

UPDATE.28

GERRESHEIMER

Customer Newsletter
July 2019

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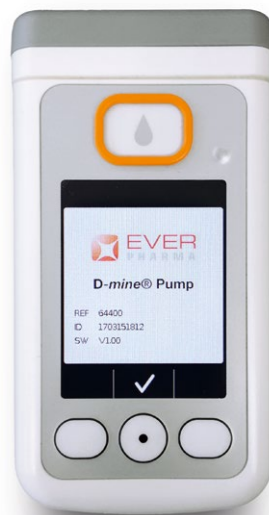
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Small Batch Production Glass Wackersdorf (Germany)

WFI (water for injection)
system for completed

**Innovative
micro-infusion pump**
developed and
successfully launched for
EVER Pharma



**GOOD
DESIGN**

Good Design Award
for the Design of
Drug Delivery Devices
by Sensile Medical

Dropper bottle System E

Eye dropper bottles
with fixed TE ring



New plant in Skopje (North Mazedonia)

Additional manufacturing capacity for medical systems

PLASTICS & DEVICES



Gerresheimer is investing in a new plant in Skopje, North Macedonia, for medical plastic systems and syringes

Gerresheimer AG is to build a new plant in Skopje, Republic of North Macedonia. "As part of our growth strategy, we require additional manufacturing capacity and are expanding our European production network. We will build a new plant in Skopje to produce plastic systems for both the pharmaceutical industry and the medical technology sector as well as prefillable syringes. North Macedonia is an ideal location for expanding our production. The country offers good infrastructure, cost structures, trained personnel and excellent support from the authorities," said Dietmar Siemssen, Chief Executive Officer of Gerresheimer AG.

Gerresheimer is investing a mid-double-digit million Euro figure in the new plant in the North Macedonian capital of Skopje, an amount that is already included in the company's medium-term investment plans. Construction is beginning now, with completion of the building and the start of interior work scheduled for 2019 as well. Production is set to begin in the second half of 2020. 12,500 m² of usable and production space including cleanroom capacities are planned. Initially, around 7,500 m² will be created for production purposes. The space can easily be expanded later on, however, thanks to a modular structure. The plant will initially manufacture

medical plastic systems prior to adding prefillable glass syringes lines following a further expansion phase. Up to 400 jobs may be created in the medium term.



The plant will belong to the Plastics & Devices Division where it will fall under the Medical Systems Business Unit. Construction work, staff training and production ramp-up will be closely supervised and supported by the Gerresheimer competence center in Wackersdorf, Germany, together with European sister factories in Pfreimd and Buende in Germany as well as Horšovský Týn in the Czech Republic. Gerresheimer has production facilities in North and South America as well as in Europe and Asia. The Skopje plant will be Gerresheimer's first in South-Eastern Europe.

PLASTICS & DEVICES

Ultra-pure water for glass production

WFI system for Small Batch Production Glass completed



The new water treatment system supplies Small Batch Production Glass with the ultra-pure water required for the RTF process

One year after laying the foundation for the TCC expansion, tooling optimization and traineeships have now moved into the new building. Setup of small batch production (SBP) for glass products is also making good headway.

In the future, all processes in injection production, from glass forming to needle assembly and baked-on siliconization down to ready-to-fill (RTF) processes can be realized in small batches. Production takes place in the qualified cleanroom in accordance with GMP Grade C and D and provides our in-house development and glass customers with a special system for testing, sampling, clinical studies and small series batches. One specific focus is to get newly developed products ready for start of production in order to relocate them to the production plant later on. SBP works at the same quality level as large-scale production but is designed for quick-changing products, making it especially fast-paced and flexible. With the setup of an ultra-pure water system, an important component of small batch production has now successfully passed its test run.



Water that meets the strictest of requirements

We wash the Gx RTF® syringes, siliconize them if necessary and package them in nests and sterilize them so that pharma customers can feed them into their pharmaceutical systems without pre-treating them. The RTF process requires large volumes of ultra-pure water that have to meet water for injection (WFI) requirements, which are as strict as those placed by manufacturers of medical solutions given to patients via injection. These ultra-pure water requirements are defined in international pharmacopoeias, in our case the European Pharmacopoeia PhEur, which specifies that the water in a validated process must meet a wide range of quality criteria. We continually test electric conductivity and the total organic carbon (TOC) as part of in-process checks during WFI production. We regularly take samples for nitrate content testing at our laboratories, as well as for microbiological testing at an external laboratory.

