

Customer Newsletter
May 2016

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WELCOME



Our Converting Machine Project is progressing well. It's an ambitious machine upgrade project with a several year timeframe that commenced in 2013. We're successively

rolling out identical, state-of-the-art machines at all our vial manufacturing plants around the world. Now that the roll outs are almost finished at our North American plants in Morganton, Forest Grove and Mexico based Querétaro, we'll be going over to Europe to install the machines at the Bolesławiec plant in Poland, and then to our Asian facilities.

We aren't just investing in glass technology, though; there have also been a number of investments at our plastic plants. Gerresheimer Bolesławiec is in the process of putting its third plastic production clean room into operation. It's 2000 m² in size. At Triveni in India, a 5,000 m² production hall has just been equipped with new machines and technology. Last, but not least, our US Medical Systems plant in Peachtree City, GA has just upgraded its machine park for the production of a new inhaler.

Enjoy reading!

Jens Kürten

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Highest quality vials

New machines in Querétaro (Mexico) and Bolesławiec (Poland)

Gerresheimer has set up an investment program spanning several years to install state-of-the-art converting machines for vial manufacturing at all its plants. The latest-generation machines and global high standards will enable us to meet even more stringent future requirements of product quality. The aim of this project is absolutely clear: We want to supply our customers with significantly improved vials in the highest possible quality. The latest generation of machines, monitoring and inspection systems guarantees the same high Gerresheimer quality standards at every single one of our tubular glass converting plants around the world.

The rollout of the new machine strategy in the USA is now almost finished. It commenced at the Gerresheimer plant in Morganton, NC, the Gerresheimer Group's Center of Excellence for Vials, and the second US tubular glass plant at Forest Grove in Vineland, NJ, in 2014. Then it was the turn of our plant in Querétaro, Mexico, at the end of 2015. This shifted the upgrade focus there to vials, after the installation of new machines, tech-

nology, inspection and camera systems for ampoule production at Querétaro in 2014. Six new vial machines have been installed to date, and another three will be in place by the end of the year. So Querétaro now uses the very latest technology and produces vials in exactly the same quality as the US plants in Morganton and Forest Grove.

The new machine strategy is now being introduced at the Polish sister plant in Bolesławiec, where the first of the new vial machines was installed in April. Two more will be installed and be put into operation by the end of the year.



COVER STORY



Machine strategy roll out in Querétaro, Mexico

A new era began for our tubular glass converting plant in Querétaro, Mexico in the fourth quarter of 2015 when three brand new vial machines were installed and put into operation.

Before that could happen, extensive infrastructure refurbishment work had to be performed within a very narrow timeframe. This included the total renovation of production building 4, with the replacement of its flooring and lighting system, and the installation of a controlled environment for packaging operations. More importantly, though, the best operators and packers had to be selected and trained to use the new technology. The Mexicans were supported in this process by a competent team of colleagues from the USA sister plants. They spent six months training the machine operators and hot-end technicians so that they were competent in the use the machines, and able to troubleshoot and perform maintenance, giving them the knowledge they needed to manage a production process based on entirely new technology. Camera technicians also received training in the use of the new Gx RHOC® and Gx G3® inspection systems. (You can read more about these later on).

Six new machines have already been installed and production operations at Querétaro are running smoothly thanks to the hard work and commitment of everyone involved in the project. Now the plant is supplying our North American and Mexican customers with serum vials in PharmaPlus quality. Three more machines will be up and running by the end of the year.

Gerresheimer Bolesławiec in Poland is the next milestone

The first new machine was installed at our tubular glass converting plant in Bolesławiec in April. As in Querétaro, extensive refurbishment work had to be performed at the plant before this could happen. The floor and lighting systems were replaced, the clean room was upgraded and extended, and the existing machine layout was changed. These are just a few aspects of the extensive refurbishment program that was implemented to prepare the plant for the new, ultra-modern machines. The second and third machines are also scheduled for installation this year, and further machines will follow in 2017 and 2018.

What happens next?

Our investments have already more than paid off; reflected by the fact that the new machines manufacture vials in cosmetic and



dimensional quality that surpasses the industry standard. Initial customer feedback has therefore been very positive.

We're in the process of building a new tubular glass plant in Kosamba, India, where we will also be installing the latest-generation machines and inspection technology. Soon afterwards, we'll be upgrading the machine parks and investing in camera systems at our Chinese plants.

