

Always the highest quality ...

... that's our mission - Fresenius Kabi's concern-wide quality management.

Dear Readers,

For many of us in different parts of the world, the soundtrack of this summer was a loud buzzing noise. Football fans or not, I'm sure we all caught something of the drama and colour of the World Cup. Some say it's only a game; but playing games and having fun is very human. I hope you enjoyed this summer, especially if you went on vacation.

And back in the midst of business I hope we can remember that what we do is about helping people to be well enough that they can have some fun, play games, and enjoy life.

In this issue of Insight, we'd like to tell you about an expansion of our contract manufacturing services at our Neufahrn site in Germany. This facility specializes in individual compounding of parenteral and oncological iv drugs, and in a new development, it now offers a full service preparing sterile solutions for clinical trials.

The next story is about Fresenius Kabi's concern-wide quality management group, which is unifying and supporting all our local quality units: keeping the quality of the Fresenius Kabi portfolio and of the products we make for our partners at the top.

And finally, this issue's Spotlight is on one of our state of the art European manufacturing locations in Vilassar, Spain. This plant specializes in blow-fill-seal technology, with a high-throughput concept that ensures excellent cost-effectiveness. A recent investment in equipment has increased the plant's volume capacity even further.

Greetings to everyone who visited our booths at the Interphex trade fairs in New York and Tokyo. It was a pleasure to meet you in person and learn about your current and future outsourcing needs. We are looking forward to seeing you in Paris (ICSE) and New Brunswick (Contract Pharma TT) soon.

And as a take home message, please challenge us with your needs, requests and inquiries. I am pretty sure we can surprise and inspire you with our ideas, proposals and solutions.

Sincerely yours,
Uwe Wölk

Exhibitions

- **Contract Pharma Table Top**
(Sep 23, New Brunswick, NJ - USA)
- **ICSE 2010**
(Oct 5-7, Paris - France)
Booth 4E4B



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Fresenius Kabi Neufahrn site, a competence centre for compounding activities



Made to order

Neufahrn, Germany is in the northern suburbs of Munich. Fresenius Kabi's facility there is a centre of excellence in aseptic compounding of infusion solutions for individual patients. About 100 qualified and experienced employees work at the site. The first product group is parenteral nutrition solutions for home care and dialysis patients; for these, the individual compounding enables a precise response to the patients' nutritional needs. The other group of compounds handled at Neufahrn are cytostatic drugs, whose dosage needs to be adjusted carefully to balance therapeutic and toxic effects.

Support & Accessories

In Germany, total parenteral nutrition (TPN) bags and other iv solutions have to be delivered through pharmacies. We provide an advisory service to assist clinicians and pharmacists in drawing up therapy plans. Along with the solutions, customers can order all the equipment needed to administer them. Individually compounded products can be packaged with a range of medical devices for delivery, and with additional standard solutions (vitamins, electrolytes, etc.) needed by the same patient. We can also supply infusion stands, fridges, and electronic infusion pumps.

Centre of excellence

Besides its role as a national supplier, Neufahrn is also the leading centre of competence for Fresenius Kabi's international network of more than 20 compounding centres.

Clinical trials

The new development in Neufahrn is our service producing infusion solutions for clinical trials. If you need a trial drug in

the form of an infusion, we can handle the entire cycle of producing and supplying the drug to trial centres. The package includes the following steps:

- Compounding
- Labelling and blinding
- Controlled storage
- Storage of retain samples
- Controlled shipment to national and international trial centres
- Management of all investigational medicinal products returned from trial sites
- Destruction of investigational medical products, if desired.

Naturally, these processes are all done in compliance with the relevant national and international guidelines.



Quality

The plant is licensed by the competent authority for aseptic manufacturing of parenteral nutrition and parenteral medication (cytostatic drugs) according to GMP guidelines and the German Drug Law (AMG). An additional license that covers the process of preparing drug products for clinical trials was granted in 2010. The plant is also certified under DIN ISO 9001 by the TÜV Süd Management Service.

History

- 1993: Compounding of parenteral nutrition solutions begins
- 1995: Compounding of iv drugs begins
- 1998: Site acquired by Fresenius; distribution of standard parenteral solutions begins
- 2003: Site reorganized to a production unit
- 2006: Start of compounding concept
- 2008: New clean room built
- 2010: Launch of clinical trial activities

Other activities

The Neufahrn site also carries out stability studies on compounded iv solutions, in cooperation with a contract laboratory. It is a test centre for new developments within Fresenius Kabi (e.g., medical devices, new technologies). And it provides a validation service for in-house and outside clients.

Quality makes the difference

Fresenius Kabi is producing and marketing health care products such as Pharmaceuticals, APIs, Clinical Nutritional Products and Medical Devices on an international, global basis.

Fresenius Kabi is committed to what matters most in healthcare: improving the patients' quality of life. This commitment requires the application of a Quality Management System that assures the highest possible quality of products in terms of safety and efficacy.

