

SCHOTT forma vitrum NEWS FLASH

PHARMACEUTICAL PACKAGING

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NEWS

TopLine vials production in Asia

To meet the demand of the high end market in Asia, SCHOTT forma vitrum will open a new production facility for TopLine vials in its Indonesian manufacturing plant. The new "TopLine production department" is scheduled to go into operation in April of 2007.

SCHOTT Igar Glass in Indonesia is the pharmaceutical packaging center of SCHOTT forma vitrum in Asia. It ranks as the largest manufacturer of primary pharmaceutical packaging products in Southeast Asia and mainly supplies its products to Asia and Australia. The site was built in 2002 and produces around 750 million ampoules, vials and pipettes per year.

Highly advanced inspection technology ensures constantly high quality.



„TopLine“ production department at SCHOTT Igar Glass, Indonesia.

The "TopLine department" in Indonesia produces tailor-made product solutions for the highest requirements. The state-of-the-art manufacturing lines are equipped with the latest technology and provide six-sigma quality for dimensional parameters and zero defects for critical cosmetic aspects. High quality standards are assured with ISO 9001:2000 and full compliance with GMP (Good Manufacturing Practice). Quality assurance is not dependent on human inspection but relies on

EDITORIAL



Dear Readers,

Customer satisfaction is our main objective and guideline of our actions. When reading this edition, you will discover a number of activities in different fields that are driven by our declared will to *live* customer orientation. Examples of which you will be reading are the opening of our new TopLine manufacturing department in Indonesia, where we are preparing to supply the most demanding

customers in Asia with our top products locally, or our activities in Europe, where we further improve the reliability of the working processes to achieve an improved service to our customers, or our efforts to exchange knowhow with the customers (Ben Venue) through interactive workshops.

Customer orientation represents an important part of our corporate culture. We are also more than willing to be measured on how well we live up to this ideal. The feedback we receive during visits to customers encourages us to continue to march in this direction.

We are looking forward to receiving also your feedback, it will help us to progress and serve you even better in the future.

Please enjoy reading the new Newflash.

Sincerely yours,

Christof Hanschke
Vice President, Business Segment
Pharmaceutical Packaging

sophisticated visual inspection technology which is far more reliable than human inspection.

The **Automated Inspection System (AIS)** by SCHOTT forma vitrum is a proprietary, highly sensitive visual inspection technology, developed in close cooperation with a leading Swiss university over more than a decade. It assures the reliable classification of smallest defects by type, size and even the position of the defect on all key surfaces of the container. AIS is a validated and fully inte-

grated system for inline process control and optimization.

To ensure that the demands of the exigent Asian customers are understood and executed correctly, Hiro Maruyama, a technical head from Japan, was hired. Says Maruyama: "With the support of a specially-trained team, we will ensure consistently high quality, stable processes and a service philosophy oriented towards Japanese business practices."

CUSTOMER FOCUS

Pan-European Organization at SCHOTT forma vitrum

By adopting a new organizational structure across Europe, SCHOTT forma vitrum is looking to optimize customer service and customer orientation. This was one of the first actions taken in the context of an internal project launched under the name PEP (Power up European Plants).

Driven by the strong market growth in Europe in the last few years, it aims at the closer cooperation and the consolidation within the European production and service network and supports a focused approach of all customer-related activities in the future.

"We will be improving the reliability of the working processes at our European sites in Germany, France, Hungary and Switzerland, as well as further unifying our systems and facilities," explains Markus Hersche, Director Operations Europe. This will not only

result in improved delivery times, but also enable the company to react to customer demands more quickly and with greater flexibility.

