activities.
* Sampling of Finished samples, Control samples and its periodic review.
* Review of BPCR
* Review of SOP’s.
* Online monitoring of NVPC during filling.
* Execution of process validation protocols.
* Execution of cleaning validation protocols.
* Online deviations reporting to IPQA – Manager.
* Monitoring of Online documentation.
* Monitoring of environmental monitoring.
* Handling of Deviations and change controls.

**MAR 2010 TO JUN 2011 AT CELON LABS LTD, HYDERABAD, INDIA.**

* Giving line clearances for Dispensing, Compounding, filling and packing
* Giving line clearances for Dispensing, Lubrication, Compression, Coating and packing
* In process checks, online documentation, Monitoring of Clean rooms.
* Online deviations reporting to IPQA – Manager.
* Monitoring of Online documentation.
* Monitoring of environmental monitoring.
* Verification executed log books of all equipment’s.

**FEB 2009 TO FEB 2010 AT SARVOTHAM CARE LTD,HIMACHALPRADESH INDIA.**

* Reporting to QA manager about all the production and packing activities related to Sterile

Injectables, tablets, capsules and liquid orals.

* To co-ordinate with quality control department for getting in-process test request form,

finished products analytical reports and other line activities.

* Preparation and formatting of BMR and BPR.
* Preparation of Sop’s. Responsible for issuing batch records, and batch record review.
* Mainly concentrating of in-process quality control checking like line clearance, physical

parameter checking, approval of products and checking of log books of all machineries, during

the process like dispensing, granulation, blending, compression, coating, compounding, filling,

* sealing and packaging.
* Batch Processing Record Review for BMR &amp; BPR
* Finished Product Release
* Product dispatch inspection and approval.

**EDUCATION QUALIFICATION:**

* M.Sc. (Biotechnology) from Periyar University with 70%.
* B.Sc (Microbiology) from SV University with 65%.
* Intermediate from Board of Intermediate Education with 60%.
* S.S.C from Board of Secondary Education with 62%.

**OTHER ACHIVEMENTS:**

* One of the leading team members who participated in shop floor activities for USFDA audit preparations.
* Successfully participated in various regulatory audits like USFDA, WHO, IDA& ELI LILLY etc.
* Attended training on “Whispering microbes & Talking inspectors” by Vienni Training & consulting LLP.
* Attended training on “Visual inspection product lifecycle workshop” by Roy T.Cherris& Bridge associates international LLC.
* Attended training on “Particulate matter in difficult to inspect sterile products”by Roy T.Cherri’s& Bridge associates international LLC.
* Regular ISO and GMP trainings.

**AUDITS FACED:**

Regulatory:

* USFDA, MHRA, ANVISA, FIMEA, WHO.

Customer:

* GSK, SAGENT, SANDOZ, PFIZER.

**LANGUAGES KNOWN:**

* Telugu - Native
* Hindi - Fluent
* English - Fluent
* Tamil - Fluent

**DECLARATION:**

I here by declare by that the above mentioned are true and correct to the best of my knowledge.