

R. JITHENDRA BABU

Manager – R&D | API Process Development | Technology Transfer | Commercial Scale-Up | Oncology APIs

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EXECUTIVE SUMMARY

Accomplished API Process Development leader with 19+ years of experience in Synthetic Organic Chemistry, Oncology APIs, Process Development, Technology Transfer, Commercialization, and Manufacturing Support. Demonstrated success in developing and commercializing API projects, executing technology transfer programs, and supporting DMF regulatory filing projects.

Proven expertise in developing robust, scalable, and cost-effective processes from laboratory development through commercial manufacturing. Extensive experience in process optimization, route scouting, impurity control, crystallization development, process troubleshooting, and commercialization of small-molecule APIs.

Successfully scaled processes up to **2000 L at Biocon** and **5000 L at Anugraha Chemicals** while leading teams of **8–10 scientists and chemists**.

KEY CAREER HIGHLIGHTS

- 19+ years of industrial experience in API Process Development and Synthetic Organic Chemistry
- Scale-up experience up to **2000 L at Biocon** and **5000 L at Anugraha Chemicals**
- Managed and mentored teams of **8–10 scientists and chemists**
- Extensive experience in **Oncology APIs** and **Small Molecule Development**
- Strong background in process optimization, crystallization development, impurity control, and troubleshooting
- Supported **DMF regulatory filing projects**
- Contributor to **3 US patents**

CORE COMPETENCIES

Process Development & Manufacturing

- API Process Development
- Synthetic Organic Chemistry
- Route Scouting & Route Selection
- Route Optimization
- Process Optimization
- Process Troubleshooting
- Commercial Scale-Up
- Technology Transfer
- Commercialization
- Manufacturing Support
- Crystallization Development
- Impurity Profiling & Control

Leadership & Project Management

- Team Leadership
- Cross-Functional Collaboration
- Technology Transfer Management
- Project Planning & Execution
- Resource Management
- Technical Mentoring

Regulatory & Documentation

- Process Development Reports
- Technology Transfer Dossiers
- DMF Support
- Technical Documentation
- Patent & Literature Search

PROFESSIONAL EXPERIENCE

Anugraha Chemicals Pvt. Ltd., Bangalore

Manager – R&D

Aug 2025 – Present

Responsibilities

- Lead API and advanced intermediate process development programs.
- Develop scalable and commercially viable synthetic routes.
- Manage and mentor a team of 8–10 scientists and chemists.
- Drive process optimization, technology transfer, and commercialization activities.
- Support manufacturing campaigns and process troubleshooting.
- Collaborate with Production, QA, QC, Regulatory Affairs, and EHS teams.

Key Achievements

- Successfully supported scale-up activities up to **5000 L manufacturing scale**.
- Improved process robustness and manufacturing readiness.
- Led high-performing development teams delivering project milestones within timelines.

Professional Career Break

Jan 2025 – Jul 2025

- Planned career break for personal health recovery.
- Maintained technical engagement through scientific literature review, patent evaluation, and industry developments.
- Returned to full-time employment as Manager – R&D.

Biocon Limited, Bangalore

Associate Scientific Manager – API R&D

Jul 2010 – Dec 2024

Responsibilities

- Led API process development projects for generic and oncology molecules.
- Developed scalable and cost-effective synthetic routes.
- Executed process optimization and impurity reduction studies.
- Conducted technology transfer from R&D to pilot plant and commercial manufacturing.
- Authored Process Development Reports and Technology Transfer Dossiers.
- Supported manufacturing campaigns through troubleshooting and continuous improvement initiatives.

Key Achievements

- Successfully commercialized multiple API development programs.
- Executed technology transfer projects supporting pilot and commercial manufacturing.
- Scaled processes from laboratory development to **2000 L manufacturing scale**.
- Established oncology development capabilities and containment practices.
- Supported DMF/ANDA-related development projects.

Alkem Laboratories Ltd., Bangalore

Research Scientist – API R&D

Sep 2009 – Jul 2010

- Conducted process development and optimization studies for generic APIs.
- Supported route optimization, impurity control, and manufacturing activities.
- Assisted scale-up and technology transfer programs.

Bal Pharma Ltd., Bangalore

R&D Officer – Synthetic Organic Chemistry

Mar 2007 – Sep 2009

- Performed synthesis of API intermediates and active pharmaceutical ingredients.
- Conducted process optimization and laboratory scale-up activities.
- Supported pilot plant operations and technology transfer programs.

TECHNICAL EXPERTISE

Analytical & Characterization Techniques

- HPLC
- GC-MS
- LC-MS
- NMR
- IR
- UV Spectroscopy
- Flash Chromatography

Specialized Equipment

- HEL Polyblock Systems
- Oncology Isolators
- Automated Reactors

Software

- ChemDraw
- Microsoft Word
- Microsoft Excel
- Microsoft PowerPoint
- Scientific Literature Search Tools

- Patent Search Databases

SCALE-UP EXPERIENCE

Organization	Scale
Biocon Limited	Up to 2000 L
Anugraha Chemicals	Up to 5000 L

PATENTS & INTELLECTUAL PROPERTY

Process for the Preparation of Teriflunomide

US10526279B2

Contributed to process development, optimization, and scale-up activities supporting commercial manufacture.

Polymorphic Forms of Dasatinib

US11059813B2

Contributed to development and characterization of Dasatinib polymorphic forms and solvates.

Process for Preparation of Cabozantinib

US20240190825A1

Contributed to development of a scalable and commercially viable synthetic process.

EDUCATION

Master of Science (M.Sc.) – Organic Chemistry

Sri Venkateswara University, Tirupati
2006

Bachelor of Science (B.Sc.) – Chemistry

Sri Venkateswara University, Tirupati
2004

LANGUAGES

- English
- Telugu
- Kannada
- Tamil

PROFESSIONAL PROFILE

API Process Development | Oncology APIs | Technology Transfer | Commercial Scale-Up |
Synthetic Organic Chemistry | Process Optimization | Crystallization Development | Impurity
Control | Manufacturing Support | Team Leadership | Commercialization | Regulatory Support