

Looking for a CMO for Drug Products in China?



Stefan Czvitkovich

Dear Readers,

I hope you have had an enjoyable summer so far. After giving you an overview of our Asian production sites in our last Insight, in this issue we would like to introduce you more specifically to our Chinese sites.

In recent years, China with its huge market potential has become the focus of a growing number of industries. Better access to education, higher income, and constantly increasing standard of living are making the country a prime market for exports. By now, a huge number of companies have settled there to set up manufacturing facilities ranging from low-tech to high-tech products for local, regional or global supply. The same is also true of the pharmaceutical industry, with large international companies increasingly establishing operations there.

Here, we would like to introduce you in more detail to Fresenius Kabi manufacturing sites in China, which are located in Beijing, Wuhan, and Wuxi. All three sites have state-of-the-art equipment, quality assurance systems running according to the Fresenius Kabi corporate guidelines, and the technological capabilities and capacities to supply China and also other markets competitively. Each of these three plants brings its own pedigree to Fresenius Kabi and to our customers. Beijing, besides its ability to manufacture sterile liquids, is one of Fresenius Kabi's main locations for manufacturing of oral solid dosage forms. In contrast, Wuhan focuses mainly on preparing cytostatic drugs in liquid or lyophilized form. Finally, Wuxi offers a rich platform of diverse technologies for different presentations of sterile liquid parenterals.

With the Chinese national regulatory guidelines in a process of evolution, new opportunities are arising for contract manufacturing out of manufacturing sites located in China for the Chinese market. The Fresenius Kabi sites in China are well prepared and are looking forward to providing their expertise, quality, and capacities to third-party manufacturing.

Further, we would like to give you an insight into proprietary solutions for needle-free drug reconstitution. Fresenius Kabi has developed freeflex®+ bags at different sizes with an integrated luer-lock port for needle free addition of solutions by syringes. This system is also available for fill/finish services for third-party drug products.

We are always interested in talking to you to discuss new opportunities and solutions for your product. You can contact us at any time by email or by phone, or come and meet us in person at one of the exhibitions shown below.

Sincerely yours,
Stefan Czvitkovich

Exhibitions

- **Contract Pharma's Contracting and Outsourcing Table Top Exhibition 2016**
(Sep 22, New Brunswick, NJ - USA)
- **CPhI/ICSE Europe 2016**
(Oct 4-6, Barcelona - Spain), Booth 3L70, Hall 3
- **AAPS Annual Meeting & Exposition**
(Nov 14-16, Denver - USA), Booth 1925
- **Interphex USA 2017**
(March 21-23, New York - USA), Booth 1630
- **CPhI North America 2017**
(May 16-18, Philadelphia - USA), Booth 2938
- **CPhI/ICSE Europe 2017**
(Oct 24-26, Frankfurt - Germany)

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Editorial

In the Spotlight:
Fresenius Kabi Contract
Manufacturing Services
in China

The Needle-free Solution
for Drug Reconstitution

Our spotlight in this issue is on selected Fresenius Kabi manufacturing facilities in China. Fresenius Kabi has set up state-of-the-art manufacturing facilities in China, offering highly automated production capacities for sterile pharmaceutical products. The company's experience and expertise in these operations could be your gateway to China's and Asia's emerging markets.

Fresenius Kabi operates three manufacturing sites for the manufacturing of injectable pharmaceuticals in China, located in Wuhan, Beijing and Wuxi. The plants develop and manufacture injectable pharmaceuticals and oral dosage forms - and they offer contract manufacturing services for our international partners.

Beijing



Wuxi



Wuhan

The Wuhan facility in central China focuses on manufacturing sterile oncology drugs. This facility was built in 2014 and carries out aseptic filling and lyophilization in glass vials from 2 to 50 ml for the Chinese market. Including a state-of-the-art analytical laboratory (UHPLC, GC, AAS, TLC and TOC) and R&D capabilities, the facility is our development and manufacturing center for cytotoxic oncology products in China.

