

Customer Newsletter
October 2016

CATEGORIES

Welcome	1
Gerresheimer at CPhI	1
Plastics & Devices	4
Plastic Packaging	6
Life Science Research	8
Recommended Reading	9
People	9
Web & Event	10



WELCOME



CPhI marks the beginning of the last quarter of 2016, and it's one of the highlights of our year! This leading pharmaceutical trade show is a great platform for us to present

our latest products. The big news at this year's CPhI is the new Gx RTF® ClearJect® syringe – the first COP syringe to be manufactured in Europe. We introduced COP as a syringe material to meet new primary packaging-related challenges, such as delivering suitable packaging solutions for biologics. Drug delivery systems for biologics have to satisfy stringent requirements of total particle loads, which is why we're working on minimizing particle loads in all our syringe components. You can read the results of a particle load study in our second major syringe feature on pages 4 and 5.

This issue also includes articles on the photovoltaic system at our Kundli plant in India, and the modernization of the cleanrooms at our Butanta Plant in Sao Paulo, Brazil (page 6). You can also read about our latest product relaunches which involve plastic eye drop bottles and tablet containers (page 7).

Enjoy this latest issue of Update!

Jens Kürten

Group Senior Director
Communication & Marketing
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Gx RTF® ClearJect® syringe is manufactured in Europe

Gerresheimer at CPhI 2016 – innovative solutions for sensitive pharmaceutical drugs

The first Gx RTF® ClearJect® syringe in COP (Cyclo-Olefin-Polymer) to be made in Europe is one of the innovations on show at CPhI from October 4–6 in Barcelona. Gerresheimer's international team of experts will be presenting them to visitors at stand 2H28 in the Fira de Barcelona Gran Via exhibition center. Two of those experts will also be making presentations on multi-layer tablet containers and the use of tungsten in syringe production.

Gerresheimer is now manufacturing the first Gx RTF® ClearJect® plastic syringe made of COP in Europe

The new Gx RTF® ClearJect® syringe with canula offers key advantages with regard to the primary packaging of demanding medications, especially when it comes to biocompatibility. COP does not leach any metal ions into the liquid pharmaceutical drug. The entire syringe, including the needle overmould, is produced in one single step and the product is also tungsten and adhesive-free. COP has a high pH tolerance and, unlike glass, there is no change in pH value over time during storage. Another key argument in favor of the Gx RTF® ClearJect® syringe is excellent user safety. COP is extremely inert and break resistant, so it is an excellent choice as a packaging material for sensitive or toxic active ingredients. High elasticity in comparison to similar materials also enhances the Dupont impact strength of COP syringes.

The use of a high-viscosity silicone oil to coat the inside of the syringe barrel reduces the level of syringe content contamination with silicone particles. The application of a concept to create the entire innovative COP syringe out of standard components ensures its cost-efficiency. It has standard needles, plungers, plunger heads, backstops and closures.



COVER STORY

Gerresheimer currently offers a range of prefillable COP syringes produced by long-time company partner Taisei Medical Co. Ltd. in Japan. Gerresheimer is assuming the sales and technical consulting roles for ClearJect® syringes for customers in Europe and the US. The company is now expanding its product portfolio of COP syringes and is combining the tried-and-tested RTF® (ready-to-fill) concept of glass syringes with ClearJect® to create the new Gx RTF® ClearJect® brand. In close cooperation with the company's Japanese partner, the new syringe will be produced at a European production facility of Gerresheimer Medical Systems. The first product of this line is a 1 ml long syringe with integrated cannula.

What is COP?

COP (Cyclo-Olefin-Polymer) is a high-performance plastic. As a primary packaging in prefillable syringe format, it is particularly suitable for biologics and high viscosity applications. Like all cyclic olefins, COP is extremely break resistant, has glass-like transparency and low gas permeability. Pharmaceutical companies today face the challenge of minimizing the risk of potential interaction between the primary packaging and pharmaceutical drug without impairing function. Auto-injectors are another new challenge that tests the proven material of glass to its limits. When integrated in plastic drug deliv-

ery devices, COP-based syringes are associated with the advantage that they are more resistant to breakage than glass and permit narrower production tolerances. Injection moulding makes it possible to integrate high-precision LuerLock adapters in the syringe barrel, which is an advantage when the syringe is used with mounted needles and IVD connectors. Optimized silicization and radiation sterilization minimize the risk of extractables and leachables, as well as sub-visual particle contamination, especially silicon oil particle contamination.

ClearJect® is a trademark of Taisei Medical Co. Ltd.



All the strengths of the new Gx RTF® ClearJect® syringe at a glance.

“COP is an interesting alternative to the traditional glass syringe as a result of the new demands on primary packaging posed by innovative active ingredients. These demands are coming from different directions. Requirements of chemical and particulate purity are becoming increasingly stringent to minimize potential interactions with the sometimes very complex, modern protein-based drugs. Functional specifications such as break resistance and special design requirements are also becoming more challenging. ClearJect syringes in COP are one solution. When we developed the Gx RTF® ClearJect® we kept the costs down by using elastomer components that are also used for glass syringes.”



