



Our CMC department focuses on establishing large-scale synthetic routes along with formulation development and quality control, our drug categories can be proprietary drugs or generic drugs. All studies are complied with

➤ Project Advisory & Planning

- Feasibility study
- Project planning

➤ Synthesis

- Establish synthesis
- “Freeze” the synthesis
- Establish large-scale

➤ Formulation Development

- Preformulation testing
- Formulation development
- Process optimization
- IVIV correlation
- Scale up



➤ Analytical Development ➤

- Establish HPLC methods for API, impurities, isomers and drug product
- Develop HPLC method for stability testing
- Conduct HPLC method validation
- Set API and drug product specifications

➤ Stability Study ➤

- Perform stability study for API and drug product under ICH & SFDA guidelines
- ICH / CFDA

➤ Regulatory Submissions ➤

- Prepare documentation for regulatory submissions
- Prepare supporting documentation and data package

Our CMC experts with decades of experience are familiar with various ICH and CFDA regulations and guidelines, and have helped many clients completed their pre-formulation and formulation studies to provide reliable data for the regulatory submissions. We have already successfully assisted many clients completed the 1.1 class, 3.1 class and 6 class new drugs for CFDA application.

我们CMC专家拥有数十年的工作经验，熟悉各种ICH和CFDA的法规和协助或法规指导，帮助很多客户顺利完成申报，他们的药物制剂前和药物制剂研究，申报川疆澳、西藏、爱、漆、著、虞忧、臣、竜丞于很多影响，申报1.1类、3.1类和6类新药，CFDA申报。

Robust methodology! Precise analysis! Accurate results!

Please contact us for more information on how we can help move your drug along the development pathway.