



A leading integrated operator with its core  
competitive advantage in global pharma market

A light gray world map is centered in the background of the slide, showing the outlines of continents and major landmasses.

# **Introduction of CRO&CMO Service**

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# Brief Description of R&D and Some Highlight Points



# Profile

- Located at the innovation park of Taizhou chamber of commerce
- Total area: 3000 sqm
- Total employees: 20 chemists ( 3 PhD, 17 MSc technicians )
- Equipped with advanced test instruments such as HPLC, GC-MS, Particle size analyzer, UV, IR, Multinuclear NMR(400MHz)
- What we can offer
  - Synthesis of new compound
  - New highly-safe synthetic routes Selection
  - Process Development & Optimization in Industrial Scale
  - Analytical Method Development and Qualification



# Partnership-Based R&D Philosophy

- Focus on new inherently highly-safe synthetic routes
- Applying innovative approaches to synthesis that provide our customers with the highest levels of science, industrial technology and innovation
- Constantly evaluating and adopting new emerging technologies and improved techniques in chemical synthesis
- Optimizing API synthesis and purification processes
- Specific Projects evaluation and Technology Transfer Task Forces
- Full respect for our customers' Intellectual Property.

# Broad-based Chemical Expertise

- Sulfur (thiols and thioethers) and oxidated sulfur (sulfoxides and sulfones)
- Metalorganic chemistry
- Non-conventional oxidation reactions
- Free radical chemistry
- Hoffmann degradation / rearrangements
- Synthesis of chiral compounds
- Classical condensation reactions (including Aldol and Claisen)
- Mild and catalytic C-C bond forming reactions (including Heck and Suzuki-Miyaura)
- Cryogenic carbanionic chemistry
- Heterocyclic chemistry

# Key Technologies

- Chiral synthesis
- Catalytic technologies using organo-transition metal chemistry
- Grignard reactions and processes
- Metal hydride reductions
- Azide chemistry
- Ozonolysis
- Oxidations (hydrogen peroxide, sodium hypochlorite, Swern type etc.)
- Diazotization and related reactions
- Ion exchange chromatography
- Asymmetric amino acids transformations by diazotation
- Low and High temperature reactions (from  $-80^{\circ}\text{C}$  to  $250^{\circ}\text{C}$ )



# Team Leader & Senior Project Supervisor

- Doctor of Science of Lanzhou University
- Research in the synthesis of natural products and technology development of pharmaceutical fine chemicals and published more than 10 papers
- Involved in 6 application technology development projects
- Leader in 2 projects supported by the National Natural Science Foundation of China
- Won first prize of Science and Technology Progress Award by the Ministry of Education (2008)
- Won second prize of National Science and Technology Progress Award (2009)



Shijun Da, Ph.D.

# Team Leader & Senior Project Supervisor

- Doctor of Science of Lanzhou University
- Research in preparation and application of industrial catalyst and Nano catalyst.
- Leader in the project in Gansu province supported by National Natural Science Foundation for Distinguished Young Scholars of China and other two Foundation projects supported by Gansu Province, publish more than 10 SCI papers.
- Lead school-enterprise cooperation projects to improve the industrial development.



Zhengping Dong, Ph.D.

# Team Leader & Senior Project Supervisor

- Doctor of Science of Shenyang Pharmaceutical University
- Rich experience in new drug development, production and drug registration
- Expert in the research and application for drug delivery system and Industrial pharmacy
- Leader in 2 projects in Guangdong province supported by the National Natural Science Foundation of China, publish more than 6 SCI papers and hold 4 national patents