Authors:

Christian Duschinger, Global Head of Quality Engineering, Team 2, Gerresheimer Regensburg GmbH, Wackersdorf
Holger Heining, Head of Small Batch Production, Gerresheimer Regensburg GmbH, Wackersdorf

In accordance with PhEur, WFI is produced in three steps. In the first step, hardening ions such as calcium and magnesium are bound by means of hardness stabilization. In the second step, reverse osmosis is used to filter out sodium ions and other impurities, resulting in very clean purified water (PW). In the third step, this PW is distilled to produce ultra-pure sterile water for injection (WFI).

The site acceptance test (SAT) that verifies function in line with specifications was passed in week 5, allowing us to begin with performance qualification (PQ) in March. This test, which will take until the first quarter 2020, ensures that the system maintains the required quality criteria even with changing supply water qualities, as well as climatic influences varying due to the season and changing production environments. At the end of the year, safety injection Gx InnoSafe® is scheduled to be the first RTF product manufactured in Small Batch Production Glass.



Inline TOC measurement, which measures how much organic carbon the water still contains



This system part brings the water to WFI standard in the last treatment step of distillation

ADVANCED TECHNOLOGIES



Innovative micro-infusion pump from Gerresheimer subsidiary Sensile Medical developed and successfully launched for EVER Pharma

Developed specially by Sensile Medical for EVER Pharma under the brand name *D-mine*®, this wearable micro-infusion pump recently received European CE certification and has already been launched in several European countries. The compact, patient-friendly infusion pump is used for the continuous subcutaneous administration of drugs to treat Parkinson's disease. The first micro pump from Gerresheimer subsidiary Sensile Medical to be available on the market, gives Parkinson's patients greater independence in their day-to-day lives.

The *D-mine*® pump is used to administer apomorphine in the advanced stages of Parkinson's treatment. Simple handling, safety, and ease of use were the main aims behind the development. The compact design is down to Sensile Medical's special micro-rotation pump technology and is straightforward to use thanks to an intuitive menu interface.

"In developing the EVER Pharma *D-mine*® pump for treating Parkinson's disease, we have completed a very challenging project with a tough set of requirements," explains Georges Kahwati, General Manager at EVER Pharma GmbH. "This product signals clearly that EVER Pharma is committed to focusing on the needs of patients and providing them with customized solutions and innovative medical products."

"With EVER Pharma's successful market launch, Sensile has delivered an ambitious project with highly innovative user requirements," adds Derek Brandt, CEO of Sensile Medical AG. "Parkinson's patients now have an innovative solution at their fingertips. Our integrated pump technology is already proving its worth in other treatment areas."

Parkinson's patients often have difficulty moving and appreciate the pump's ease of use, such as the automatic dosing function, the lack of complicated flow rate calculations, and the intuitive menu system. Its integrated choice of languages and the full-text display

on its color screen make it easier to learn the ropes, while modern technologies such as data storage and individually adjustable basal rates support better treatment management. The *D-mine*® pump comes with a specially designed charging station and does not need any conventional batteries.

With its brand of the Parkinson's drug apomorphine and its own medical product, EVER Pharma now offers a comprehensive treatment package.

You can find more information at www.d-minecare.com.

"With EVER Pharma's successful market launch, Sensile has delivered an ambitious project with highly innovative user requirements,"

Derek Brandt
CEO Sensile Medical AG



ADVANCED TECHNOLOGIES

GOOD
DESIGN

Good Design Award for the Design of Drug Delivery Devices by Sensile Medical



Sensile Medical Design Language

The micro pump-equipped drug delivery devices of Sensile Medical, a subsidiary of Gerresheimer AG, have an unmistakable design. The design was the creation of Team Consulting, an agency based in England which in 2018 received the renowned Good Design Award in the category "Medical 2018" for its work. At CPHI North America in Chicago Sensile Medical has showcased its innovative solutions for digital and electronic drug delivery devices at the Gerresheimer booth from April 30 up to May 02.

"We are continuously working on improving quality of life for patients who rely on injection aids,"

... says Sandra de Haan, CBO at Sensile Medical. With SenseCore micro pump technology, Sensile Medical ensures the safe, simple, and precise administration of liquid drugs by the patient themselves at home or on the move, and always with absolute reliability. This injection aid is impressively simple and discreet to use and the patient does not see the needle, making it suitable for all manner of different applications.

In 2017, Sensile Medical commissioned the British agency Team Consulting, which specializes in medical devices, to package these requirements and attributes of its drug delivery devices in a patient-friendly design. The Chicago Athenaeum Museum of Architecture and Design Good Design Award is the world's oldest and most prestigious design award, open to manufacturers, companies and emerging start-up businesses.

