**RESUME**

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**~ Pharmaceutical and Sterile Manufacturing ~**

##### **Snapshot**



* A result-oriented professional with **4 years** of experience in Sterile Manufacturing of API facility **(Orchid)** – Manufacturing of cephalosporin
* A very challenging ~3.0 years of experience in the Green field project of the new startup tablet and film coating facility in Singapore (**MSD)**
* A very good exposure of 5 years manufacturing and packing experience in Tablet Manufacturing and Film Coating Process.
* A very challenging ~2.0 years of experience in the Green field project of the new startup ophthalmic solutions facility in Singapore (**Alcon)**
* Depth experience in manufacturing and packing of ophthalmic products (Alcon Singapore) as a Technician and production superidentant.
* Successfully trained **48 days in Belgium for aseptic processing skills and 7 days in Italy** for serialized numbering project and actively participated in technology transfer of key products and execute the **Process Validation study** followed by the **Process stability Batches**.
* **Steril-Gene Life Sciences Private Limited, Pondicherry, India** as a **Manager --- Quality Assurance department (IPQA Head and QMS in-charge)**
* **Spinos Life Science and Research private limited, worked as a Senior Manager QA taking care of clinical research activities**
* **An effective leader & communicator** with strong interpersonal, analytical & relationship management skills.



##### **Core Competencies**

* **Apr 2019 to Till Date: Manager QA at Steril-gene life sciences private limited pondicherry, taking care of entire pharmaceutical quality assurance and training section.**
* **Nov 2018 to Jan 2019: Senior Manager QA at Spinos life sciences private limited Coimbatore, taking care of clinical trials and review of BA, BE study documentation and managing Quality Audits.**
* **Mar 2018 to Nov 2018 : Manager QA in Steril-Gene Pondicherry, Quality Assurance department (IPQA Head and QMS in-charge) for all blocks**
* ***Mar 2015 to Jul 2016: Assistant Manager Production compliance for liquid injectables***
* ***Aug 2016 to Feb 2018: Deputy Manager for* Production and warehouse Compliance for entire multiproduct Facility inclusive of liquid injectables, DPI, soft gelatin capsules,Tablets, capsules and dry syrups.**

**Roles and Responsibilities:-**

* Job Function as a Production Manager:
* Allocation of Duties to the below executives and prodcution officers.
* Monitoring the day to day operations for improvement and to assure quality of the product.
* Taking care and handling of QMS related documents
* Handling deviations and investigating market compliants
* Training to the department personnel.
* Job Functions as a QA Manager:
* Assist vice president of QA to take care of his duties while his absence.
* Motivate and support team to achieve production target without delay in an compliance manner
* Train the operators and supervisors about cGMP, cGDP and Aseptic processing and non-aseptic processing operations.
* Perform gap analysis for the completed audit observations.
* Guide the team, about the RTPS – Real Time Problem Solving Methods
* Implementation of lean six sigma tools into the shop floor
* Implementation of 5S tools to the shop floor
* Perform and train the supervisors to enhance their deviation writing skills and decision making skills.
* Conduct periodic analysis of aseptic behavior of the personnel involved in aseptic operations.
* Participate and lead the audits to reduce observations by implementing compliance in every manner
* Improve productivity in an quality manner by implementing 5S and Lean principles
* Review and guide the team for preparing SOPs.
* Train the team for preparing incident reports and risk assessment reports
* Prepare training calendars
* Review SOPs prior to approval.
* Perform and train the personnel to perform self inspections.

***Aug 2010 to Jun 2014:* Production Superidentant at Alcon Singapore Manufacturing Private Limited, Singapore.**

**Roles and Responsibilities:-**

* Prepare all the Standard operating procedures and Manufacturing Batch records for the Media Hold and Media Fill activities.
* Prepare and review MBR to assist QA inregulatory process to file the products to EMA, HSA, KFDA other regulatory authorities.
* Handled and walk down with all major auditors from EMA, HSA, KFDA and Corporate audits.
* Lead the team to execute all the day to day activities to meet the production target.
* Identifying areas of improvement and recommending process modifications to enhance operational efficiencies of the systems.
* Review, train and executing the cleaning validation protocols for all products.
* Timely reporting the manufacturing deviations followed by investigation and developed the CAPA.
* Handling the Engineering change control and Process Change control.
* Working closely with QA Validation during Commissioning to meet the IQ-OQ, PVS (Process Validation Study), PSB (Product Stability Batches) & Commercial Production deadlines.
* Acting as Manager for 6months during the absence of the manger.
* Conduct interview and hire technicians to provide On the Job training.
* Provide continuous motivation and mentoring to the team members.
* Conduct performance review and prepare development plan for technicians to provide a path for the Job progression.
* Developed a robust training and qualification package for the technician and closely work with the learning and development department to keep records up to date.
* To update all the production activities with the Site Leadership Team during Tier meetings.
* Excellent knowledge and understanding on ICH, EU and FDA regulations and cGMP.

