

SCHOTT forma vitrum NEWS FLASH

PHARMACEUTICAL PACKAGING

ISSUE 6 OCTOBER 2006

NEWS

Expansion of Syringe Manufacturing A commitment to growth and excellence

"Committed to growth and excellence" was the motto of an international conference on prefillable syringes on October 5 – 6 in St. Gallen, Switzerland. More than 100 customers from the global pharmaceutical industry attended the event and, at the same time, celebrated the 75th anniversary of SCHOTT forma vitrum Switzerland.

The highlight of the first day was a tour of the expanded, modern syringe manufacturing facility. At the international symposium on the second day, the latest trends and developments of prefillable syringes were discussed.

With this latest step towards expansion, the manufacturing capacity for glass and polymer syringes (forma 3s, forma 2s and TopPac) at SCHOTT forma vitrum will be tripled. Close to 20 million Euros have been invested, for the most part, in glass shaping, as well as the infrastructure, clean rooms and WFI (water for injection) facilities with regard to sterile applications.

Approximately half of the expansion has already been completed.

"With the new, state-of-the-art syringe production facilities, we will expand our manufacturing capacity and improve our prod-



Latest technology and expanded capacity at the syringe production in Switzerland.



Dr. Klaus Holtzhauer presented new developments on prefillable syringes at SCHOTT forma vitrum.



uct offer", said Markus Hersche, General Manager of SCHOTT forma vitrum Switzerland. "In addition, a number of measures have been taken to further optimize logistics and guarantee an excellent service to our customers."

More than 100 customers of the global pharmaceutical industry attended the international customer event in Switzerland.

EDITORIAL



Dear Readers,

After five years of managing Pharmaceutical Packaging, I have decided to explore new professional challenges.

When saying farewell, one tends to look back on all that has been achieved. As an avid sailor, all I can say is that the ship we all refer to as SCHOTT forma vitrum is in excellent shape.

We have provided the market with many innovative impulses in recent years. Areas, such as coatings, syringe and pen systems are just a few examples that come to my mind. We also set up our sales organization in a more customer-ori-

ented manner, invested heavily in new machinery and proprietary vision systems, built new plants, modernized old sites and invested more than 100 Mio. Euro overall, with an increasing part in novel R&D activities

Today, we can truly say that SCHOTT forma vitrum is the product of our successful work. For me, participating in this success was always a great pleasure.

I would especially like to say thank you to our customers for the many exciting and extremely interesting encounters that we had, as well as their valuable input which generated many helpful ideas and solutions.

Our well-established team at SCHOTT forma vitrum definitely makes saying goodbye much easier for me. After all, they are the reason for the extremely important continuity and long-term stability of SCHOTT, and I'm proud of what they have reached as a crew.

In closing, I would also like to wish my successor all the best, fair winds and following seas.

Sincerely Yours,
Dr. Peter Knaus
Vice President, Business Segment
Pharmaceutical Packaging



quality and goes on to include development projects. And despite all of the success that SCHOTT forma vitrum can rightfully be very proud of; there are obviously many more things that we can do for our customers. Here, I only need to refer to interfaces that can still be harmonized, back-up solutions that we must improve in order to be able to supply our customers with products that offer the same level of quality despite being manufactured at various sites.

There is one thing that I have already learned during my very first days with the company: SCHOTT forma vitrum is an extremely reliable partner and this will not change. In this respect, it is important for me to note that we have been able to convince Peter Knaus to provide us with consulting support, particularly during this transition period.

I am really looking forward to this new challenge and I take great pleasure in wishing you all enjoyable reading of this edition of the Newsflash.

Sincerely Yours,
Christof Hanschke
Vice President, Business Segment
Pharmaceutical Packaging

Dear Readers,

Many of you might be slightly surprised at first to learn that I come from the automotive industry. However, I'm sure you'll begin to realize that there are quite a few parallels.

Safety plays a major role in both the automotive and pharmaceutical industries, as do stable processes, a high level of customer service and orientation, but also the long lead times required in developing new products.

Continuity is of the greatest importance to me. This begins with contact to the customer, continues with respect to concentrating on

PEOPLE

On the move for continuous improvement worldwide

"Every day, for my own satisfaction, I want to deal with new challenges."

Strapped in his black motorcycle leathers, Abelardo Riveron looks just like what he is: a man on the move. Currently production manager with SCHOTT Igar Glass in Lippo Cikarang, Bekasi, Indonesia, he has worked thus far at SCHOTT forma vitrum facilities in Mexico, Colombia, Brazil, and yes, once before, in Indonesia.