This is what the jury at the Good Design Awards based their decision on



The Sensile Medical Design Language provides a unified look across a range of injection devices. Different product varieties can be clearly identified as belonging to a single family with key attributes of the Sensile technology – the flexible modular approach and low-cost disposable component.

The modular structure of the device reduces waste.

The Sensile family of products addresses many of the key user and commercial concerns that surround wearable injection devices; namely ease of use, comfort, discretion, reduction of waste, flexibility and ease of customization.

By creating a uniform product family range from a coherent design language, Sensile's range is significantly strengthened. Its customers in particular rely on the devices offering a consistent user experience, independent of the primary packaging for medication.

Source: <https://www.chi-atheneum.org/medical-2018/2018/12/18/sensile-medical-design-language-2017/>

About Sensile Medical AG

Founded in 2004, Sensile Medical AG is a Swiss medical technology company that has been a subsidiary of Gerresheimer AG since 2018. Working with pharmaceutical companies, it develops devices to deliver liquid drugs for the best level of treatment. The patented SenseCore technology forms the heart of the

system. The micro pump is extremely precise in dosage. The products are characterized by modularity and flexibility. Sensile Medical has a workforce of some 120 employees at its headquarters in Olten, Switzerland.

www.sensile-medical.com

PEOPLE

Dr. Bernd Metzner is Chief Financial Officer of Gerresheimer AG



Dr. Bernd Metzner (48) took up the position of Chief Financial Officer of Gerresheimer AG on May 15, 2019. Dr. Metzner had been Chief Financial Officer of SDAX-listed Ströer SE & Co. KGaA since 2014.

"I very much welcome the financial expertise and years of industry experience that Dr. Bernd Metzner brings to the Management Board. Together with him and Dr. Lukas Burkhardt, we make a strong Management Board team that will drive Gerresheimer's sustainable growth forward," says Dietmar Siemssen, CEO of Gerresheimer AG.

After studying business administration in Siegen, Germany, completing his doctorate and starting his career at a law firm, Dr. Metzner held various management positions in finance at the Bayer Group between 2002 and 2011. Among other roles, he was responsible for coordinating the carve-out and initial public offering of Lanxess, and held the position of CFO at Bayer Italy as well as that of global CFO in Bayer's Pharmaceuticals Division. Before joining Ströer, he served as CFO of the global, family-owned Döhler Group from mid-2011 to mid-2014.

The Management Board of Gerresheimer AG

(as of May 15, 2019):

Dietmar Siemssen

CEO responsible among other things for the Plastics & Devices and Advanced Technologies Divisions

Dr. Bernd Metzner
CFO

Dr. Lukas Burkhardt
Management Board member
responsible for the Primary Packaging
Glass Division

Changes in the Primary Packaging Glass Pharma Europe & MENA Sales Organization

A new Primary Packaging Glass Sales organization for Pharma Business in Europe & MENA (Middle East/North Africa) will start now its business, effective May 15, 2019. We set up a new pharma sales organizational structure splitting the Primary Packaging Glass Europe & MENA sales team into two new segments:

1

Primary Packaging Glass Pharma Parenteral Sales Europe & MENA:

selling all Primary Packaging Glass products for parenteral, i.e. injectable & infusion drug administration.

2

Primary Packaging Glass Pharma Oral / ENT / Dermal Sales Europe & MENA:

for all Primary Packaging Glass products for drugs with mainly oral, ear-nose-throat (ENT) & Dermal drug administration.

Whereas glass packaging for parenterals includes Tubular Glass and mainly Moulded Glass Type II and Type I, Oral / ENT / Dermal mainly includes Moulded Glass Type III.

In this segment-specific organization, we will have dedicated **Key Account Managers (KAM)** for selected Key Accounts with strong sales & growth potential and **Area Sales Managers (ASM)** covering the countries in Europe & MENA and the manufacturing sites of the Key Accounts in their country.

The new organization will be supported by a new leadership structure:



Hans-Ulrich Pieper

will lead the new role as Senior Director Sales Pharma Parenteral Solutions Europe & MENA PPG.



Frank Egert

is now Vice President Sales Pharma Oral/ENT/Dermal Solutions & Moulded Glass Food & Beverage Solutions Europe & MENA PPG.

In addition to the new sales force, we have set up the function of Product Management in Primary Packaging Glass Pharma:

Lothar Haaf

took over the role as Director Product Management Vials & Ampoules Europe Tubular Glass.