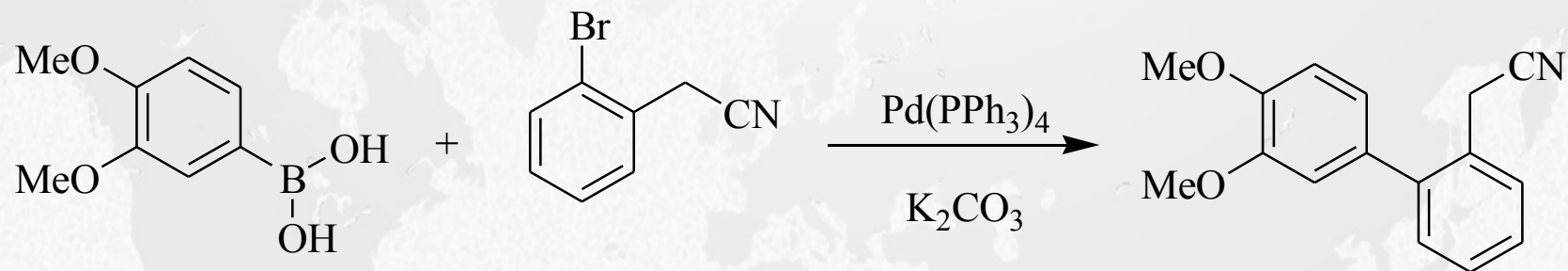
Shixia Guan, Ph.D.

# Contract Lab

- 600MHz Nuclear Magnetic Resonance Spectrometer for Liquid-solution
- 400MHz Nuclear Magnetic Resonance Spectrometer for Liquid-solution
- Esquire 6000 Ion Trap Mass Spectrometer
- Fourier Transform Ion Cyclotron Resonance Mass Spectrometer
- TRACE DSQ GC/MS
- X-ray Single Crystal Diffractometer
- XRD-6000 Diffractometer
- Thermal Analyzer