Born and raised in Cordoba, Veracruz, Mexico, Riveron began his journey at the nearby Orizaba Institute of Technology where he studied to become a mechanical engineer. After graduation in 1992, he chose to join SCHOTT forma vitrum, a major presence in his hometown. What was surprising was his first position with the company.

"My first job at SCHOTT forma vitrum was as machine operator," says Riveron, admitting that this might sound unusual: Why, you might ask, is a mechanical engineer working as operator? His answer is typical Riveron: "The glass forming process for me is



After work on the road: Abelardo Riveron likes to ride his motorbike.

really interesting and I accepted this position because it would give me a real opportunity to live and know the process from the ground up. For me it was the right choice, because now the process is something really transparent; there are no dark areas." Four months later he was promoted to "set-up" man in vials, and two years after that to production manager.

The company's commitment to the highest standards of quality on a global basis meant for Riveron, for example, several visits to Switzerland for training purposes. Says Riveron, "Switzerland started to transfer the technology and know-how to forma vitrum Mexico right at the beginning of its operations in 1990 and I was involved in this process from the time I started.

"When the forma vitrum group joined the SCHOTT Group in 1998, know-how exchange and technology exchange were consequently extended and intensified worldwide. I became more and more involved in the process, working in many of our 'sister units' and, since 2000 assisting in the transfer of technologies. Today as in the past, personnel transfers among the sister sites are strongly encouraged and best practice examples are regularly discussed and promoted within the group, for example on the occasion of the yearly meetings of production managers and quality managers respectively."

This is a strong focus of the SCHOTT forma vitrum group and one which Riveron has honed over the years. Named quality manager in Mexico in 1998, he took what he had learned on the road when he began assignments at SCHOTT forma vitrum locations in various countries. Among his most memorable was his three-year stint (2003-2006) in Colombia, where as technical director he worked with employees to develop new products, update technology, and

improve quality. One of his achievements there was the introduction of a program of technical visits to customers. Also in Colombia he created and led the Emerald Project that stands for the optimization of production processes. That project this year even won the first prize in its category of the Vision Award in Schott."

Now, since May, in Indonesia, production manager, he hopes to repeat that success. "I like Indonesia; my wife and I have been here before. The country is beautiful and the people are warm and friendly and work very hard. One of the things I like best about my job is working with people from different cultures and backgrounds, reaching goals even in the most difficult environments thanks to their almost unlimited support. Knowledge exchange is not just about technology and information. It's also about helping people to find themselves a way to reach the goals and in the mid-run to enable them to develop a solution on their own.

At the end of the day, that's the real challenge."

QUALITY

Leading the Way in Quality

SCHOTT forma vitrum in Brazil has implemented an improvement program that is being used as a reference for other companies in the region.

Quality is key to success for parenteral packaging. Guided by the standards of the European Foundation for Quality Management (EFQM), excellence in quality is measured and improved at SCHOTT forma vitrum worldwide on a continual basis. At SCHOTT forma vitrum Brazil in Itupeva/Sao Paulo, Six Sigma is proving a successful methodology for both company and customers to meet its EFQM goals most effectively.

"Since implementing Six Sigma, we have identified 31 projects for improvement, 12 of which we have successfully completed," says Felipe Gramacho, Quality Manager and Six Sigma proponent since 2004. "In addition, we also have 19 projects currently in progress. And, because improvement must be continuous in order to be effective, we are always on the lookout for more."

Commitment to quality improvement has been part of the culture at the SCHOTT Sao Paulo facility from the beginning: a scant year after it was commissioned in 2001, Six Sigma was implemented with a "champion," two "black belt" project leaders and a passion for



Quality inspection at SCHOTT forma vitrum in Brazil.

improvement. Since then, they have been joined by five additional "black belts" with 160 training hours each and 44 "green belts", each with 80 training hours.

"For us Six Sigma is a tool, not a philosophy," says Gramacho. "It is a general map that helps the integration of improvement tools and can be used for any kind of process: HR, Sales, Financial, Manufacturing, etc. Every work is a group of interconnected processes. The key to improvement is to systematically attack and reduce the variations that are inhibiting the process."

At Sao Paulo, projects for improvement are identified at monthly black belt meetings using the strategic plan and customer inputs. "The first step of our definition phase is to identify the challenges that are critical to the customer. Reducing variations without knowing what the customer wants



is a waste of time." Team members are then assigned, continuing through the five phases of the process: Definition, Measurement, Analysis, Improvement and Control (DMAIC) as shown in the example at the right.