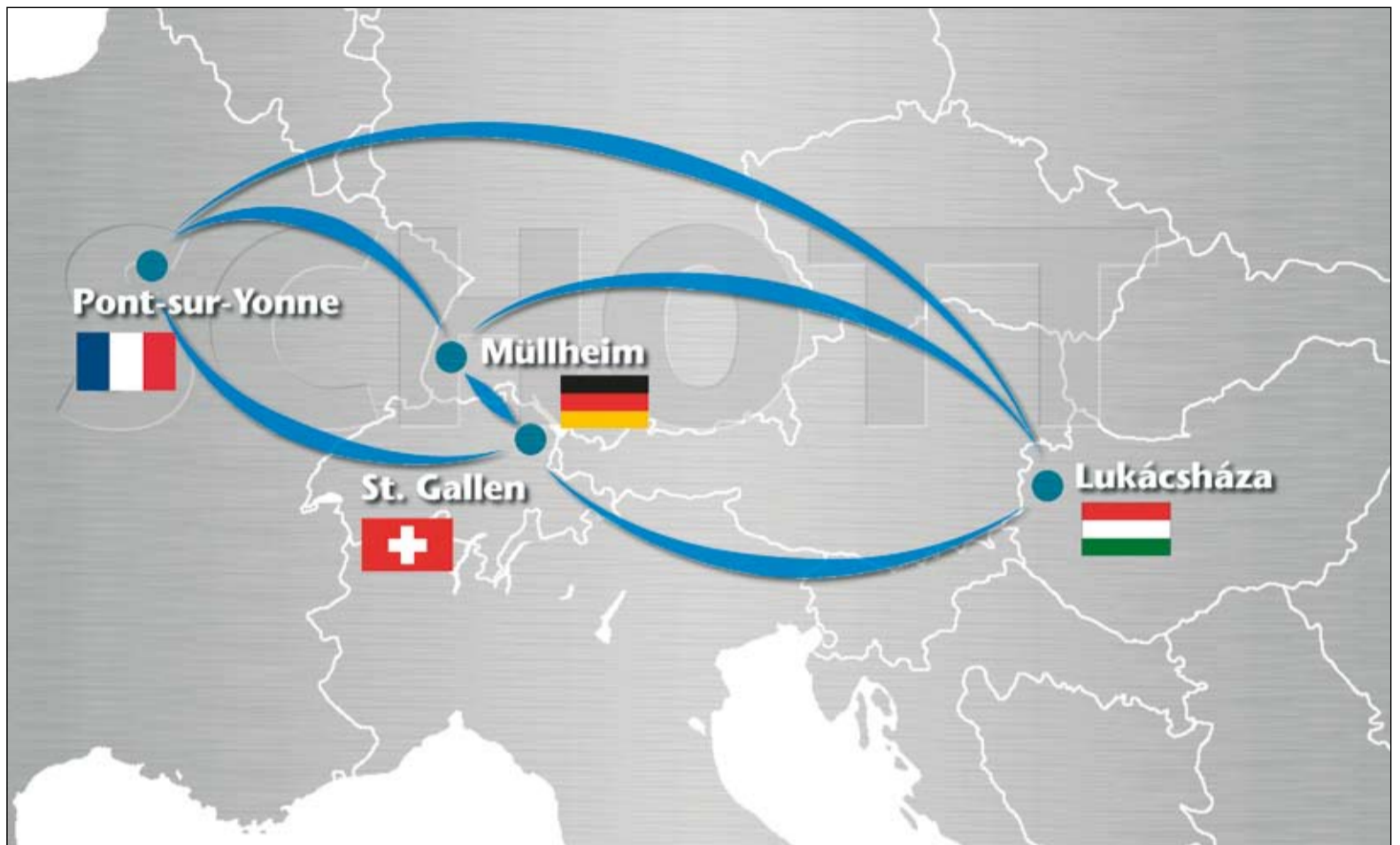
A number of actions have already been initiated to reach the goals. For example, system-

atic exchange of expert knowledge is driven forward in order to facilitate effective transfer of know-how. An important step to prepare for the organizational change was the introduction of one common ERP system (SAP)

Continue page 2

CUSTOMER FOCUS

at all European sites in 2006. It is a prerequisite for the effective realization and coordination of group activities within Europe. Further, additional investments have taken place in machines and technologies. "A lot more actions are to come", announces Hersche. "One of them will be to adapt the structure of customer service to enable customers to deal with only one contact in the future."



Organization network of SCHOTT forma vitrum Europe

PEOPLE

Face to face with the customer

As Director North America Sales and Marketing for SCHOTT forma vitrum, Gary Waller travels the region, meeting with customers face to face in order to help them develop long term strategies for meeting their packaging needs.

