*RESUME*

**GANESH KUMAR SEMWAL**
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**Profile Synopsis**

- A focused individual with nearly 21 years of Experience in Engineering filed- Projects, Operations and Maintenance, commissioning, developing & implementing new systems within a Pharmaceutical OSD/ Injectables formulation plant.
- Design, Execution, commissioning, qualification, validation, developing design and layout of facilities.
- Handled Projects i.e. Green field, brown field, energy saving projects, efficiency improvement, 6S, lean management projects in different organizations.
- Exposure of multiple regulatory audits i.e. USFDA, ANVISA, MHRA, TGA, UKRAIN, MCC, etc.
- Experience in Managing Engineering Activities i.e. Predictive, Preventive (schedules and monitoring), troubleshooting activities, Opex and capex budgeting (monthly, quarterly and Annually), manpower management.

**SKILL AND STRENGTHS**

Project Management, design, Engineering, work-ethics, problem-solving, time management, Agile approach, collaboration, speed, simplification, teamwork, adaptability, patience, empathy, teamwork etc,

**CORE COMPETENCIES**

- Operation and Maintenance
- Engineering design coordination
- Material management
- Environment, health and safety
- Resources management
- Project planning and control
- Vendor development
- Installation and commissioning
- Technical support
- Internal Audits

**Designation : Head (Engineering & Projects)**

**M/s Akums Drugs and Pharmaceuticals** is among the largest domestic market-focused Indian CDMOs on a revenue basis serving IPM, with a market share of 9.3% by value in FY23 in the total addressable Indian domestic CDMO market and 8.8% by volume in the total IPM market in FY23. While the market share by value increased to 10.0%, the volume share remained almost stable at 8.7% in FY24. In the Indian domestic CDMO market, the company had a market share of 30.2% by value in FY24, which increased from 26.7% in FY21.

With dedicated pharmaceutical personnel and standardized practices, Akums has been successful in attaining national and international accreditations and building trust on Efficacy, Safety & Quality. The organization is certified with WHO-GMP, ISO 9001:2015, ISO 14001:2015, ISO 50001:2018, ISO 45001:2018, and ISO 22000:2018

certificates and various international accreditations, like; FDA Philippines, NMPB Sudan, NDA Uganda, Cambodia, Indonesia, Nigeria, Malawi amongst others.

Project completed successfully: E- Block Expansion (30 Crores), PW, WFI and PSG line upgradation (3 crores), Replacement of G3 line @300 AMP (9 crores) etc.

Job responsibilities:

Leading Engineering and Project department:

- Providing technical leadership to all engineering and development areas
- Developing and executing an engineering strategy for the company
- Managing and mentoring a team of engineers
- Overseeing project schedules and delivery dates
- Managing budgets and ensuring optimal usage of financial resources
- Implementing best practice engineering methods
- Providing technical guidance to engineering teams and top management
- Ensure daily maintenance and monitoring of equipment to maintain high reliability. Participate in designing, implementing, and monitoring continuous improvement initiatives.
- Participating in preventative maintenance tasks and procedures
- To be involved in designing and maintaining facilities. This includes premises, equipment, and building systems.
- Ensure compliance with Good Manufacturing Practices (GMP and ISO), safety policies, and quality standards.
- Improvement in process with innovation and ideas.
- Implement saving projects i.e. Energy, manpower, optimization etc.

**Designation : Associate Manager (Technical Projects)**

Working with **M/s Baxter Pharmaceuticals India Private Limited**, Ahmedabad, Gujrat from Jun 2019 to till date. Baxter Pharmaceuticals India Private Limited, BPIPL, is Ahmedabad-based generic injectables facility. Formulate, fill and finish a broad portfolio of essential generic medicines with complementary strengths in anesthesia and analgesics, critical care and renal medicines, and anti-infectives in a variety of presentations including bags, vials and ampules.

Project completed successfully: QC lab Expansion (6 Crores), Micro Lab Expansion (4.5 crores), WFI and PSG Loop upgradation (7 crores), VIP Projects (5 crores) etc.

Job responsibilities:

Leading Process department of the Projects:

- Direct and coordinate engineering activities within the pharmaceutical manufacturing facility.
- Providing technical leadership to all engineering and development areas
- Developing and executing an engineering strategy for the company
- Managing and mentoring a team of engineers
- Overseeing project schedules and delivery dates
- Managing budgets and ensuring optimal usage of financial resources
- Implementing best practice engineering methods.
- To be involved in designing and maintaining facilities. This includes premises, equipment, and building systems.

- Ensure compliance with Good Manufacturing Practices (GMP and ISO), safety policies, and quality standards in project design.
- Improvement in project processes with innovation and ideas.

