AJAY KUMAR RUNGTA

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An Overview:

- A "Performance Driven, Result Oriented &Self-motivated Professional" having good interpersonal, communication & organizational skills with proven abilities in team management.
- Rich experience of over 33 years' in managing the manufacturing strategy & plant operations at
 multiple locations to meet production plans & schedules and manufacture quality zero defect
 Injectable, Solid & Liquid oral and external preparations dosage forms also practiced specialized
 techniques of Aseptic processing, Lyophilization, Multiple Unit Pellet System, Hot Melt Extrusion
 etc. for regulated & other markets to meet the sales requirements, strategic corporate plans &
 goals.

Academic Overview:

- (b) M. Pharm form Panjab University, Chandigarh in the year 1987.
- B. Pharm from Birla Institute of Technology, Ranchi in the year 1985.
- MBA (Human Resource Management) through distance education from IGNOU in the year 1999.

Core Competencies:

Operations:

- Practice a culture of continuous improvement throughout the organization through employee involvement, education, support, improving process & operational efficiencies using OE tools etc.
- Maximize the control, equipment effectiveness, and optimally utilize the resources such as utilities, production capacity, and manpower, waste reduction. Evaluate, investigate and troubleshoot, deliver the high quality products & improve yields.
- Comply with Good Manufacturing Practices, quality, regulatory, safety & statutory requirements.
- Coordinate with supply chain, production, engineering, and HR, quality and external agencies to ensure timely availability of resources & facilitate corrective action for delays & issues.

Technical:

- Update regarding the changes in the quality guidelines & regulations, review feasibility of new or revised systems and procedures and implement the relevant changes.
- Conduct internal technical audits to gain an understanding of strengths and possible improvements and guide team for bridging any gaps/deviations with the required standards.
- Maintain Validation status, guide team on the Quality Management Systems, preparefacing international regulatory bodies and customer audits and ensurecompliance with standards.
- Ensure upkeep of facility, equipment as per regulatory and statutory requirements.
- Experienced to setup a new manufacturing facility from project stage to its operational stage.

People Management:

- Develop the organization structure for own function with clearly defined roles and responsibilities and staffing requirements; ensure optimum staffing for achievement of functional objectives.
- Identify the training and development needs and ensure fulfilment, build a capable team.
- Set annual performance goals for the team, monitor and support achievement of goals and provide constructive feedback and counselling support to team to improve performance.
- Create a healthy working environment by employee development, team work& respecting the core values& maintain harmonious industrial relations environment etc.

Strategic:

- Design and implement operational policies and procedures to manage operations at different plant locations efficiently and meet the production targets as per operational standards.
- Develop the annual operating plan; define plant objectives and performance parameters for different plants, provide key inputs for production planning (including material planning, inventory control and dispatch planning) and ensure appropriate capital allocation for optimal utilization.

- Implement the strategic business plans to meet the organizational objectives and goals.
- Implementmanufacturing strategy to meet the Business' objectives and participate in long-term planning including strategic tie-ups, outsourcing opportunities, expansion of infrastructure, longterm production capacity planning, conversion and equipment planning, new machinery and new projects. Support capital investment programs ensuring timely execution.
- Contribute to the development of plans for investment in new technology, technologyupgradation, automation, and product innovation to achieve the company's objectives.

Financial Responsibility:

- Forecast, prepare and manage the functional / annual budget, approve expenses as per set limits.
- Review MIS reports, expenses, value generated, trend & take corrective actions to control cost.

Internal and External Coordination:

- Top Management: Analyze and collate status and present update to managementas per requirement. Discuss strategic plans, performance and critical operational issues.
- Research &Development: Interact on developmental, commercialization and modifications.
- Supply Chain Management: Material planning for manufacturing sites &loan licensee locations.
- Finance: Budgeting for capital & operating expenditure, accessories & equipment procurement.
- Quality Systems & Regulatory Affairs: Quality and regulatory compliances & customer queries.
- Business Development: Trends, customer requirements to service them, production planning.
- Legal: Formalize strategic partnerships for loan licensing and contract manufacturing etc.
- Industry Associations: Current trends in the industry and to promote the company's brand image.
- Vendors/Service Providers: Evaluate, negotiate, long term contracts & service agreements.

Organizations-Associated With:

Worked as Vice President Technical (Plant Head) from 25.04.2019 to 12.07.2021 in the Green field project and successfully made operational after qualifications and validations at PSAC&P at Pithampur having Oral Solid Dosage forms and external preparations.