Claudia Petersen
Global Director Business
Development Medical Systems

Lectures at CPhI 2016

TUESDAY, OCTOBER 04 2016 | 11:30–11:55 AM

Innovation in High Quality Primary Packaging:

Multilayer containers for solid formulations and Duma® Twist-Off Protect and closure solutions (senior friendly)



Dr. Wolfgang Dirk

Vice President
Product Innovation
(Plastic Packaging)

Gerresheimer has recently developed a new generation of protective packaging for tablet containers. Duma® Twist-Off Protect offers a new level of water vapour and oxygen barrier for sensitive solid dose formulations. Addressing the rising demand of the industry for high quality packaging components Duma® Twist-Off Protect will provide improved stability for moisture and

oxygen sensitive products and by this allow prolongation of shelf life.

Today the industry uses desiccants or scavengers to reduce or eliminate both water vapour and oxygen from the primary packaging, a widely used and well-proven practice for many solid dose formulations. Duma® Twist-Off Protect offers with its improved barrier a passive protection of the content, an advantage which will in example avoid overdrying of the content by the desiccant.

A commercial benefit is that the elimination of desiccant or scavenger bags allow the reduction of the packaging size which will contribute to the over-all cost for the supply chain of the relevant product. Another benefit will be experienced by the patients using the new Duma® Twist-off Protect. The elimi-

nation of desiccant or scavenger bags will facilitate the withdrawal of the tablets and prevent that the bags will block the content.

Wolfgang Dirk, PhD in chemistry at RWTH Aachen, Germany working on hydroboron-based cage-structured molecules for cancer treatment, had hold management functions at Schweizerhall Pharma GmbH and Indukern Chemie AG. Before joining Gerresheimer he worked four years at West Pharmaceutical Services as Manager for Technical Support on primary packaging components for parenterals. At Gerresheimer Plastic Packaging Wolfgang is responsible for Product Management and Innovation and the development of the parenteral business.

WEDNESDAY, OCTOBER 05 2016 | 10:30–10:55 AM

Use of Tungsten in the Glass Syringe Forming Process



Bernd Zeiss

Manager Technical
Support Medical
Systems, Business
Development

In the forming process of prefilled glass syringes tungsten pins are frequently used to form the bore of the syringes. Tungsten has been the material of choice due to its good physical and mechanical properties. In certain cases, tungsten and tungsten oxide residuals may cause visible protein aggregations after the syringe has been filled. This is a rare event and only very few liquid formulations are sensitive to the traces of the metal in the bore. Nevertheless glass syringe manufacturers like Gerresheimer have addressed the problem and offer low tungsten as well as tungsten free syringes for sensitive applications.

Bernd Zeiss, Dipl.-Biol. studied biology, microbiology and chemistry at the University of Göttingen, Germany. He works in the Gerresheimer Centre of Excellence for prefilled syringes as Manager Technical Support. His main areas of work are investigating possible interactions between syringe components and drug as well as the evaluation of innovations like COP syringes in comparison to glass. Bernd also carries out in-house functionality studies on prefilled syringes and prepares technical documentation for customers called „Technical Bulletins“.

PLASTICS & DEVICES


Prefilled Glass Syringes in Biologic Drug Delivery:

Lubricious Coatings for Substantial Reductions in Silicone Oil Droplets and Total Particle Loads

In 2015 more than 3 billion prefilled syringes (PFS) were sold worldwide, and the market continues to grow. Still anti-coagulants and vaccines dominated in the PFS market, today the number of biologics stored and administered in prefilled syringes is constantly increasing. Due to the sensitivity of biologics during storage and the complexity of their mechanisms of action upon administration, primary packaging components used for biologics are faced with the most demanding requirements compared to those used for any other injectable class of drug. The prefilled syringe (including the glass barrel and the elastomeric closure) needs to act as a chemically inert, secure delivery system. The rise of auto-injectors and the integration of additional safety features add to the complexity of this syringe system.

For biologic drugs, a major concern is the generation of proteinaceous particles in prefilled syringes. Under certain circumstances therapeutic proteins can interact with syringe components, in particular, the silicone oil that is typically used as a lubricant on both the barrel and the plunger.

Today, due to the increased scrutiny over particle levels and new regulations around combination products, the manufacturing of primary packaging materials is considered to be an extension of the drug manufacturing process itself. As such, prefilled syringe and elastomeric closures vendors are requested to offer the lowest possible particle loads on the individual components. Both Gerresheimer and Datwyler are addressing these industry needs through innovation in materials, processes and production facilities.



