Dr. Bhaskar's Process Solutions

We drive innovation with collaboration

Dr. P. Muni Bhaskar, Ph.D.

Scientific & Technical Strategist

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About Us

- **Dr. Bhaskar's Process Solutions is a science based innovation driven firm offers solutions for chemical process development of pharmaceutical active ingredients (APIs) / Intermediates and Key starting materials.**
- **We partner with Life sciences and Pharma companies to support Drug Discovery & Development and Active Pharmaceutical Ingredient (API)/ Intermediate process development projects.**
- **Located in Hyderabad with a Chemical Research Laboratory and a team of experienced scientific and technical professionals.**
- **We stand ready to help R&D efforts in achieving the project goals with collaboration.**

Scientific & Technical Leadership

Dr. Bhaskar's Process Solutions

- Organic chemist with 21+ years of hands-on experience in pharmaceutical process R&D, specializing in process development, scale-up, and technology transfer of APIs and intermediates.
- Brings a strong blend of technical excellence and business acumen, adding value by pioneering robust R&D solutions, addressing complex scientific challenges, guiding teams, and working closely with multiple stakeholders to deliver results.
- Recognized for effective investigation, proactive problem-solving, and clear, timely communication throughout the project lifecycle

Dr. P. Muni Bhaskar

Organic Chemist | Process R&D

Education & Achevements

- BSc, S.G.S. Arts College, Tirupati (Sri Venkateswara University), (A.P.) 1992
- MSc (Organic Chemistry), Sri Venkateswara University, Tirupati, (A.P.) 1994
- Ph.D. from Indian Institute of Technology Madras, Chennai (1995-2000).
- Post-Doctoral Fellow at TCHK, RWTH Aachen University, Germany (2001-2003).
- Published 4 research articles in referred journals, 5 patent applications and 2 LinkedIn articles.
- Lean Six Sigma Black Belt training from American Society of Quality (ASQ).

Dr. Bhaskar's Process Solutions

Vision	Mission
To be a premier scientific and technical organization delivering trusted solutions, innovative products, and deep expertise across the chemical, pharmaceutical, and allied sectors.	To add value to our customers through continuous learning, adaptable thinking, and the development of smart, effective solutions using the most suitable technologies

Our Values

Innovation

We share our knowledge and decades of expertise to drive innovation.

Commitment

We always stretch for the success of our clients and partners.

Trust

Building lasting relationships with integrity and transparency.

Collaboration

We Work hand-in-hand with clients and empower them in making decisions.

Quality

We always strive to deliver excellent quality.

Our in Expertise in Chemisty

Dr. Bhaskar's Process Solutions

- We are proficient in organic synthesis and process development of active pharmaceutical ingredients (APIs), intermediates and starting materials.
- Our key areas of expertise in chemical process development include
  - Organic synthesis, carbohydrate chemistry, oleochemistry, heterocycles, macrocycles.
  - Peptides, Oligonucleotides
  - chiral ligands, asymmetric synthesis, chiral separations.
  - Heterogeneous catalysis, zeolite catalysis
  - Complex APIs, High potent APIs,
  - Identification, synthesis and isolation of impurities
  - Crystallization and polymorphism,
  - Characterization using analytical techniques.
  - Process scale-up and Technology Transfer

We have expertise in developing efficient synthetic routes and delivering products from milligram to kilogram quantities meeting the needs of different customers.

Our Expertise in API / Intermediates

Dr. Bhaskar's Process Solutions

We have extensive experience in process development for Active Pharmaceutical Ingredients (APIs) and intermediates across various therapeutic segments, including:

- Anti-cancer drugs
- Cental nervous system drugs
- Atypical antipsychotics
- Antifibrinolytics
- Parkinson’s disease
- Cardiovascular drugs

Our expertise enables the development of robust, efficient, and well-characterized processes that adhere to GMP standards and regulatory requirements

Chemical Reaction Capabilities

- Alkylation & Acylation
- Amination
- Bromination
- Condensation
- Friedel-Crafts acylation
- Grignard Reactions
- Suzuki-Miyaura Coupling
- Esterification & Trans-esterification
- Amidation
- Azidation
- Aromatic nucleophilic substitution
- Hydrolysis
- Oxidation & Reduction
- Hydrogenation

Lab Facilities

600 Sq. feet area research laboratory. Work benches with exhaust system. Overhead and magnetic stirrers. Rotary evaporator. UV Chamber. High Vacuum pumps. Electronic balances. Refrigerator.

End-to-End Process Development Partnership

Dr. Bhaskar's Process Solutions

We support NCE and API/intermediate process development from early-stage route design and optimization through scale-up and commercial manufacturing.

LITERATURE REVIEW, ROS PROPOSAL	FEASIBILITY STUDIES, ROS SELECTION	PROCESS OPTIMIZATION, VALIDATION	PROCESS SCALE-UP, TECH TRANSFER	MANUFACTURING
• **Literature search,** • **Design of ROS** • **Evaluation with respect to:** • **raw material availability,** • **number of stages,** • **workup and purification,** • **yield, quality,** • **raw material cost,** • **safety.**	• Feasibility studies, • ROS selection • Justification for selected ROS (e.g., novelty, nonobvious, industrial applicability and cost-effectiveness) • IP management, • RMC evaluation	• **Optimization of reaction conditions, DOE and QbD.** • **Critical process parameters (CPP),** • **Identification of impurities and control** • **In-process and intermediate controls,** • **API specifications,** • **Process validation,** • **Solvent recovery, reuse,** • **TTD preparation**	• Review of TTD, • Process safety, Equipment selection • Cleaning and decontamination procedures. • Trial batches, • Process modification with a change control, • Process validation on large scale. • Support on DMF submission and approval	• Manufacturing with Validated process • Storage • Stability data evaluation • Address DMF queries from customer/ regulatory authority • Continual improvement

Process Research & Development

We stand ready to assist and collaborate with your R&D team to support process research and development for APIs/ Intermediates and related molecules. We support on to development of a novel process or improvement of an existing process.

