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 ICH and CFDA guidelines.

美迪西为客户提供合成工艺优化、合成路线确定、制剂工艺研究和药物质量研究等制剂与质量研究服务，药物类型从专利药到仿制药，所有的实验研究均按照ICH和CFDA指导原则执行。

Project Advisory & Planning

- Feasibility study
- Project planning

项目咨询规划

- 项目注册法规可行性
- 项目技术可行性

Synthesis

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

合成工艺研究

- 合成路线确定
- 合成工艺优化
- 合成工艺放大

Formulation Development

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

制剂工艺研究

- 处方前研究
- 处方筛选
- 工艺优化
- 体内外相关研究
- 工艺放大

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

质量分析研究

- 原料药，杂质，异构体及制剂分析方法建立
- 分析方法稳定性研究
- 分析方法验证
- 质量标准确定

Stability Study

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

稳定性研究

- 按照ICH和CFDA指导原则进行长期稳定性试验和加速试验

Regulatory Submissions

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

注册申报

- 注册资料的整理
- 注册资料的翻译和数据整理

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 calss 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的法规和指导规则，帮助很多客户顺利完成了他们的药物制剂前和药物制剂研究，为申报资料提供了可靠的数据。其中，我们成功地协助很多客户完成了1.1类，3.1类和6类新药的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.