

➤ Chemieliva is a key hi-tech enterprise which is famous for its high technology, and highly-optimized R&D technology, marketing and human resources. Powered by this, Chemieliva is specialized on developing and producing generics drugs and pharmaceutical intermediates. With these advantages, our logistic department will make the goods delivered at customer's appointed destination safely in the shortest time.

➤ It intensively cooperates with the China's best pharmaceutical university China pharmaceutical University and Chemical faculty of Nankai University. It has the abilities to offer clients products from gram-degree to ton-degree, and our company has established a wide range of cooperative relations with more than a hundred companies at home and abroad, including the international pharmaceutical giants.

➤ Additionally, customer synthesis is strength. We can offer services from synthetic route design, to synthesis, purifying and structural identification in strict accordance with terms on confidential agreement. We can offer clients target compound in the shortest time, from small scale test to the research, development and contract-manufacturing.

➤ When we pursue the company development, we meanwhile pay enough attention to the environment protection, and we never achieve the development at the cost of environment deterioration. Also "Making profits and rewarding the society" is one of our important operation philosophies.

# MILESTONE & MISSION



1999 In Shanghai, we established as a consultant firm in the chemical fields, and provided service of synthesis route designing, patent information providing, technology transferring, and new product launching support for the pharmaceutical company. During that time, we were acquainted with many important figures among the worldwide pharmaceutical giants, such as Pfizer, and Lilly.

2003 In Nanjing, we established our lab under the help of Professor Mr. Li Jiaoyu from China Pharmaceutical University. We accumulated many useful resources in the consultant firm, so we provide the customer synthesis for the international famous pharmaceutical companies (Laboratory scale). Once this phase is successful, we will enter pilot scale phase. And there are other three factories can provide us Outsourcing service.

2008 Chemieliva Pharmaceutical Co., Ltd was established, and the assets from the Consultant firm and laboratory had been injected in this new company. We formed the business scope from Laboratory R&D, pilot scale manufacturing, industrialization manufacturing to contract manufacturing service and international trading

2010 We signed the strategic contract with kimegle Industria e Comercio Ltda to engaged in the filed of emulsifier, which become another important business branch.

2013 We bought 37% stock right of acinopeptide Co., Ltd, which professionally engaged in the production of Amino and Peptide and their derivatives only.

Chemieliva is to support the growth of our customers on the long term by providing secured supply on a cost effective basis. Chemieliva main areas are:

Custom manufacturing of key intermediates for the pharmaceutical and cosmetology industry within a dedicated cGMP plants (FDA inspected, GMP compliant);

Manufacturing of patented active pharmaceutical ingredients under cGMP guideline (FDA inspected and GMP compliant).

Today, the largest pharmaceutical and biopharmaceutical companies are routinely utilizing Chemieliva as their approved partner, developer and manufacturer for high-profile, proprietary compounds.

With the improvement of the economy, the quality of road become more and more important in the transportation sector, and we can supply bulk of asphalt emulsifier for building good road under ISO system. We will increase the emulsifier of asphalt to 2000MT within 2011.



## MILESTONE MISSION

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# CORE VALUE & CAREERS

## Hardware facility

We used the most advanced equipment imported from USA, Germany, Italy and Japan so that we can have hardware to keep a continuous innovation and creativeness on the development of the new products and quality assurance of regular products. There advanced facilities are equipped into the process from R&D center, pilot plants, mass production base to Testing & Analysis center.

## Human Resources

Our human resources are key value to our success. We have a highly experienced, enthusiastic, and motivated team of chemical engineers, and over 30% of which are qualified to PhD level. Our team routinely delivers compounds to a stringent set of QC requirements and one of most important point is > 99% purity by HPLC or GC and other method. As a result chemieliva is quite welcome among the buyers and distributors and respected for delivering products of the highest quality.

## Our Inspiration

Our inspiration begins with listening. We understand that our customers are unique and we will take the time to establish your requirements, whether it be for individual products or longer term collaborations. Also, we will put in place the necessary confidentiality agreement to give peace of mind that your IP will be respected.

