

## Product Partnering

*Fresenius Kabi Product Partnering*

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### Vital Statistics

**Key Personnel:** Gerald Hofer, Senior Director Product Manufacturing, Anton Gerdenitsch and Uwe Woelk, Directors Product Manufacturing, all responsible for sterile liquid dosage forms; Stefan Vogt, Director of contract manufacturing, responsible for sterile devices.

### Who We Are

Fresenius Kabi Product Partnering is a global leader in contract filling and finishing of sterile liquids, development and manufacture of sterile disposable products and its application technology. As part of Fresenius Kabi we offer access to the expertise of more than 20 innovation and manufacturing centers for sterile products. High-quality production capabilities are coupled with a track record of quality compliance, flexibility and a spirit of innovation. This has made Fresenius Kabi Product Partnering the supplier of choice for many pharmaceutical and medicinal product companies.

### Major Markets

Fresenius Kabi Product Partnering serves pharmaceutical and medical device companies all over the world. Our offerings cover the entire lifecycle of sterile products. Starting at the early stages of development and regulatory filing, typically followed by the manufacture of clinical supplies or prototypes to come to full commercial production. At later stages of the lifecycle we satisfy the worldwide demand according to customer requirements and market conditions, constantly improving our performance by experience and innovation.

### Services Offered

#### Toll Manufacturing

Fresenius Kabi Product Partnering covers more than 20 Fresenius Kabi manufacturing facilities for sterile liquids and medical devices operating in strict conformity with international quality standards (FDA cGMP, EU GMP, ISO 13485, ISO 9000). New products are evaluated by means of an initial feasibility assessment study in which the best fit between the client (e.g. location, regulations), product (e.g. container closure system, manufacturing process) and facility (capacity, technology and available services) is determined. As a result of this feasibility an initial assessment of cost and timelines is provided.

The implementation and/or development of the production process is supported by a project team with the project manager as the single point of contact for all operational questions.

Time to market is minimized by an efficient development, qualification, validation and stability program, where the expertise from development, regulatory, QA/QC and production functions are brought together in a single project plan established in close cooperation with the client.

Application specialists for the seamless integration of products and application sets support the teams as needed.

#### Major manufacturing services include:

- filling and finishing of I.V. bags (PVC and latex free), bottles (glass and plastic), vials (glass and plastic) ampoules (glass and plastic), pre-filled syringes (glass and plastic), as well as cartridges and customized containers
- manufacture of sterile medicinal products for the application of sterile liquids
- aseptic processing and terminal sterilization
- manufacture of emulsion and suspensions
- antibiotics powder filling
- packaging, sterilization and final inspection of finished products by QA
- analytical support (physicochemical and microbiological)
- regulatory assistance
- worldwide shipping and distribution

#### Development Expertise

Fresenius Kabi Product Partnering offers development expertise of sterile liquids and medical devices at a number of competence centers. The expertise includes the following areas:

- Development of formulations (solutions and emulsions)
- Development of drug delivery systems (enhancement of bioavailability through the proprietary HESylation technology)
- Development and Engineering of medicine-technical disposables for infusion therapy, enteral therapy and subcutaneous application
- Design, selection and qualification of primary and secondary container closure systems
- Development including O-series prototype manufacture to fully or partially automatic mass production
- Setup and validation of analytical methods
- (c)GMP compliant manufacture of clinical trial batches

#### Our approach: integral support

We provide our clients a support through the entire product lifecycle of their sterile products. After a successful setup of the manufacturing process in the early stage our support continues to through commercial production. Continuous improvement and innovative support such as active supplier management or the implementation of new regulatory requirements such as barcode printing keep the product tailored to clients' requirements all the time.

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