Silvio Carrico

took over the role as Senior Product Manager Moulded Glass Pharma & Food and Beverage Europe. Silvio joined Gerresheimer in November 2018 coming from Aptar with a long experience in Product Management.

PEOPLE

Gary Waller has been appointed as Senior Vice President Americas Primary Packaging Glass



Gary Waller has been appointed as Senior Vice President Americas Primary Packaging Glass effective from April 8, 2019. Gary will also become President of Gerresheimer Glass Inc. Gary Waller is well known to Gerresheimer. From 1993 until 2005 he worked for Gerresheimer Glass, where in his last function he was Director of Sales Midwest, West & Canadian. In his last function he worked as President of Sales & Marketing Americas at Nipro PharmaPackaging Americas. Before that he was Vice President of Sales & Marketing North & Central America at Schott Pharmaceutical Packaging.

Remigiusz Podcaba has been appointed as Senior Plant Director Boleslawiec Tubular Glass and Chairman of the Management Board of Gerresheimer Boleslawiec S.A.



Remigiusz Podcaba has been appointed as Senior Plant Director Boleslawiec Tubular Glass and Chairman of the Management Board of Gerresheimer Boleslawiec S.A. effective from March 1, 2019. Before joining Gerresheimer Remigiusz held the position of Plant Manager at LM Wind Power Blades. Prior to that, he worked for IQ Metal as Plant Manager and before that for Agusta Westland PZL Swidnik, also as Plant Manager.

Andreas FÜRER has been appointed as Plant Director & Managing Director Wertheim Tubular Glass



Andreas FÜRER has been appointed as Plant Director & Managing Director Wertheim Tubular Glass effective from April 1, 2019. Before joining Gerresheimer Andreas held the position of Head of Operations at Heraeus Sensor Technology. Prior to that he worked for Schott Solar as Head of Cell Production and for Schott as Project Leader.

Hong Cui has been appointed as Director Operations China Tubular Glass



Hong Cui has been appointed as Director Operations China Tubular Glass effective from March 15, 2019. Before joining Gerresheimer Hong held the position of Plant Manager at Kunshan Veritas Automotive Systems. Prior to that, he worked for Contitech China Rubber & Plastic Technology as Production Manager.

WEB & EVENT



Annual General Meeting of Gerresheimer AG approves dividend increase to EUR 1.15 per share

Payment of a dividend of EUR 1.15 per share was approved at the Annual General Meeting of Gerresheimer AG held on June 6, 2019 in Duesseldorf.

"At Gerresheimer, our foundations are strong. After making a good start to 2019, we need to keep up the pace in the coming quarters in order to achieve our goals for the year. We are systematically implementing the projects we planned, thus paving the way for future growth and increased productivity. We stepped up as Gerresheimer's new Management Board with the objective of putting the company on a path to sustained, profitable growth," said Dietmar Siemssen, CEO of Gerresheimer AG, at the Annual General Meeting.

The dividend has been raised by 4.5% to EUR 1.15 per dividend-entitled share. A dividend of EUR 1.10 per share was distributed in the prior year. The dividend will be paid out on June 12, 2019.

The detailed voting results on all items of the Annual General Meeting agenda and the CEO speech delivered at the Annual General Meeting are available here: www.gerresheimer.com/en/investor-relations/annual-general-meeting

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

WORTH A READ



www.worldpharmaceuticals.net

Connected devices for daily use
World Pharmaceutical Frontiers,
March 2019, page 34

Sensile Medical's innovative pump platform is detailed here, with regard to its suitability and ease of everyday use, as well as its sensory value for the product at hand.

www.ondrugdelivery.com

Microlitre dosing with prefillable syringes – when does a device make sense?

On Drug Delivery No. 97, May 2019,
pp. 29 – 31.

In this article, Bernd Zeiss, Head of Global Technical Support, Gx® Solutions & Syringe Systems at Gerresheimer Bünde, and Gautam Shetty, PhD, CEO of Congruence Medical Solutions, outline factors that need to be weighed when considering a device-based approach to microlitre injections.