## Delivering Results

We know that results count. Except the regular products, the customer synthesis products are also our very important proportion of our business. It is very important to guarantee the lead time of these products. So we have the flexibility to prioritize custom work to ensure that we can always start your projects at short notice and we can ensure that the right chemists are assigned to projects that require their specific skills.

# ◀ CORE VALUE ▼ CAREERS ▶

## Making profits and rewarding the society

We never forget our original intention of establishing enterprise, when making the profit, and we should rewarding the society, and make the contribution to the society

## CAREERS AT CHEMIELIVA

We are constantly on the lookout for talented individuals to join the Chemieliva team and contribute to our success.

We provide our employees with the chance to develop their professional skills in a dynamic and motivating environment.

What we look for in a candidate

As well as the ability to carry out their roles in a professional manner, we look for individuals with the following key qualities:

- a passion for their work
- the desire to keep learning and improving
- a determination to meet their goals
- an ability and willingness to working as part of a team

Our values

Our business culture is based on a strong set of values that we translate into concrete actions and activities every day. Our objective is that these values are fully shared by all those who join our company!

Join our team

Do you think that Chemieliva could be the company for you? Take a look at the current vacancies. If you can't find what you are looking for but you

believe you could strengthen our team, send us your CV or send your resume to [info@chemieliva.com](mailto:info@chemieliva.com)

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# RESEARCH DEVELOPMENT

Our research and development activities mainly take place in our headquarters in our branch office in Nanjing. By the 1st May 2009, our research and development team have 42 research scientists and technicians, and over 30% of which are qualified to PhD level. Respectively a broad range of relevant synthesis and testing equipment are available to develop new processes. Our R&D activities focus on improving the product quality, reducing the manufacturing time and lowering manufacturing costs.

Development of new production processes is highly integrated with quality assurance procedures, which include strict record keeping of all procedures and monitoring procedures to ensure the consistent application of our manufacturing processes. We maintain quality control manuals for internal distribution among our factory managers and employees to maintain consistent practices. Several major international pharmaceutical companies have audited our facilities and independently issued third-party reviews.

The Departments have three main functions :  
Synthetic Research and Process Development;  
Analytical Research and Development;  
Kilo-lab and Pilot Production.

This professional research team develops new synthetic routes and supplies lab samples of new compounds or generic API's according to scalable and no-hazardous processes. It also optimizes and scales up synthetic processes through lab work and pilot production. It has gained customers' recognition by some exceptional achievements, made possible by the team's dedication and expertise. We see its relatively small size as the best option to guarantee efficiency without bureaucracy.

The kilo-lab and pilot plant are equipped with vessels ranging from 20 l to 600 l. Processing temperature conditions can range from -80°C to +300 °C and the synthesis can be carried out under strict cGMP rules. These equipments are the replica of the industrial equipment in the production plants at a scale of 1 to 10. This makes scale-ups and operating processes easier, faster and more reliable.

## RESEARCH DEVELOPMENT

Research, industrial development and manufacturing teams are located on the same site and they liaise permanently for fast industrialization and quick troubleshooting.

The Analytical R&D is equipped to support the process development and DMF registrations with HPLCs, GCs, IR & UV, GC-MS. Chemieliva has also validated sub-contractors under CDA for other analyses such as NMR, specific surface, platinum content

The R&D department also maintains cooperation agreements with Universities. This enables Chemieliva to validate and use the latest technologies in organic synthesis, as well as to access specific expertise



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## Preclinical

When your compound is ready to move from lead optimization to clinical candidate, we provide a variety of key chemical services to help develop and shepherd preclinical compounds into clinical trials.

Our chemical development department excels in quality, speed and reliability. We can scale-up compounds for preclinical testing, as well as develop a new synthetic route to your target compounds. A few of our capabilities include custom chemical synthesis, scale-up synthesis, process optimization and hazard assessment. In addition, we perform a full range of analytical services to bridge the gap from early discovery to clinical trials, in order to help you advance your lead compounds through the R&D pipeline.

