

MANISH CHOUDHARI

RESOURCE LEADER-PRODUCTION INJECTABLE & OSD



+91-8146554215
manishcp39@gmail.com

Enterprising leader with 23+ years of proven track record in Production, Packaging Operations & Development, Equipment Qualification, and Computer System Validation within the pharmaceutical industry. Seeking challenging roles to leverage extensive experience in optimizing processes, ensuring regulatory compliance, and driving organizational success.



PROFILE SUMMARY

- ❖ Accomplished Resource Leader specializing in Production Packaging, Equipment Qualification, and Computer System Validation within the pharmaceutical industry, with a proven track record at Dr. Reddy's Laboratories.
- ❖ Expertise in qualifying sterile and non-sterile equipment with isolator technology for potent and anti-cancer products, including OSD (Bottles & blisters), injectable vials, once-sleeving vials and pre-filled syringes, an autoinjector; a visual inspection machine; Ointment & Cream dosage form, managing a team of 7 professionals to ensure compliance with stringent regulatory standards.
- ❖ Proficient in handling techno-commercial discussions for equipment procurement, from design and R&D stages to final execution, ensuring seamless integration of new products.
- ❖ Skilled in developing, designing & de-risking packaging material, new change part development with machine perspective considering product characteristics for OSD / Injectable new launches as per regulatory requirement to ensure smooth operation of the machine.
- ❖ Proficient in designing and implementing customized packaging solutions for a range of dosage forms, including OSD, Parenteral, Ophthalmic, Inhalational, and Topical, utilizing innovative assembling and packaging machines.
- ❖ Strategic thinker driving manufacturing strategy and capacity assurance from concept building to final unit deployment, ensuring alignment with cGMP requirements.
- ❖ Demonstrated ability to combine business acumen with packaging technology expertise to eliminate operational bottlenecks, satisfy market demands, and drive innovation.
- ❖ Proven expertise in productivity improvement, breakdown analysis, capacity planning, and equipment selection, enhancing operational efficiency and performance.
- ❖ Extensive experience in equipment and facility qualification, including handling consent decree (CD) remediation projects and ensuring compliance with regulatory standards.
- ❖ Strong focus on standardization of validation processes, SOP development, team building, and implementation of QMS.
- ❖ Proficient in managing software-based quality systems & leading project coordination to meet timelines and regulatory requirements.
- ❖ Strategic leader driving manufacturing strategy development, technical evaluation of equipment, and identification of new supplier bases to meet future business needs.



TECHNICAL SKILLS

- ❖ Quality by Design/ DOE
- ❖ Packaging Technology Transfer
- ❖ Aseptic manufacturing techniques
- ❖ Packaging and operation development
- ❖ Deviation investigations
- ❖ Computer system validation
- ❖ New technology implementation

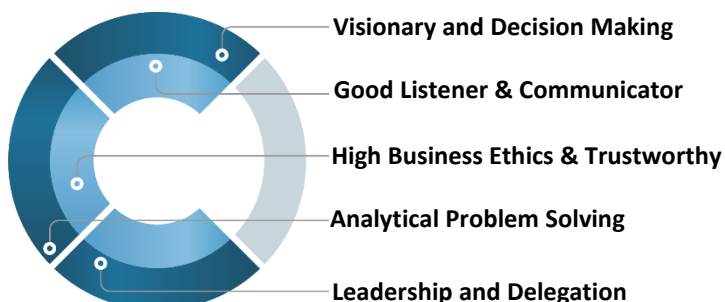


CORE COMPETENCIES

- ▶ Production Planning & Control
- ▶ Operations & Execution
- ▶ Audit Compliance
- ▶ Rejection Analysis
- ▶ Process Improvement
- ▶ Liaison & Coordination
- ▶ Stakeholder Management
- ▶ Faced Audits: USFDA, MHRA, PMDA, WHO, ANVISA
- ▶ Packaging Operation & Development
- ▶ Quality Assurance & Quality Control
- ▶ Vendor Development
- ▶ Team Building & Leadership



SOFT SKILLS



MAJOR PROJECTS

- ❖ Harmonization and simplification across sterile FTOs
- ❖ Low-cost automation
- ❖ Agility improvement
- ❖ Yield improvement
- ❖ Asset robustness
- ❖ Product Robustness
- ❖ Change Over Time Reduction
- ❖ Process and packaging simplification
- ❖ Multiskilling of operators
- ❖ Reduction of Qualification time & improvement of equipment operation time as per regulatory requirement.



CAREER TIMELINE (recent 4 engagements)



WORK EXPERIENCE

Since Dec'15 | Resource Leader-Production Injectable & OSD | Dr. Reddy's Laboratories

- ❖ Orchestrating operations, procurement, value engineering, and design initiatives within the pharmaceutical packaging sector, encompassing OSD, Parenteral, Ophthalmic, Inhalational, and Topical dosages.
- ❖ Spearheading the customization of packaging solutions for diverse dosage forms, overseeing the design and development of intricate assembling and packaging machinery tailored for complex devices and pack presentations.
- ❖ Collaborating with multifarious business units to devise and implement technology-driven solutions addressing critical requirements.
- ❖ Formulating comprehensive manufacturing strategies and ensuring capacity assurance, overseeing the entire process from design conceptualization through to deployment at the final unit level.
- ❖ Synthesizing business acumen with packaging technology expertise to optimize service delivery, cater to evolving market demands, and streamline operations through innovative solutions and continuous refinement.
- ❖ Directing both direct teams comprising a substantial workforce and cross-functional teams, leveraging extensive knowledge and experience to drive cohesive and efficient collaboration.

