Rucha Lodhawala (M.Sc.)

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PROFESSIONAL SUMMARY

- Pharmaceutical manufacturing professional with a Master of Science degree and 6 years of experience in GMP-regulated sterile injectable environments
- Experienced in deviation investigations, root cause analysis, CAPA implementation, and Quality Management Systems (QMS) while supporting global regulatory inspections (USFDA, EU, WHO)
- Skilled in batch record review, production documentation, visual inspection, and packaging operations as a Designated Approved Technical Person for Parenteral Manufacturing
- Proficient in Track Wise, EDMS, PharmaSuite, and Microsoft 365 with strong expertise in GMP/GDP compliance, audit readiness, and regulatory documentation
- Known for structured problem-solving, cross-functional collaboration, and driving continuous quality improvement
- Canadian-certified in Standard First aid CPR-C & AED and Multilingual competence

CORE SKILLS

Manufacturing & GMP	Sterile Injectable Manufacturing | GMP & Regulatory Compliance | Batch Execution | BMR/BPR Review | Batch Record Accuracy | Line Clearance | Visual Inspection | Packaging Operations | In-Process Controls | Sanitation & Hygiene Monitoring | Material Handling & Inventory Control
Quality System	Deviation Management | Root Cause Analysis (5-Why, Fishbone) | CAPA coordination | Change Control | Audit Readiness | SOP Management
Operations & Leadership	Shop-floor Supervision | People Management | Training & Coaching | Cross-Functional Coordination | Troubleshooting | Continuous Improvement | Safety Compliance | Production Reporting
Software	Track Wise | EDMS | BRMS | LMS | PharmaSuite | Microsoft 365 Suite

WORK EXPERIENCE

Senior Production Officer (Lead Investigator-QMS Team) 2024 – 2025

Sun Pharmaceutical Medicare Ltd. • Baska, Gujarat, India

- Led end-to-end deviation investigations in GMP-regulated sterile manufacturing, developing investigation strategies, coordinating cross-functional data collection, performing root cause analysis (RCA), and implementing effective CAPA.
- Managed investigation records within Track Wise and Quality Management Systems (QMS), ensuring documentation integrity, regulatory compliance, and adherence to investigation timelines.
- Supported global regulatory inspections (USFDA, EU, New Zealand authorities) through audit preparation, shop-floor readiness, compliance gap assessments.
- Conducted GMP, GDP (Good Documentation Practices), and hygiene training programs, mentoring production teams on investigation practices, documentation standards, and quality compliance while supporting internal audits and addressing observations.