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

SUMMARY:

- Bachelors of Pharmacy (B. Pharm), MBA with over 20 years of exclusive pharmaceutical and biopharmaceutical experience, contributed to firm growth by executing business strategies using strong decision making abilities.
- 20 years of cumulative experience in leading Product Development team, optimization, scale-up, process validation, cleaning validation, in semi-solid (cream, ointment, gel, lotion), liquids (topical and oral), solids (tablets and capsules) pharmaceutical manufacturing facility.
- 20 years of cumulative experience in managing and steering new product transfer for Phase 1, 2(a), 2(b), 3 and commercial process from R&D to operation. Managed technology transfer and initial manufacturing activities for clinical supplies to meet customer and corporate objectives.
- Strategy to identify product for pipeline, First to File Generics, ANDA, 505(b)(2) based on information from FDA's Orange Book, brands with expiring patents and IMS group data.
- Experience dealing with CMC section and technical rationales to support the regulatory filling for NDA, ANDA and 505(b)(2). Support quality responses to FDA response letter. Set-up cross-functional teams to facilitate the remediation process for the mitigation of identified gaps.
- 10 years of project management skills.
- 20 years of experience in equipment qualification (IQ, OQ and PQ), utilities qualification (Steam, WFI, Purified Water, Compressed Gases etc.), process and cleaning / sanitization validation experience in biopharmaceutical manufacturing facility- biologics, solid dose, medical devices, vaccines and plasma proteins.
- 10 years of experience in operation and handling of Kaye Validator, Autoclave and SIP Validation, thermal mapping, SIP qualification of large and small tanks (confined space), de-pyrogenation tunnel/oven, lyophilizer, autoclave, etc.
- 10 years of Cleaning and Process Validation experience - Cleaning/Process Validation SME. Cleaning/Process optimization, troubleshooting, Cleaning/Process implementation.
- 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 gaps.
- Proficiency in the Commissioning & Qualification projects – Equipment & Room Qualification and Automation.
- Shipping Validation, Proficiency in Cold Chain Transportation – International Shipping of Intermediate and Final Products.
- Excellent communication skills [written and verbal] & strong interpersonal skills
- Management Consulting and QA Remediation Strategist, Coach, Mentor and Trainer on best validation and safety practices, a leader and an excellent team player.
- Risk Assessments and mitigation strategy and GAP Analysis
- Continuous Process Improvement, Production Efficiency, Process Optimization, Trouble-shooting 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.