Now the focus is on finishing all the rollouts and on the world-wide vial supply of our global customers who require a consistently high quality.

In 2016 Gerresheimer is planning to supplement the vial machine program funding with further investments to introduce the very latest cartridge manufacturing technology at our plants in Forest Grove, NJ (USA) and Querétaro, Mexico.

COVER STORY

PRIMARY PACKAGING GLASS

MACHINE TYPES AND TECHNOLOGIES

We've installed two types of machines. The first was developed by our own engineers and built for our tubular glass plants by a partner, and the second was sourced from a European machine manufacturer. All tubular glass converting plants that manufacture vials are equipped with these two machine types, plus standardized Gx® G3, Gx® RHOC and Gx® THOR monitoring, inspection and packaging technology. Gx® G3, Gx® RHOC and Gx® THOR were developed in-house by Gerresheimer and are part of a stringent TQM system that guarantees maximum precision and quality assurance in line with the latest standard.

Gx® G3

for cosmetically flawless vials

- Five HD cameras ensure superior defect detection
- Smart defect recognition and classification

Gx® RHOC

for superior dimensional quality

- Three high-resolution matrix cameras on each side
- Hyper-centric ID camera
- Extremely accurate handling system
- Integration with the forming machine
- Integration with Infinity SPC software

Gx® THOR

for delamination-resistant vials

- New technologies are integrated into the existing forming lines
- Gx® Thor links critical areas of the converting process
- Statistical process controls are used to check targeted levels of acceptability
- All vials are inspected for optimum temperature profile

Gerresheimer Shuangfeng – three production facilities under one roof



Gerresheimer Shuangfeng has two reasons to celebrate 2016. Firstly, it was founded 30 years ago in April. Secondly, it has been operating very successfully in the Chinese market as a Gerresheimer joint venture for 10 years.

Our Chinese plant in Shuangfeng comprises three tubular glass converting facilities in Danyang and Zhenjiang. The Danyang I facility, which was built 30 years ago, is around 220 km away from Shanghai. It is also the headquarters.

With the help of Gerresheimer's technologies, funding and market reputation, Shuangfeng has been able to build its business and adopt western standards over the last ten years. Shuangfeng also has the Gerresheimer Management System (GMS), which involves annual audits to ensure compliance with Gerresheimer-wide best practice standards.

Shuangfeng uses the same machines as the German, Mexican and Polish sister plants, and many of the Chinese employees were trained in the use of the machines at those sister plants. Further investments are also planned at this plant to upgrade the machine park and install new camera systems so that further quality improvements can be achieved.



PLANT-INFORMATION

Name: Gerresheimer Shuangfeng Pharmaceutical Glass (Danyang) Co., Ltd

Division: Primary Packaging Glass

Founded: 1986 (Danyang I), 2002 (Zhenjiang), 2009 (Danyang II)

Gerresheimer take-over: May 29, 2006

No. of employees: over 1,000 at the three plants

Certifications: ISO 9001, ISO 14001, ISO 15378, ISO 17025

Product portfolio: vials, ampoules, cartridges, laboratory vials, test tubes

PLASTICS & DEVICES

Gerresheimer Bolesławiec (Plastic Packaging)

Third ISO class 7 clean room

Gerresheimer Bolesławiec has completed its third clean room for plastic product manufacturing. The new production building is 2,000 m² in size and divided up into different areas for the following production process steps:

1. An injection room for IM (injection molding) and IBM (injection blow molding) machines on a 715 m² area that has an extremely efficient air-conditioning system. The high-tech ventilation system is designed to save energy and meets the most stringent air-conditioning requirements.

2. An ISO 14644-certified class 7 clean room of 387 m² in size for the foil packaging of products.

3. A packing room, where products are packaged in boxes and put onto pallets. This room is separated from the clean room and injection area by double door systems to prevent product contamination.

All the systems in this infrastructure are geared to saving energy. There are separate water systems for the free cooling of molds



and machines, and there is LED lighting in all production areas.

This new production area increases the total machine park size by another 18 machines. 7 machines have already been installed and put into operation, and the others will be following soon.

