# Boehringer Ingelheim Biopharmaceuticals in China

# Your Reliable Contract Manufacturing Solution Provider

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## Boehringer Ingelheim Biopharmaceuticals China

As one of the world's leading organizations in the area of biopharmaceutical contract manufacturing, we at Boehringer Ingelheim are the first multi-national pharmaceutical company to bring our over 30 years of experience to China, to better serve patients and the biopharmaceutical industry – both in China and in the world.

Supported by an experienced and fully-trained team, our well-designed GMP compliant facilities in Shanghai are able to supply you with world-class-quality therapeutic biologics for pre-clinical, clinical, and commercial phases. Our dedicated project team is able to help you establish the entire biologics CMC from cell line development to regulatory approval, and to stable and reliable market supply.

## Our Long-Term Commitment to Biologics CMO in China and around the World

As a family-owned company with 130 years of continued success, Boehringer Ingelheim is dedicated to long-term development and growth. Contract manufacturing is one of the key strategic business areas of Boehringer Ingelheim globally and in China. We are committed to keeping our world leader position as a biologics CMO through continuous innovation and service excellence. We are convinced that a long-term strategic partnership and collaboration with our customers is the best recipe for mutual success.

The biopharmaceutical industry is one of the key sectors in China's long term development plan and the industry is expected to experience high growth during the next decades. We believe China will become one of the world centers of research & development and of manufacturing therapeutic biologics.

We are highly convinced that Boehringer Ingelheim's well-established strengths will help the development of China's biologics industry, in terms of setting up high-level quality standard, introducing advanced technologies, and applying our international drug registration experience. In this regard, we envision ourselves to extend to China our world leading expertise as a CMO provider. We are dedicated to keeping the same high Boehringer Ingelheim standard of services in China as at all of our other worldwide sites to provide "in-China-for-China; and in-China-for-global" manufacturing for our clients. We are the industry leader in developing your biologics products to meet global quality standards and regulatory requirements, as well as to successfully enter the global market from a CMC perspective.

## What Can We Offer to Our Customers in China?

We provide a full range of service to our clients from cell line development to drug product manufacturing and release, and finally to regulatory approval for market (CMC part). The development activities will be supported by our global Boehringer Ingelheim network. Our first-in-class technology and skill centers will deliver well developed, stable, and high-quality processes and analytical methods to our clients. This will serve as a solid basis for starting your project at Boehringer Ingelheim with an advanced status.

Our manufacturing sites are located within one of China's largest biologics centers - Zhangjiang Hi-Tech Park, Shanghai. As the first multi-national biologics CMO provider with a strong reputation and track record both in the area and in China, we have gained strong support from local and national-level regulatory authorities as well as from local Government organizations. This support benefits not only Boehringer Ingelheim but also ensures our customers' success.

We are already in full GMP operation at our "BioLab" on the Boehringer Ingelheim pharma site. Supported by a process transfer laboratory and equipped with cutting edge fermentation and

purification platforms, the BioLab provides disposable mammalian cell culture and purification capabilities up to 500L scale. Based on this we are able to provide our customers with material for pre-clinical, non-clinical, and clinical studies (phase I/II). The BioLab also has state-of-the-art analytical testing and release equipment which ensures that the running manufacturing processes and final products are under full quality control.

By the end of 2016, our new "Oasis" manufacturing site will be constructed and in operation to provide late phase clinical and early phase commercial material supply. Oasis will be equipped with several most advanced disposable 2,000L fermentation and purification lines, and furbished with an automated Fill & Finish drug product production unit. The Oasis facility is positioned as a product launch site as it is able to provide the full range of first-in-class manufacturing and release services to our clients ensuring successful market entry and market supply of our customer's products. Worth mentioning, the Oasis site is also able to expand its capability by establishing large scale stainless steel manufacturing lines which can be up to 5,000L.

*Picture 1: Oasis site design and expansion option*

## Our Global Concepts

### Quality

Quality is the most important success criterion of Boehringer Ingelheim Biopharmaceuticals in China.

