Boehringer Ingelheim BioXcellence™

Integrated and powerful contract manufacturing services in Shanghai, China.

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Boehringer Ingelheim Biopharmaceuticals China

As one of the world's leading biopharmaceutical contract manufacturers, 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.

From our purpose-built, GMP-compliant facilities in Shanghai, our experienced team supplies you with world-class quality therapeutic biologics for pre-clinical, clinical, and commercial phases. We can help you establish the entire biologics Chemistry, Manufacturing, and Controls (CMC) from cell line development to regulatory approval, as well as to stable and reliable market supply.

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

We are a family-owned company with 130 years of continued success and a dedication to long-term development and growth. Both in China and around the world, contract manufacturing is one of our key strategic businesses. We are committed to keeping our world leader position as a biologics CMO through continuous innovation and service excellence. There is no doubt in our minds that long-term strategic partnership and respectful 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, expected to experience strong growth over the coming decades. We believe China will become one of the world centers for both research and development and manufacturing therapeutic biologics.

With our well-established strengths, we are in an excellent position to help the development of China's biologics industry in terms of setting up high-level quality standards, introducing advanced technologies, and applying our international drug registration experience. By extending the same high-quality standard of services to our customers in China as anywhere else in the world, we are dedicated to providing them with "in-China-for-China" and "in-China-for-global" manufacturing. As the industry leader in developing biologics products to meet global quality standards and regulatory requirements, and to successfully enter the global market, we are best equipped to make that possible.

Our Offer to Our Customers in China

Our full range of services encompasses anything from cell line development to drug product manufacturing and release, as well as regulatory approval for market introduction (CMC part). Development activities will be supported by our global Boehringer Ingelheim network, delivering well-developed, stable, and high-quality processes and analytical methods through first-in-class technology and specialized skill centers. In other words: Any project you start with us will already have an advanced status.

Our manufacturing sites are located in Zhangjiang Hi-Tech Park, Shanghai, one of China's largest biopharmaceutical centers. We have a strong reputation and track record both in the area and in China, with strong support from local and national-level regulatory authorities, as well as from local government organizations. We take advantage of this support to advance our customers' interests and ensure their success.

Since 2014, we have been in full GMP operation at our "BioLab" on the Boehringer Ingelheim pharma site. The BioLab provides disposable mammalian cell culture and purification capabilities up to 500 L scale, supported by a process transfer laboratory and equipped with cutting edge fermentation and purification platforms,. This setup enables us to provide our customers with material for pre-clinical, non-clinical, and clinical studies (phase I/II).

In addition, the BioLab's state-of-the-art analytical testing and release equipment ensures that running manufacturing processes and final products are under full quality control.

Our commercial production site "Oasis" is designed to host up to 4 disposable lines with a capacity of 2,000 L each for mammalian cell culture. Currently, Oasis is equipped with one highly advanced disposable 2,000 L fermentation and purification line, and furbished with an automated Fill & Finish drug product production unit. The expansion of a second 2,000 L fermentation and purification line is ongoing. In January 2017, GMP operation to provide the late phase clinical and early phase commercial material supply started at the site. 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 customers, ensuring successful market entry and market supply of their products. The Oasis site is also able to expand its capability by establishing large scale stainless steel manufacturing lines with a capacity of up to 5,000 L.

Picture 1: Oasis site design and expansion option

Our Global Concepts

1. Quality
2. Integrated Contract Manufacturing Solution
3. Manufacturing Technologies
4. IPP Concept
5. Team

1. Quality

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

We have an outstanding global track record and reputation due to the very high quality standards of our operations and products. We are determined to continue this tradition of excellence in China and will provide high-quality services and products to our customers and, ultimately, to the patients.

Our manufacturing facilities and operations in Shanghai fully comply with GMP requirements according to major regulatory bodies such as US FDA, EMA, and China FDA, allowing us to provide CMO services targeting the global market. With Boehringer Ingelheim's worldwide reputation for excellent quality, we will support our customers' product submissions to position them in the best possible way with the regulatory agencies of major pharmaceutical markets.

2. Integrated Contract Manufacturing Solution

In China, we implement the same global "one-stop-shop" concept as in all our locations and projects. Providing integrated contract manufacturing solutions to our customers worldwide is a key feature of our services portfolio and sets us apart from our competitors.

We have carefully defined work processes, roles, and responsibilities for different functions within our organization for seamless handovers and interfaces during the

different project phases. Those phases include the project inquiry and acquisition phase, the proposal and contract negotiation phase, the project implementation phase (development and clinical supply), and the product life cycle management phase (commercial supply).

3. Manufacturing Technologies

Our fully disposable upstream and downstream production manufacturing platform in China is part of the Boehringer Ingelheim Biopharmaceuticals global network, which enables seamless technology interfaces and process transfer between different sites all over the world. Applying the same platform technology at all of 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, these platform technologies also ensure high stability and reproducibility of the process and product quality during and after the transfer.

Our Shanghai site is a multi-product facility with a high degree of flexibility in terms of flexible control units and modular purification systems. This makes it possible to flexibly adapt to different single-use bioreactor systems and combinable pacification units for the fastest possible transfer and adaptation of our customers' processes at our site.

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

4. Information Protection Principles (IPP) Concept

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

Both at our BioLab and the 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.

Strict principles on data storage, distribution, and management rules are applied to ensure that confidential information regarding customer projects is controlled and protected. Only official project team members who have been screened and trained according to Boehringer Ingelheim's strict Intellectual Property Protection policies are granted access to this information.

We are proud to have in place one of the industry's strictest IPP policies and will enforce it without compromise to offer our customers and their projects optimal intellectual property protection across all our facilities.

5. Team

Success always comes down to people. Currently, we have a team of approximately 150 experts from different cultural backgrounds, and with different levels of expertise and work experience. We employ US-China or Europe-China returnees and expatriates with more than 20 years of experience in the biopharmaceuticals field, both in other multinational companies or with Boehringer Ingelheim. Furthermore, we are joined by local experts who are very familiar with regulatory and GMP operations requirements specific to China.

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 showing them exactly what we mean when we say: We deliver progress – and it's our pleasure.

Contact

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