Triveni Polymers, Kundli (India)

A new production hall with new machines



2015 was an exciting and challenging year for our pharmaceutical plastic packaging plant Triveni Polymers in Kundli, India. The plant was able to introduce many new machines and technologies for the production of plastic vials and child-safe closures

thanks to the new 5,000 m² production building with an ISO class 5 clean room and several ISO class 4 controlled environments that was built there. The clean room houses various machines from leading manufacturers under one roof, including a brand new Sacmi compression blow forming machine. This makes Triveni the first company to use compression blow forming outside the USA, and it has already manufactured 25 million vials with it.

Triveni has been part of the Gerresheimer Group since the end of 2012. It is a leading manufacturer of pharmaceutical plastic packaging products and closures, and the first Indian company to file a Type III DMF with the US FDA in respect of packaging components for the regulated Indian market. The company specializes in plastic packaging for solid-dose pharmaceuticals with child-safe closures, screw caps and caps with integrated desiccants. It recently also commenced production of plastic vials for liquid-dose pharmaceuticals and ophthalmological products.

Peachtree City, GA (USA)

New inhaler



After a comprehensive upgrade, the Medical Systems plant in Peachtree City, GA (USA) will be commencing production of an asthma inhaler for the US market this year. The upgrade process last year included the construction of another new production building, the installation of state-of-the-art clean-room technology, the first injection molding machines and precision molds, the commencement of the validation process, as well as the installation and testing of the assembly lines.

Global demand for easy-to-use drug delivery devices such as insulin pens and asthma inhalers continues to grow. Gerresheimer has responded to this development by continuously expanding the production capacity at its ultra-modern Peachtree City plant over recent years. We believe that this segment in the USA offers numerous growth opportunities and that our Peachtree City plant will play an important role in the process.

RECOMMENDED READING & VIEWING



Gerresheimer in the US – Fully focused on core business,

Drug Development & Delivery, April 2016, Vol. 16, no. 2, www.drug-dev.com

Drug Development & Delivery caught up with **Roger Kurinsky, Senior Vice President of Tubular Glass Americas**, to discuss recent strategy shifts, the importance of the US pharma market, and how Gerresheimer's investments in the US can benefit pharma companies.

Ready-to-Fill RTF® Syringes meet Present and Future Biotech Requirements,

Pharmazeutische Industrie 78, no. 1 (2016), p. 121-130, Bernd ZeiB, Claudia Petersen, Gerresheimer Bünde GmbH.

Prefillable syringes are both a pharmaceutical primary packaging and drug delivery devices. End users, drug administration agencies and the pharmaceutical industry are imposing increasingly stringent quality

requirements on prefillable syringes in both these functions. Optimized production and inspection processes ensure that the syringes can meet these requirements. Although it is crucial as a lubricant to the proper function of the plunger in the syringe body, silicization has to be reduced to the minimum in syringes for innovative biotech drugs. A long-term study investigated the factors that affect break loose and gliding forces in syringes during the injection process. It is important to understand these factors, particularly in the case of auto-injectors, so that they will reliably deliver the correct dose of the drug even after long periods of storage.

Exceeding expectations,

Pharmaceutical Manufacturing and Packing Sourcer (PMPS), no. 2 (2016), p. 40-43.

Niels Düring, Global Executive Vice President of Gerresheimer Plastic Packaging, talks to PMPS about his role in the company, the necessity to work closely with your customers, and the importance of selecting the right packaging for pharmaceutical drugs.

Big vials mean wasted billions for payers and patients:

www.fiercepharma.com/story/big-vials-means-bigger-revenue-cancer-drugmakers-wasted-billions-payers-and/2016-03-01

Pharma price hikes aren't alone in driving up drug costs. Pharma packaging is, too. That's the conclusion of a new US study, which

found that large cancer-drug vials are fueling \$3 billion in waste every year. Many drug makers package their expensive cancer therapies in vials that contain too much drug for most patients. Nurses draw what they need to dose each patient according to body weight and toss the rest because of safety rules. The authors of the study propose ideas to fix the problem.

FDA lists difficult-to-use devices that will be subject to human factors validation testing:

www.fiercemedicaldevices.com/story/fda-lists-difficult-use-devices-will-be-subject-human-factors-validation-te/2016-02-04

The FDA just released a draft list of devices whose applications for marketing approval should include human factors data to ensure usability is considered during the design and regulatory process. The growing use of home healthcare poses a challenge to the FDA and makes usability even more crucial. Due to the rise of biologic medications (which typically don't come in oral formulations), patients are increasingly being asked to inject themselves, but a December 2014 study found that only 16% of patients use auto injectors properly, with more than half skipping three or four steps.