"It's critical in our business to continually communicate our value proposition to the customer that will reinforce their decision to build a long term relationship with SCHOTT forma vitrum," says Waller. "What will separate suppliers in the future is the ability to offer innovative packaging solutions, eg in terms of container material such as COC polymer, and coatings that have the ability to enhance product performance."

This, combined with the SCHOTT forma vitrum reputation, is what drew Waller to the company little more than a year ago. "I've been involved in different facets of glass manufacturing over 25 years – most of my working life." During summer vacations from college he worked as a lehr attendant. Over the past 14 years he has worked directly in the primary packaging industry that supports pharmaceutical, diagnostics and cosmetic market segments at various sales levels in North America.

"Historically, SCHOTT forma vitrum's name in the primary pharmaceutical packaging industry has been associated with pre-



Meeting customers: Gary Waller

mium tubing and state of the art container manufacturing process. This is supported through our global business structure with 10 manufacturing sites and sales coverage in over 38 countries. Our fully integrated processes from raw material to the finished product allows SCHOTT forma vitrum to control each and every stage of the container and fulfill the highest standards required by our customer base."

He was also impressed with SCHOTT forma vitrum's continued strategy of investment – 10% of sales – into technology develop-

ment and facilities. "It enabled us to expand our Switzerland, syringe operations in 2006 and make way for syringe production in North America in 2008."

To help customers make the most of all this innovation, Waller works with a dedicated team reorganized last year into three regions for the U.S. and Canada: west, central and east, each under a regional sales manager, with customer service support in Lebanon. He also oversees a Mexico/Latin America sales manager and team, whose customer service is based at the Cordoba facility near Vera-

cruz, Mexico. "The regional sales structure increases our face time with the customer and reinforces our continued support to their primary packaging requirements," he says. "Each sales manager has been through a manufacturing training session as well as product training for each item sold by SCHOTT forma vitrum. We believe it's critical to have a high level of technical expertise of our production base to support the customer's needs and to set us apart from the competition."

Because he takes his face time seriously, Waller spends 75% of his time on the road. Based in California, this can be a challenge, with sales calls, trade shows and the recent reorganization. He does, however, find time to coach as well as play in roller hockey leagues with his two sons and jog with his wife

and dog. "I enjoy the Southern California living with the ocean, mountains and desert just over an hour drive in each direction. These activities re-energize my mind and body from the daily challenges I face at work or after traveling."

Now with the reorganization accomplished, he's focused on several other activities to support the sales organization. "I spend time working with customers on agreements, developing long term strategies that will ensure continued growth, and targeting new accounts that will support our investments. It's critical for SCHOTT forma vitrum to understand the customer's future primary packaging needs so that we can develop the correct portfolio that will support future demands of our clientele."

Masthead

SCHOTT forma vitrum
NEWSFLASH

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QUALITY

ISO 13485 - Syringes are also a Medical Device



To guarantee the quality of products and services is the purpose of quality management. Maintaining and, whenever possible, increasing the satisfaction of customers represents another important goal, next to motivating, training and ensuring the qualification of employees and standardizing activity and working processes.

Certifications and norms signalize to the customer that all of the necessary requirements are being fulfilled. For instance, SCHOTT forma vitrum in Switzerland is certified according to the ISO norm 15378, the new standard that defines the rules for "Good Manufacturing Practice" (GMP) in primary packaging, but also the ISO norms 9001 and 13485.

ISO 9001, for example, describes the entire quality management system in an exemplary manner and provides the basis for a comprehensive quality management system. ISO 13485 builds up on ISO 9001 and also takes individual demands placed on medical devices into consideration. Whereas vials, ampoules and cartridges are not in themselves considered

medical devices, the situation is different with pre-fillable syringes made of glass or polymer materials. Due to how these products are put to use, they come extremely close to medical devices. After all, they are already manufactured under clean room conditions and then sent to the customer in sterile form, so that customers are immediately able to fill them in a sterile environment. As this indicates, specific medical demands are met under ISO 13485, such as requirements with respect to validation, qualification, operational hygiene, testing, storage conditions and shelf life.