**Designation : Manager (Projects)**

Worked with **M/s Akorn India Pvt. Limited, Paonta Sahib** from Oct 2014 to Jun 2019. Akorn is niche pharmaceutical company that develops, manufactures and markets generic and branded prescription pharmaceuticals as well as animal and consumer health products.

Project completed successfully: QC lab (40 Crores), Upgradation of GB Block (4.5 crores), Upgradation of Store (3 crores).

Going On Project: GB expansion (160 crores)

**Job Responsibilities:**

- Design, Planning, Execution, Commissioning, Handing Over and Feedback.
- Execution of Project.
- Budgeting and Scheduling.
- Ensure quality of construction and equipment.
- Site project management (during execution).
- Budget control.
- Support qualification / validation team for Commissioning and qualification activities (Facility, clean utilities i.e. HVAC, tertiary water system, Compressed air, nitrogen, Plant machineries i.e. Manufacturing vessels, DPBs, Pharma Part washer, Liquid vial filling lines etc.
- Execution of Project activities related to HVAC (Heating Ventilation and air Conditioning), Facility, Process Machinery, Utilities, Validation, and Qualification etc.
- Ensures that the Project Plan (project specific) is prepared and approved.
- Responsible for co-ordination, scheduling and reporting as agreed.
- Responsible for providing regular, timely, accurate, progress reports, cash flow and cost of completion forecasts.
- Responsible for expediting purchases orders and payments of the project as agreed and defined.
- Ensure that Safety systems are clearly understood and followed.
- Has direct responsibility for completion of the Project as execution team member.
- Responsible for the control and co-ordination of all contractors and suppliers.
- Ensure facilities shall be designed meeting International and Domestic regulatory guidelines.
- Ensure bringing new cost effective and energy efficient systems in new facilities.
- Ensure timely completion of the projects with quality in work.
- Ensure compliance to QMS (Quality Management System).
- Report any quality issues in their respective areas with their HOD / Manager and QA.

Worked with **M/s Glenmark Pharmaceuticals Limited**, Baddi from Feb 2008 to Oct 2014. Glenmark is the most leading & Emerging Pharmaceutical Company, having the regulatory approvals (USFDA, ANVISA, MHRA, TDP, WHO, SUDAN, MCC etc.). The plant is in the Manufacturing of oral dosage i.e. Tablet, liquid, ointment, MDI, DPI and Nasal.

**Designation : Assistant Manager (Engineering)**

**CORE FUNCTIONAL STRENGTHS**

- Technical support
- Maintenance
- Regulatory audits (USFDA, ANVISA, MHRA, MCC)
- Investigation of failures and providing CAPA.
- Man power management
- Internal Audits
- Energy conservation

**Job Responsibilities:**

- Responsible for engineering operations independently for Regulatory approved plant of External Preparation, liquid, Tablet and Nasal.
- Leading Engineering department in regulatory block i.e. External Preparation includes material planning, utility operations and maintenance as per production plans.
- Interfacing with commercial and purchase department for arranging spares and consumables on scheduled time.
- Responsible to use through knowledge of mechanical engineering maintenance practices including budgeting, scheduling, preventive maintenance, predictive maintenance standards and cGMP techniques for External preparation.
- Maintenance of plant machines, HVAC, Compressed Air & Water Systems as per preventive maintenance schedule.
- 100% auditing compliances by maintaining all cGMP documents.
- Actively participates with internal teams focused on continuous improvement on the machines operations.
- Preparation and review of documents like SOPs, Qualification and Validation Protocol, Calibration, Drawings etc.
- Innovation in upgradation of the plant machinery to fulfill production requirements.
- Erection & commissioning of New and old Machines.
- Liasoning with AMC providers for plant machinery maintenance, vendors for on time material delivery and further projection of materials.
- Scheduling and monitoring daily engineering activities.
- Furnishing updated MIS report to facilitate decision making in management meeting.
- Preparation and monitoring of revenue and capital expenditure budgets.
- SAP implementation.

**M/s Biodeal Pharmaceutical Pvt. Limited, Nalagarh** is leading Contract Manufacturing Pharmaceutical Company in India having a product range of tablet, capsule, Ointments, Nasal, powder in formulation range of product.

From: July 2007 to Feb 2008.

**Designation : Sr. Executive – Engineering**

**Job Responsibilities:**

- To Schedule Preventive Maintenance for Plant & Utility Machinery.
- Modification, Rectification and Troubleshooting in Plant Machinery.
- Involved in Internal audit programme activities inside the plant.
- Handling of documentation of the department independently.
- Erection & Commissioning of HVAC System and water System.

