

SCHOTT forma vitrum NEWS FLASH

PHARMACEUTICAL PACKAGING

ISSUE 10 June 2008

NEWS

Pharmaceutical Packaging License for China

SCHOTT forma vitrum in Suzhou, China, has now received the official license to manufacture and supply vials and ampoules to the Chinese pharmaceutical industry by China's State Food and Drug Administration (SFDA).

The People's Republic of China recently introduced a rather demanding approval process for suppliers of primary pharmaceutical packaging under the auspices of the State Food and Drug Administration (SFDA) in Beijing, an agency comparable to the Food and Drug Administration (FDA) in the United States. To be able to market their products in China, manufacturers who intend to enter the market now have to meet a broad range of strict requirements on material and processing quality. In setting such high standards, industry experts feel that China is setting a clear trend towards quality improvement of pharmaceutical packaging.

"This is good news for our customers in the pharmaceutical industry, because higher quality packaging translates into better protection and storage of medications", says Bernhard Elsener, Vice



Pharmaceutical packaging from SCHOTT forma vitrum, Suzhou, meets international quality standards.

President Global Sales & Marketing at SCHOTT forma vitrum. The Suzhou pharmaceutical plant was built in accordance with the same high standards that SCHOTT forma vitrum production sites adhere to on a global basis, including state of the art production equipment, visual inspection systems, clean room environment and compliance with Good Manufacturing Practices (cGMP). The site in Suzhou also has access to the entire global research and manufacturing expertise that exists at SCHOTT. According to

current plans, the plant will employ approximately 50 people.

The facility uses SCHOTT "Fiolax" Type 1 borosilicate glass, a high quality tubing glass that complies with international standards (USP, EP, and JP) to produce the complete range of ampoules and vials that the Chinese market is currently demanding. Only a few weeks ago, SCHOTT-Rohrglas had become the world's first certified importer of Type 1 glass tubing in China. All packaging products satisfy the highest international requirements for pharmaceutical primary packaging made of glass and therefore put SCHOTT in the unique position of being able to support the growth of the high quality market segment.

"We can offer our customers a variety of tangible benefits. These include quick delivery, local customer support and services without language barriers, as well as full support from SCHOTT's global network", Elsener adds. The site in Suzhou will supply its high quality packaging products to both new and existing customers in China, many of whom have been accustomed to receiving deliveries from various other SCHOTT sites in the past. In addition, the plant will serve as a backup facility for the sister plant SCHOTT Igar Glass in Indonesia.

EDITORIAL



Dear Readers,

We are going ahead – in China, India and Russia. Our company is the first certified manufacturer for vials and ampoules of world class quality in the Chinese market. The acquisition of this license through a demanding approval process also shows the commitment to our quality philosophy.

Besides China, another emerging market is in our focus. With the formation of our joint venture in India under the name SCHOTT KAISHA PRIVATE LIMITED, we will support the Indian pharmaceutical industry on the way towards reaching international quality standards.

At the end of 2007, we informed you about our plans to build a new greenfield plant in Bor, Russia. Thanks to the success of Marina Ovsyannikova, whose profile you can read in this issue, you will realize that we are on a well prepared path

in developing the Russian market and the Commonwealth of Independent States.

Not just new factories but also new products underline our innovative power. In April 2008, we completed our range of high-tech polymer vials. In addition, we presented a coating innovation for pharmaceutical packaging – the SCHOTT „TopLyo“ vial with a hydrophobic coating on the inside surface and an improved geometric design for freeze-dried substances.

Finally we need to address the impact of the global trend in raw material and energy cost. As every consumer at the gas station, we face drastic increases in energy prices. Our material and production cost are further affected by significant increases of raw material cost. These effects can only partly be compensated by our continued thrive for productivity improvements, which is forcing us to adapt our prices significantly. With respect to the mutual benefit of our business, we hope for your understanding and look forward to the continuation of our successful cooperation. For today, we hope you enjoy reading our latest edition.

Sincerely yours,
Ralf Bouffleur
Vice President, Business Segment
Pharmaceutical Packaging

PRODUCTS

Hydrophobic Coatings for Sensitive Biotechnology Preparations

At Interpack in April 2008, SCHOTT forma vitrum has presented a new coating innovation for pharmaceutical packaging applications. SCHOTT TopLyo™ containers with a hydrophobic coating on the inside surface and an improved geometric design offer optimum efficiency for the lyophilisation process.

