

newsflash

PHARMACEUTICAL PACKAGING



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NEWS

Joint Venture in Japan – SCHOTT NAIGAI

SCHOTT and the Japanese company Naigai Glass Industry Co., Ltd. have founded a joint venture for pharmaceutical packaging activities in Japan.

The new company is called SCHOTT NAIGAI K.K. and is based in Osaka, Japan, where Naigai has already been operating a production site for many years. The joint venture will manufacture high-quality vials for the Japanese pharmaceutical industry mainly from SCHOTT's pharmaceutical tubing glass "Fiolax®."

"The founding of this joint venture in Japan represents yet another important milestone in our global growth strategy for our core business of pharmaceutical packaging. With Naigai, we have found a strong partner who shares the same high commitment to quality that SCHOTT has. This will allow us to significantly strengthen our market position inside the world's second largest pharmaceutical market," explains Prof. Udo Ungeheuer, Chairman of the Board of Management of SCHOTT AG.



SCHOTT NAIGAI will manufacture high-quality vials for the Japanese pharmaceutical industry.

SCHOTT and Naigai have already been working together successfully in a buyer-supplier relationship for many years. SCHOTT has been supplying Naigai with pharmaceutical glass tubing which the company needs in order to make primary pharmaceutical packaging products.

Naigai will be shifting its existing vial manufacturing activities over to the new company and SCHOTT will be contributing its highly advanced Automatic Inspection System (AIS), which is

even more reliable than human eye inspection. Over the next few years, SCHOTT NAIGAI plans to expand its capacities by adding new production lines and leveraging technological know-how from SCHOTT.

"As a result of this collaboration, customers will benefit from the high quality and technology standards, as well as supply safety along the entire supply chain," says Dr. Juergen Sackhoff, Executive Vice President at SCHOTT Pharmaceutical Systems.

EDITORIAL



Dear Readers,

First of all I would like to express my special thanks to you, dear customers, for your valuable feedback on our customer survey. It reflects a very positive overall picture. Nevertheless, it also shows there is still room for improvement. As a consequence of the customer survey, a detailed action plan that includes product and service-related aspects for each region has already been set up. Fortunately, most of the main topics are already being addressed by projects that we are currently

working on. In any case, I greatly appreciate all of the remarks and suggestions that will help us improve our products and services in the interests of our customers.

Thanks to our innovative new products and global expansion strategy, we are actually present where our customers are expanding and wherever lucrative new markets are likely to form, regardless of whether this is in Argentina, Mexico, China or Japan. Staying close to our customers is important to us for many different reasons: short delivery times, faster response, but mainly our ability to supply consistent and comparable quality from multiple sites, something we refer to as our backup strategy. For today, we hope you enjoy reading our latest edition.

Sincerely yours,
Andreas Reisse
Vice President,
Business Segment
Pharmaceutical Packaging

NEWS

UltraSafe Passive Technology for SCHOTT Injente Prefillable Syringes

At the PDA conference "The Universe of Prefilled Syringes and Injection Devices" in Las Vegas in October 2010, SCHOTT and SafetySyringes, Inc. (SSI) introduced the UltraSafe Passive® Needle Guard to ensure needlestick protection for the "SCHOTT Injente" prefillable syringe.

The new safety device relies on the proven UltraSafe Passive technology and complies with all anti-needlestick legislation. SCHOTT Injente™ offers a number of

novel features for the benefit of highly sensitive drugs, in particular. Its unique design stands for improved drug stability, and gentle application. "The drug doesn't come into contact with the needle during storage," says Carmen Heiter, Product Manager for Syringes at SCHOTT. "This prevents sensitive drugs from interacting with the adhesive or the metal of the needle." A robust tamper-evident closure is integrated in the unique design of the syringe. As

soon as the system is opened, this part will break and cannot be re-connected. This allows physicians or patients to determine whether or not a syringe has already been used.

