Cover Letter

Vijay Agrawal
M. Pharm (Pharmaceutics)
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Dear Team,

I am writing to express my interest in the suitable position of **Formulation R&D**. With over 13 years of hands-on experience in pharmaceutical formulation development, technology transfer, and regulatory compliance, I am confident that my expertise aligns with the innovative and high-performing culture of your organization.

In my current role as **Senior Manager at Corona Remedies Private Limited**, I have successfully overseen the development and technology transfer of multiple oral solid dosage forms, specializing in oncology and general formulations. My experience spans Immediate Release, Extended Release, and Delayed Release formulations, alongside advanced manufacturing technologies such as wet granulation, roller compaction, and spray drying. I take pride in delivering products for regulated markets, including the US, EU, and Brazil, while ensuring compliance with GMP standards and regulatory requirements.

A particular highlight of my career has been the successful development and transfer of over 25 products including anticancer (Tinib molecules and Cytotoxic Oncology formulations), many of which have received regulatory approvals. Additionally, my strong foundation in project management, coupled with my ability to collaborate across functional teams, allows me to drive process optimization, cost reduction, and timely project completion.

I am particularly drawn to because of its commitment to innovation and excellence in pharmaceutical research, and I am excited about the opportunity to contribute to your R&D initiatives. I am confident that my technical skills, leadership experience, and passion for developing impactful pharmaceutical solutions would make me a valuable asset to your team.

I look forward to the opportunity to discuss how I can contribute to the continued success of your organization. Thank you for considering my application.

Sincerely,
Vijay Agrawal

RESUME

Mr. Vijay Agrawal M. Pharm (Pharmaceutics)
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CAREER OBJECTIVE

"Seeking challenging assignments in formulation R&D and Technology Transfer, utilizing extensive experience in pharmaceutical research to drive innovative solutions within a reputed organization."

PROFESSIONAL SUMMARY

"Experienced Formulation R&D Manager with over 13 years of expertise in the development and technology transfer of oral solid dosage forms, including general and oncology (Tinib) products. Proven track record in managing formulation R&D, technology transfer, and documentation teams. Specialized in Immediate Release, Extended Release, and Delayed Release formulations of tablets, pellets, and soft gelatin capsules. Skilled in advanced manufacturing technologies such as wet granulation (Top Spray, RMG, Roller Compaction), Direct Compression, Hot Melt Extrusion, and Spray Drying, with a focus on delivering for regulated and global markets."

KEY SKILLS

Formulation Development: Specialized in quality risk assessment and QbD-based formulation development. Proven track record in ideation, innovation, and intellectual property generation for non-infringing and generic product development.

Scale-Up, Technology Transfer & Process Validation: Skilled in scaling up processes from lab to production scale, managing seamless technology transfers, and overseeing process validation, optimization, and troubleshooting.

Regulatory Affairs: Experience in ANDA submissions and handling regulatory queries for the US, EU, and global markets.

Project Management: Proficient in collaborating with cross-functional teams, managing project timelines, and implementing cost evaluation and reduction strategies.

GMP, Quality & Regulatory Compliance: In-depth knowledge of GMP standards and global regulatory requirements, with a strong focus on documentation and compliance.

Leadership & Team Development: Experience in mentoring, developing, and managing high-performing R&D teams.

ACCOMPLISHMENTS AND ACHIEVEMENTS

"Developed and successfully transferred over 25 products for regulated markets, including the US, EU, Brazil, India, and global regions, with many receiving regulatory approvals."

PATENT RELATED ACCOMPLISHMENTS

"Led and completed patent-related activities for innovative formulations, including Soft Gelatin Capsules, Higher Strength Tablets, and Novel Sublingual Tablets, contributing to the development of intellectual property and enhancing product differentiation."

KEY RESULT AREAS AND TECHNICAL SKILLS

- Conduct literature searches, reference product characterization, and prepare strategy, product development, and dissolution method development reports for Oral Solid Dosage Forms (OSD) and oral liquid formulations.
- Plan and execute preformulation studies, prototype development, stability study batches, pilot bioequivalence studies, and DOE/QbD/optimization batches, along with maintaining associated documentation.

- Manage licensing activities and procure raw materials, tooling, change parts, and reference products.
- Assist in scale-up, process optimization, validation, bioequivalence/clinical study batches, technology transfer, API variation management, and third-party collaborations.
- Prepare critical documents, including specifications, Product Development Reports (PDR), Master Formula Records (MFR), Batch Manufacturing Records (BMR), technology transfer protocols, and regulatory query responses.
- Write and review lab notebooks, compile analytical data, and maintain updated project presentations.
- Design 505(b)(2) like formulations for incremental innovation, new strengths, dosage forms, novel combinations.
- Contribute to intellectual property generation through ideation and innovation; assist with patent drafting.
- Travel to CROs, CDMOs for clinical, scale-up, product launch, and process validation batch activities.
- Coordinate cross-functional resources with departments such as Business Development, Analytical Development Lab (ADL), Corporate Quality Assurance (CQA), Procurement, Production, MS&T, IP Management, Clinical, and Regulatory Affairs.

TECHNICAL EXPOSURE AND WORK EXPERIENCE

- Expertise in BCS-based bio-waiver requirements and IND applications, particularly for cytotoxic products.
- Proficient in developing dosage forms, including Immediate Release (IR), Modified Release (MR), Extended Release (ER), Delayed Release (DR), Bilayer, Minitablets, Osmotic, Matrix, Sublingual, Orally Disintegrating Tablets (ODT), Effervescent, and Multiple Unit Pellet System (MUPS) tablets, as well as pellets and hard/soft gelatin capsules.
- In-depth knowledge of regulatory standards, including cGMP, ICH guidelines, SOPs, and quality procedures.
- Skilled in non-infringing, first-to-file applications, prior approval supplements, reformulations, process improvements, troubleshooting, lifecycle management, market extension and supplement filings.

ORGANISATIONAL EXPERIENCE DETAILS

Senior Manager: Corona Remedies Private Limited, Bhayla (Ahmedabad region) — May 2024 – Present

Manager: IPCA Laboratories Limited, Mumbai — August 2022 – April 2024

Deputy Manager: BDR Pharmaceuticals International Private Limited, Vadodara — March 2021 – July 2022

Senior Research Scientist: Alembic Pharmaceuticals Limited, Hyderabad — July 2018 – February 2021

Associate Scientist: Lupin Limited (Lupin Research Park), Pune — October 2014 – July 2018

Scientist: VerGo Pharma Research Private Limited, Goa — February 2013 – August 2014

Product Development Officer: Accela Pharmaceuticals Private Limited, Pune — April 2012 – February 2013

Apprenticeship & On-Job Training: Shreya Life Sciences Private Limited, Aurangabad — 2011 – 2012

ACADEMIC CREDENTIALS

M. Pharm (Pharmaceutics) 2008–2010: Sudhakarrao Naik Institute of Pharmacy, Pusad, First Class (73%) – SGB University, Amravati, Maharashtra, India. **GATE Scores: 97.07 percentile (2008), 86 percentile (2007)**

B. Pharm 2005–2008: Government College of Pharmacy, Amravati, First Class (70%) – SGB University, Amravati, Maharashtra, India

PERSONAL DETAILS: Date of Birth - 7th December 1984, Languages Known - English, Hindi, Marathi

Mr. Vijay Agrawal