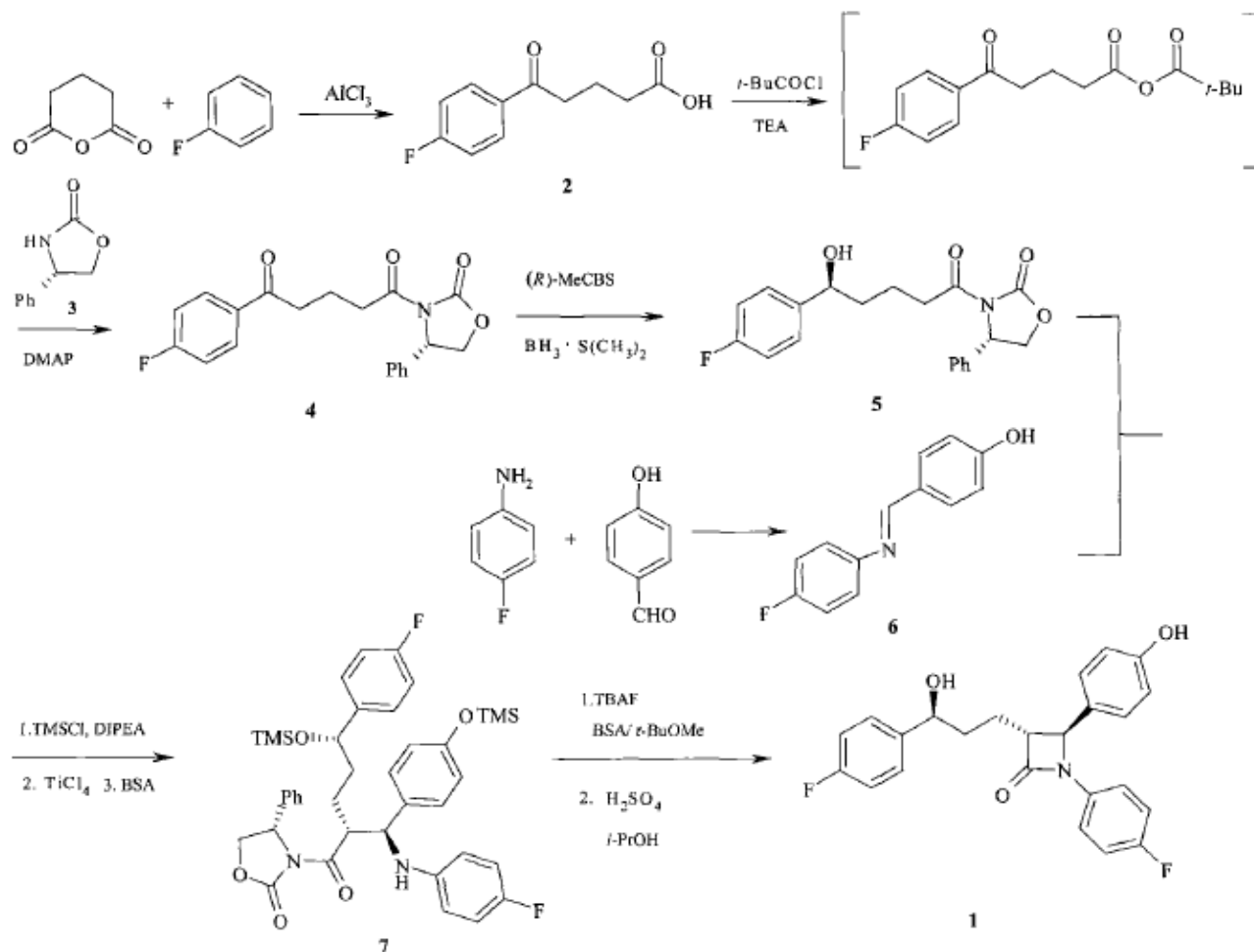


# Good Examples



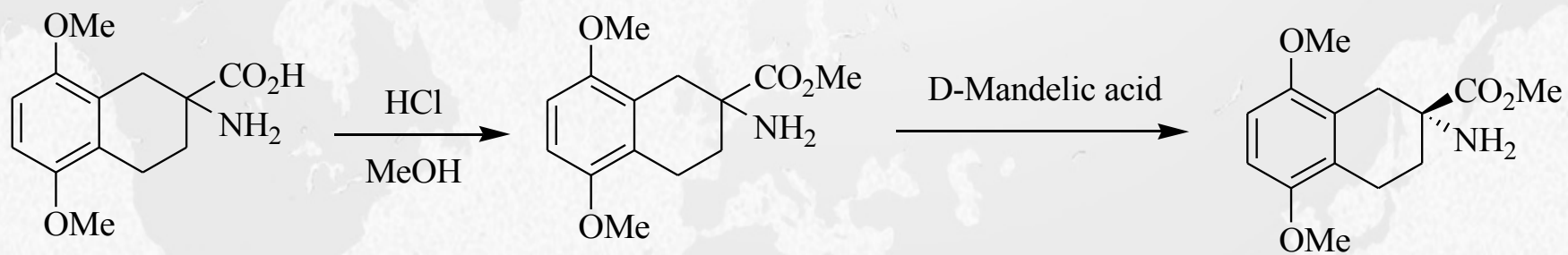
HECK Reaction

# Good Examples



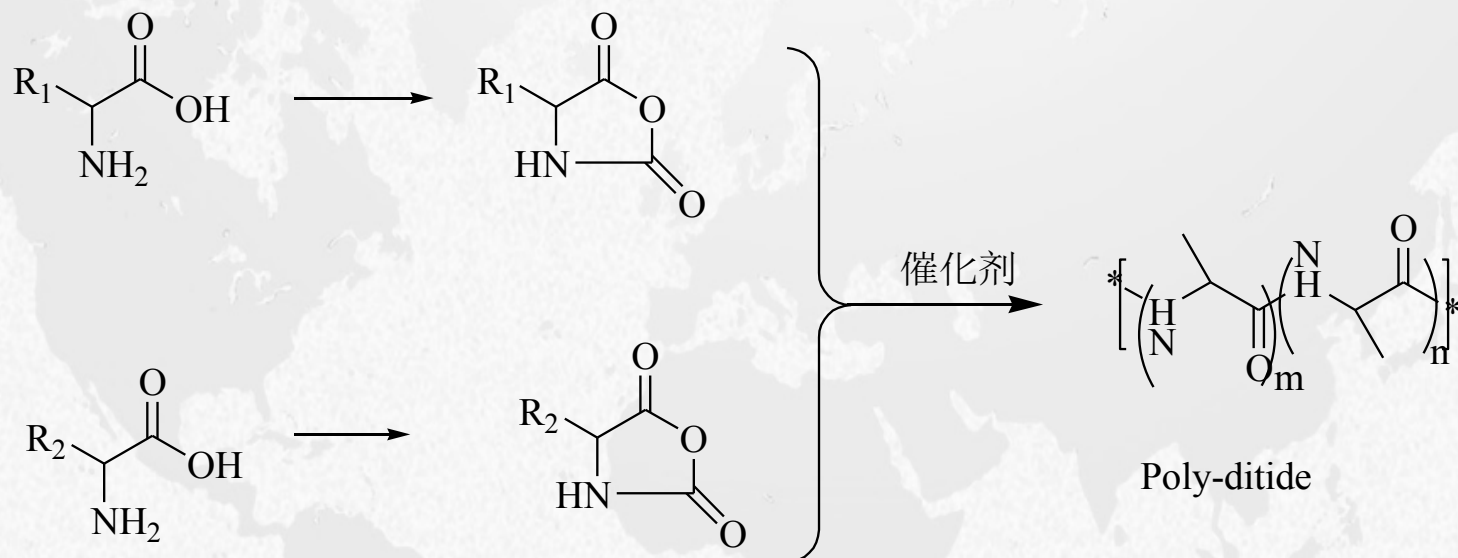
Chiral Chemistry

# Good Examples



Chiral resolution

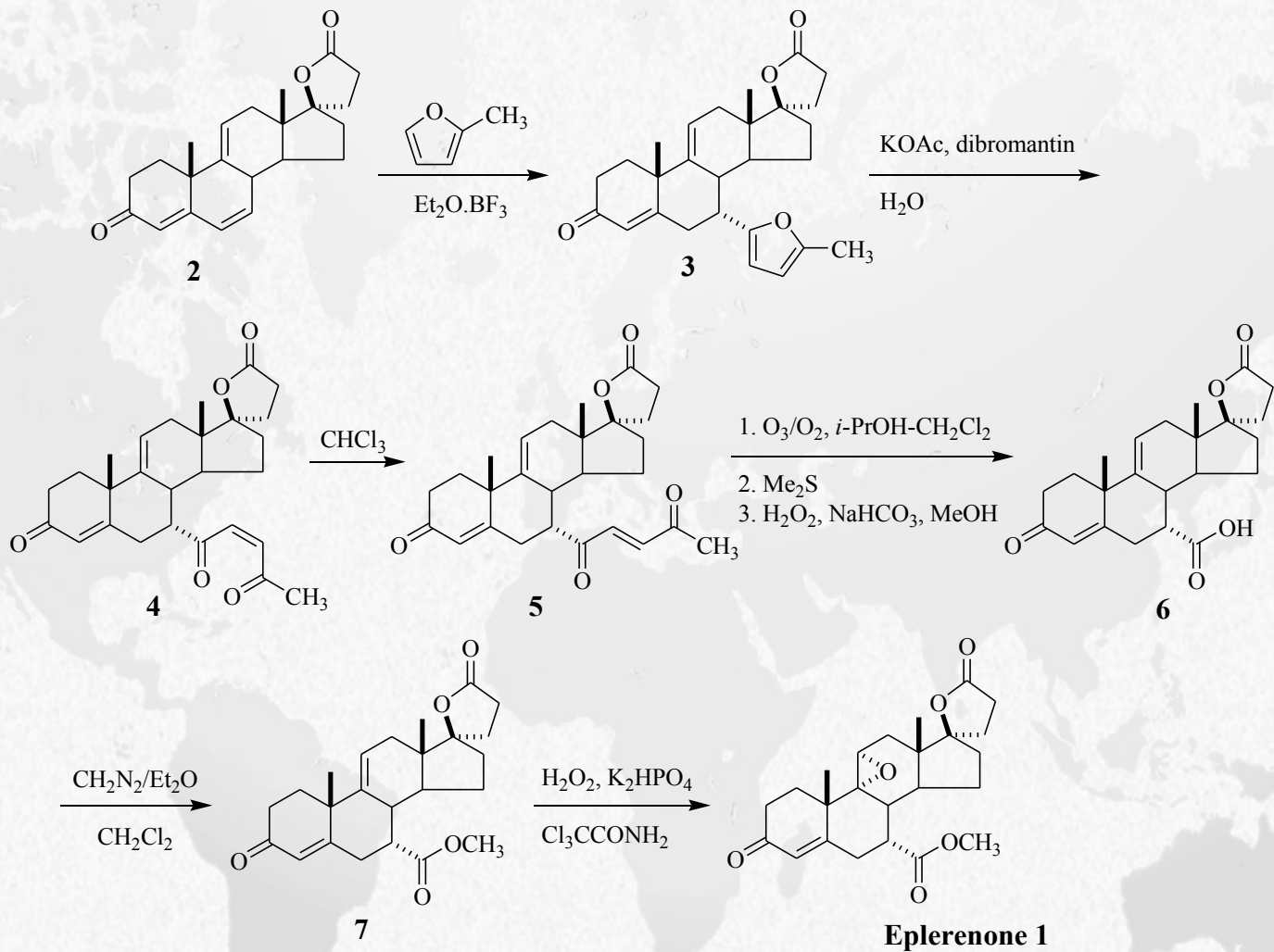
# Good Examples



Poly-peptide Reaction



# Good Examples



Ozonation Reaction

# Production on Pilot & Industrial Scale



# Pilot Capacity

- Total area: 1300 square meters
- Total reactor capacity: 60,000L, include 200L/300L/500L/1000L/2000L/3000L
- Production output: 20 tons intermediates/ APIs per year
- Finishing area classified as class D: 500 square meters
- Temperature range : -40°C-250°C



# Industrial Capacity

- Construction area: 12,000 square meters
- Total reactor capacity: 1,500,000L
- Production output: 5,000 tons intermediates/ APIs per year
- Clean room is designed and operated in strict accordance with current GMP standard. And the finishing area classified as Grade D: 3,000 sqm.



