Dr. SUBHASH KUMAR PANDE

Master of Pharmacy,
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PROFESSIONAL SYNOPSIS

About 29 years of experience in Pharmaceutical Industry.

R&D, Manufacturing Quality Assurance and Quality Control functions of sterile, Oral Solids, dosage forms, Sterile API, Animal health care products Lyophilized Injections, DPIs, MDIs, Nasal sprays, Bio similar, vaccine and Pre-Filled Syringe products.

Execution of green field and expansion Projects with lean concept.

For last 15 years worked in Senior management – strategic and leadership role, ensuring organizational goals objectives, and business opportunities, through problem solving approach, within cGMP compliance framework.

Now associated with GXPZONE Pharma Solutions as a **Technical Director and Principal advisor**

Key initiatives and achievements

- Enhancement of organized Quality systems for sustained compliance.
- Risk, impact assessment, investigations and cause identification
- Harmonization of procedures and Practices
- Automation in Pharmaceutical Industry. Work flow development,

Interface for software applications and automation in Pharma Industry**. *[Documentum, Art work Management, Personnel Training, SAP and PM Module, Minitab, Development of portals for data analysis and organized informatics].***

- Quality Intelligence, CAPA tracking for proactive measures.
- Auditing and qualification of vendors for procurement of APIs, components, packing materials
- Personnel Training with practical case studies and solutions.
- Personnel and Quality culture development,
- Planning; service level and productivity improvement, efficient work culture by waste reduction;
- Due diligence and developing contract manufacturing sites for various dosage forms manufacturing.
- Team building with quality culture.
- Installed effective Market Complaint cell, Master data cell, Public testing laboratory for stability sample Analysis and monitoring the results
- Monitoring and improvement of service level agreement [SLA] of QC.
- Monitoring of Quality and facility Index

Member of Quality Review Board for resolution of New product, other quality and stability issues

Regulatory Inspections and Exposure	USFDA Inspections – Oral Solids, Sterile and Non Sterile APIs , Semi Solids (Ointment and Creams) MHRA / Eu GMP – Dry Powder Injectable, Oral Solids, Semi Solids ANVISA - Dry Powder Injectable, Oral Solids; Inhaler's; Biologics Semi Solids ANVIMA - Oral Solids; Biologics Other Agencies –Injectable , Oral Solids, inhalers , Semi Solids ,Vaccines, Biological products WHO GMP – Oral Solid, semi Solids , Injections , Lyophilization process.
Previous Assignments	• Cynamid India Limited , [OSD and Oral Liquid] • Lupin Limited Dry powder injectable, OSD and APIs • Glenmark Pharmaceuticals – Corporate QA Functions API and Formulations – OSD, Ointment creams, Inhalers • Cadila Health Care (Zydus) - Corporate QA Functions API and various formulations .
Awards and Appreciation	➢ Appreciation by IBC Asia , Singapore for holding workshop at Singapore and Malaysia ➢ Illustrious Alumni Life Time award by University of Sagar on Diamond Jubilee of Department of Pharmaceutical Science. ➢ Long service awards at Lupin and Glenmark Pharmaceutical Limited. ➢ Best trainer award by Health Quest Foundation ➢ Appreciation for skill development program and other social activities. ➢ Lifetime achievement award inferred by Prisal Pharmaceutical Royal International Society.
Publications	Research Publication and General articles in National and International Journals.
Contribution to Academics	• Successfully guided four research scholars for award of the Ph.D degree. • Member (honorary) of the council of Industrial and Higher Education collaboration for Central University , as per the directives of Ministry of HRD , Government of India, • Examiner for Universities for Post-graduation and Ph.D. • Member of syllabus committee at Technical University, Bhopal • Associated with e learning projects of Delhi University , supported by skill development program of Government of India .
Member Ship	Life member of IPA. ISPE, PDA.

Persistent Focus on	➢ Continuous training to build an efficient team to achieve quality culture in the organization and cGMP compliance 24X7 ➢ Efficient project planning .execution from primary stage as per applicable regulations and GMP compliance, including QC laboratory and Microbiology. ➢ Support Automation in Pharma Industry such as SAP (different modules) , Documentum, Trackwise Artwork approval and others as applicable . ➢ Approach to ensure an integrated and comprehensive quality monitoring and management system for GMP, Analytics. ➢ To work for continues improvement and sustainability of the business in different geographies through compliance ➢ Identification of gaps and waste in the system for simplification of processes to achieve productivity efficiency , data reliability and cost reduction ➢ Collaborating with the other stakeholders and business partners .and agencies. ➢ Continues improvements/simplification of Good Manufacturing Practices (GMP through positive team work and system implementation ➢ Collection, tracking and analysis of relevant data. ➢ Scheduling and conducting training ➢ Quality culture and Competency building through training ➢ Development and partnering with contract manufacturing sites for long term support for consistent product quality and compliance status. ➢ Reviewed dossier submission as per applicable formats to avoid queries and approval delays.