Because of the unique design of "SCHOTT Injente," the needle point is fully protected and does not touch the needle shield or any other material. This guarantees best needle lubrication and straight needles; hooks are avoided. The syringe is completely



The new UltraSafe Passive® Needle Guard ensures needlestick protection for the "SCHOTT Injente" prefillable syringe.

tungsten-free and allows for the use of particularly thin needles of up to 31 gauge which results in a reduction of pain for the patients during injection.

Innovation doesn't stop here: To offer effective needlestick protection for healthcare professionals, a special protective needle safety mechanism that shields the needle immediately after injection has now been developed by SSI. Its added handling benefits are obvious.

A wider plunger head, finger flanges and a rounded body design offer qualified personnel safe support, and no special pro-

cedures are necessary to put the syringes into operation. "The UltraSafe Passive safety mechanism shields the needle automatically right after injection which is a key requirement for effective needlestick protection, as a large portion of needlestick injuries happen after injection when the bare needle is removed from the injection site," says Alexander Jaksch, Vice President of Business Development & Marketing at Safety Syringes. One-handed operation is possible and no new injection technique is necessary. In addition, these syringes come pre-assembled in ready-to-use-packages.

PROFILE

Quality is More than just a First-Class Product

Andreas Reisse, the new head of the Pharmaceutical Packaging Business Segment, likes to travel – a passion that will definitely be of great benefit to him in the new position that he has held since September 1, 2010. With over 600 production lines in 14 countries around the world, SCHOTT manufactures more than seven billion syringes, vials, ampoules, cartridges and other specialty items that are made of either premium glass tubing or high-tech polymers.

SCHOTT's global presence and well-positioned production sites are important selling points that convince many of the customers who are interested in secure supply. The logistics behind this is all the more important in making sure that the exact quality levels that the customer requires are delivered from all of the sites when they are needed.

"Logistics is an important key that helps our customers lower their working capital," Reisse explains. "Nevertheless, logistics



Reisse likes to relax while riding his BMW 1200 GS motorcycle.

also means increasing customer loyalty by offering better service, short delivery times and faster response," he adds.

Reisse studied "industrial engineering" at the university in Karlsruhe, Germany, in the field

of manufacturing with a strong focus on logistics. This will be of great advantage in his new position. Even more, he has known the pharmaceutical industry for over 15 years. In 1995, he took over responsibility for the phar-

maceutical tubing factory in Barcelona, Spain, and later served as the Managing Director of Sales for SCHOTT-Rohrglas in Mitterteich before heading the business segment Tubing for several years. SCHOTT borosilicate glass tubing, one of the most important starting materials for pharmaceutical packaging, is manufactured here. The worldwide wellknown "Fiolax" is considered to be a globally recognized product that meets the highest demands for quality and is also produced in the same high quality at various sites around the globe.

"Maintaining and constantly improving the worldwide quality leadership we've achieved is an important goal for us," Reisse adds. For him, quality consists of more than just a first-class product, but also the entire logistics of the supply chain. The enormous investments in innovations with respect to new products and new processes clearly demonstrate that pharmaceutical packaging

is an important future field for SCHOTT. Nevertheless, SCHOTT is also building new factories, especially in the emerging markets like Argentina and Russia – regions in which the pharmaceutical industry will become a lot more conscious of quality in the years to come.

"Based on our expertise and experience, we are able to support pharmaceutical companies worldwide in their efforts to meet the ever increasing quality requirements as a strong partner," Reisse says. "Being committed to the highest quality standards, we speak the same language and we have the common goal of reaching "Zero Defects"."

In his spare time, Reisse likes to relax while riding his BMW 1200 GS motorcycle. He also likes reading crime novels and travel literature and occasionally even transmits his love of traveling over to his wife and two children. "It's always exciting to meet up with new cultures, languages and people of other cultures."

EVENTS

20th Anniversary in Mexico

Together with customers from Mexico and Central America, SCHOTT celebrated the 20th anniversary of SCHOTT in Mexico in October 2010.

More than 80 representatives from the pharmaceutical industry visited the SCHOTT plant at Cordoba, Veracruz, to discuss latest market trends, quality requirements and process control, glass characteristics and manufacturing. Also suppliers of container components and production machines were invited to present key trends to the industry. One of the highlights of the event was a tour through the state-of-the-art production site, where SCHOTT manufactures vials, ampoules and cartridges for the highest quality requirements.

