

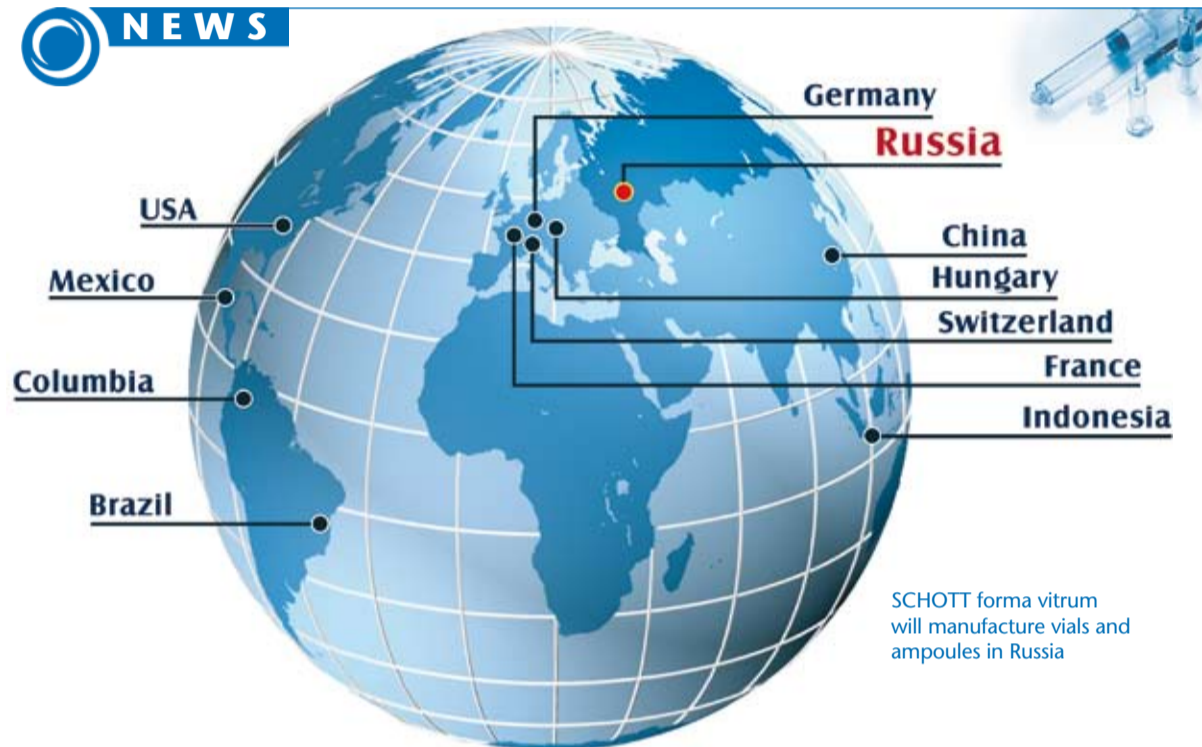


SCHOTT forma vitrum NEWS FLASH

PHARMACEUTICAL PACKAGING

ISSUE 9 December 2007

NEWS



New Production Site in Russia

SCHOTT forma vitrum has announced to build a new production facility located in the Russian Federation. The new plant will manufacture vials and ampoules according to the company's high, international quality standards and is expected to become operational in 2009. The facility will be based in Bor, a city located near the fourth largest city in Russia, Nizhny Novgorod.

"This move is of great strategic importance to SCHOTT forma vitrum, it will strengthen the compa-

ny's leading position and allow for pharmaceutical customers based in the Commonwealth of Independent States to be served more effectively," says Dr. Juergen Sackhoff, Executive Vice President BU Pharmaceutical Systems.

High quality pharmaceutical containers are currently experiencing strong double-digit growth in Russia and the Commonwealth of Independent States, therefore SCHOTT forma vitrum has decided to support the further market

development by building a production site in Russia. SCHOTT forma vitrum has been active in the Russian market for parenteral primary pharmaceutical packaging for years by serving this region from its existing plant in Hungary.

During phase 1, SCHOTT forma vitrum will begin manufacturing primary pharmaceutical packaging with approximately 150 employees and a capacity of approximately 300 million units will be installed.