Vials with these hydrophobic coatings have such homogeneous surfaces that freeze-dried (lyophilized)

substances find it difficult to adhere to the inside walls of the vials. The result is not only an improved cosmetic look of the lyophilisation cake and less disruption of dry material, but also reduced breakage during the lyophilisation process.

The coating is applied by the proprietary SCHOTT PICVD technique – "Plasma Impulse Chemical Vapor Deposition", in a validated and permanently inspected process. The entire layer is only 40 nanometers



SCHOTT "TopLyo" – hydrophobic coating and improved geometry for freeze-dried drugs.

thick and, therefore, has no effect on the dimensions of the pharmaceutical container. It is stable to pharmaceutical procedures like washing, sterilization and depyrogenization (heat treatment of 300° C).

In the field of pharmaceuticals, lyophilization is primarily used to extend the shelf life of highly sensitive ingredients, such as proteins, that are often produced biotechnologically. "This is an important field for the future. After all, biomolecules are already being used today in over 50 percent of all product developments in the area of pharmaceutical therapy", explains Dr. Claudia Dietrich, Product Manager Vials & Coating at SCHOTT forma vitrum.

The advantages of freeze-drying are that products are preserved for

longer, their effectiveness remains stable and the highly effective and sensitive ingredients are better protected. Such preparations are used in oncology, for example.

The benefit for the customer is a lower rate of rejects caused by collapsed lyophilization cakes and a reduced risk of breakage. As both effects have an impact on process costs, there is also a financial advantage to use this product.

"The interests of both the pharmaceutical industry and patients alike are rather obvious. They are seeking to provide their valuable and costly medications with the highest possible protection and ensure that they remain effective for as long as possible", says Dr. Dietrich.

ON TOUR

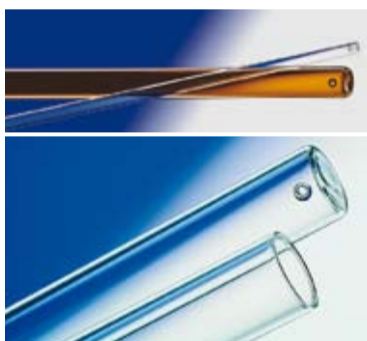
Innovative and Market-Oriented – Specialized Glass Tubing from Mitterteich



SCHOTT-Rohrglas in Mitterteich, Germany.

For the specialized glass manufacturer SCHOTT-Rohrglas in Mitterteich, Germany, continuous product improvements in response to customer demands have clearly become a recurrent theme when it comes to market orientation and innovation during the company's 126-year history. Today, Mitterteich is responsible for coordinating global manufacturing and quality assurance for all glass tubing, developing and testing new products in its own laboratories, as well as overseeing marketing and sales activities.

Working with glass has a long tradition in the Bavarian city of Mitterteich. In fact, the first glassworks to produce mirrors and eyeglasses on a large scale set up operations here back in 1883. Around that same time, Otto Schott founded his glass technology laboratory some 100 kilometers northwest of Mitterteich which later became Jenaer Glaswerk Schott & Genossen. In 1911, SCHOTT finally introduced a glass product that qualified for the first hydrolytic resistance class and ex-



SCHOTT "Fiolax", a high-tech product.

hibited extremely high resistance, neutrality, density and rigidity. It was introduced to the market under the name SCHOTT "Fiolax".

The fact that SCHOTT "Fiolax" has been setting the standard for glasses used in premium quality pharmaceutical packaging for decades is hardly by accident. In fact, consistent improvements to the quality of this product have resulted in its market success.

Innovations like "Densocan" that allow for pharmaceutical tubing to be separated and closed while it is still in a warm and soft state during the production pro-

cess are but one of the milestones with respect to technological developments. Especially with vials and ampoules, closing the ends helps to prevent contamination during the process chain both before and during processing. These innovations range from packaging to transportation. After all, "Densopack" is a packaging technique developed by SCHOTT-Rohrglas that improves safety during transportation and reduces the occurrence of particles to the highest degree possible. In addition, the special pallet certificate for pharmaceutical tubing guarantees the smooth transfer of this important data into the production processes used by customers.

