A professional with development, technology transfer & commercialization experience from concept to completion.

PRAVIN ROTHE

Summary

- ✓ *cGMP/Business Recoveries*
- ✓ *Lean Six Sigma*
- ✓ *Continuous Improvement Leadership*
- ✓ *Project Management (Facilities/Utilities/Equipment/SAP)*
- ✓ *Sterile Aseptic Processing & Biologics*
- ✓ *Controlled Substances Operations*
- ✓ *Solid Oral Dose Leadership*
- ✓ *Lyophilization Processing*
- ✓ *Validation and Qualification*
- ✓ *Clinical Trial Operations*
- ✓ *Medical Device (Combination Products)*
- ✓ *Blow-Fill-Seal Technology*
- ✓ *Terminal Sterilization Processing*
- ✓ *Regulatory Filing & Inspection Liaison*
- ✓ *Metrics & Key Performance Indicators*
- ✓ *Isolator Technology*
- ✓ *Internal Site and Vendor Audits*
- ✓ *NDA/ANDA Submissions*

Education

M. Pharm, Pharmacology

Pune University, Nashik, MS, India

Certifications

Lean Six Sigma Yellow Belt/Green Belt University System of Georgia, 2020

Project Management – DRL Coursework Implications for Business Strategy Program

MIT Sloan & MIT CSAIL *Artificial Intelligence 2019*

Biotechnology Business Leadership and Management Strategies, **FAES**, *2015*

Regulatory Affairs Certificate: Pharmaceuticals, **RAPS**, *2012*

IPPCR, **The Johns Hopkins University School of Medicine**, *2007-2008*

Positions Held	
2024 - Present	ELANCO – Advisor EGQCA
2018 - 2024	MS&T CV Lead (Director), Novartis (Sandoz)
2019 - 2023	Advisory Committee at FDA
2017 - 2018	VP, RA, Technical & Project Services, Aavis Pharma
2015 - 2017	Sr. Mgr. Technical Services, Glenmark Pharmaceuticals
2006 - 2015	Validation & Technology Transfer Analyst, Pii

- Led multiple regulatory inspection at pharmaceutical manufacturing facilities that are in startup and established phase.
- Launched and led three successful Continuous Improvement Programs with $2MM in savings identified for each in the first year.
- Responsible for the completion of numerous Lean Six Sigma initiatives that resulted in significant yield, cycle time, and scrap reduction improvements.
- Provided hands-on project management leadership and support for numerous capacity enhancement initiatives, including installation of commercial scale manufacturing and packaging lines.
- Completed extensive compliance remediation work on a variety of critical utilities, including HVAC, Purified Water, Clean Steam, and Compressed Air Systems.
- Served as primary point of contact for general and product specific (PAI) regulatory manufacturing process inspections for compliance to US, Japanese and European regulatory requirements.
- Responsible for two successful SAP implementations, one as the Project Lead for US implementation and the other as the Production SME.
- Managed various operating environments producing biological, device, aseptic, oncolytic, blow-fill-seal, controlled substance, lyophilized, and solid oral dose products.
- Directed plant operations through successful completion of clinical trials, while also providing project lead support for NDA, ANDA preparation and submission.
- Extensive experience writing and reviewing Deviations, CAPAs, Root Cause Analysis, Change Controls, SOPs, Policies, Batch Records, PMs, and Calibration documents.
- Introduced Project Management Rachana Programs, with direct oversight of company priority projects.
- Completed numerous product technical transfers to the manufacturing sites.
- Improved quality, availability, and pricing of APIs, excipients, and components through vendor contract negotiations, with direct hands-on involvement with implementation onto the production lines.
- Conducted internal site & vendor compliance audits serving as process SME.
- Validated latest pharmaceutical technology such as Hydrogel nanotechnology, Hot Melt Extrusion, ODT, Bilayer Tablet, Tablet in Tablet, Liquid in Capsule, Tablets in capsule, and Pellets in capsule and Tablet in Softgel.
- Introduced site Governance Program that encompassed preparation and management of site metrics, Key Performance Indicators (KPIs) and Master Validation Plans.
- Challenged major operating facilities by performing mock FDA inspections and assisting with constructing remediation plans and leading corrective action implementations.
- Facilitated problem-solving exercises and served as SME for resolution of several high-profile exception events/deviations, including media fill, water system and product contaminations. Active member of Novartis Human Rights Ambassadors Network and Environmental Sustainability forum.

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