# Quality Control

## List of Main Testing Instrument

Name	Quantity
高效液相色谱仪 (HPLC)	10
红外光谱仪 (IR)	2
紫外可见分光光度计 (UV)	2
气相色谱仪 (GC)	8
电子分析天平 (Electronic balance)	7
顶空进样器 (Head space Injector)	2
超净工作台 (Clean bench)	3
自动旋光仪 (Automatic Polarimeter)	2
电位滴定仪 (Electronic Titrator)	2
卡氏水分测定仪 (Karl-Fischer Moisture Titrator)	3
稳定性试验箱 (Stability Chamber)	5
浮游菌采样器 (Microbio Air Sampler)	1
尘埃粒子计数器 (Dust Particle Counter)	1



# Quality is our Key Driver

QA/RA team to ensure compliance with the highest international standards and implementation for GMP :

- Certified as GMP compliance by Chinese CFDA, Japan PMDA, EU authorities.
- Audits from major worldwide multinational companies.



# Respect for the Environment

- The waste disposal are strictly performed according to the requirements for the national laws and regulations.
- Advanced waste treatment facilities are put into operation with the investment of USD 5 million and annual operating expense up to more than USD 1.5million.
- Capacity of wastewater disposal: 5,500 MT per day.
- Discharge Standard:  $COD \leq 500\text{mg/L}$  ;  $BOD \leq 300\text{mg/L}$  ;  $SS \leq 400\text{mg/L}$ ,  $pH = 6-9$ .



# Caring for the Health

- Materials are conveyed by pipeline as far as possible.
- All employees are given physical examination regularly.
- Protective apparels, such as eye protector, gloves, anti-poison respirator, labour suit and etc. are provided.





# Paying Attention to the Safety

- Wear labour suit, use safety protective apparel articles to avoid the occupational injuries.
- Follow SOP strictly to conduct all production activities.
- All equipments and facilities are equipped with safety protection devices or labeled warning signals to prevent the incidents occurring.
- Conduct periodic safety inspection.