Because the facility has been so successful with its projects, Gramacho was recently invited to address a quality conference at the International Quality and Productivity Center (IQPC) in Sao Paulo. Attending were representatives of such companies as GE, XEROX, Johnson & Johnson, Coca-Cola, American Express, and Siemens. His message: While the methodology is important, it is not dictatorial: "You have to follow the idea but with your own reality," says Gramacho.

"SCHOTT Brazil created its own Six Sigma structure with success and is now a reference for other companies."

Example of improvement project according to DMAIC:

Definition:

Reduce the glass waste rate by 8% in the production of ampoules (without consideration of technical waste and waste in the clear area)

Measurement:

Special waste containers which were used close to the line were monitored.

Analysis:

Root causes:

- transfer from the machine to the line
- transfer from the line to the annealing oven
- bad printing quality

Improvement:

- modification of the transfer system
- use of a material with low expansion coefficient for transportation into the annealing oven
- use of a reinforced screen frame and adjustments on the ampoule elevator

Control:

Use of Failure Mode and Effects Analysis (FMEA).

Result:

Reduction of glass waste rate by 7% resulted in substantial savings of a six digit US\$ figure per year.

Masthead

SCHOTT forma vitrum
NEWSFLASH

Issue 6 / October 2006

Copyright 2006:
SCHOTT Schweiz AG

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SCHOTT

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Layout:

Bonewitz Communication GmbH

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ON TOUR

Positioned for growth in Pennsylvania



SCHOTT forma vitrum site in Lebanon, Pennsylvania.

Only three years old, the pharmaceutical packaging facility for SCHOTT forma vitrum in Lebanon, Pennsylvania, is already upgrading in order to meet customer needs in a growing market.

Like a gem in its setting, the Lebanon facility stands in gleaming contrast to the countryside surrounding it. Manicured lawns and angular architecture speak of the serious work within. Beyond are the rolling hills of America's Appalachian Mountains. Nearby, an Amish farmer, eschewing modern methods, harvests his crops via mule-driven wagon, his tiny daughter in bonnet and apron leading the six placid animals.

SCHOTT forma vitrum has had a foot in these foothills for more than

40 years, the original works dating back to a prior owner in northern New Jersey. But what's been happening at the Lebanon facility is the stuff of the future.

Inaugurated in October 2003, the newly built facility has all the earmarks of SCHOTT forma vitrum state-of-the-art quality and production: the most advanced technology and practices including automated camera inspection and a clear room for final packaging. Operating on a three shifts production schedule, Lebanon's 135 employees produce nearly 500 million pieces a year of vials and cartridges, all of Type 1 borosilicate glass. As with all SCHOTT forma vitrum facilities, it complies with current good manufacturing practice

(cGMP) required by the US Food and Drug Administration (FDA) and has held ISO 9001:2000 certification since opening.

At 173,000 square feet (warehouse, production, utilities and front office) on 24 acres, Lebanon was built for expansion. "The North American market represents nearly one quarter of the world's demand for pharmaceutical packaging made of glass tubing," says Simon Williams, Vice President Pharmaceutical Packaging SCHOTT North America, "and we are committed to continuous improvement in both people and process in order to meet it." Toward that end, Lebanon has taken a number of steps, including a Total Productive Management (TPM) initiative that employs Six Sigma, Lean Manufacturing, and other methodologies in order to achieve new and greater levels of performance both for itself and its customers.

"We are also in the process of upgrading four of our existing production lines and installing six more state-of-the-art lines which incorporate all of the latest thinking and innovations from Schott forma vitrum worldwide," says Williams. "These lines will increase both quality and productivity." The project is one of several. Preparations are currently underway toward the design and installation of an entirely new product line, ready-to-fill syringes, which will take the facility to even higher levels of production technol-



Ongoing upgrading of production will increase quality and productivity.

ogy and quality. Start-up is scheduled for 2008; training has already begun both on-site and at the SCHOTT forma vitrum competence center for syringes in Switzerland. In addition, employees have just completed the transfer of one product from Europe for a customer who wants to be supplied closer to the North American market, and are

about to start training on another planned to transfer in late 2007.

"SCHOTT forma vitrum gives us global reach and global capabilities," says Williams. "We plan to continue to invest in both our people and our processes to parlay these into a future of even greater growth for the company as well as our customers."

Site at a glance

Pharmaceutical Packaging -SCHOTT North America Inc.