Why is a cough medicine bottle brown?

The German TV stations ARD and KIKA broadcasted a 'Sendung mit der Maus' program about our plant in Essen on April 3, 2016. The mouse asked "Why is a cough medicine bottle brown"? And Gerresheimer Essen answered its question. The program can be found in the 'Sachgeschichten' section at www.wdrmaus.de/sachgeschichten/filme.php5. Parts of the „Sendung mit der Maus“ show have been broadcasted in almost 100 countries to date, including Argentina, Australia, Algeria, Mauretania, Senegal, Indonesia, Saudi Arabia, Kenya, Russia, the USA and most European countries. The English name of the program is Mouse TV.

PEOPLE

Volker Rekowski is the new Chairman of the Quality Council



Volker Rekowski has been appointed as Chairman of the Quality Council effective from February 22, 2016, in addition to his current role as Director Quality Europe & India Tubular Glass. He joined Gerresheimer in April 2014, and has been a member of the Quality Council since then.

Martin Moser has been appointed as Senior Plant Director of Pfreimd Medical Systems



Martin Moser has been appointed as Senior Plant Director of Pfreimd Medical Systems, Germany, effective from March 1, 2016. Before joining Gerresheimer Martin Moser held the position of Plant Manager / CEO at Kromberg & Schubert in Pinghu (Shanghai), China. Prior to that, he worked for Grammer Interior in Shanghai, China, and Schmoelln, Germany, and for Knorr-Bremse in Berlin, Germany.

Carsten Hurth has been appointed as Global Director of Operational Excellence Moulded Glass



Carsten Hurth has been appointed as Global Director of Operational Excellence Moulded Glass effective from March 1, 2016. Carsten Hurth joined Gerresheimer in 2014 and was previously responsible for the Moulded Glass plants in Europe as Head of Operational Excellence. Prior to that he worked for PricewaterhouseCoopers as Business Transformation & Process Improvements Manager.

WEB & EVENT

Gerresheimer expects around 9% growth in 2016

Gerresheimer AG brought financial year 2015 to a successful close and sees strong growth prospects for the years ahead. "2015 was not only a successful but also an important year for us. In Centor, we successfully acquired a market-leading and profitable company in the USA. Similarly important was the sale of the glass tubing production activities, with which we further sharpened our focus on pharmaceutical packaging and made our business less capital-intensive. We are successfully implementing our strategy, and I look forward with great confidence to the years ahead," said Uwe Röhrhoff, CEO of Gerresheimer AG.

Pharmaceutical packaging manufacturer Gerresheimer boosted revenues by 6.8% to EUR 1,377.2m in financial year 2015 (December 1, 2014 to November 30, 2015). On an organic basis, revenues increased by 1.5%, within the 1% to 3% target corridor. Notable revenue growth was generated with pharmaceutical plastic packaging as well as products for safe and simple drug delivery such as insulin pens, skin-prick aids for diabetics and asthma inhalers. Business with pharmaceutical primary packaging glass picked up in the course of the year after a slow start in the USA. The market for premium cosmetic glass packaging developed well, largely driven by the trend toward elaborate design and the associated finishing processes. Revenues with laboratory glassware, which is primarily sold in the USA, increased solely as a result of exchange rate changes. At constant exchange rates revenues showed a slight decrease.

Gerresheimer successfully completed two key transactions in financial year 2015. With the acquisition of Centor, the Company realized its long-term goal of occupying a stronger presence in the plastic pharmaceutical packaging segment in the USA. Centor is the market leader in plastic containers used by American pharmacies to package prescription tablets. In addition, Gerresheimer sold its glass tubing production activities, entered into a long-term supply contract for this intermediary product and established a joint venture for future innovation in the pharmaceutical glass segment. Prior to the two transactions, the overall financing arrangement from 2011 was replaced in June 2015 with a EUR 450m revolving credit facility.