- Preparation, review of departmental documents i.e. SOP's, Protocols,

**M/s Ind Swift Ltd.,** leading Pharmaceutical organization in India having a product range of tablet, capsule, Injection, Ointments, Dry Syrup, Liquid Syrup in formulation range of product and turn over around 400 Crores/ Annum from last two years and target for this year is 700 crores/annum and having International certification for quality, safety and environment i.e. ISO 9001.From Jan 2006 to July 2007.

**Designation : Sr. Executive (Projects & Maintenance)**

**Job Responsibilities:**

- Design of Layouts, Process and Instrumentation Diagrams, Flow Diagrams.
- Preventive Maintenance schedule preparation for Plant & Utility Machinery.
- Modification, Rectification and Troubleshooting of Problem arrived in Plant Machinery (Tablet, Liquid, Injection, Capsule, Ointment,).
- Involved in the Internal audit programme activities inside the plant.
- Core Team Member of the ISO 9001: 2000 committee.
- Work according to the cGMP & ISO 9001:2000 guidelines.
- Handling of documentation of the department independently.
- Erection, commissioning and qualification of Oral dosage form Machines fluid Bed dryer, Blister Machines, Strip Packing, Fluid Bed Dryer, Vibro-Shifter, Coating Machine, Compression machines
- Erection, commissioning and qualification of External preparation machines Manufacturing vessels, Single head & Multi head Ointment Filling Machine.
- Erection, commissioning and qualification of Oral liquid dosage for machines manufacturing and holding vessels, Liquid filling and Sealing Machines, Cam cartonator.
- Erection, commissioning and qualification of Solution preparation vessel, Ampoule Eight Head filling & Sealing Machine, Multicolumn, WFI and other pharma equipments.
- Erection & Commissioning of HVAC System and water System.

Half year with M**/s Ranbaxy Laboratories Ltd, Mohali** which international pharmaceutical company producing quality, generic medicines, from July 2005 to Jan 2006, works in the Project department (Formulation). On retainer basis

**Job Responsibilities**

- Design of Layouts, Process and Instrumentation Diagrams, Flow Diagrams.
- Preparation of Design Qualification, Installation Qualification, Standard Operation Procedures, Operational Qualification of HVAC system.
- Site Supervision for Mechanical Erection of Piping and HVAC system.
- Involved in Checking of Equipment Drawings for approval.

Three and half years in **M/s Engineers Auto, Chandigarh (**an ISO 9000:2001 Company). The leading vendor of M/s Punjab Tractor Limited, M/s Swaraj Mazda Limited, M/s Ashoka Leyland, M/s Eicher Tractors limited, Hero Honda etc. from June 2001 to July 2005.

**Designation:** Quality and Production Engineer.

**Job Responsibilities**

- Inspection and checking of Incoming, In Process and Outgoing Components as per the drawing.
- To maintain Quality of the Components.
- To do the Calibration of the Measuring instruments used inside the company for daily use.
- To maintain the Calibration Schedule of all the measuring Instruments and gauges.
- To develop new components according to Drawing with R& D persons.
- To maintain the documentation according to ISO.

## TRAININGS

- Analytical skills and decision making, Personal power principles, Presentation skills
- TPM, OEE
- Undergo 22 days Industrial training in Guru Gobind Singh Super Thermal Plant, Ropar.
- Undergo 15 days Industrial training in M/s D.C.M Engineering Products, Nawanshahar.

## COMPUTER LITERACY

Basic Knowledge of Computer, MS Word, Ms-Excel, MS Power Point, Auto CAD, Pro-E, CATIA.

## REFERENCES

**Mr. Manish Kumar (**Principal Consultant)

M/s PQE Group

Mobile No. 08126911113

**Mr. Karthikeya K M T (Director**)

M/s GxPFONT consulting group

Mobile No. 09920079884

## PERSONAL INFORMATION

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|---|---|---|
| NAME | : | **GANESH KUMAR SEMWAL** |
| FATHER'S NAME | : | SH. BHAGWATI PARSHAD |
| DATE OF BIRTH | : | 22.01.1983 |
| SEX | : | MALE |
| NATIONALITY | : | INDIAN |
| MARIAL STATUS | : | MARRIED |
| LANGUAGES KNOWN | : | ENGLISH, HINDI, AND PUNJABI |
| HOBBIES | : | PLAYING HOCKEY, LISTENING MUSIC |

I would like to add that I have desired and capability of doing my best with distinctive and noticeable efforts.

DATE: _____ **(GANESH KUMAR SEMWAL)**