## Clinical

Developing a drug candidate for clinical trials can pose numerous challenges, including meeting aggressive deadlines with a new compound and synthetic route. Unexpected things have a potential to happen during this period. Therefore choosing a reliable & experienced partner at this stage is critical to success. As your compound transitions into human clinical trials, we provide cGMP synthesis of active pharmaceutical ingredients and intermediates. Our experienced scientists, with the ability to conquer even the most difficult challenges, along with specialized capabilities in the development and production of controlled substances make us a preferred partner. All of our synthesis capabilities are fully supported by in-house analytical services, including preparative chromatography, solid state characterization, hazard assessment and regulatory services. Our full menu of technologies allows us to minimize technology transfer issues.

## Chemical Development

Our chemical development scientists at Chemieliva Pharmaceutical Co., Ltd have the skill and experience to meet a wide range of outsourcing needs: from custom synthesis to scaling up an existing route, to process development and optimization. At each step of the process development cycle, complete hazard assessment tools are available to allow for safe production of your compounds. We offer full-scale commercial cGMP manufacturing. Our chemical development department can assist you through.

## Custom Synthesis of Milligram to Kilogram Quantities

If you need milligram quantities of material, think of our chemical development department. We have a proven track record of preparing a wide range of compounds on an equally wide range of scales. As your requirements expand, we meet your needs in a timely and cost-effective manner. Since the initial synthesis used to prepare a few milligrams may not be suitable to prepare tens to hundreds to thousands of grams of your target compound, we will adapt and adopt a synthesis that makes the best suits your needs.

## Separation & Purification Services

We can assist you in identifying and developing practical purification strategies, whether it is for chemical purification or control of polymorphism of crystalline compounds.

# PHARMACEUTICAL DEVELOPMENT

## Large-Scale Synthesis & Commercial Manufacturing

Once your project reaches this level, we provide commercial cGMP manufacturing at Chemieliva Pharmaceutical Co., Ltd. Your project will benefit from seamless technology transfer as the team that guided your project through development follows it through commercial manufacturing.

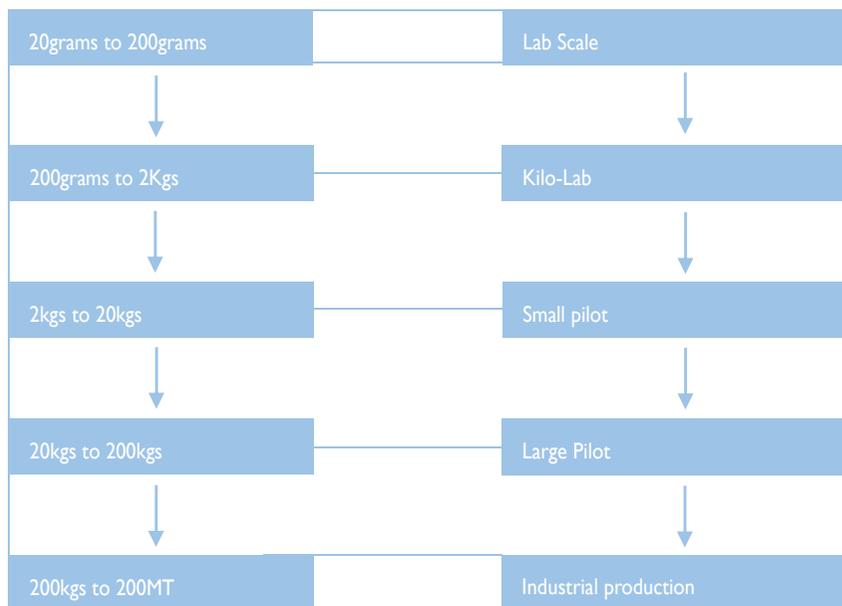
## Scale-up of Existing Processes

If you already have a demonstrated route and need it reproduced in a timely and efficient manner, we will exceed your expectations. Along the way, we will identify and develop steps as appropriate for scale or safety considerations. Process Research, Development & Optimization

We can develop new and proprietary routes to existing compounds, or take an existing synthesis and develop a scalable process using our in-house talent and state-of-the-art technology, including, statistical design of experiments (DoE), real-time reaction monitoring to generate detailed reaction/impurity profiles, and reaction calorimetry for hazard assessment and further process development. Our staff has experience in developing and transferring projects from our research laboratories to our cGMP manufacturing plant.

