

**OBJECTIVE:** To serve your organization with **quality** and **result** driven approach.

**SUMMARY:**

- Ph.D in Chemistry with 20 years of professional experience.
- Excellent hands-on experience for **Manufacturing Process Improvement, Technology Transfer** and **Scale up** activities.
- Served as Site Head for **Analytical Science and Technology (AS&T)** and **Product Steward** in Novartis.
- Well familiar with **PAT (Process Analytical Technology)**.
- Well familiar with **Analytical Trend Analysis** using **Minitab** software.
- Well familiar with **API compatibility** and role of **key excipients** in formulation.
- Well familiar with **FMEA** approach to evaluate potential risk associated with the process.
- Draft and review of Protocols, Reports and **SOPs, CAPA** as needed for improvement of the process.
- Writing and reviewing **APR** (Annual Product Review).
- Excellent hands on experience for Analyzing, writing and managing **Stability Studies Program** for marketed and Research Products.
- Extensive Experience in conducting Audit of API Manufacturer, Contract Manufacturing Sites, Contract Testing Facilities, and Warehouse Facilities (North America, Europe and Asia).
- Well familiar with 21 CFR Part 11 pertaining to **Data Integrity**.
- Well familiar with **Change Request System** and **NCR** (Non Conformance Report).
- Excellent interpersonal and organizational skills with leadership capabilities.
- Resource planning on daily and weekly basis, ensuring maximum utilization is achieved.
- Dexterous, goal oriented team player and problem solver, capable of accomplishing targets under minimum supervision.
- Computer proficient with effective written and oral communication skills.
- Well familiar with HSE practices and served as HSE Representative for Oncology Facility.
- Experience dealing with technical rationales to support the regulatory/quality responses to FDA observations in the warning letter.
- Set-up cross-functional teams to facilitate the remediation process for the mitigation of identified gaps.
- Excellent communication skills [written and verbal] & strong interpersonal skills
- Continuous Process Improvement, Production Efficiency, Process Optimization, Troubleshooting and Process Reengineering
- Strategic Planning and Skillset of Staff Development

**CAREER PROFILE:**

An accomplished professional with a proven track record for building and leading world-class Pharmaceutical and Bio-Pharmaceutical Companies with demonstrated leadership skills. Known within Pharmaceutical and Bio-Pharmaceutical industry for driving business results and maximizing profitability through the delivery of exceptional product quality and services and prudent management of people, technology and processes. Proven ability to manage budgets, align technology strategy with corporate strategy.

CONTACT MS REMEDIES INC. FOR COMPLETE RESUME