"This was an excellent opportunity for us to share with our customers the latest information about glass technology and the current performance of SCHOTT and also to exchange ideas about future trends and requirements," says Carlos Ortega, Regional Sales Manager for Mexico and Central America. "This will enable us to take the required actions to stay a well-trusted and reliable supplier in the upcoming years."

Located in the region of Veracruz, the Mexico facility was put into operation in 1989. In 1994, the site obtained ISO 9001 certification and in December 2002, ISO



One of the highlights of the event was a tour through the state-of-the-art production site.



14001. ISO 15378 was received in 2007. The company combines its material expertise with a strong commitment to quality and the use of the latest technology – in-line measurement control, SPC and advanced visual inspection technology.

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EXHIBITIONS & EVENTS

Come and see us at

- Pharmapack, Paris (F), February 23-24, 2011
- Pharma-Kongress, Düsseldorf (DE), March 22-23, 2011
- PDA Parenteral Packaging, Berlin (DE), March 22-24, 2011
- Interphex, New York (USA), March 29-31, 2011
- Glass Breakage Seminar, Ulm (DE), April 5-6, 2011
- Pre-filled Syringes Americas, Boston (USA), April 5-7, 2011
- PDA Annual Meeting, San Antonio TX, (USA), April 11-13, 2011
- CPhI Japan, Tokyo (Jp), April 18-20, 2011
- API China, Chengdu (CN), April 21-23, 2011
- Pre-Filled Syringes, London (UK), May 10-11, 2011
- Interpack, Düsseldorf (DE), May 12-18, 2011
- AAPS Bio, San Francisco CA (USA), May 16-18, 2011
- Pre-filled Syringes, New Brunswick NJ (USA), May 18-19, 2011
- CPhI China, Shanghai (CN), June 21-23, 2011
- Koreapack, Seoul (KR), June 14-17, 2011
- Interphex Japan, Tokyo (Jp), June 29 - July 1st, 2011

MASTHEAD

SCHOTT forma vitrum
NEWSFLASH

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ON TOUR

A Strong Partner to the Argentinean Pharmaceutical Industry

With the opening of the new plant in Argentina in November 2010, following Brazil (since 1959) and Columbia (since 1999), SCHOTT has now three pharmaceutical packaging production sites in South America.

The motto of the inauguration ceremony in Argentina's capital Buenos Aires was "Confidence – Technology – Innovation." Around 200 representatives of South American pharmaceutical companies, politicians from the Buenos Aires region and the German

ambassador to Argentina, Günter Kniess, took part in the event.

"With this new, modern plant, we are further expanding our position as the leading supplier to the pharmaceutical industry in South America. At the same time we are systematically continuing our global growth strategy in the important core business of pharmaceutical packaging," explained Professor Dr. Udo Ungeheuer, Chairman of the Management Board of SCHOTT AG, at the plant inauguration.

In summer 2009, SCHOTT acquired parts of the two Argentinean pharmaceutical packaging manufacturers, Medical Glass S.A. and DIESCA S.A., and incorporated their business activities into a new subsidiary, SCHOTT Envases Argentina S.A. The company has now consolidated production, previously spread over two locations, at the new, modern plant in the north of the greater Buenos Aires area. The plant – producing pharmaceutical ampoules and vials – has been developed with SCHOTT expertise and will initially provide 150 jobs.

SCHOTT is the only foreign pharmaceutical packaging manufacturer in Argentina. "With this local production base, we will be gaining access to Argentina as an important growth market," commented Juergen Buhr, Director of SCHOTT Pharmaceutical Packaging in South America.

"The combination of the company's local market experience, access to customers, and technological know-how makes SCHOTT a strong partner for the Argentinean pharmaceutical industry. At the same time, this will open up

opportunities for us in other South American markets as well," he added.