EDITORIAL



Dear Readers,

Quality of primary packaging is of vital importance for the reliable protection, secure storage and administration of injectable drugs to the patients. The high relevance of this topic today as in the past is reflected by the ever increasing quality requirements worldwide. SCHOTT forma vitrum has always been strongly committed to quality. With our recent, global activities we confirm the company's positioning as a quality leader in the packaging industry.

In response to the strong growth in demand for high-grade containers for primary packaging in Eastern Europe, for example, we decided to build a new production plant in the Russian Federation. The new plant will manufacture vials and ampoules according to SCHOTT forma

vitrum's high international quality standards. To meet the increasing quality requirements in Asia, SCHOTT forma vitrum opened a new production facility for TopLine vials in Indonesia earlier this year. The many positive reactions of our customers – for example in the form of TopLine sampling requests or also by verbal interest expressed at our Tokyo customer symposium – confirm our chosen course.

We were proud to see our constant efforts to produce high quality not only being rewarded by a customer award for "Excellence in Quality" in 2007. Also our global customer survey 2007 reflects a very positive overall picture. Nevertheless, it also shows some room for improvement. I would like to express my special thanks to you, dear customers, for your valuable feedback which will be our guideline to optimize our products and services for the future. After all, we are aware that our commitment to quality implies continuous improvement with respect to technology, facilities and processes, on all levels.

For today, we hope you enjoy reading our latest edition.

Sincerely yours,

Christof Hanschke
Vice President, Business Segment
Pharmaceutical Packaging

QUALITY

Amgen Award for Excellence in Quality

SCHOTT forma vitrum has been awarded the Supplier Award "Excellence in Quality" in the category "Fill & Finish" by the U.S. biotechnology company Amgen. This prize that Amgen presented for the first time ever is based on a two-year observation period. On the one hand, it takes the ratings given by Amgen manufacturing plants that mainly received vials from the SCHOTT forma vitrum site in Veracruz, Mexico, into consideration. At the same time, data on quality non-conformance and audit results were also analyzed.

"With SCHOTT forma vitrum, we were particularly pleased about their quality systems and the effective use of technology to ensure high quality products ...," explains Narayan Balachandran, Director in Strategic Sourcing at Amgen.

"SCHOTT forma vitrum has had a close partnership with Amgen for many years", explains Simon Williams, Vice President SCHOTT forma vitrum North America. "We are very proud to see our constant efforts to produce high quality being rewarded by Amgen today."



About Amgen

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com

ON TOUR

World Class Manufacturing in the Heart of France

It all began in Montreuil, near Paris, in 1933. At the age of 18, Simone Caillet started a business making glass ampoules by hand ("hooked" ampoules for hospitals) in a disused workshop belonging to her father, with no financial backing. She founded the company SCHOTT France SAS, which at that time was called La Verrerie Médicale (Medical Glassworks), with the help of a few glass blowers. Since she was under-age, her father had to vouch for her and sign the checks.

In 1956, Madame Caillet signed an agreement with the only manufacturer of neutral glass in Europe, SCHOTT, which thus became her main supplier. In July 1956 she purchased a property at Pont-sur-Yonne, close to the sandpits at Nemours and, together with Erich Schott, set up a company, "Pont-sur-Yonne Glassworks", for manufacturing glass tubes. When the SCHOTT Group backed out of the project, Madame Caillet opened the Medical Glassworks factory at Pont-sur-Yonne on July 15, 1959, since her workshop in Montreuil had become too small. In 1976, Madame Caillet sold her business to SCHOTT.



The Pont-sur-Yonne site currently employs 200 staff producing about 800 million ampoules and perfume sampling vials per year.

Pont-sur-Yonne lies near Auxerre in the northern part of Burgundy which is known as one of France's great wine regions. The major local wines are Irancy, Coulanges, Epineuil, and Côtes d'Auxerre.

The Pont-sur-Yonne site currently employs 200 staff producing about 800 million ampoules and perfume sampling vials per year. The main customers are the large pharmaceutical laboratories and major names in the French perfume

business such as Chanel, Guerlain, Dior, Armani, etc.

