STERILE INJECTABLES
FILL-AND-FINISH
LYOPHILIZATION

PAIZABIO®

For China, In China, To Western Standards

CHINA = GROWTH

With 1.4 billion people, China is larger than North America, South America and Europe combined.

Rising affluence, increasing disease burden, and the government's commitment to making health care accessible to more people have made China the world's fastest growing market for pharmaceuticals. Currently valued at $150 billion (US), China's drug market is predicted to reach the equivalency in value to the United States as early as 2021.

Many Western companies consider expansion into China essential to a strong balance sheet. Maturing markets, lucrative branded drugs coming off patent, and government mandates that encourage generic drugs threaten sales and profit margins. While many multinationals have already expanded their commercialization footprint in Asia, most are focused exclusively on solids and oral dosage forms.

Sterile injectables, which require the highly technical and critically demanding parenteral aseptic fill-and-finish manufacturing process, represent a lucrative niche – with the right partner. Aseptic fill-and-finish manufacturing is largely conducted in the United States and Europe and subject to import licensing by Chinese authorities, creating an unpredictable and expensive variable. The solution is to identify a proven contract manufacturing partner in China that specializes in sterile injectables for the Chinese market. **That partner is PaizaBio.**

PaizaBio's name comes from a golden paiza given to Marco Polo by Chinese Emperor Kublai Khan, ensuring safe travels. PaizaBio offers western pharmaceutical companies safe passage into China's sterile injectables market.

Sterile Injectables. For China. In China. To Western Standards. U.S.-based PaizaBio provides western-based pharmaceutical companies with immediate access to the Chinese sterile injectables market, with minimal economic risk and significantly reduced capital outlay; all while ensuring that clients' products are manufactured to Western quality and regulatory compliance standards. We are the portal of entry for companies that want to fast track a strong manufacturing presence in the sterile injectable drug sector in China to meet the burgeoning demands of Chinese consumers. We offer aseptic fill-and-finish, packaging and warehousing of finished products, as well as sophisticated lyophilization and analytical services.

PaizaBio is the logical, low risk alternative to green fielding in China. Establishing a new aseptic manufacturing operation in China is costly, time consuming and risky. With our deep knowledge base of China's manufacturing and regulatory requirements and CMO partner Ausia BioTech's two decades of producing sterile injectables for the Chinese market, clients enjoy rapid market entry in China with little capital outlay.

The benefits are clear: manufacturing innovation and quality products that meet China's regulations, in the formats and packaging consumers prefer. PaizaBio is a logical solution for Western pharmaceutical companies that want to test the market before constructing their own manufacturing operations as well as those that want a virtual manufacturing presence through us.

China's increasingly affluent population equates Western drugs with quality. PaizaBio enables Western pharmaceutical companies to accelerate market entry by manufacturing sterile injectables in China, in the formats and packaging consumers prefer, with low risk and capital outlay.

STERILE INJECTABLES

IN CHINA, FOR CHINA

PaizaBio offers an in-country solution for Western pharmaceutical companies for the technically demanding manufacture of sterile injectables, a solution that includes Western cGMP quality standards and state-of-the-art manufacturing practices. Our partner, Ausia BioTech, has established a reputation as China's quality leader in the aseptic fill-and-finish market segment, with two decades of experience and extensive capabilities in high volume filling and lyophilization to Western standards.

Located in Hangzhou, just 120 miles/180 kilometers from Shanghai. Ausia BioTech occupies a 40,000-square-meter compound, including a 25,000-square-meter production facility and 10,000-square-meter warehouse. CMO fill-and-finish operations include:

- Product formulation
- Nine high-speed automated filling lines
- Annual capacity in excess of 300 million units (vials, cartridges, syringes)
- Full packaging facility with automated and manual options
- Vial washing and capping
- Laboratory facilities for testing, validation, analysis, and development
- Regulatory support
- Climate controlled warehouse.

PaizaBio's CMO partner, Ausia BioTech, has an annual capacity of 300 million units (vials, cartridges, syringes) of sterile injectables, and operates a 25,000-square-meter sophisticated production facility and 10,000-square-meter warehouse in Hangzhou, China, 120 miles/180 kilometers from Shanghai.

Advanced lyophilization services. We operate a freeze drying cycle research and development laboratory through Ausia BioTech that can perform lyophilization optimization services normally available only in an academic environment or a third-party specialty laboratory. Our sophisticated lyophilization development capability enables us to optimize freeze drying cycles, thereby accelerating production, improving quality and consistency, and minimizing cost. This in-house service helps ensure repeatability of the full manufacturing process, resulting in lower costs and faster turnarounds.