**Project Planning & Management:-**

* Handling the Project and scheduled to work out for various requirements with respect to utilities, machines, man power & monitoring overall project operations for ensuring timely completion.
* Prepare URS for new equipment and involved in FAT, SAT, IOQ, PQ and OQ.
* Ensuring site operations are carried out smoothly with erection, commissioning & procurement operations.
* To develop robust plans for the execution of Ophthalmic Products, Media Hold and Media Fill and liaise with the QA operations and planning teams in the development of schedules.

**Major Achievements:-**

* Promoted as a **Production Superintendent** in Aug 2012, started in Alcon Singapore manufacturing in Aug 2010 as Production Technician.
* Special Training in Belgium for Aseptic Practices and implemented in Alcon Singapore Filling & packaging department.

**Employment Profile**



***Dec 2002 to Jul 2010. M/s Merck Sharp &Dohme Ltd, Singapore. – Lead Pharmaceutical Technician.***

**Roles and Responsibilities:-**

* Monitored and Controlled the Granulation and Drying process parameters through PLC control systems.
* Performed Dismantled, Cleaned and Reassembled the Granulators, Fluid Bed Dryers, Rotary Particle Separators, Azo Charging Systems, etc.,
* Performed manufacturing operations within cGMP regulations, Manufacturing process description and Standard operating procedures in place.
* Monitored and Executed the CIP and COP activities during product change over.
* Achieve the daily production target using the standard work and lean manufacturing practice.
* Lead the High Shear module and train the new technicians in that module.
* Review all the manufacturing batch records before submit to QA.
* Highly involved in the automated powder dispensing project.
* CAPA, Deviation, FMEA, RTPS, Lean six sigma, Risk assessment.
* Qualified first aider and risk responder.
* Certified technical trainer.

**Achievement:-**

* Awarded as an “**Award of Excellence**” for more than 10 times for Technical Trouble shooting.



* Special Experience:   
  1. I joined Merck Sharp & Dohme (in Singapore) as a pioneer batch, played a critical part in the Commissioning, Qualification and Validation (IQ, OQ, PQ, and PV & CV) activities at the project start-up.  
  2. I have accumulated a number of years of experience with vendors and specialists of automation, engineering or PTO (Pharmaceutical Technology Operation) and PPE (Pharmaceutical Process engineer) from the different countries. I underwent the successful audits by FDA & SFDA, EMEA, HSA, and MHRA.
* Projects gone through:  
  a) Deep dive kaizen project for high shear module dew point and final temperature alarms.  
  b) Lean sensei Six Sigma project For High Shear Module Work Standard.  
  c) Black Belt Project for Cycle Time Reduction of High shear Module Clean in Place recipe.  
  d) Double High Shear Project Which Improve The Volume Of Products without Changing The Module Which Save To Introduce Another high Shear Module Cost About 100M US Dollars.  
  e) Film coating module project: from commissioning to get ready for routine production.  
  f) MK-0974 project in FC module



***Oct 1998 to Nov 2002. M/s Orchid chemicals and Pharmaceuticals Private limited, Chennai, India as a Production Officer.***

* 1. Review batch records and sent to QA.  
  2. Deploy jobs for operators and make sure keep on running production systems as per schedule  
  3. Trouble shoot equipment as well as process related operations during any problem.  
  4. Self confidence motivates colleagues, and transfer job knowledge to fellow workers.  
  5. Experience in operating crystallizer, ANFD, ribbon and sieve blenders, AZO packaging systems, ML tanks ,GLRs, SSRs ,HUF system, PSG system, WFI system, VFDs, SHS and DHS.  
  6. Primary job is to remove the microbial organisms from the API powders by sterilizing them.  
  7. 4 year plus experience in class 100 area and clean room operation as a supervisor.  
  8. Having knowledge about autoclave & DHS operation and validation.  
  9. Having experience in performing plate exposure test, Air borne particulate test, DAP test, UV validation.  
  10. Having exposure to handle critical situations in decision making.
* 11. Act as a Production Manager Backup while he is absent or Not available.
* 12. Lead the team to perform technical trouble shooting to handle issues.
* 13. Prepare SOPs, BMRs, BPRs, and CAPA.
* 14. Deviation Handling.

##### **Education**



* Bachelor Degree in Chemistry from Bharadhidasan University, Trichy, Tamilnadu, India and Scored 69% of Marks. First Class

##### **Certified Courses**



* Got certified as Train the Trainer course.
* Certified as a First Aider and Fire Warden.
* Certified as CERT member.
* Certified as a Technical Trainer

##### **Personal Details**



Father’s Name : R.K.Ramachari

Date of Birth : 29.11.1977

Sex : Male

Marital Status : Married

Children’s : 2 Sons

Nationality : Indian

Languages known : English, Tamil, Hindi.

Passport Number : M3996823 Exp: 26/11/2024

Living Status : Citizen of India.