At Fresenius Kabi, quality is an integral part of our day to day operations, of our business strategy and business philosophy. Our corporate Quality Management System guarantees full compliance with national and international legal requirements and meets the expectations of our partners and customers. The basis for our lasting and successful partnership with our customers is the consistently high and ever improved quality of our products and services.

Therefore, the worldwide network of Fresenius Kabi is operating according to quality standards which are common for all our sites.

Fresenius Kabi's Quality Management System is certified to comply with the international standard ISO 9001 by an accredited, internationally recognized certification body, the TÜV Süd Management Service.

All specific legal requirements for Pharmaceuticals and APIs (GMP-Regulations), Medical Devices and Clinical Nutritional Products are embedded into the Quality Management System.

Fresenius Kabi has also established an Environmental Management, certified according to ISO 14001, as an integral part of its Quality Management System. Our ISO 14001 certification documents the company's dedication to the management of the ecological aspects of its business activities and demonstrates our commitment to environmental protection. The environmental policy is targeted to analyze the company's environmental responsibility, processes, steady improvements and supply chain management from an environmental point of view. The company's goal is ensuring that its business activities for protecting the environment in all areas as e.g. product development, production and even logistics are systematically and continuously improved. Fresenius Kabi's Quality Management System is

maintained by the corporate Quality Management of Fresenius Kabi, operating from Fresenius Kabi's headquarters in Germany.

Our Quality Management System is regularly reviewed during internal quality audits and by external auditors from our certification body.

As a Quality Management organization, this corporate function is coordinating and executing such internal audits at the Fresenius Kabi sites on a global basis. Fresenius Kabi Quality Management is also coordinating the international certification activities and the quality audits by the certification body.

The steady improvement of quality related processes is of importance in the pharmaceutical industry. Knowledge Management and Training are decisive factors therein. Therefore, Fresenius Kabi's Quality Management System - as the competence center - coaches and supports all Fresenius Kabi sites with

respect to quality related questions in line with the ISO 9001 and ISO 14001 standards, the international GMP-regulations for Pharmaceuticals and APIs, ISO 13485 and further international regulations for Medical Devices and the quality standards for Clinical Nutritional Products.



In the Spotlight: Competence in Catalonia



The production site of Fresenius Kabi's Spanish affiliate, Fresenius Kabi España S.A., is located in Vilassar de Dalt, 25 km outside of Barcelona.

Operations began here in 1964 in the form of a pilot plant for standard solutions in glass bottles, in a building of just 264 square meters. Today, the plant houses a cutting-edge blow-fill-seal (BFS) facility, with about 100 employees working in 5 shifts to keep the production running 24/7. The site has its own quality, logistics and administration departments and a warehouse.

Top quality

The quality unit has outstanding analytical competence - beginning with analysis of the starting materials, continuing with IPC production surveillance and finally in the release of the finished products. There are climate chambers where stability studies can be done in accordance with ICH requirements.

Blow-fill-seal

The plant produces a huge variety of sizes. The most recent extension of the BFS capability, in 2007, added a state-of-the-art bottle-pack machine dedicated to 5 mL & 10 mL polyethylene (PE) Luer-lock ampoules, with a capacity of about 100 million units per year.



Ampoules take heat

The Luer-lock PE ampoules are simple to use; safe handling and sound performance are guaranteed. The easy-opening twist-off cap and the highly collapsible shape give these ampoules a clear competitive advantage. Also, they can be sterilized at 112°C to achieve an FO value of higher than 9, which eliminates microbiological risks.

Drainjet

Another type of container produced at Vilassar is the Drainjet irrigation bottles. These are squeezable bellows bottles that allow precise manual irrigation. They have a thermo-finished nozzle for easy connection to flexible tubing, and are available in 60 mL and 120 mL sizes.

Markets

Vilassar supports customers within Fresenius Kabi as a complete service provider and is therefore a crucial part of the global Fresenius Kabi supply chain, delivering products like standard infusion solutions (NaCl, glucose, Ringer lactate etc), irrigation solutions and Luer-lock PE ampoules to many European countries, like Spain, UK, Germany, Italy, France and the Netherlands.

And of course the plant also works for business-to-business customers, who include both domestic and international pharmaceutical companies. Processes and services are usually tailor made to meet the client's needs. You could be next.

Key data Fresenius Kabi Spain Vilassar Plant

Markets:

European scope

Technologies:

Blow fill seal - bottles

Blow fill seal - ampoules

Customized BFS Containers (e.g. Drainjet Solutions)

Terminal sterilisation

Batch-Sizes:

Bottles - Infusion:
max. 4000 L

Bottles - Irrigation:
max. 4000 L

Ampoules: max. 4000 L

Containers:

Bottles - Infusion:
100, 250, 500 and 1000mL

Bottles - Irrigation: 60, 100,
120, 250, 500 & 1000 mL

Ampoules: 2, 5, 10 & 20 mL

Certifications:

EU GMP

ISO 9001 (Quality)

ISO 14001 (Environment)

CE Mark (for Irrigation
Solutions)

Services:

QC Support

Stability Studies

Warehousing and Shipping

Regulatory Support