PaizaBio offers high capacity lyophilization services with superior product stability and improved shelf life. We can develop new processes or transfer and adapt existing lyophilization cycles to our equipment, thus ensuring product specifications are met. Services focus on:

- Cycle development and optimization
- Cycle validation
- Risk control
- Innovation in freeze-drying technologies

Analytical services. PaizaBio offers a full range of analytical services, utilizing Ausia BioTech's extensive laboratory facilities for testing, validation, analysis, and development. Our analytical testing is primarily focused on the analysis of the API/ABI active ingredients and characterization, during and after manufacturing to ensure the integrity of the finished product. Ausia BioTech has developed and validated its analytical techniques following established industry guidelines. Compendia testing is performed according to CFR, USP, NF, EP, JP, AOAC and other standards. We follow Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (cGMP), and are ISO 17025 compliant.

PaizaBio delivers the highly technical and critically demanding parental aseptic fill-and-finish processing Western pharmaceutical companies need to command market share in China with quality, precision, efficiency, and above all, confidence.

QUALITY ASSURED

Ausia BioTech's 40,000-square-meter manufacturing operation meets all standards for producing aseptic drugs in a sterile environment and includes the latest equipment, some of our own design.

PaizaBio never forgets that our business is about people. We strive to deliver nothing less than exceptional quality so that patients' health is protected, clients' reputations remain intact, and ultimately, clients succeed in China's dynamic marketplace. Our comprehensive, integrated quality control system addresses four areas:

- Project and alliance management
- Sophisticated sterile manufacturing environment
- BAO-Gong® remote digital and video manufacturing monitoring system
- Commitment to aseptic training and ongoing education

Project and alliance management. PaizaBio serves as a strategic ally to our clients, drawing upon unique, first-hand experience navigating in a culturally and linguistically complex region such as China. We build relationships with our clients based on respect, trust and transparency. Each client has a project and alliance management team that is available 24/7 in the client's preferred language. Our client-focused approach enables us to provide high quality aseptic fill-and-finish services in China that meet clients' quality standards and cFDA regulations, providing a secure and local supply chain at a highly competitive price.

BAO-Gong® ensures quality compliance and performance half a world away. PaizaBio has implemented the pharmaceutical industry's most comprehensive real-time remote manufacturing monitoring system. The Bioanalytical Operations Global Observation and Navigation Guidance System (BAO-Gong®) represents a new industry standard for remote quality control capabilities and CMO-client relationships.

This novel quality control monitoring system is composed of two components: Hitachi's HITPHAMS® manufacturing execution software system, which captures and reports on multiple technical and environmental metrics across the manufacturing process. This is integrated with a live stream closed circuit television system in all Ausia BioTech manufacturing suites so clients can watch their project from start to finish. This gives clients a virtual "person in the plant" with strict control in reviewing, in real-time, the aseptic fill-and-finish of their drugs into final dosage forms and packaging via laptop, PDA, or smart phone anywhere in the world.

PaizaBio ensures an exceptionally trained aseptic workforce via TPA-IT®, the Trans-Pacific Aseptic Institute of Training®. Located on the campus of Ausia BioTech in Hangzhou, China, the $8 million dollar sterile university was originally established for Ausia BioTech employees. As TPA-IT, the curriculum has been expanded; it is now open to other pharmaceutical companies, contract manufacturing organizations, and government and regulatory entities from around the world.

This comprehensive, full-scale training center ensures a workforce capable of the highest level of cGMP quality manufacture. Training includes structured lecture and hands-on learning experiences in the principles of sterile manufacturing, quality management and regulatory compliance. The interactive curriculum is taught in facilities that include qualified clean rooms with fully functional HVAC systems and commercial grade equipment, and a lecture hall that accommodates 50 students. The experience is designed to accelerate learning and maximize students' retention of information and skills.

PaizaBio invites you to learn more about the China opportunity. China's growth offers an unprecedented opportunity to multinational pharmaceutical companies seeking to participate in what will be the largest market in the world. Serving as a strategic partner, PaizaBio will assist client companies in optimizing this unprecedented opportunity in a highly unique and complex commercial market.

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PaizaBio and HITACHI have partnered to create BAO-Gong®, the most comprehensive real-time remote digital and video drug manufacturing monitoring system, giving clients anywhere in the world a virtual "person in the plant" and complete confidence in quality.

PaizaBio's manufacturing operations are located in Hangzhou, one of Marco Polo's favorite destinations due to its beauty and thriving economy, qualities that exist today. Hangzhou is less than two hours from Shanghai. We encourage you to visit PaizaBio in Hangzhou, tour our manufacturing operations, and enjoy our home city in China.

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