Also risk management is an issue that plays a decisive role with ISO 13485. Conducting risk analysis is essential, particularly whenever new innovations or changes in manufacturing processes are involved. For example, the path a product takes must be tracked, even after it leaves the plant, and further market developments must be observed. Basically, one must always be in a position to provide the customer with any data and information that might be required on very short notice.

EXHIBITIONS & EVENTS

Come and see us at

Interphex Show, New York (US), April 24 - 26, 2007

Koreapack, Goyan-Si, Ilsan (Korea), April 24 - 27, 2007

PMP Copenhagen (Denmark), May 8 - 9, 2007

API China, Nanjing (China), May 15 - 17, 2007

SCHOTT forma vitrum Pharmaceutical Packaging Technical Workshops, in: Baltimore (MD) on May 15, 2007, and Chicago (IL) on May 18, 2007, and Irvine (CA) on May 24, 2007

Interphex, Tokyo (Japan), June 20 - 22, 2007

ON TOUR

Vials from the Border Triangle



SCHOTT PICVD Coating Technology improves the product properties of pharmaceutical packaging.

The town of Müllheim is located in the outside corner of Germany's southwest, inside the border triangle of Germany, France and Switzerland, where the "south" begins.

This is not far from the pharmaceutical capital of Basel, only five kilometers away from the French border along the Rhine, Europe's most important interior river, right in the middle of the Markgräflerland wine region and directly adjacent to the Elsass, where borders hardly play a role and plenty of labor is available. An excellent location for a company specialized in pharmaceutical packaging. Over time, the trading company founded in 1948 developed into a manufacturer of glass and polymer pharmaceutical packaging.

In 1970, SCHOTT recognized the potential of the company and decided to acquire it. At that time, SCHOTT was already an important supplier of tubing glass for use in manufacturing vials for parenteral products.

Today, pharmaceutical vials are the main products manufactured in Müllheim. More than 230 million units are made each year. In addition, the site has several coating lines using the PICVD technique patented by SCHOTT to apply a special quartz-like coating to the inner surface of the vials. The final products, inert vials for use with highly sensitive pharmaceuticals and costly ingredients, are known under the brand name "SCHOTT Type I plus".

By the beginning of the 1970s, SCHOTT already had its own poly-

mer department in Müllheim. Here, 45 million plastic closures and other polymer products are produced each year by injection molding machines. In addition, Müllheim manufactures vials of COC polymer for pharmaceuticals and diagnostic products.

In Müllheim, the vial manufacturing lines produce different product versions. These can be broken down into StandardLine, ClearLine and TopLine quality categories. The TopLine production lines produce customized solutions for the highest customer requirements. They are equipped with AIS inspection systems developed by SCHOTT forma vitrum. Müllheim has also achieved a global leadership position when it comes to manufacturing large vials of 50 to 100 ml in TopLine quality. "We will continue to grow our business with regard to larger, high quality vials, in particular. In fact, last year alone, we were successful in doubling our sales in this area," says site manager, Norbert Reisert.

The Müllheim site, with its roughly 200 employees, generates revenue of 28 million euros and is growing at a rate of roughly ten per cent per year. Its customers are based mainly in central Europe. Müllheim markets its "SCHOTT Type I plus ®" and "large vials" globally. Reisert is convinced that the coating sector also offers potential. "In cooperation with the prestigious SCHOTT Research Center at the group headquarters in Mainz, Germany, we are looking forward to making many exciting things happen," he adds.



SCHOTT forma vitrum in Müllheim doubled sales last year.

Site at a glance

SCHOTT forma vitrum Germany

Location:	SCHOTT AG, Müllheim
Employees:	200
Products:	Vials, "SCHOTT Type I plus"®, "SCHOTT PURGARD"®, plastic closures
Capacity:	280 million units per year
Production area:	7,000 square meters
Quality certification:	ISO 9001, GMP, ISO 15378

EVENTS

Ben Venue Glass Day Event



Ben Venue – one of the most experienced contract manufacturer of lyophilized products in the United States.

Ben Venue Laboratories Inc., a U.S. subsidiary of Boehringer Ingelheim, is one of the most experienced contract manufacturers of sterile injectables in the world. Ben Venue's abilities include production of clinical to commercial material of either liquid or lyophilized dose forms. As part of the training that Ben Venue offers to their employees, the company hosted a "Glass Day Event", presented by SCHOTT forma vitrum.