Key services include:

- Assessment of quality target product profile (QTPP) and critical quality attributes (CQAs) of an API / Intermediate.
- Route of synthesis (ROS) design for a proposed API/ Intermediate.
- Feasibility studies, evaluation of raw material cost (RMC) and justification for selected ROS.
- Intellectual Property (IP) management aspects such as patent infringement analysis, design of patent non-infringing process.
- Process optimization based on quality by design (QbD) approach and Process validation.
- Supporting on experiment design to improve process efficiency and cost reduction.

Process Scale-up and Tech transfer

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We help to achieve success in process scale-up and tech transfer of APIs and Intermediates as a trusted partner in collaboration with different departments of your company including R&D, quality control, quality assurance, production and environment health and safety (EHS).

Key services include:

- Assessment and control of impurities (e.g. process, degradation, genotoxic, nitrosamine and elemental impurities) to ensure product quality
- Process review with a science-based quality risk management (QRM) approach to ensure product quality and safety.
- Perform gap analysis and suggest required control experiments (e.g., what if studies) to achieve “First Time Right” and to ensure process robustness.
- To help on troubleshooting a chemical process during scale-up and manufacture.

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Structural Elucidation and Characterization

Structural elucidation and characterization is an important aspect to ensure the quality of raw materials, intermediates and final API and reference standards used for analytical method development.

Key services include:

- Helping on use of right analytical techniques for structural elucidation and characterization.
- Analytical services (e.g. NMR, Mass, LC-MS, IR, UV/VIS, DSC, TGA and XRD)
- Interpretation of analytical data for characterization of APIs, Intermediates, KSMs and impurities;
- identification and structure elucidation of known and/ unknown impurities;
- characterization of different polymorphic forms of an API.
- Preparation of structural confirmation report which can be used for regulatory filings.

Solid State Chemistry

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Polymorphism is the property of a solid-state chemical substance to exist in different crystalline forms.

The subject of polymorphism has a special interest in pharmaceutical industry as it affects discovery, development and manufacturing process of a drug substance and has impact in legal and regulatory decisions.

Key services include:

- Polymorph screening of APIs
- Different solid forms of an API – salts, co-crystals, solvates and hydrates.
- Amorphous solids
- Characterization of solid forms
- Stability studies
- Intellectual property and Regulatory issues

Contained Chemistry

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Leveraging the continual understanding of disease with advanced technologies showed a significant and increasing portion of high potent drugs in pharmaceutical industry.

Key area of services offered in potent API process development and manufacture include:

- Categorization of potent compounds.
- Process development
- Facility design and containment controls for safe handling of potent compounds and manufacture operations.
- Cleaning and decontamination procedures.
- Training

Project Management Services

We provide strategic guidance and project management services, which includes:

- Creating project plans and defining objectives.
- Support documentation to ensure critical information, provide guidance for preparation of technology transfer documents (PDR/TTD).
- Supporting on review of third-party technology transfer documents and to help on process scale-up and technology transfer to manufacturing site
- Conducting due diligence and overseeing project progress.
- Offering guidance on current Good Manufacturing Practices (cGMP) and regulatory compliance.
- Support on Chemistry, Manufacturing, and Controls (CMC) sections for regulatory submission documents such as Drug Master File and New Drug Application (NDA)

In conclusion our offerings include

Dr. Bhaskar's Process Solutions

- **Consultancy Services**

  Organic Synthesis, Process Research, Characterization, Risk assessment,

  IP Management, Technology Transfer, Quality & Regulatory compliance.

- **Trainings**

  Process Development, Potent compounds, Documentation, Data Integrity, GMP,

  ICH guidelines, SOPs

- **Custom Synthesis Services**

  Process R&D services for Technology Development, Synthesis of KSMs, Intermediates,

  Synthesis of API related substances, Crystallization & Polymorphism

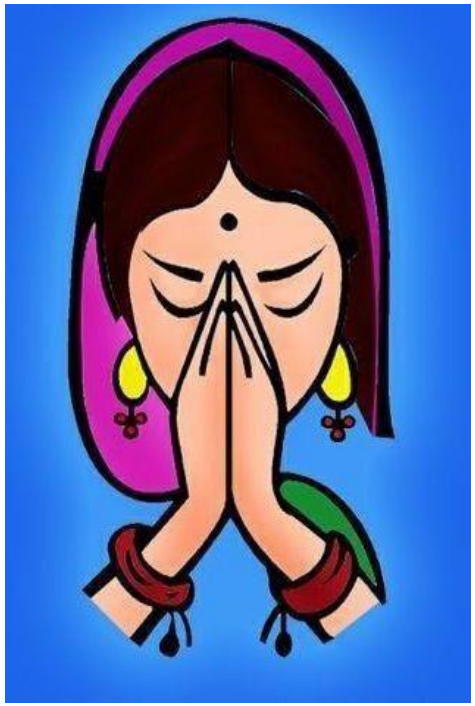
- **Project Management Services**

  Due diligence, Guidance on GMP and regulatory submissions

- **Products**

  KSMs, Intermediates and Impurities.

  For product list visit: www.drbhaskarssolutions.com



THANK YOU

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