The ability to manufacture the most advanced tubing with the same high quality and extremely low tolerances of glass that has a temperature of 1600° Celsius obviously requires the highest possible precision. From the arrival of the raw materials until each product is shipped, everything is constantly monitored. "We rely entirely on optoelectronic techniques based on GMP regulations to continuously analyze our manufacturing process", explains the site manager, Thomas Gassner. SCHOTT-Rohrglas has been certified according to ISO 9001, ISO 14001 and even ranks as the first tubing manufacturer to ever be certified according to ISO 15378.

By the way, tubing products can also be coated to resist scratches, if desired, whereby the respective coating products have all been registered with the FDA (Food and Drug Administration). SCHOTT "Fiolax" amber and clear are the starting products that customers then process into syringes, vials, ampoules or cartridges.



SCHOTT "Fiolax" is setting the standards for tubing glass used for pharmaceutical packaging.

Altogether, SCHOTT-Rohrglas and its various operations have production sites in Europe, South America and Asia and offer innovative services, such as an e-commerce ordering system that simplifies the entire procedure of ordering and processing orders for customers and reduces the costs as a result. Here, global access to technical and scientific consulting that customers have access to, including the analysis of defects that occur during processing, the transfer of know-how

through training sessions that even feature simulations and test operations in the company's own technical center can be considered a special highlight.

Nevertheless, the more than 1200 employees who work at the site in Mitterteich rely on their 18 tanks to produce not only pharmaceutical products, but also technical tubing for many different applications in areas like lighting, plant construction, laboratories, as well as flash and halogen lamps.

Site at a glance

SCHOTT-Rohrglas GmbH

Location:	Mitterteich, Germany
Employees:	1226
Products:	Pharmaceutical tubing (SCHOTT "Fiolax" clear and "Fiolax" amber), Technical tubing
Production area:	approx. 80,000 m ²
Quality certification:	ISO 9001, ISO 15378, ISO 14001

CUSTOMER FOCUS

New: SCHOTT forma vitrum Europe ag

In order to simplify processes for customers in Europe, SCHOTT forma vitrum has announced the foundation of a new company, named SCHOTT forma vitrum Europe ag. In the future, this will be the only order and billing address in Europe, which will make interactions for clients much easier and more efficient according to Hans Peter Manser, Director of Sales for Europe.

"We currently have customers who order ampoules in France or Hungary", says Manser, "but also



SCHOTT forma vitrum Europe ag is located in St. Gallen, Switzerland.

vials in Germany or syringes in Switzerland. This calls for dealing with four different legal entities, a situation that will now be resolved." With its headquarters in Switzerland, SCHOTT forma vitrum Europe ag will represent the central point of contact on all sales matters for all customers, regardless of where their pharmaceutical products are shipped from. The new company was founded on June 1st and will begin operations on August 1st, once it has been duly registered and received formal customer approval. Because the activities of the

new sales company will be limited to ordering and billing procedures, this change will have no impact on site approvals or validations of individual sites. Each customer will still receive products directly from the sites that have been validated. Likewise, this change will have no impact on current customer service contacts. The foundation of SCHOTT forma vitrum Europe ag is part of an internal project called PEP (Power up European Plants) that is mainly aimed at the harmonization and standardization of processes and systems.

PEOPLE

Be Precise and Always Keep your Promises

When Marina Osvyannikova became SCHOTT's Area Sales Manager for Russia and the Commonwealth of Independent States, she was facing a challenging task. "When I began in 2004 there were nearly no sales in Russia, so I had to create a strategy of penetration into the market, to define the circle of potential customers, and to create advertising of SCHOTT in general. This meant I had to be a developer, and a marketing and relationship manager at the same time", she says.

Wearing more than one hat is nothing new for Marina. Before becoming a sales manager, she was a trained ophthalmic surgeon. After five years of performing eye surgery, some friends introduced her to a new career. Marina took her precise medical experience and applied it to the field of sales and marketing. She says that her background has certainly helped, especially in communicating with her customers in research and development. "Scientists appreciate

my understanding of the medical profession."

After several years of working in the packaging business, Marina joined SCHOTT and quickly became part of a new team which embarked on penetrating the Russian Market.

