P·R·R
01/21/22

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

Master of Pharmacy, 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	
2018 - Present	Cleaning Validation Lead, Novartis Advisory Committee at FDA
2017 - 2018	VP, RA, Technical & Project Services, Aavis Pharma
2015 - 2017	Sr. Mgr; Technical Services, Glenmark
2006 - 2015	Validation & Technology Transfer Analyst, Pharmaceutics Intl. Inc.
2002 - 2005	Technical Mgr; Dr. Reddy's Lab. Ltd.
2000 - 2001	Asst. Mgr; Manufacturing, Gland Pharma
1998 - 2000	Officer; Manufacturing, Sun Pharma

- 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. Designed and qualified hormonal and oncology dosage development lab.
- 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
- Led multiple Deviation, CAPA, Change Control, PM, Calibration, and Maintenance Work Order reduction task force teams, to include implementation of harmonization programs that streamlined existing systems.
- 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.

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