SCHOTT has conducted business in this region for over 100 years. "Primarily we delivered heat-resistant glass cylinders for gas lighting in this area," said Ungeheuer, "some decades later we began to establish our own production and sales companies."

Professor Dr. Udo Ungeheuer, Chairman of the Management Board of SCHOTT AG, opened the event with an introduction to the SCHOTT group.



Some 200 participants took part in the inauguration ceremony in Argentina's capital of Buenos Aires.



Part of the ceremony was a performance of Argentine tango, a dance which originated in the suburbs of Buenos Aires at the end of the 19th century.

NEWS

FIOLAX Academy in Indonesia – Technical and Scientific Insights

To support customers with the use and processing of special glass tubing for pharmaceutical packaging, SCHOTT provides specialized trainings with technical and scientific support under the name FIOLAX Academy.

One of these trainings was held during the "International Pharma Expo" (IPEX) in Jakarta, Indonesia, at the end of last year organized by the Association of Indonesian Pharmaceutical Companies and Pharma Materials Managers Club. IPEX is a specialized exhibition of pharmaceuticals products, equip-

ment and machinery. At the FIOLAX Academy, experts from the SCHOTT international technology group share their knowledge with their customers. The specialized training modules cover topics such as the composition and production of pharmaceutical glass tubing, the specifics of different Type I glasses, drug-container interaction, protein adsorption and lyophilisation as well as international standards and regulatory aspects.

The training program is named after SCHOTT "Fiolax" glass tub-

ing, the most widely used pharmaceutical container material worldwide.

Fifty-eight participants from 18 pharmaceutical companies and some university students attended the seminar in Indonesia.

"It was a successful event as shown in the overwhelming interest," says Gunawan Setokusumo, Commercial Director at SCHOTT Pharmaceutical Packaging in Indonesia. "The FIOLAX Academy provided the participants with highly valuable information for their daily work."

In 1954, Schott assumed ownership of an existing plant in Rio de Janeiro that has been producing pharmaceutical glass tubing until today. In 1969, SCHOTT opened its first South American sales office in Buenos Aires. It still exists and will also be moving to the new plant.

Besides the three plants for primary packaging in South America, SCHOTT has one production site in Rio de Janeiro to produce pharmaceutical glass tubing and one in Indaiatuba, both in Brazil, to produce special flat glass for the household appliance industry.

"We are counting on Argentina and South America as emerging markets," explained Ungeheuer, "especially in the pharmaceutical packaging sector. We see excellent opportunities for our business here." According to a study conducted by Espicom Business Intelligence in June of 2008, total sales of pharmaceuticals in Latin America are estimated to be worth 50 billion U.S. dollars. By 2013,



Marcelo Iturralde, Gerente General of SCHOTT Envases Argentina, thanked customers for their trust and gave an outlook to SCHOTT's next steps in Argentina.

average annual market growth of 9.9 percent is projected. With a 12 percent market share, Argentina is the third largest sales market behind Brazil and Mexico.



Fifty-eight participants from 18 pharmaceutical companies attended the SCHOTT FIOLAX Academy in Indonesia.

Site at a glance

SCHOTT Envases Argentina S.A.

Location:	Buenos Aires, Argentina
Employees:	150
Products:	ampoules, vials
Production area:	3000 m ²
Quality certification:	ISO 9001

EVENTS

Customer Event in Suzhou – Highest Quality Made in China



API exhibition in Suzhou offered a great opportunity for SCHOTT to invite customers to its nearby state-of-the-art plant.

One day before the opening of the “API China” – the leading exhibition for the pharmaceutical manufacturing sector in China – SCHOTT invited its customers to an event at its nearby state-of-the-art manufacturing plant in Suzhou in November 2010.

“Due to the fact that we are present on site with our plant in Suzhou, the API exhibition is basically a home game for us and a great opportunity for both our current and future customers to get to experience the SCHOTT philosophy at close

range so to speak,” explained Joerg Doescher, Sales Director Asia SCHOTT Pharmaceutical Packaging.