Since May 2007, Eric L'Heureux, also the Managing Director of the SCHOTT forma vitrum site in Hungary, has taken on the office of President of SCHOTT France. Operational management at the site has been entrusted to the local management team consisting of Françoise Hennequin (spokesperson for the site) and Olivier Leprince. At the same time, Guillaume Bony took over responsibility for Manufacturing in addition to Process and Product Development.

This summer, the site invested in a new clear room in order to fully perform its role as backup for the sister plants. This packingroom is attached to 15 production lines. It also has the advantage of offering the staff better working conditions in terms of noise and ambient temperature.

To be able to progress further, the Pont-sur-Yonne site has also initiated a World Class Manufacturing



process (called TopOne at the site) which has even won a prize by the Schott group in the category "stable processes". The overall goal of the process is to achieve zero accidents, zero breakdowns, and zero defects. The methodology is based on nine pillars: safety and environment, cost deployment, autonomous maintenance, planned maintenance, people development, customer satisfaction, early equipment man-

agement, quality maintenance, and focused improvement.

"Thanks to our permanent improvement process and to the motivation of our staff, SCHOTT forma vitrum will succeed in taking up the challenge of improving quality to meet the high level of its pharmaceutical customers' expectations in Western Europe also in the future", Françoise Hennequin emphasized.



SCHOTT France SAS invested in a new clear room in 2007

Site at a glance

SCHOTT forma vitrum France

Location:	SCHOTT France SAS, Pont-sur-Yonne
Employees:	200
Products:	ampoules and perfume vials
Capacity:	800 million units per year
Production area:	9500 square meters
Quality certification:	ISO 9001, Certipharm, ISO 14001

CUSTOMER FOCUS

The same product from two different sites

"More and more customers are expecting us to be able to manufacture their products at multiple sites," explains Hans-Peter Manser, Director of Sales Europe at SCHOTT forma vitrum. The reason for their interest is obvious. Designating a backup site improves the security of supply. To make it simple for customers who decide to validate a second plant, SCHOTT forma vitrum has defined a systematic and controlled workflow which can be adapted to customer needs.

The validation process starts with a quality agreement between the SCHOTT forma vitrum site that has been manufacturing the product in the past, also called the master site, and the new back up site. All relevant information is exchanged between the two sites, including information on the product, how it is manufactured, customer specifications, instructions and special features, including everything from packaging to printing. At the same time, a feasibility study is conducted and the technology and machines

are upgraded, if necessary. As soon as the backup site issues a commitment that it is capable of producing the desired product in exactly the same quality, all of the necessary steps are discussed and agreed upon with the customer. This can include audits or the supply of validation lots.

The possibility to manufacture a product at two different sites offers customers, as well as SCHOTT forma vitrum, a number of advantages, including more viable planning, higher flexibility, higher reliability

and better delivery performance. "Now that capacities have been increased, two sites offer us greater flexibility and we are able to react smoothly to changes and limitations," Manser says. On the other hand, the customer no longer needs to devote as much attention to coordinating things. In fact, he already has a guarantee that both sites can produce the same product, operate under the same manufacturing conditions and are on the same level with respect to their information. At the end, he receives the very

same product, packaged the same way, from two different sites. Which manufacturing site manufactured a specific product is carefully documented to ensure full transparency to the customer at all times.

"Currently, we are working very hard to improve our service even further," Manser adds. "In the context of an internal project called PEP (Power up European Plants), we continue to harmonize and standardize all of our processes and systems. Among other things, we are also developing a centralized planning tool that will be introduced next year. Here, our main objective is to provide our customers with shorter delivery times," he concludes.

PEOPLE

Dedicated to Quality

As Quality Manager of the SCHOTT forma vitrum production facility near Jakarta in Indonesia, Hiro Maruyama uses both experience and expertise to meet the exacting needs of discerning pharmaceutical customers in Japan and the Asia Pacific region.

Balanced on his board on a breaking wave in Bali, Hiro Maruyama attacks the swell with the assurance of the 20-year surfer that he is, reading the surges and currents like a scientist, calculating the confluence of factors, then, once launched, adroitly adapting to the changing conditions, always pushing, always pressing, all his focus, all his efforts fully committed to finding the perfect place for the perfect ride, and enjoying the exhilaration of it all.