Patrick Gruening, New Development Manager, SCHOTT forma vitrum North America, was invited to present the daylong seminar:

1. The first session was a highly technical presentation geared to-

wards R&D and scientific personnel which included an in depth discussion on chemical composition of glass and vial formation.

2. During the "Brown Bag Lunch" session, all Ben Venue personnel were invited to attend an hour long presentation containing a general overview of glass and tubular vial formation. Attendees enjoyed their lunches, viewed a brief video, received an overview of glass composition and participated in a question and answer session. This seminar was well attended by over 50 Ben Venue employees.

3. The final training session also provided an overview of glass

and focused on other areas such as defects and glass composition. This session had a greater concentration of quality professionals in attendance.

"The Glass Event enabled us to bring together Ben Venue expertise in pharmaceutical filling with SCHOTT forma vitrum expertise in glass pharmaceutical packaging", Gruening summarized after the seminar. "More than 90 attendees altogether participated in the three sessions of the event. It was an excellent opportunity for a targeted audience to learn more about specific topics of interest in a condensed period of time."



Patrick Gruening represented SCHOTT forma vitrum at the „Glass Day Event“.



Ben Venue Laboratories are based in Bedford, Ohio.

SUCCESS STORIES

SCHOTT forma vitrum OPC Ampoules Go Japan

Since October 2006, Ancaron IV® by Sanofi-Aventis is available in Japan in 3ml OPC ampoules by SCHOTT forma vitrum.

With this product, the production site in Ambarès, France was the first Sanofi-Aventis plant in Europe that was successfully inspected and authorized by the PMDA (Pharmaceutical and Medical Devices Agency), the Japanese equivalent of the American FDA or European EMEA. Based on a new law from 2005, Japan only permits pharmaceutical products to be imported after they have been successfully inspected by the PMDA. For Sanofi-Aventis, the successful PMDA inspection marked an important step towards meeting the objective of introducing Ancaron IV® in injectable form to the Japanese market. Ancaron IV® is an antiarrhythmic drug also known under the name Cordarone® and has been available in Japan in tablet form since 1992.



Ampoules for Sanofi-Aventis manufactured by SCHOTT forma vitrum.

In April of 2006, the plant in Ambarès was scrutinized thoroughly for 2 and a half days. As Fabien Sciamama, responsible for quality at Sanofi-Aventis in Ambarès, puts it: "We are used to undergoing inspections, however, the inspection that the PMDA performed took on a totally new dimension." The site in Ambarès prepared for this occasion for more than a year. "We formed a dedicated task force that consisted of approximately ten employees from the areas industrial quality

and compliance, industrial development, production and quality," explains Fabien Sciamama. "Furthermore, our outstanding cooperation with our colleagues in Kawagoe, Japan, really helped us prepare for the cultural differences. For example, the Japanese are extremely sensitive to purity. They regard even the slightest of defects in ampoules that would lie within the tolerance zone for us to be inexcusable."

The 3 ml ampoules for Ancaron IV® were supplied by SCHOTT forma vitrum. "These OPC (One Point Cut) ampoules meet the highest quality requirements with respect to dimensions, aspect and breakforce, says Denis Devaux, Area Sales Manager for France at SCHOTT forma vitrum. "Their excellent breakforce properties were tailored to the specific needs of the customer, especially for the requirements of the Japanese market. The result is total safety for the user of the ampoule



thanks to easy and consistent opening, as well as a low ppm defect rate for the highest product safety and process capability (cpk) for excellent machinability at the filling and packaging facilities."

Since October of 2006, the Ancaron IV® ampoules have been taking the following route: They are manufactured by SCHOTT forma vitrum, filled at Sanofi-Aventis in Ambarès, delivered by St.-Loubes to the Japanese Sanofi-Aventis plant in Kawagoe, where they are labeled and subjected to conditioning. "With this high quality product, we are well positioned for the future", says Devaux: "After all, Japan is one of the most demanding markets for pharmaceutical packaging in the world. Soon the demands now being expressed in Japan will apply to Europe, as well."

Japan is one of the most demanding markets for pharmaceutical packaging worldwide.