Medicilon—CFDA GLP，FDA GLP，AAALAC

Chemistry Services/化学服务

Medicilon provides fully integrated pharmaceutical services to the global pharmaceutical community. The services across biology, chemistry and preclinical research are specially designed to help clients develop their research and discovery programs from the initial idea stage to the IND filing phase. Chemistry department in Medicilon provides custom synthesis, medicinal chemistry, focus library preparation, and process and scale-up synthesis. Either in FTE or integrated project team arrangement, our medicinal chemistry group has helped clients discover novel, potent, and highly drugable chemical series. Our contribution has led to several pre-clinical and clinical candidates. We also provide scale up service to deliver kilogram of material with high-quality and on-time delivery.

Medicilon is headquartered in Zhangjiang High-Tech Park , Shanghai, China, with wholly-owned research facilities in Chuansha Economic Park, Shanghai, China. We occupy over 250,000 SF lab space. Over 60% employees have MS and PhD degrees, and over 15% of our employees have significant foreign education and/or working experiences. We has a 55,000 SF chemistry laboratory, equipped with state-of–the-art equipments, such as NMR, LC/MS, HPLC and preparative HPLC. Our chemists have extensive experiences cooperating with Medicilon biologists and preclinical scientists. We strive to enhance the potency, selectivity and pharmacokinetic characteristics of drug candidates.

上海美迪西生物医药有限公司是一家提供集化学、生物学、药效学评价、药代动力学评价和毒理学评价为一体的一站式生物医药研发服务公司。美迪西化学部提供合成定制、药物化学、化合物库合成以及工艺放大合成等服务，同时也提供FTE及一站式的项目管理服务。我们的科学家团队已经为客户开发了一系列有药学活性的有效的新化合物，并成功的筛选出临床前和临床候选物。并且，我们的化学部可规模化合成公斤级样品，能确保高品质的产品准时交货。

公司总部座落在上海张江高科技园区，并在上海川沙经济园区设有研发大楼。公司现有员工超过60%拥有博士学位或者硕士学位；超过15%的员工拥有国外教育背景和/或工作经验。美迪西拥有25,000平方米实验室，其中5,500平方米是配有先进分析仪器的化学实验室，包括核磁共振波谱仪、液相色谱质谱联用仪、高效液相色谱和制备型高效液相色谱等。我们的化学家有丰富的经验，与美迪西生物学家和临床学家的紧密合作，保证了我们提供的药物候选物具有更好的药物活度、选择性和药代动力学性质。

Our chemistry department possesses advanced synthetic medicinal chemistry skills, and has an excellent record-tracking system to progress programs and generate preclinical candidates. We can rapidly transform your drug discovery program from hit screening to SAR-driven medicinal chemistry in an efficient, and cost effective manner. We use state-of-the-art parallel synthesis and purification technology to prepare high-quality compound libraries. Our chemists have extensive experiences in working with clients on hit to lead and lead optimization for candidate's programs, and in converting medicinal synthetic routes of compounds into processes that make multi-kilogram quantities to support animal studies within a restricted time frame.

我们的化学部拥有专业的合成技术，对推进项目和生产临床前候选药物有良好的追踪记录。我们能以高效率，低成本的方式，迅速转换从化合物筛选到基于构效关系的化学药物开发项目。我们使用最先进的高通量平行合成技术和纯化技术制备高品质的化合物库。我们的化学家有丰富的经验，能将医药化合物的合成转化到数公斤的工艺路线，确保动物研究能在非常严格的时间限制内完成。

Medicinal Chemistry

- Hit to lead and/or lead optimization
- Computer aided drug design (CADD)
- Structure Activity Relationship (SAR) campaign
- Final lead optimization and candidate nomination
- Process development of preclinical candidate

药物化学

- 先导化合物筛选和优化
- 计算机辅助药物设计
- 构效关系研究
- 先导化合物和候选化合物的确定优化
- 临床前候选化合物的工艺优化

We utilize medicinal chemistry efficiently and cost-effectively to move forward our clients' drug discovery projects to candidate nomination, preclinical development, and IND.

我们利用药物化学高效率地推动客户的药物研发项目，促使新药流程更早地进入候选物的确定、临床开发和新药申请，有效地帮助客户控制了新药开发成本。

Custom Synthesis

- High quality products from mg to kg scale
- Reagents, intermediates, building blocks, and scaffolds
- Preparation of API or reference standards
- Development of synthetic routes for impurities and metabolites

客户订制合成

- 从毫克级到公斤级高质量产品制备
- 特殊试剂、中间体和分子片段制备
- 原料药或相关物质的制备
- 杂质和代谢产物合成设计和制备

Medicilon has synthesized over 10,000 individual compounds from gram to kilogram quantities, and many compounds are synthesized with more than ten synthetic steps. The overall synthesis success rate is over 95%.

美迪西已经合成了超过10,000个从克级到千克级别的化合物，其中许多化合物的合成步骤超过10步，成功率达到95%。

Process and Scale up Synthesis

- High quality products in multi-kilogram quantities
- Process development, route scouting and optimization

工艺放大合成

- 公斤级高质量产品制备
- 工艺研究和路线设计优化

We have sucessfully supplied one client 6 kgs of product with eight synthetic steps within a very short period, including reaction optimization.

我们曾经在很短的时间内提供客户6公斤的具有8步合成步骤的产品，并且成功地优化了工艺路线。

Library Synthesis

- Design and synthesis of focused libraries
- Solution phase parallel synthesis
- Hands on experience in solid phase synthesis
- Automated purification capability

化合物库的合成

- 针对特定靶标化合物库的设计与合成
- 液相的平行合成
- 固相合成
- 自动纯化能力

We utilize medicinal chemistry and computational chemistry to design and synthesize drug-like templates and libraries of compounds to increase our clients' compound collections. The annual capacity of library production is more than 100,000 compounds.

我们利用药物化学和计算机化学设计合成出类药模板化合物和化合物库，给客户提供更多更好的选择。我们每年化合物库的生产能力超过100,000种化合物。

Analytical Chemistry

- High throughput purification and analysis capability
- Structure and purity determination
- Impurity characterization
- Chiral purification
- Water content and residual solvent
- Certification of analysis (COA)

分析化学

- 高通量分离纯化和分析能力
- 结构和纯度鉴定
- 杂质鉴定
- 手性化合物分离纯化
- 水分含量和溶剂残留测定
- 分析报告

Well-designed and well-validated analytical methodology is critical to data integrity and central to our approach. We work closely with clients to ensure that our methodology will yield accurate results. Meanwhile, our precise quality systems ensure that all the facilities, equipment, methods, practices, records, and controls will be tightly complied with our regulations, study protocols, and standard operating procedures.

分析方法的精心设计，良好的验证是数据完整性至关重要的因素，也是我们方法最关键的部分。我们与客户紧密合作，以确保我们的方法将产生出准确的结果。同时，我们严谨的质量体系确保设施、方法、执行、记录、控制、维护都符合法规，研究协议和标准操作程序要求。

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.