## cGMP Synthesis

Few decisions in pharmaceutical R&D are as critical as selecting the right cGMP manufacturer for a small molecule drug. Promulgated by the U.S. Food and Drug Administration, cGMP (current Good Manufacturing Practice) regulations and guidelines govern the manufacturing, use and testing of drug products and their components, including active pharmaceutical ingredients (APIs), intended for use in humans. APIs manufactured to cGMP standards for clinical research or commercial sale must meet requirements for identity, strength, quality and purity. Our strength in process research and scale up, coupled with our wide range of cGMP synthesis capabilities, is well known in the industry.



## CONTRACT MANUFACTURING

We are your worldwide partner on the customer manufacturing service for the pharmaceutical industry. We are the privileged partner throughout your whole pharmaceutical development process

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## ANALYTICAL DEVELOPMENT

Analytical services are critical at every stage of pharmaceutical R&D, from the first synthetic step of even the shortest process, all the way through manufacturing. We provide broad analytical support for preclinical, clinical development, and manufacturing. To support the development and manufacture of active pharmaceutical ingredients (APIs), we provide analytical method development and validation services, the capability to synthesize and certify analytical reference standards, and an ICH-compliant bulk active stability program. All customer projects are supported by an on-site analytical team with equipment and expertise in HPLC, GLC, GC-MS, ICP, LC-MS, ion chromatography and NMR. To support drug development, we provide the following analytical services:

### Chromatographic Assay Development

The foundation of any analytical development team is the chromatographic development group. Our experienced team of analysts can reliably develop and validate stability indicating and impurity assays for active pharmaceutical ingredients. Our facilities and instrumentation includes HPLCs (including UV/PDA/RI) and multiple GCs. We have particular expertise in API/impurity assays.

### Chiral Assay Development

One of our core strengths is developing chiral assays to evaluate enantiomeric purity. Often, the biggest challenge in chiral assay development is to evaluate many different chromatographic stationary phases in order to find the right conditions for the separation. We know that time is imperative; with our state-of-the-art chiral screening platform, we can evaluate up to 18 different chiral stationary phases and multiple solvent conditions in order to identify a preliminary separation, typically within 24 hours.

### Impurities Identification

With expertise in isolation and spectroscopy, our scientists can rapidly identify the structure of unknown impurities/degradants in active pharmaceutical ingredients and, intermediates. Our analytical team uses state-of-the-art instrumentation to isolate, analyze and identify impurities. Instrumentation includes several 300 MHz and 500 MHz NMR units, with multinuclear capabilities (1H, 13C, 31P, 19F and 15N), LC/NMR, FTIR, LC/MS/MS, and GC/MS.

### Stability Testing

We provide stability testing on pharmaceutically relevant compounds, including APIs and synthetic process impurities. Our services include long-term, intermediate and accelerated testing of APIs and process intermediates. We offer:

Stability protocol design

Storage of stability samples under ICH conditions

Development and validation of stability-indicating methodology for APIs and drug products

Chromatographic analysis of APIs, preservatives, and determination of impurity profiles

We can develop and validate the appropriate methods or transfer your validated methodology into our laboratory. We welcome client audits to review our Standard Operating Procedures and verify our compliance with current Good Manufacturing Practices.

# EHS POLICY

Chemieliva takes EHS as an integral part of our business, operations and practices. We believe EHS management is our responsibility to the world we live, which is vital to sustainable development of our company, economy, pollution prevention and social responsibility.

Environment, Health & safety (EHS) target  
ZERO healthy injury.  
ZERO safety accident.  
ZERO environmental pollution.

## Environment, Health & safety EHS performance

### Environment, Health & safety (EHS) management system

#### Component

Environment, Health & safety are considered to be a tangible value creation wherefore the reliance of the customers, business partner and shareholders is amplified. The company has established the HSE committee and department to ensure the HSE management according with the inner HSE Specifications as well as meeting the ISO9001:2000 Quality requirement.