Marina and her team gained more and more insight into a new market that is rapidly growing and still unpredictable. Within a year, she started to see results. She explains, "As a first step we started with ampoules as a standard product. Later we introduced vials and cartridges and more recently syringes have become part of our pharma life. The market is ready for them, and we have participated in that preparation." Optimistic by nature, Marina sees more opportunity in the developing market in Russia in the future.

Marina's office is located in Moscow, but her sales duties involve lots of travel. "Sometimes it is necessary to travel quite far. For example, I had a flight to Khabarovsk

which took 8,5 hours and I was still in the same country. Can you imagine that? But this is the only way to really understand the market."



Marina Osvyannikova (right) sees a lot of opportunities in Russia.

Marina has experienced firsthand the changes that have occurred in Russia and the CIS over the past 20 years. She says: "Our market is getting more and more

professional, more precise, and more quality oriented." Marina sells a full range of products with an emphasis on quality. SCHOTT

Although she says her free time is somewhat limited, she enjoys visiting art galleries when she is abroad. "I very much like classical painters, especially those related to the epoch before the renaissance. Dürer, Jan van Eyck and Peter Brueghel are my favorite artists."

Her commitment however to precision might be best explained by her more active hobby of shooting. "I have a rifle and a shotgun. It gives me relaxation after a stressful week or period of time," she says. In the immediate future, Marina may find her time even more limited. On June 2nd she gave birth to her second child.

Marina credits her overall success within SCHOTT forma vitrum to persistence, optimism and a basic philosophy. "Be precise and always keep your promises," she explains. But of equal importance is the superior support of her team. Marina has high praise for her colleagues. "Only with this wonderful group of people have we reached such outstanding results."

PRODUCTS

Full Range of High-tech Polymer Vials



SCHOTT "TopPac" vials are break resistant, light weight and transparent like glass

SCHOTT forma vitrum has extended its range of cyclic olefin copolymer (COC) containers and can now offer 2ml, 6ml, 10ml, 20ml, 50ml, and 100ml vials under the SCHOTT TopPac® brand. They are suitable for liquid fill or lyophilisation.

"COC polymer offers a few important advantages over glass", explains the Product Manager, Wolfgang Streu. "Glass has been

a well-tried and accepted material for parenteral packaging by the pharmaceutical industry for decades, but depending on the drug and its application, it has also certain limitations." In these cases COC polymer can offer a very good alternative. The main benefits of COC polymer include better breakage safety, excellent barrier properties, high chemical resistance as well as freedom of de-

sign. It is transparent like glass and also free of ions and heavy metals. SCHOTT offers also syringes made of COC polymer.

"We notice a strongly rising interest in this product, some 90 potential customers have been supplied with product samples over the last few months, for example", Streu says. "We've identified very interesting points of contact in the area of ophthalmics, where our COC vials are used to store one-way contact lenses. Inquiries have also come from both oncology and veterinary medicine. Other typical applications are emergency drugs, diluents and toxic preparations."

TopPac® vials are currently produced at the SCHOTT forma vitrum plant in Müllheim, Germany, where state-of-the-art technology and strictly controlled processes ensure the excellent quality of this product. On top of this, SCHOTT is also working together with manufacturers of filling machines to ensure optimum manufacturing conditions for the specific requirements of this product for the pharmaceutical company. "More than 10 years of experience with COC polymer put us in a position to act as a problem solver for our customers in the area of pharmaceutical packaging – not only for glass but also for high tech polymers", Streu notes.



SCHOTT "TopPac" vials are made of cyclic olefin copolymer (COC) of the highest purity

Masthead

SCHOTT forma vitrum
NEWSFLASH

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NEWS

New Joint Venture in India



SCHOTT KAISHA will manufacture StandardLine ampoules and vials for the Indian market.

SCHOTT forma vitrum and KAISHA Manufacturers Private Ltd., an Indian company, announce the formation of a joint venture, SCHOTT KAISHA PRIVATE LIMITED. The new joint venture will manufacture primary pharmaceutical packaging made of glass for the Indian market.

The joint enterprise will have operations in Mumbai and Daman. "With this double-digit million euro investment, SCHOTT continues on its course to growth and quality leadership. Addition-

ally, we are securing our access to a very promising market", says Professor Udo Ungeheuer, Chairman of the Board of Management of SCHOTT AG.