The Beijing facility with around 300 employees is located in the southern suburbs of the Chinese capital. The plant focuses on manufacturing of tablets as well as on sterile filling of IV bags and packaging of a variety of IV containers such as vials, ampoules and bottles. Newly built in 2014, the ISO-certified facility operates state-of-the-art manufacturing equipment and serves both Chinese and international markets (including the EU).

Contract Manufacturing Services in China

Finally, the Wuxi facility with around 600 employees and a floor area of more than 60,000 m² was built in 1982 and has undergone major extension since then. The plant focuses on preparation, filling and packaging of sterile emulsions and solutions in ampoules, vials, bottles and bags. It also has a full range of lyophilization capabilities. The ISO-certified facility serves the Chinese and international markets (including the EU).

Fine chemicals did it long ago, automotive and electronic suppliers have already been there for years. How about manufacturing pharmaceutical products, not just APIs in China? The Fresenius Kabi facilities fulfill the requirements to supply markets in Asia and in Europe.

In China one can find well-educated and highly motivated people. GMP guidelines and the level of quality have highest standards. Also, Fresenius Kabi's facilities in China are built on the company's global experience and internal best practice.

The key to quick entry and success in the Chinese markets, as elsewhere, is the understanding of the regulatory processes. Also the interaction with local authorities during the process of outsourcing a pharmaceutical product is essential. With its decades of experience with manufacturing and marketing pharmaceutical products all over the world, Fresenius Kabi is the partner to turn to for contract manufacturing services in China.

Key Data: Fresenius Kabi - Contract Manufacturing in China

Facilities:

- Beijing
- Wuhan
- Wuxi

IV-Containers:

- Glass vials: 1-50 ml
- Glass ampoules: 5-20 ml
- Glass bottles: 100-1000 ml
- IV-bags (PP): 100-500 ml

Markets / Certifications:

- China and Asian countries
- EU

Technologies:

- Lyophilization
- Aseptic liquid filling
- Liquid filling + terminal sterilization
- Manufacturing of tablets

Services:

- QC and regulatory support
- Secondary packaging
- Stability studies
- Warehousing & shipping



freeflex[®]+

The Needle-free Solution for Drug Reconstitution

Need to ensure safe and convenient dissolution of your powdery drug products? Fresenius Kabi Product Partnering has the solution. Package your drug product with our diluents in freeflex[®]+ bags. Co-packaging of your drug product with our diluent makes for the safest and most convenient handling process for healthcare staff, and also ensures the use of the best quality diluents. To find out how this works in practice, you can get a first glimpse by reading this article. Contact us directly for any further information.



Working in a hectic hospital environment is always a challenge. Many tasks have to be done at nearly the same time for and around the patients and every work step has to be done right first time - otherwise patients and hospital personnel could be in danger. Due to the nature of modern drugs, one activity that has become much more frequent is dissolving powdery products in diluent containers. Especially when the compound being handled is toxic, it is critical to make these routine procedures safe, reliable and easy to perform. Classical dilution procedures involve using syringes with needles, which are needed to penetrate septum stoppers on the drug vials, and then to transfer the dissolved drug into an infusion bag. Working

with needles is one of the most prevalent risks for injuries to the hospital personnel and is especially hazardous when either toxic substances or biological samples such as blood are involved.

Fresenius Kabi is a specialist in diluent solutions and smart systems for use in hospitals, and provides an effective and convenient solution to this problem. Fresenius Kabi has developed a needle-free system for adding the solvent to the vial with a luer-lock adapter for syringes without needle, and the same luer-lock system can be found on Fresenius Kabi's freeflex[®]+ bags. This means that the hospital staff can perform the complete dissolution procedure without a needle - significantly reducing the risk of injuries and leading to a less stressful working environment.

The freeflex[®]+ system is available with a variety of different bag sizes (from 50 ml up to 1000 ml) and different infusion solutions. A huge number of different drug products have been proven safe to use with the bag material and the port system.

If you have a product that has to be stored as a powder and are looking for a safe and convenient dissolution system, please contact us at Fresenius Kabi Product Partnering. We are happy to discuss any question or request you might have with regard to diluents.



Vial adapter



Luer-lock connector between syringe and bag



freeflex[®]+ connectors