Employer: Agio Pharmaceuticals Ltd.

Tenure: From 30th October 2018 to 23rd April 2019 (**Injectable**, OSD & External preparations).

Designation: VP Technical (Plant Head) (Responsible for overall plant operations)

Employer: Akums Drugs & Pharmaceuticals Ltd.

Tenure: From 28th October 2015 to 29th October 2018 (Injectable, OSD & Externals).

Designation: Sr. GM Operations (Plant Head) (Responsible for overall plant operations)

Employer : Plethico Pharmaceutical Ltd., Indore
Tenure : From 19 June 2013 to 22nd October 2015

(Injectable, OSD, Lozenges, <u>Nutraceuticals</u>, Herbal, Liquid oral & External preparations) **Designation**: Associate Vice President Operations (Responsible for overall operations)

Employer: Mylan Laboratories Ltd., Nasik,

Tenure: From 4th September 2011 to 18th June 2013 (OSD)

Designation: General Manager – Production (Responsible for managing Production)

Employer: Marksans Pharma Ltd., Verna, Goa,

Tenure: From 1st March 2010 to 27th August 2011 (OSD)

Designation: General Manager- Production (Responsible for overall operations)

Employer: Indoco Remedies Ltd, Verna, Goa

Tenure : From 17th January 2008 to 28th February 2010 (OSD, Liquid orals & Externals)

Designation : General Manager–Production (Plant Head) (Responsible for overall operations)

Employer: Alkem Laboratories Ltd., Daman

Tenure : From 16th July 2000 to 16th January 2008 (Injectable, OSD and Liquid orals)

Designation : Assistant General Manager – Production (Responsible for overall operations)

Employer : Laboratories Griffon Ltd., 20 Haines Road, Mumbai-11
Tenure : From 2nd May 1988 to 15th July 2000 (OSD & Liquid orals)

Designation: Senior Executive – Manufacturing (HOD of Tablets & Liquid Orals sections)

Employer: Hoechst India Itd., Mumbai - 400 080

Tenure: From 12th October 1987 to 30th April 1988 (**Injectable**, OSD, Liquid orals & Externals)

Designation: Apprenticeship Trainee-Production

Achievements:

- Successfully lead the team for regulatory inspections (MHRA, ANVISA, WHO, MCC, TGA, USFDA etc.) & customer audits (Abbott, Merck, Ajanta, Hovid, Unilab etc.) without critical observations.
- Handlednew projects, launchednew products, FAT of machines including Sejong Korea.
- Implemented cost / waste reduction, productivity enhancement& yield improvement projects.

Professional Enhancement Initiatives:

External training programs / Seminars attended

- ❖ Effective Use of Personal Protective Equipment (CLI, Mumbai, 9 to 11th April 96);
- Environmental Management Systems (CLI, Mumbai, 27 & 28 Jan 99);
- Complying With WHO GMP (Raytheon E&C, Mumbai, 20 & 21st Jan 00);
- Fire Fighting (Agni Shaman Consultancy S&S, Daman, 12th Oct 04);
- Water System (Ion Exchange, 15th Nov 02);
- Stability Studies of Pharmaceuticals (Dr. Saranjit Singh, Daman, 7th Oct 05);
- Aseptic Techniques (Mr. C.K.Moorthy, Daman, 8th Oct 05);
- Conducting & Facing GMP Audits (Autal Shirgaonkar, Insight Systems Inc. 24 & 25th Jan 06);
- Magic of Empathy (Dr. Anand Kulkarni & Dr. Kuldeep, Goa, 22nd May 08);
- Train The Trainers; Total Quality Management (TQM); Lean Six Sigma;
- Equipment Qualification; Process Validation;
- Cleaning Validation (Autal Shirgaonkar, Insight Systems Inc.);
- Automated System Validation (Epitome Technologies);
- Environmental Monitoring; Isolators (Bectochem);
- Alternative Treatment concept etc.:
- Management Development Program at IIM Indore, duration 6days, October 2011;
- One day Leadership Development Training by Marshall Goldsmith on 05.11.12.

Computer Proficiency:

* Expertise in Internet browsing, good innumeracy and IT skills, particularly in MS Office.

Professional Memberships:

Life Member of IPA & IPGA

Personal Snippets:

Date of birth : 7th April 1962;

Nationality : Indian.

Languages known : Hindi and English.

Place : Indore

Date:

Ajay Kumar Rungta