It's much the same for him on the job at SCHOTT forma vitrum.

A member of the SCHOTT forma vitrum team since January 2006, Maruyama was brought on board as Technical Manager. His mission: to shepherd the instal-

lation of production lines for the purpose of producing SCHOTT forma vitrum's premier quality TopLine pharmaceutical vials for customers in the Asia Pacific region and Japan in particular. "It was an exciting challenge," says Maruyama. "My undergraduate degree is in biomedical engineering but, with my graduate degree in statistics, my career had taken a turn toward the financial side. It was good to be back."

Long known for its exacting standard for quality, Japan is an important market for pharmaceutical packaging in the world and a close, competitive one at that, according to Maruyama. "It's a hard market to enter. Their attitude towards quality is unrelenting; their demand is perfection and they are hesitant about doing business with anyone who does not share or understand their policies and culture."

Born and raised in Japan but university educated in the U.S., Maruyama seems tailor-made for



He likes perfection – Hiro Maruyama, Quality Manager of SCHOTT forma vitrum Indonesia with his son...



...and at the facility in Indonesia

the position. "I had even implemented a similar project for my previous employer, Baxter Healthcare International, in Japan." With his team of engineers, Maruyama flew to St. Gallen, Switzerland for two months of training on the new machines, then on return, working

with the combined team to install, validate and begin sampling for prospective customers on the new line. Along the way, he developed a "Q" (for quality) mapping system that graphically depicts the entire process, from upstream through downstream, that he uses to support SCHOTT's already impressive automatic monitoring systems for quality control. "With the Q Map I can show each member of the team which part of the process is directly his or her responsibility. It's a roadmap that gives everyone a sense of ownership."

Recently promoted to Quality Manager for the entire plant, Maruyama still devotes much of his time to courting Japanese customers, working closely with Shigeru Takahashi of the SCHOTT Nippon sales office in Tokyo, to which he travels every three months for consultation and customer meetings. "Today my job is about 50% engineering and 50% customer support," he says. Customer audits are a priority. "Our state-of-the art

facility is concrete evidence of our commitment to quality." TopLine has also attracted attention from key manufacturers in India.

Meanwhile, he and his family are enjoying the Indonesian lifestyle, which he finds ideal as it caters to the mixed traditions of his own family. "My wife is a Muslim from Singapore, my sons attend the International School and are learning to speak British English with an Indonesian accent, and we have restaurants with foods from all over the world." Traffic is intense but he's close to favorite surfing spots in Bali for vacations, "although my boys (Rudy, 5 and Eddy, 4) are beginning to demand a change." A surfer since his college days, however, he is trying to pass along the tradition. His philosophy can be applied to his sport as well as business: create quality, standardize the process, make it efficient, keep it as simple as possible so it can be learned, repeated and transferred to the next generation.

EVENTS

Pharmaceutical Symposium 2007 in Japan

The first Pharmaceutical Symposium by SCHOTT forma vitrum in Japan was very well received. Some 50 representatives of the Japanese pharmaceutical industry (among them Astellas Pharma, Chugai Pharmaceutical and Nipro Pharma) and also from the media participated in the "Pharmaceutical Symposium 2007" in Shinagawa, southern Tokyo.

The full-day event focused mainly on the latest trends in parenteral packaging. The presentations conducted by experts from SCHOTT and by representatives of the Pharma Industry dealt with key market trends and regulatory requirements, research studies, latest product trends and innovations for pharmaceutical packaging.

Airi Yukawa, Managing Director of SCHOTT Nippon, took the op-



Osamu Shirokizawa from Pharma Solutions discussed technological and regulatory requirements for syringes in Japan.

Some 50 participants from the Japanese pharmaceutical industry and press participated in the SCHOTT forma vitrum symposium

portunity to introduce activities at SCHOTT and noted that SCHOTT has been present in Japan for 40 years. Also speaking was Bernhard Elsener, Vice President Global Marketing & Sales for the Pharmaceutical Packaging Business Segment. "Manufacturing pharmaceutical primary packaging ranks as a strategic core competence for the SCHOTT Group," he emphasized. "Our commitment to growth and high standards shows in our continuous investment in technology and facilities. This clearly distinguishes us from our competitors."

