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, impurites, isomers and drug product
- Develop HPLC method for stability testng
- Conduct HPLC method validaton
- Set API and drug product specificatons

Stability Study

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

ICH CFDA

Regulatory Submissions

- Prepare documentaton for regulatory submissions
- Prepare supportng documentaton and data package

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

我们CMC专家拥有数十年的工作经验，熟悉各种ICH和CFDA的法规和助或艒规鞾褒鬻助很多僉跟核曮刭利核婳鍕了他们的药物制剂前和药物制剂研究襯瀢癸寮Ⅲ缰攥ヴ薤鼈跕鏰誼漆畣一剟廮忧昗镸嚹褺臂彲很多影鉿炚髓舄碃1.1类谚3.1类和6类缘坐 y CFDA申抱夺

Robust methodology! Precise analysis! Accurate results!

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