**PARESH R. MAKWANA**

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**An accomplished professional having total 25 years of functional experience in API Manufacturing (22 Years), seeking challenging assignments in a pharmaceutical company.**

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**PROFESSIONAL SYNOPSIS**

* A production professional with global regulatory exposure of various agencies.
* Capable to develop new project with R & D.
* Understanding of various regulatory guidelines and manufacturing requirements.
* Proven leadership skills in managing, developing and motivating team to achieve common objectives.
* Dedicated to maintain high quality standards.
* Able to work on own initiative and as a part of team.
* Constantly strive to improve process efficiencies to enhance productivity through optimum utilization of available resources.

**KEY RESPONSIBILITIES**

* **Production**
* Production planning to meet preset production targets, conceptualizing and implementing process modifications to enhance operational efficiency & to optimize resource utilization.
* To ensure process operations as per Standard procedures with Safety & cGMP.
* Spearheading the functions of manufacturing activities in coordination with other departments.
* Analyzing process performance and product quality.
* Trouble shooting during process operations and malfunctioning of equipment/ system.
* To prepare Daily production report (DPR) and Monthly consumption sheet (MCS).
* Responsible to ensure online documentation as per regulatory requirements.
* Upkeep of equipment and manufacturing facility by periodic performance verification and requalification.
* Responsible for Inventory and control of documents.
* Well versed with automation systems like DCS, HMI, SCADA, Historian and PLC.
* Manpower management and handling.
* Maintaining shop floor discipline and high morals in employees.
* Imparting regulatory, developmental, activity based (Qualification, Validation) and organization specific trainings to sub-ordinates and upgrades their skill and knowledge.
* To involve in preparation of Budget, Capex, Production accessories, Consumable items.
* To prepare various Standard operating procedures (SOPs) and provide training to subordinates for execution of activities as per respective SOP.
* To prepare Batch manufacturing record (BMR), Batch cleaning record (BCR) and other relevant documents like Sampling Plan, Master formula card (MFC) and Process flow chart (PFC) for optimization, validation and commercial manufacturing.
* To prepare equipment/ system and area qualification documents and executes qualification activities.
* To prepare process validation documents, involve in validation execution and completion of validation reports.
* To involve in cleaning validation and DEHT & CEHT study execution.
* **Quality Management**
* Responsible for initiation, implementation and closer of change control.
* Responsible for promptly reporting of deviations.
* Responsible to investigate deviations, OOS and OOT to find out the root cause.
* To decide corrective and preventive actions to eliminate the cause of existing and potential non conformities.
* To perform risk assessment for system based and occurrence-based activities as per ICH Q9.
* **Audits and Compliance**
* Faced various regulatory audits such as EU-GMP, USFDA, KFDA and MHRA.
* To handle a responsibility of internal auditor for various departments.
* To handle internal as well as external cGMP & customer audits and visits.
* To prepare response for all critical, major and minor observations and recommendations.
* To implement the actions, decided in audit response report in the plant.
* **New Projects**
* Site coordinator for implantation of MES (eBMR) system for API manufacturing.
* Working as a department coordinator for ISO & OHSAS certifications.
* Having responsibility for new coming API plants at site.
* Handling of decommissioning and commissioning activities and preparation of related documents.
* **Safety**
* To ensure safe operations while manufacturing.
* To ensure compliance of all statuary requirements in the plant and surrounding.
* To ensure safety awareness training to all subordinates.
* To ensure availability of PPEs & safety accessories and its proper usage during process operations.
* To ensure compliance of environment as per ISO14001 and occupational health as per ISO45001.
* Member of environment, health and safety committee.

**TRAININGS**

* Training on “Importance of HSE in Good Governance” organized by Gujarat Safety Council
* Training on “Behaviour Based Safety” by Mr. H.K. Kaila
* Training on “Process Validation” as per new ICH guideline by Mr. Atul Shirgaonkar
* Training on “cGMP” by Mr. Rohn Johnson (EX. FDA Auditor)
* Training on “Communication & Presentation Skill” by Mr. Shashank Kasliwal
* Training on “Time Management” by Mr. V. Aswatha Ramaiah
* Training on “5-S Awareness” by Sudhir Tiwari
* Training on “Effective Supervisory Skill” by Lt.Col. V.K.Gautam
* Training on “Internal Auditor for ISO” by Mr. Suhas Rishbood

**SOFTWARE PROFICIENCY**

* MS Office applications
* TMS (Training), Track-Wise, QEdge (Change control, Deviation), DMS (SOP, STP, Specifications)
* SAP System (R/3 Module)

**ACHIEVEMENTS**

* + Promoted to next supervisory levels in the year 2007 & 2009.
  + Certificate of appreciation in the year 2008 and 2010 for outstanding performance and exceptional commitment.
  + Appreciation award in safety competition in the year 2009 on safety day.
  + Received Spot reorganization award for the year 2010 for exemplifying exceptional performance.
  + Became the outstanding performer in annual performance appraisal for the year 2011 and 2014 for innovative approach and quality orientation.
  + Having certification of “First Aider”.

**PROFESSIONAL QUALIFICATION**

* + Qualification : M.Sc.
  + Specialization : Chemistry
  + Year of Passing : April 2011
  + University : Madhya Pradesh Bhoj University, Bhopal (Madhya Pradesh)

PROFESSIONAL EXPERIENCE

**PERIOD COMPANY DESIGNATION**

* June 2019 to till date BGP Healthcare Pvt. Ltd. Production Manager
* May 2012 to June 2019 Torrent Pharmaceuticals Ltd Asst. Manager
* May 2005 to May 2012 Ranbaxy Labs Ltd Sr. Officer Production
* Oct 2003 to May 2005 Cadila Pharmaceuticals Ltd Production Chemist
* Jan 2002 to Oct 2003 KNPL Shift Chemist
* June 1998 to Dec 2001 Ralchem Limited Production Supervisor

**PERSONAL MINUTES**

* + Father’s Name : Rajendra S. Makwana
  + Date of Birth : 24/03/1978
  + Nationality : Indian
  + Sex : Male
  + Marital Status : Married
  + Present Address : 404, Kritika Tower, Antrix Residency, GNFC-Zadeshwar Road,

Zadeshwar, Dist: Bharuch (392011), Gujarat.

* + Permanent Address : As above
  + Language Proficiency : Hindi, English, Gujarati
  + CTC : 20.65 lack PA