At the event, the participants were presented information about the more than 125 years old German-based technology group and packaging specialist SCHOTT and its products, the quality standards and philosophy that it is renowned for, and last but not least, on its innovations.

The customers were also invited on a detailed plant tour. The feedback of the customers was very positive. “I was highly impressed by the ultra-modern facility and the high level of the quality standards,” said a participant from a big Chinese pharmaceutical company, for example.

At the manufacturing plant in Suzhou, SCHOTT produces ampoules and vials of glass for the highest international quality requirements for pharmaceutical primary packaging.

To guarantee the high quality standards of the final packaging product, the facility relies on



The high quality level of SCHOTT impressed the participants of the customer event.

SCHOTT “Fiolax”, Type I borosilicate glass, a highly resistant tubing glass that complies with international standards (USP, EP, and JP), as a raw material.

The modern plant was built in accordance with the standard approach that SCHOTT Phar-

maceutical Packaging production sites follow on a global basis: state-of-the-art production equipment and visual inspection systems, clear room environment and full compliance with currently valid Good Manufacturing Practices (GMP).

NEWS

Customer Survey 2010 – Very Positive



Highly advanced camera inspection technology by SCHOTT for the highest requirements: the company received good marks for its product quality and technological expertise.

To meet the product and service requirements by customers even better, SCHOTT carried out a global customer survey in 2010.

Customers were asked about SCHOTT’s overall performance, products and services compared to its competitors and also for possible areas for improvement. After 2007 and 2009 it was now the third customer survey. “This time we integrated the pharmaceutical packaging survey in the first worldwide SCHOTT group customer survey,” explains Christa Fritschi, Director Marketing at SCHOTT Pharmaceutical Packaging. “That’s the reason for the

unexpected one year interval. Now we go back to our two-year rhythm and thank our customers for understanding.”

The survey results show a very positive overall picture in comparison with competitors. “Sixty-five percent of all the customers who participated in the survey rated the overall performance of products and services very good or even excellent,” says Fritschi, “and we see even a positive trend compared to the last surveys.”

The company received good marks from its customers especially for its product quality, technological expertise, innovation

capabilities and for its technical customer support. International presence and environmental orientation, the SCHOTT image within the industry and social responsibility also scored very well.

The analysis showed some room for improvement in the area of supply chain and delivery quality, with customers asking for shorter lead times, more flexibility and delivery reliability. They would also appreciate better responsiveness to inquiries and improvements in complaint handling.

“As a consequence of the customer survey, a detailed action plan has been set up for each region,” explains Michael Vollgold, Vice President Global Marketing & Sales SCHOTT Pharmaceutical Packaging. “Some of the topics are already being addressed by running projects.”

“We take this opportunity to sincerely thank our customers who participated in the survey,” says Vollgold. “Of course we are very pleased about the positive feedback which we understand as a confirmation of our efforts to supply the best packaging solutions to our customers worldwide. On top of this we are especially obliged for the critical remarks and suggestions which will help us to improve our products and services in the interests of the customers.”

NEWS

New Website

The new website of SCHOTT Pharmaceutical Packaging has been completely restructured, updated and refreshed to meet the information requirements of our customers and business partners.

As a result, it shows a clear and modern look. Its new structure and navigation provide easy access to relevant information. The users find more detailed information about our company, our products and services. For customers interested in our packaging solutions for the growing segment of biotech solutions, we offer an application-oriented entry.

“At present, our homepage is available in English,” says Simone Haag, the project manager responsible at SCHOTT Pharmaceutical Packaging. “Other language

versions are currently under development. We will start with Portuguese, Spanish and German, other languages will follow.”

The feedback on the re-launch has been very positive. The number of clicks on the website increased immediately after the go-live. “We have also received many positive comments directly from the users,” says Christa Fritschi, Director Marketing SCHOTT Pharmaceutical Packaging. “Besides general comments on the user-friendliness and the visual design, we have received a lot of compliments for our application-oriented approach for biotech solutions and for the video animations that illustrate the manufacturing process of our products, for example.”



The new website of SCHOTT Pharmaceutical Packaging has been completely restructured, updated and refreshed.