Horst Koller, Head of Scientific & Regulatory Advisory with SCHOTT forma vitrum, devoted his presen-

tation to the current regulatory requirements of the U.S. FDA (Food and Drug Administration) and EMEA (European Medicine Agency Inspection). He also presented latest findings from extractables and leachables studies.

Osamu Shirokizawa from Pharma Solutions addressed the technological and regulatory requirements for syringes in Japan. Hiro Maruyama, Quality Manager at SCHOTT Igar Glass in Indonesia where a new production facility for TopLine vials was opened this year, underscored how well SCHOTT forma vitrum has been able to adjust to the high requirements for quality of the Japanese pharmaceutical companies. The TopLine department in Indonesia produces tailor-made product solutions that meet even the highest demands.

Dr. Michael Rössler from SCHOTT Rohrglas GmbH concentrated on the chemical composition and characteristics of glass containers made of borosilicate glass.

Dr. Robert Hormes, Director Product Development at SCHOTT forma vitrum presented latest product trends and developments. He also discussed the benefits of the SCHOTT PICVD plasma coating technique on container inertness and chemical stability of Type I borosilicate glass, especially for sensitive biotech drugs. The topic of protein surface interaction was presented by Rajendra J. Redkar, a research scientist at SCHOTT North America.

"All in all, the reactions from the participants in the Pharmaceutical Symposium were very positive; many of them were especially impressed about our innovation power," explains Michi Arakawa, SCHOTT Nippon.



Masthead

SCHOTT forma vitrum
NEWSFLASH

Issue 9 / December 2007
Copyright 2007:
SCHOTT Schweiz AG

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SCHOTT Schweiz AG

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Layout:
Bonewitz Communication GmbH

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SUCCESS STORIES

SCHOTT forma vitrum goes Beauty

My Blend, a new brand from the Clarins Group, represents a revolutionary new approach to highly personalized skin care that was just launched on the American market. SCHOTT forma vitrum supplied the syringes.

"My Blend offers a highly personalized solution for skin care, because it takes into account every woman's unique biology, age, lifestyle, preferences and changing needs," says Brigitte Wigand, Senior Vice President International Marketing & Communication for My Blend. The My Blend line carries three product categories: the Essentials (creams and lotions), the Emergency Boosters (additional pure actives conditioned in syringes from SCHOTT) and the Specifics (complementary products).

The Essentials represent the first stage of personalization with 8 highly fine-tuned cosmetic formulas for day and night care. The Emergency Boosters are the second level of customization. The syringes contain a precisely pre-measured mega-dose of targeted ingredients *without preservatives* to be injected and blended into the smaller 15 ml cream or lotion size of any Essential formula to prepare an "emergency cure" treatment for a special skin problem. All Essential and Booster formulas are completely compatible (which represents an extremely difficult technical exploit), but the stability of the boosted formula can



SCHOTT forma vitrum supplied the sterile 2.25 ml luer cone glass syringe for My Blend, a new brand from the Clarins group.

only be guaranteed for 3 weeks, because the Booster actives are coming pure, *without preservatives*. "My Blend represents a new generation of "intelligent" skincare built on top of scientific technology" says Brigitte Wigand.

Dr. Olivier Courtin, renowned French skin expert and son of the founder of Clarins Cosmetics where he heads the R&D Laboratories, is behind this innovation. Until now, a woman's skin was always considered to be more of an "envelope" than a living organ

that shows completely different reactions to changing life conditions, stress situations, pollution, health, sickness, hormonal changes, etc. This is where Dr. Olivier Courtin sees the difference: "Through my personal experience as a surgeon, I was able to witness on a daily basis how each woman's skin reacts and heals differently over time, that her overall lifestyle and skin care has an extremely important influence on her skin metabolism and her cicatrization capacities," he explains. For this reason, he is convinced

that skincare should respond to these constantly changing needs through a line of customizable cosmetic products. The development and testing of the 30 available formulas took over three years, another 6 months were necessary to test all possible "blends" between each and every Essential and the 5 available Booster formulas, which also can be combined by two halves of two different Boosters (225 different blends possible in total).