### Emergency Aid Management

The company has sufficiently prepared for the indigenous emergency risk existing in the chemical manufacture. The company has established an emergency organization so as to deal with the accident and emergency. Various self-saving activities can be developed before the professional persons come to the site, therefore, it can reduce the accidental damage toward person, material, facility and environment to the rock bottom.

### Transport Safety

Select transportation subcontractors with proper competency and official permission, according to the physical & chemical properties/hazard class of our products. Provide Material Safety Data Sheets (MSDS) to driver for emergency reference.  
Support the prevention of incidents or accidents occurring during the transport of chemicals to or from Lianhe chem-tech's facilities, or during the related loading or unloading of chemicals at these premises. Make product classification and defines the labeling and packaging requirements according to the national and international regulations and legislation. Give advices on safe and environmentally compatible means of transport. Assess transport risk for highly hazardous chemicals transportation.

### Production in security

Safety first, and prevention first. We put the personnel safety into the first level all the time. Safety is the duty for all staff, and everyone is basically responsible for the safety and health on their job. The company has found the specific HSE organization to have the safety measure in the work program implemented and consummated step by step. The company established an exclusive HSE department to ensure that the implementation and continuous improvement of security measures in working plans.

Knowledge is the guidance to action. Only by enhancing the security awareness can employees behave with self-conscious. Therefore, the company attaches great importance to employee training which can improve their security quality to realize normalization of process measures as well as to reduce job injuries.

### Energy and Water

The company's main consumption of energy resources is liquid fuel and electricity. The utilization of heat energy generated itself is also a small part of its resource, which is obtained by incineration of hydrogen and a few byproducts recycled in manufacturing process. Water usage is divided in two main classes: process Water and non-contact cooling Water. All Water used is the municipal administration running Water. The process Water is only 10% of the total fresh Water consumption.

### Waste Gas & Waste water

The company adopts advanced technology to process waste gas. The gas from manufacturing process is treated by on-line installations. All of these installations together with production installations are furnished with chain protective facilities. When on-line installations go wrong, the production installations will stop automatically and so will the gas emissions. Thus the efficient treatment of all gas emission is ensured. The company invested to set up a waste Water treatment system and has got efficient results.

### Culture of EHS

It is still too many even if there's only one accident  
All accidents and profession disease are preventable  
Safety is the primary responsibility of the production and management  
All operation can be controlled  
Supervisors are responsible for training of every employee to operate safely  
To provide safe working environment  
Correct security awareness, attitude and behavior is one of the working requirements  
Safety is the duty of everyone.  
Working in a safe way is one of the employment conditions.

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# COMPANY PROFILE



## QUALITY MANAGEMENT

### Quality Management

Chemieliva Brand stands for quality, trust and reliability, which come from the complete quality management. Chemieliva continuously improves the quality management through the implement of a complete, advanced, scientific quality management system according to current GMP, national and international standards. We guarantee that each product will be manufactured under strict controls, which consistently meet present standards of safety, efficacy, quality and purity. Quality is a conscious commitment and a permanent goal to match the high expectation of our customers. Excellence in quality systems will be achieved through the team effort with trained personnel. Quality is the responsibility of all persons involved in manufacturing.

### Quality policy:

Implementation of the quality policy is done through quality systems based on current Good Manufacturing Practices in conformity with national and international standards.

We are committed to ensure that every product manufactured consistently meets with preset standards of safety, efficacy, quality and purity.

Excellence in products, processes and systems is to be achieved through active involvement, collective responsibility of our trained and professional employees.

Nitration reaction  
Grignard reaction  
Hydrogenate reaction  
addition reaction  
Oxidation reaction  
Reduction reaction  
Esterification reaction  
Condensation reaction  
Etherification reaction  
Nitrate Nitrogen reaction  
Alkylation reaction  
Friedel-Crafts reaction  
Substitution reaction  
Ammoxidation reaction  
Heterocyclic reaction

**REACTION**  
◀ **WE CAN**  
**TAKE**

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WELCOME TO VISIT  
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