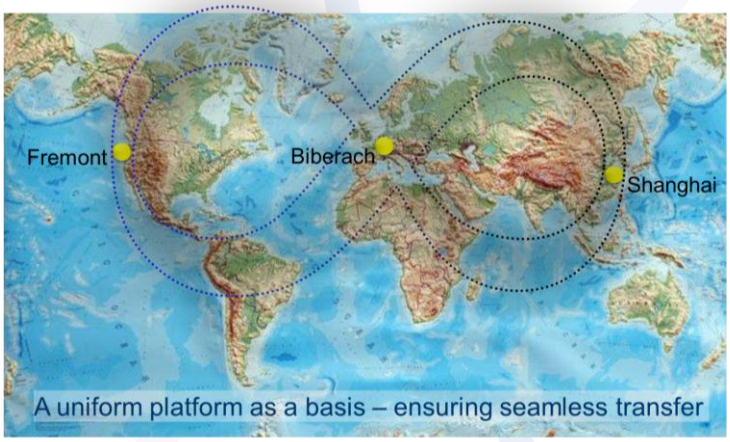
Boehringer Ingelheim has a great track record and reputation globally due to our very high quality standards of our operations and products. In China, we apply the same high quality requirements as for the global Boehringer Ingelheim manufacturing network. We are determined to continue Boehringer Ingelheim's excellent quality track record in China and will provide high-quality services and products to our customers and to patients.

We establish our manufacturing facilities and operations at the Shanghai site fulfilling GMP requirements according to major regulatory bodies such as US FDA, EMA, and China FDA, in line with our strategy to provide CMO services targeting the global market. Together with Boehringer Ingelheim's great worldwide reputation on quality, we believe we can support our customers' product submissions in the best possible way, positioning them well at the regulatory agencies of major pharmaceutical markets.

### Manufacturing Technologies

Our fully disposable upstream and downstream production manufacturing platform in China is part of the Boehringer Ingelheim Biopharma global network, which enables seamless technology interfaces and process transfer between different sites all over the world. Applying the same platform technology at all our mammalian manufacturing sites greatly shortens the timelines for transferring a developed process from one site to another, and makes troubleshooting activities much simpler and easier. In addition, the platform technologies also ensure high stability and reproducibility of the process and product quality during and after the transfer. Compared with other CMOs, this is a unique strength and advantage that we can offer to our clients due to our established global presence.

Our manufacturing site in China is a multi-product facility with a high degree of flexibility in terms of flexible control units and modular purification systems, which make it possible to adapt to different single-use bioreactor systems and combinable pacification units. This flexibility ensures that we can offer the fastest possible transfer and adaptation of our customers' processes at our site.




*Picture 2: Boehringer Ingelheim Biopharma, One World-Wide Single Use Platform*

## IPP Concept

Boehringer Ingelheim's Information Protection Principles (IPP) for client projects is an important cornerstone of our contract manufacturing service in the entire global network, including China.

At our BioLab and future Oasis facility, we have installed state-of-the-art access control, visual surveillance, and material in/out management systems in the operations and analytical areas. We also have established strict principles on data storage, distribution, and management rules, which ensure that confidential information of client projects is well-controlled and provided only to official project team members who are screened and trained according to Boehringer Ingelheim's strict Intellectual Property Protection policies.

Boehringer Ingelheim is proud of having one of the industry's strictest IPP policies and will enforce it without compromise to offer our customers and their projects the optimal intellectual property protection in our facilities.

## Our Team

We believe that our employees are ultimately the key to our success. At our BioLab facility, we currently have a team of approximately 60 experts from different cultural backgrounds, and with different levels of expertise and work experience. We employ US-China or Europe-China returnees and expatriates who have had more than 20 years of experience working in the Biopharma field at other Multinational Companies or at Boehringer Ingelheim; also joining us are local experts who are very familiar with regulatory and GMP operations requirements specific to China; our team is projected to grow to about 100 FTE by 2016.

Our team cultivates a service-driven, detail-oriented, and open-minded work environment, with a strong drive for success and great willingness to find customer's specific solutions. We look forward to working with you.

## Our Integrated Contract Manufacturing Solution

Boehringer Ingelheim Biopharmaceuticals in China implements the same "one-stop-shop" global concept and aims at providing integrated contract manufacturing solutions to our clients worldwide.

We have developed well-defined work processes, roles, and responsibilities of different functions within our organization to ensure seamless handover and interfaces during the different project phases. Those phases include the project inquiry and acquisition phase, proposal and contract negotiation phase, project implementation phase (development and clinical supply), as well as the product life cycle management phase (commercial supply). We in China are able to provide a full range of biologics CMC service of process and analytical development (via our global network), process and analytical transfer, GMP manufacturing and release, and CMC regulatory submission.

We are highly confident that we as a biologics CMO are the right partner for you. We believe we can make your molecule a success, also in China!