Location:	Lebanon, Pennsylvania, three hours west of New York City
Employees:	135
Products:	Vials, cartridges, ready-to-fill syringes (2008)
Capacity:	500 million units per year
Production area:	111,073 square feet (10319 square meters)
Quality certification:	ISO 9001:2000

EVENTS

SCHOTT forma vitrum celebrates 10 years in Indonesia

Together with customers and officials, PT. SCHOTT Igar Glass celebrated 10 years of growth and innovation in Indonesia, South Asia and Asia Pacific on August 24/25. The celebration, a two-day event, took place in Jakarta and the nearby SCHOTT forma vitrum manufacturing facility in Cikarang, Bekasi.

"This is a small way of saying thanks to our local and export customers for their support as well as for the partnerships that we have developed over the past 10 years," says Stefan Rieder, President Director SCHOTT Igar Glass Indonesia. "After a major investment in our new factory four years ago, SCHOTT Igar Glass and the Schott Group continue their commitment to Indonesia and the Indonesian and Asian pharmaceutical industry by ongoing investment above all in the latest technology to support the increasing quality requirements of local and international players. We are looking forward to contin-

uing these good relationships as a leader for primary pharmaceutical packaging in the Asian market."

More than 100 guests attended the event, including major customers from countries such as Indonesia, Malaysia, Thailand, China and Myanmar; SCHOTT forma vitrum representatives from Germany and Switzerland; and local dignitaries Anthony Sunaryo, Member of the Indonesian Parliament and Chairman of the Indonesian Pharmaceutical Companies Association (GP Farmasi) and Martin Krummeck from EKONID, the German-Indonesian Chamber of Commerce.

"The increasing demand in terms of quality and service leads to the development of partnership between pharmaceutical companies and their suppliers of primary packaging," said Sunaryo in his opening remarks. "This partnership requires technological expertise, reliability, efficiency and quality leadership especially for primary packaging for

injectable drugs. Therefore I believe that the relationship between SCHOTT Igar Glass and the pharmaceutical industry will grow stronger."

The celebration began with an opening night banquet on August 24 in Jakarta that was highlighted by the presentation of a check to Anne Dompas, representative of a local organisation of volunteers working for humanitarian projects. The donation is assigned to the reconstruction of a local school as part of the Yogyakarta earthquake relief project. Activities continued the following day with a business update, an overview of new product development and a tour of the manufacturing facility. "The feedback was very good," says Rieder. "Customers were very impressed by the facility, especially the cleanliness of the shopfloor and the state-of-the art cleanrooms."

Originally a joint venture between SCHOTT and the Indonesian plastics and glass packaging group of PT. Igar Jaya, the company has



Stefan Rieder, President Director and Gunawan Setokusumo, Commercial Director of SCHOTT Igar Glass opened the conference.



Customers were impressed by the manufacturing facility

invested more than \$20 million to maintain the highest standards of quality for a growing market. "We are the largest manufacturing site for primary pharmaceutical packaging in Southeast Asia with a production capacity of approximately 800 million vials, ampoules and dropper pipettes per year," says

Gunawan Setokusumo, Commercial Director of SCHOTT Igar Glass. About half the company's production is exported throughout Asia/Pacific, covering more than 25 countries. "With about half of the world population living in Asia, our customer base will only continue to grow."

PRODUCTS

TopLine vials for Biotech Applications

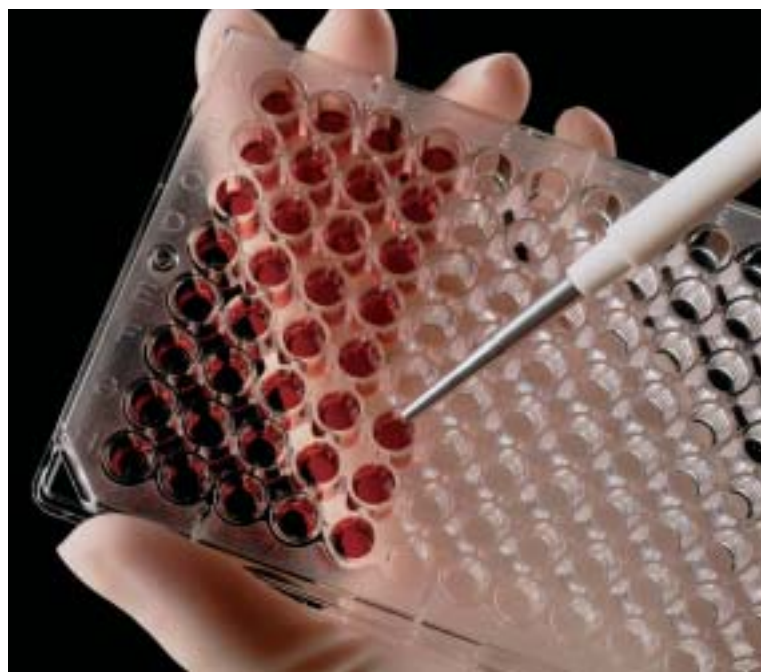


Biotech drugs present new challenges for primary packaging.