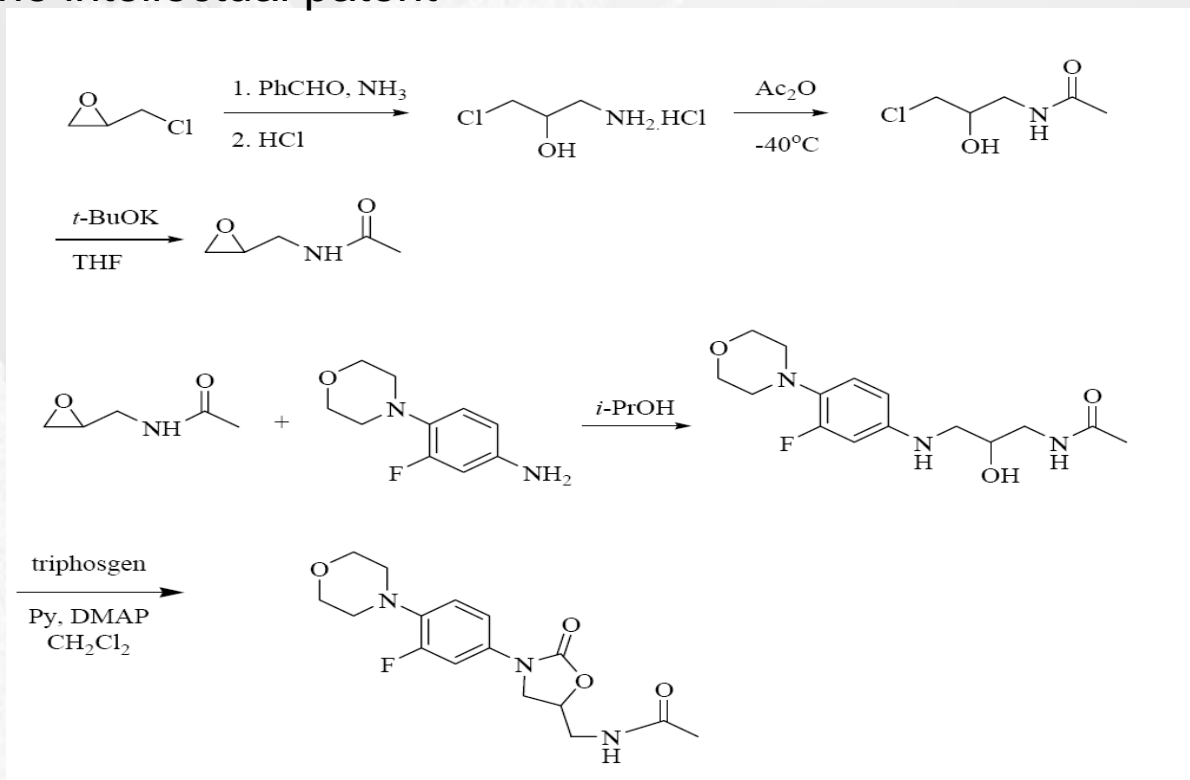


**必须戴安全帽**  
MUST WEAR SAFETY HELMET

# Case Study

## Example 1: Linezolid

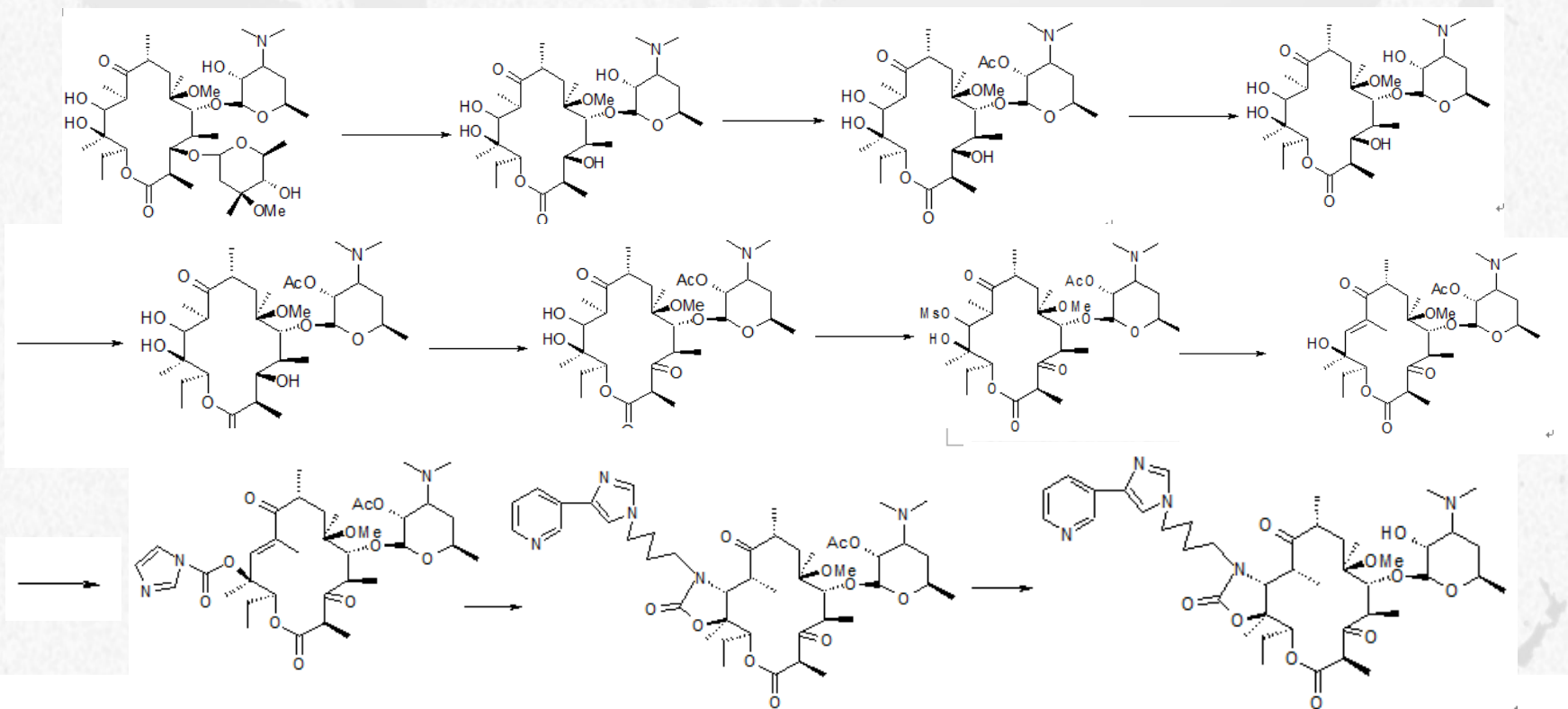
- Route of synthesis was developed within 15 days in Lab, and 100g of samples were obtained and the quality of which meet the requirements of customer.
- Hold one intellectual patent



