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**Dr. Bhaskar's
Process
Solutions**

HIGHLIGHTS

The aim of our services is to support chemical, pharmaceutical and life sciences companies to achieve the planned objectives with innovative solutions. We offer consultancy services in areas of chemistry, manufacturing, and controls (CMC) for process development and manufacture of active ingredients (APIs), intermediates and starting materials. Key services offered, including but not limited, are the following:

- Strategic plans to process development activities such as quality target product profile (QTPP) and critical quality attributes (CQAs) assessment, route of synthesis (ROS) design, feasibility studies, raw materials cost (RMC) evaluation.
- Intellectual Property (IP) management aspects such as patent infringement analysis, design of patent non-infringing process.
- Process optimization with a quality by design (QbD) approach.
- Supporting on experiment design to improve process efficiency and reduce raw material cost.
- Assessment and control of impurities (e.g. process, degradation, genotoxic, nitrosamine and elemental impurities) to ensure product quality.
- Support documentation to ensure recording of critical information, provide guidance for the 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.
- To help on troubleshooting a chemical process during scale-up and manufacture.
- 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.
- Customized training courses on topics such as ICH guidelines, technology transfer, and safe work practices.

KEY AREAS OF SERVICES

Chemicals/ Drugs R&D, APIs/Intermediates/KSMs, Impurities, High-potent APIs, Complex APIs, Organic Synthesis, Route Scouting, Process development, Process Validation, Quality Risk Management, Process Safety, Process Review, Technology Transfer, Polymorphism, Stability Studies, Regulatory compliance, GxP, Good Manufacturing Practice (GMP), Outsourcing and Training.

Please call or e-mail to discuss scope