Today, a lot of medications are developed and produced on the basis of biotechnology and genetic engineering. The increasing popularity of premium quality biotech drugs also poses new challenges for manufacturers of primary pharmaceutical packaging. "The more expensive and complex such biotechnological medications become, the greater the challenges for the packaging used," explains Rolf Lüscher, Global Key Account Manager SCHOTT forma vitrum. One important aspect is the quality of the glass surface from a cosmetic standpoint.

"Any pharmaceutical company that manufactures medications that cost several hundred or several thousand Euros per dose will insist on delivering their products in perfect packaging," Lüscher adds. Because every customer has different requirements with regard to quality, such a container is tailored to satisfy individual demands. "While one customer may not accept any visible defects on vials at all, another might very well be able to live with a few small scratches" says Lüscher. These customized pharmaceutical containers for the highest requirements are supplied by SCHOTT forma vitrum under the "TopLine" brand.

Highly sensitive, fully automated camera-controlled quality inspections enable SCHOTT forma vitrum to perform 100 percent inspections not only on dimensional, but also on cosmetic aspects, by using a high-tech vision system that the company developed on its own. TopLine quality is available in vial



sizes of between 2 and 50 ml from SCHOTT forma vitrum production sites in Europe and North America. Customers benefit by being able to perform fewer or even no incoming inspections at all. In addition, they achieve higher yield, more productivity from the filling, labeling and packaging lines, a lower rejection rate at the visual control of filled containers and assured product safety. All of these factors result in lower overall costs.

"We clearly notice an increasing interest in our TopLine vials for biotech applications", Lüscher explains. "In any case, for anyone offering a premium quality product, the packaging used must feature the same high quality and flawless appearance in order to ensure that users feel safe about using the product."

MATERIALS



Do you know the glass symbol?

Occasionally, you may run into the following graphic symbol in various, glass-related contexts: a horizontal figure 8 or an infinity character with a cross added beneath it. The symbol is also used, for example, as official signet by the German Society of Glass Technology. But, what is this all about?

Basically, the sign is an old alchemical symbol that, like more than a thousand other symbols that often had synonymous meanings, was used by chemists, physicians and pharmacists until the end of the 18th century. These symbols served to mark the contents of containers filled with medications or some raw ingredients used to make them, for example. Physicians also referred to them in their prescriptions. The graphic symbols were often designed in a beautiful, artistic way. Their meaning was only known to an exclusive group of people and they were, therefore, kind of secret symbols.

For glass, there existed numerous different symbols that were used in old manuscripts, prints and illustrations. One of them, a very old symbol that was even used in the 11th century and on through the 18th century, was shaped similar to an X, the two

lines of which could represent pieces of broken glass which may in turn refer to the fragility of glass. Yet another commonly used symbol for glass consisted of a circle with a line added to the top of it. This representation reminds one of a glassmaker's pipe (the line), and the blown ball (circle) coming out of it, which may refer to glass forming.

The symbol presented in the picture above could be a combination of the symbols discussed above and may well refer to both the fragility and the formability of glass. According to another interpretation, the infinity character could be considered to stand for the eternal and lasting, on the one hand, while the angular cross could be viewed as symbolizing earthly and fragile characteristics. This illustrates the opposing character of glass, which, on the one hand, offers high chemical resistance and has existed in the form of natural glasses since prehistoric times, yet is brittle and, therefore, in danger of breaking.

Still another interesting and absolutely non-scientific interpretation can be drawn from a common German saying among glass makers: "To make good glass one has to bear an infinite cross..."

NEWS

New Certification ISO 15378:2006

Only one year after receiving certification according to ISO 15378/FDIS as a Final Draft International Standard, SCHOTT forma vitrum Switzerland was awarded with complete certification according to ISO 15378:2006 when this new norm was published on March 1, 2006. Also the German site has received ISO 15378 certification.

SCHOTT forma vitrum was among the world's first companies to be certified according to this new norm.

This standard defines the rules for "Good Manufacturing Practice" (GMP) in primary packaging. For the first time, the foundations of GMP for manufacturing primary packaging materials were specified as part of an ISO standard.

These regulations address the specific needs of the pharmaceutical industry and determine how primary packaging materials are to be manufactured in accordance with today's standards for safety, quality and process stability.