WEB & EVENT

New flyer: Dropper bottle System E

The US Food and Drug Administration (FDA) has defined some new requirements for dropper bottles that stipulate that the tamper-evident ring is firmly attached to the bottle. Gerresheimer Boleslawiec has therefore developed a new dropper bottle System E with two different cap solutions. The two cap solutions consist of a sleeved cap, already well known in the US, and a cap where the tamper-evident ring stays attached to the bottle after opening. The tamper-evident ring has flexible parts, which act like flaps and then

create a positive retention mechanism on the neck of the bottle. The new cap just received FDA approval. The dropper bottles will be produced in the sizes 5, 10, 15 and 30 ml and the production and packaging of the caps is conducted under ISO class 7 cleanroom conditions. You can download the new flyer at <https://www.gerresheimer.com/en/products/download/plastic-bottles-and-vials-downloads.html>



PHARMAPACK 2019:

Joint presentation

Portal Instruments and Gerresheimer

Andrew Coats, Vice President of Engineering at Portal Instruments (Cambridge, MA, USA), and Dr. Wenzel Novak, Senior Global Director Business Development at Gerresheimer in Bünde, gave a joint presentation on the topic "New Meets Old: Challenges and Solutions with developing a Custom Primary Container" on Wednesday, February 6, at Pharmapack. The turnout was excellent, with over 70 listeners joining the audience. Our customer, Portal Instruments manufactures groundbreaking electromechanical medical equipment and has developed a connected needle-free drug delivery system.

The innovative injection device from Portal consists of a reusable next generation jet injector and a single-use prefilled cartridge made of crystal-clear cyclo olefin polymer (COP). This injection system allows users to easily self-administer medication without needles and automatically track their injection regimen, simplifying therapy for patients with chronic conditions.

The single-use COP cartridge was developed in collaboration between Portal Instruments and Gerresheimer Regensburg GmbH in Wackersdorf. Portal chose Gerresheimer as its partner based on the company's expertise in developing and producing COP primary packaging materials, such as the Gx RTF® Clear-Ject® syringe. An appeal of using the Gx RTF® system

is that it is backwards compatible with standard pharma fill-finish lines.

Starting the presentation, Andrew Coats introduced the new system and explained why Portal opted for a custom single-use disposable primary container fitting in a standard nest and tub, what challenges came up in particular during development and why Gerresheimer Regensburg was chosen as partner. Next, Dr. Novak presented our offering of polymer syringes, discussing their advantages and disadvantages.



Dr. Wenzel Novak
Senior Global
Director Business
Development
at Gerresheimer
in Bünde

Cartridge made of
crystal-clear COP



Gerresheimer Shuangfeng

Pharma Days China

On May 5 and 6, 2019 a Gerresheimer Pharma Days event was held by Gerresheimer Shuangfeng & Corning Shanghai in Hangzhou, Zhejiang Province, regarding the topics of Drug Related Review and Injection Packaging System. More than 100 pharmaceutical enterprises' representatives attended. During the event, Mrs Lihulan from Zhejiang Pharmaceutical Packaging & Excipients Association made the general address, Mr. Yuhui, the Director of Pharmaceutical Packaging Materials Institute of Zhejiang Institute of Food and Drug Inspection gave the Introduction to the latest laws and regulations on drug related review and approval. Mrs. Zhang Fangfang from Shanghai Food and Drug Packaging Materials Testing Institute delivered a speech on technical guidance and a case study on compatibility of injection packaging systems.

EVENT CALENDAR

SEPTEMBER 01–03, 2019

Medi-Pharm Expo
Ho-Chi-Minh-City, Vietnam

SEPTEMBER 16–18, 2019

CPhI Middle East & Africa
ADNEC, Abu Dhabi, UAE

SEPTEMBER 24–26, 2019

Injectable Summit
(Hansen Wade Syringe Conference)
San Diego, CA, USA

SEPTEMBER 25–27, 2019

Medtec China
Shanghai, China

GERRESHEIMER



Save the date

Gerresheimer Pharma Days 2019 USA

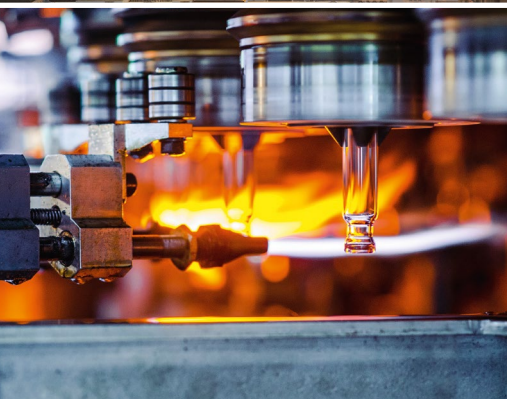
September 24–25, 2019



1ST DAY

Conference and Workshops | **Philadelphia (PA)**

- Innovations
- Solutions
- Quality



2ND DAY

On-site Plant Tours | **Vineland (NJ)**

- Elite Glass Vial Production /
Next Generation Technology & Quality Systems
- Preview: Gx® Glass Innovation & Technology Center

Invitation to follow

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