Oct'15-Nov'15 | Deputy Manager-Production | Aurobindo Pharma

- ❖ Enhanced productivity through strategic measures.
- ❖ Analyzed breakdowns and planned corrective action.
- ❖ Planned capacity and procured change parts for packaging equipment.
- ❖ Selected equipment in alignment with business requirements.

Sep'10-Oct'15 | Senior Executive – Continuous Improvement & Engineering Validation | Sun Pharmaceutical Industries Ltd. earlier Ranbaxy Laboratories Ltd./ Daichi Sankyo, Japan

- ❖ Oversaw the Qualification and Re-Qualifications of all equipment and systems for the facility, encompassing critical utilities and equipment such as visual inspections.
- ❖ Applied hands-on experience in equipment/facility qualification.
- ❖ Participated in a consent decree (CD) remediation project as an initial step to address import alerts at the Ranbaxy, Mohali site.
- ❖ Standardized validation and critical process parameters.
- ❖ Prepared SOPs, facilitated team building, provided training, and implemented QMS.
- ❖ Managed software-based quality systems like LMS, Doc hub, CAPA Trackwise LIMs.
- ❖ Coordinated projects (micro-planning, execution, and compliance), independently handling validation projects within stringent timelines by revamping facilities to meet cGMP requirements for all in-use (Legacy) Systems.
- ❖ Led and directed the execution of complex assignments.
- ❖ Updated DWM to enhance validation techniques and procedures.
- ❖ Troubleshoot validation issues, developed, organized, analyzed operational issues, and defended qualifications to meet regulatory inspections.
- ❖ Ensured document integrity and maintained readiness for audits at all times.
- ❖ Developed a Manufacturing Strategy for the Formulation business in alignment with business aspirations. Conducted technical evaluations and recommended equipment to meet business needs.
- ❖ Contributed to the conceptualization of design, characterization, and deployment to the final unit level. Identified new supplier bases to meet future requirements and for customization of assembly and packaging equipment.
- ❖ Managed cross-functional teams to align with the overall strategy.
- ❖ Directed Program Management initiatives including Operation Excellence projects, Simplification, and capability building.

Feb'06-Sep'10 | Junior Manager-Packaging Operation Development | Dr. Reddy's Laboratories Ltd.

- ❖ Directed cross-organizational efforts to evolve packaging strategies, understand product-packaging-process relationships, and foster strong vendor relationships for continuous improvement.
- ❖ Oversaw routine training programs, technical support for machine installations, inventory control, and evaluation of packing machines to enhance productivity and efficiency.
- ❖ Collaborated with technical teams to improve packing material quality, develop new materials addressing challenges, and implement automation and vision systems for enhanced quality control.
- ❖ Facilitated harmonization of packing practices across locations, ensuring effective packing controls, evaluated and implemented new packing machines, and streamlining processes for efficiency.
- ❖ Led the setup of new projects by designing packing area layouts, selecting appropriate machines, and ensuring optimal utilization of resources for project success.



PREVIOUS WORK EXPERIENCE

Sep'04-Jan'06 | Maintenance Engineer-Engineering Department | Wochkardt Ltd.

Jan'01-Aug'04 | Management Staff | Cipla Ltd.

1999-00 | Trainee Engineer-Testing and Servicing | Magnified Control



EDUCATION & CERTIFICATIONS

- ❖ Six Sigma Black Belts, MSME, Indian Government, 2020
- ❖ B. Tech Electrical Engineering, Karnataka University, 2014
- ❖ Diploma in Electrical Engineering, S. S. P Institute of Technology, Chopda
- ❖ Diploma in Packaging Development, Indian Institute of Packaging, Mumbai



ACCOMPLISHMENTS

- ❖ 2005-2006: Special Technical Innovation Award for throughput improvement (130%) of renowned product OMEZ by developing customized machine at Dr. Reddy's Laboratories
- ❖ 2007: Appreciations certification from IMA PG for successful installation of new IMA PG Express by chairman of IMA PG Mr. Satish Rao at Dr. Reddy's Laboratories
- ❖ 2007-2008: Valued Contribution for successful installation of new IMA PG Exp. And Elmach 3522 Blister pack machine, first of its kind in India at Dr. Reddy's Laboratories
- ❖ 2009-2010: Certification for designing and delivering structured Techs skill enhancement programme (STEP) for technical trainees at Dr. Reddy's Laboratories
- ❖ 2012: CPD certification for Good Engineering practices for Pharmaceutical systems at Dr. Reddy's Laboratories
- ❖ 2013: Trainer certification for workshop QCC & TPM for coordination's leads from sites at Dr. Reddy's Laboratories
- ❖ 2018: Certification of excellence for successfully completion of US-FDA inspection at FTO7 & 9 Unit through succeed project by Vikram Shukla and Shailesh Patel (Top management Leader) at Dr. Reddy's Laboratories



TRAININGS

- ❖ Participated in workshop 'Strength based Leadership team' at Ranbaxy Corporate office, Gurgaon, Delhi
- ❖ Participated in workshops related to Effective managerial skills at Dr. Reddy's Labs, Corporate Office and Amerpeth.
- ❖ Dr. Reddy's Laboratories Certificate of training for Facing Audits by David Peterson, 2016
- ❖ Selection as a Participant in virtual training on DNA champs of Dr. Reddy's on topic covered basics of pharma Industry 4.0, Implementation of digital twin, introduction to Robotic Process Automation (RPA) using UI path tool, Effective business translator program, Design thinking for machine learning (ML), Digital trends in pharma: AI-ML State of Art and AR/VR Augmented & Virtual reality, Translating a business problem through ML, IoT & Digital Twin: Architecture & Application 2020



PERSONAL DETAILS

Date of Birth : 14/01/1980
Languages Known : English, Hindi & Marathi
Location : Maharashtra, India