SCHOTT, the technology group based in Mainz, Germany, will hold a 50 percent share in the company and contribute its technological expertise in manufacturing high quality ampoules, vials, syringes and cartridges in a global environment. KAISHA will bring in its existing sites and manufacturing capacities.

SCHOTT and KAISHA have worked successfully for many years in a buyer-supplier relationship. SCHOTT supplied the pharmaceutical glass tubing to KAISHA for converting them into primary pharmaceutical packaging products. KAISHA is considered to be a quality leader in the Indian market with sales of 11 million euros in 2007.

The pharmaceutical packaging market in India is growing by approximately 10 to 15 percent per year, particularly in the higher quality segments, according to industry analysis. India has the largest number of U.S. Food and Drug Administration approved plants outside of the United States, for example.

SCHOTT KAISHA will support Indian pharmaceutical companies in upgrading products for international markets by supplying pharmaceutical packaging at an international quality level from the Indian production site. It will be a strong partner to the Indian pharmaceutical industry on the way towards reaching international quality standards. For this purpose, SCHOTT KAISHA will build production capacity for StandardLine ampoules and vials, which will be in production in the fourth quarter 2009.



NEWS

Cost increases as a global challenge

Raw material and energy prices are rising all over the world, a development that is also a cause for concern for SCHOTT forma vitrum. "Since 2003 alone, energy costs have increased by five times, the prices for rhodium have gone up by twenty times, platinum by four times and boron prices have doubled", explains Bernhard Elsener, Vice President Global Sales & Marketing. "These factors are unfortunately significant cost drivers for the production of glass tubes and glass containers."

For years, SCHOTT forma vitrum has been working to compensate for the increases in costs by introducing saving programs and improving productivity. "Our strong efforts in this field have actually

enabled us to compensate for a broad range of cost increases, rather than adapting sales prices. Nevertheless, with the recent dramatic cost developments, we have now reached the end of the line", says Elsener. "We see ourselves obliged to increase prices as soon as possible."

Also the drastic changes in currency exchange rates are causing problems for all companies that rely heavily on exports. "This situation is definitely not only a problem faced by one specific field or region, but rather a global challenge that we will have to master in the weeks and months to come", says Elsener. "It will mainly call for intensive negotiations with our customers in order to find common solutions."



EVENTS

Showcasing Solutions 'Hecho en Mexico'



90 representatives from 29 companies attended the Foro 2008.

Pharmaceutical manufacturers gathered for an intensive two-day workshop at SCHOTT forma vitrum's Cordoba plant near Veracruz, Mexico. Quality, supply chain, and innovative solutions from SCHOTT: these were only a

few of the topics on the table at Foro 2008, the customer event hosted May 22-23 by SCHOTT forma vitrum Mexico.

Held every two years since 2002 – and growing each time in size and scope – the Foro is a valuable



Brian Eller, General Manager & NAFTA Manufacturing Manager.

venue for company and customers alike. Attending this year's event were 90 representatives from 29 companies from Mexico and Central America.

"The Foro is an exchange," says Carlos Ortega, SCHOTT forma vitrum sales manager, Mexico/Central America. "Here SCHOTT specialists and key customers can meet face to face to discuss issues, opportunities, and the changing demands of the marketplace.



The plant tour was one of the highlights of the event.

This enables us to focus our efforts on targeted markets and develop strategies to help our customers meet their individual needs."

The symposium on the first day focused on topics like quality systems, ISO 15378, and product innovations. They were presented by experts from SCHOTT Switzerland, Germany and United States. It was followed by a tour of the 5,800 square meter facility where 260 employees produce 800 mil-

lion units of vials, ampoules and cartridges each year. The following day was devoted to a series of workshops, conducted by specialists in small groups of five or six, and focusing on such areas as supply chain, manufacturing, quality, innovations, and new products.

"Over the past two years we have been investing in machinery, facilities, and new offerings in order to provide our customers with more products at a competitive cost and higher volume along with the level of SCHOTT quality that they have come to expect", says Ortega. "Although price is a very important factor for our customers, they value high quality, particularly in the coming areas of biotechnology and oncology. This in turn has also sparked an interest in SCHOTT expertise in both innovative coatings and COC polymer."