# Case Study

## Example 2: Telithromycin

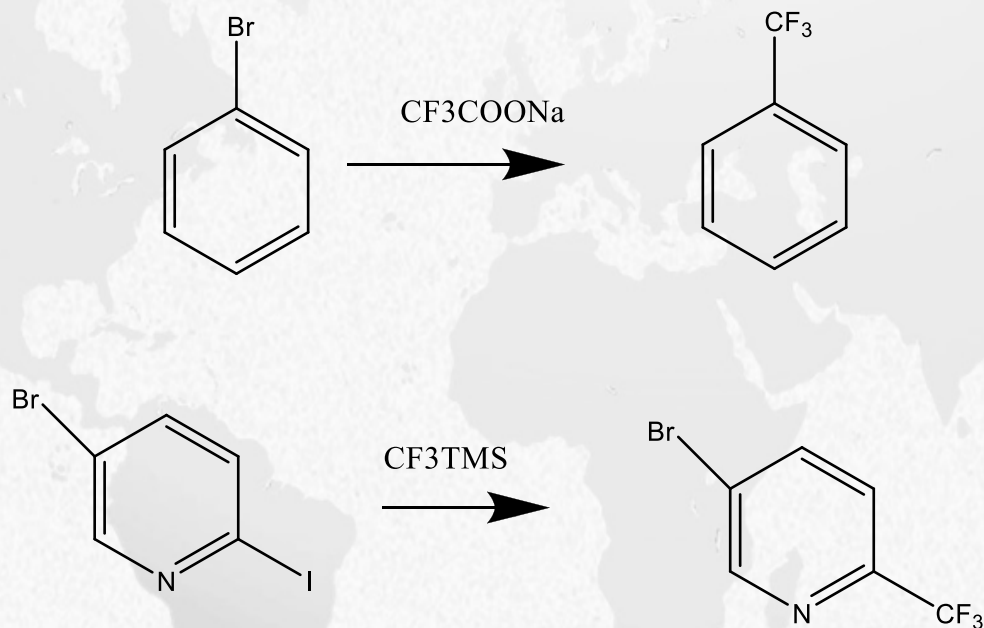
- Samples were obtained in the first three months and the process route was optimized in the fourth month, with products meeting the requirements of customer.
- Increased the yield from less than 10% to more than 20%.
- Decreased the cost by 50%.



# Case Study

## Example 3: Trifluoride

- Samples were obtained in the first one month and the production scale were achieved within three months.



Thank you for your kind attention!



**Be assured**

We are your **Reliable, Professional** and **Competitive**

**partner in Pharmaceutical field worldwide!**