"The syringes used in Emergency Boosters are not gadgets, but rather part of the scientific, technological approach behind My Blend," says Brigitte Wigand and adds: "For us, it was very important to find high-quality syringes that would allow us to rule out contamination of the contents, as we wanted to formulate the Boosters with extremely concentrated and pure actives, but *without preservatives* to guarantee the highest efficacy to the final (blended) product. In the same time, as we are a "doctor brand", we wanted a medical aspect for

the Boosters, to translate the scientific character of the brand. The idea to use glass syringes, but to "dress" them in an attractive way came from our design agency. Our search for a serious partner in terms of quality and availability of such items never used yet in Cosmetic business has taken us to SCHOTT forma vitrum who has helped us to make the right choice."

As Denis Devaux from SCHOTT forma vitrum France explains: "We worked together with My Blend in identifying the right syringes for this cosmetic application. The decision has been taken to use a sterile 2.25 ml glass syringe. In order to facilitate the implementation of the system we decided to use a Luer Cone. After the samples validation Clarins decided to order a first production lot."

Confidentially: The future product development ideas are going into possible new ideas for the extension of the Booster choices, because beauty emergencies happen ... more often than you think.

Five Boosters are available in SCHOTT syringes for five different emergencies treatments:

Emergency	Booster
Sun/wind burn, bruising, scars	Speedy Recovery
Moisture depletion, dehydration	Moisture Immersion
Redness, irritation, sensitivity	Redness Rescue
Skin stressed from the sun, diet, illness	Antioxidant Surge
Dull, lackluster, tired skin	Radiant Burst

CUSTOMER SURVEY

Results Online Customer survey 2007

To meet the product and service requirements by customers even better in the future, SCHOTT forma vitrum carried out a global customer survey in spring 2007. The survey was done online via a secure internet link to keep the customers' effort as small as possible. Realization by an independent market research institute ensured strict confidentiality and anonymity of the customer feedback.

It was the first time that the Pharmaceutical Packaging Business Segment did a customer survey at the same point of time worldwide, on group level. Customers were asked about SCHOTT forma vitrum's overall performance, products and services compared to its competitors and also for possible areas for improvement.

The final result shows a very positive overall picture in comparison with competition. 63% of all the customers who participated in the survey rated the overall per-



Coating line at SCHOTT forma vitrum, Germany: The company received good marks for its technological expertise and professional competence.

formance of products and services very good or even excellent; 60 % reported it was a very big advantage or a big advantage to deal with SCHOTT forma vitrum rather than with any other competitor. The company received good marks

from its customers especially for its technological expertise and professional competence, also for technical customer support and sales force. Product quality, international presence and environmental orientation also scored very well.

The analysis showed room for improvement in the area of delivery quality, with customers asking for better lead times and more flexibility. As a consequence of the customer survey, a detailed action plan has been set up that contains product and service related aspects, and both group-wide topics as well as regional aspects. In the meantime, the action plan has been coordinated with projects already initiated by SCHOTT forma vitrum which take up topics such as supply capability and flexibility (see also the "customer focus" article, page 2).

"We take this opportunity to sincerely thank our customers who participated in the survey. Of course we are very pleased about the positive feedback from our customers which we understand as a confirmation of our efforts to supply the best packaging solutions to our customers worldwide", explains Bernhard Elsener, Vice President Global Marketing & Sales SCHOTT forma vitrum, "but we are even much more obliged for critical remarks and suggestions which will help us most to improve our products and services in the interests of the customers."

EXHIBITIONS & EVENTS

Come and see us at

- Pharmapack, Paris (France), February 6 - 7, 2008
- Interphex, Philadelphia PA (USA), March 26 - 28, 2008
- Interpack, Düsseldorf (Germany), April 24 - 30, 2008
- API China / Interphex China, Dalian (China) May 20-22, 2008
- Interphex, Tokyo (Japan), July 2 - 4, 2008