



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

### ➤ 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,
- 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 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.