Gerresheimer's capital expenditure in financial year 2015 was EUR 125.8m (2014: EUR 126.6m), or 9.0% of revenues at constant exchange rates and excluding Centor. The target for capital expenditure was 9% to 10% of revenues. Gerresheimer is further expanding production capacity for drug delivery systems such as insulin pens and asthma inhalers, especially in the USA and Czech Republic. Late summer 2015 brought an expansion and improvements at the moulded glass plant in Chicago, USA. The global program of modernizing and standardizing injection vial production machinery was successfully continued. A new production building for injection vials and ampoules was completed in India. Production there is set to start up at the end of 2016.

The Annual Report is available here: www.gerresheimer.com/en/investor-relations/reports



Gerresheimer is a "Great Place to Work"

For the second time in a row the German Focus Magazine has given Gerresheimer the "Great Place to Work 2016" quality seal.

Around 70,000 employees of all ages and from all hierarchical levels voted for us on Xing and kununu.

Annual Report 2015 – Better and Better

For the last three years our Annual Report has featured an unconventional 'workbook-like' design. The positive feedback that we received in 2013 and 2104 encouraged us to take the concept one step further. With its sandy-colored cover and lots of handwritten comments, photos and little watercolour drawings it looks very much like the notebooks we regularly use at work. The 2015 annual report is entitled 'Better and Better'.

WEB & EVENT

Gerresheimer at CPhI Shanghai 2016:

Pharmaceutical glass for sophisticated applications

Gerresheimer is very well positioned in the South-East Asian market with six production plants for glass and plastic products. At this year's CPhI in Shanghai, Gerresheimer Shuangfeng will be presenting vials, ampoules and cartridges for the pharmaceutical industry to the fair's trade visitors.



Gerresheimer's focal exhibit this year is vials, a product that is in high demand. In fact, vials are one of the most frequently used pharmaceutical packaging products in the world. Gerresheimer manufactures vials with capacities of between 1 and 50 ml.

The production machines are currently in the process of being upgraded to achieve a sustainable improvement in quality. "We want to introduce higher global quality

standards," said Jens Heymann, Global Vice President Finance & Controlling and Chairman Tubular Glass Europe & India. The Gerresheimer production facilities in China, Europe and the USA operate as a global network, which is why all their employees are being provided with the same training in the use of the new machines.

Gerresheimer is exhibiting other core products in its portfolio alongside vials. These include ampoules, cartridges, laboratory vials and other specialty products in quality type I, II and III clear and amber borosilicate glass.

Gerresheimer Shuangfeng has over 30 years of experience in vial production and several certifications that no other competitor in that region has. The company is supplier to more than 300 pharmaceutical companies in Asia, the USA and Eastern Europe, and market leader in China.

Gerresheimer's glass experts will be at CPhI in Shanghai, which is taking place at the Shanghai New International Expo Center (SNIEC) between June 21 and 23. You can find them at booth W5E02.



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GERRESHEIMER

EVENT-CALENDAR H2 2016

MAY, 16 – 18

AAPS National Biotechnology Conference
Boston, USA
Sheraton Boston Hotel

MAY, 25 – 26

Pharma Days USA
Chicago und Chicago Heights, IL (USA)

JUNE, 14 – 16

MDM East
New York, USA
Jacob K. Javits Convention Center

JUNE, 21 – 23

CPhI China
Shanghai, China
SNIEC | Stand W5E02

OCTOBER, 04 – 06

CPhI Worldwide
Barcelona, Spain
Fira de Barcelona Gran Via | Stand 2H28

OCTOBER, 17 – 18

Universe of Pre-filled Syringes and
Injection Devices
Huntington Beach, USA
Hyatt Regency Huntington Beach
Resort and Spa

OCTOBER, 26 – 28

MedTec China
Shanghai, China
World Expo Exhibition & Convention
Center

NOVEMBER, 14 – 17

Compamed / Medica
Düsseldorf, Germany
Messe Düsseldorf

NOVEMBER, 21 – 23

CPhI India
Mumbai, India

NOVEMBER, 22 – 25

Pharmtech
Moscow, Russia
Crocus Expo IEC

DECEMBER 05 – 08

China-Pharm
Guangzhou, China
China Import and Export Fair Complex
(CIEFC)



High-Quality Gx[®] Glass Vials for Pharmaceuticals and Diagnostics

- | High performance design
- | High barrier properties
- | Superior resistance