Baked-on RTF® Siliconized Syringe:

- Minimized interaction of silicone oil and drug formulation
- Drastically reduced subvisible silicone oil particles
- Long-lasting, inert, evenly distributed lubricious coating
- Variety of syringe sizes, cannulas and needle shields
- Staked needle syringe possible

Plunger Stopper: OmniflexCP®

- No siliconization
- Ultra-low subvisible particle levels
- Superior chemical compatibility

Syringe System Benefits:

- Ultra-Low subvisible particle load
- Highly consistent delivery forces
- Optimal functionality over drug product shelf life

Particle Reduction from Prefillable Syringe Barrels and Plungers

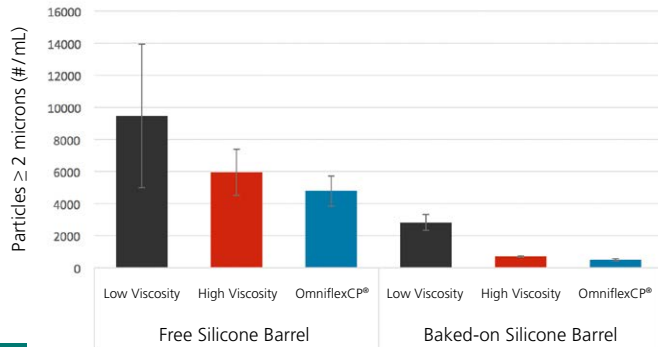
Glass syringe manufacturers have found various ways to reduce particle loads. At Gerresheimer this process starts with the barrel forming that is controlled by the proprietary camera system, G3, which detects and distinguishes all kinds of both cosmetic and dimensional defects including different types of particles. A dedicated washing process after the barrel forming can already reduce particles from this manufacturing step. In the adjacent Ready-To-Fill (RTF®) process, particle loads are again minimized by rinsing, upright transport of the syringes and by avoiding glass-to-glass contact. Above all, the use of the proprietary heat-curing process (baked-on RTF®) is advantageous to re-

duce the number of silicone-oil-based subvisible particles migrating from the syringe barrel. This proprietary baked-on lubricious silicone coating is highly uniformly distributed, inert and long lasting. The reduction of particle levels due to the Gx baked-on RTF® curing process is reflected in the new data of this publication. The Gx baked-on RTF® syringe in combination with a silicone free plunger allows very low particle loads to be achieved and the needs of the biologic drug delivery to be met.

Reducing particle loads from syringe plungers is equally as important as reducing particle loads from syringe barrels. At Datwyler,

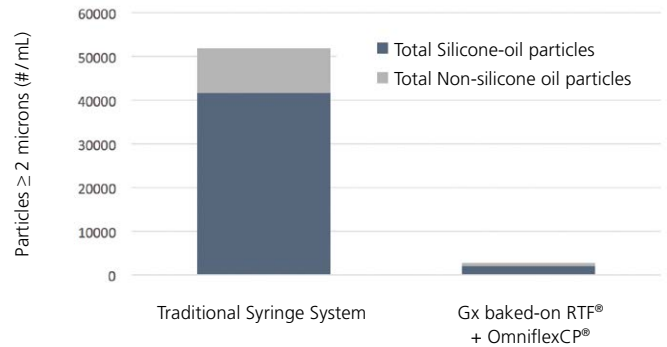
PLASTICS & DEVICES

Impact of Lubrication Type on Syringe System Particle Levels



2

Silicone-Oil-Based Particle Levels



3

this is accomplished through lubricious barrier Omniflex coatings, which do not require siliconization, and through state-of-the-art clean manufacturing facilities. In the following sections an investigation of the optimization of lubricious coatings on the syringe barrel and the plunger is presented. The aim in this study is to characterize and significantly reduce the overall particle loads and specifically the silicone oil droplet loads in a prefilled syringe system intended for biologic drug delivery. The combination of the Gx baked-on RTF® syringe and the OmniflexCP® plunger (see Fig. 1) is found to provide particle loads that can meet the new stringent pharmacopeial requirements for therapeutic protein products.

System Functionality

In addition to the focus on subvisible particles, the overall syringe performance must not be neglected. Low and repeatable break-loose and gliding forces are important syringe features not only for manual PFS's but especially for PFS's used with auto-injectors. Although low silicone levels can lead to low particle loads in the syringe, this can conversely lead to higher delivery forces. In a long-term study (see Update 16) with different plungers carried out by Gerresheimer,

the impact of storage, stoppering method and siliconization level of Gx RTF® syringes was scrutinized. One of the best results was found with the combination of baked-on siliconized syringes with the OmniflexCP® plunger. Figure 4 shows an extrusion force profile after 1 year of storage in a 1 ml long baked-on staked needle syringe with OmniflexCP®. Highly consistent delivery forces are observed for this system which makes it ideal for use with auto-injectors.

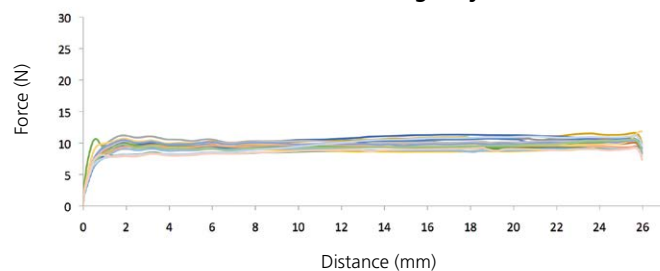
Results

The study investigated different particle-related questions:

1. Impact of Agitation
2. Impact of Plunger and Barrel Lubrication Type on Subvisible Particle Levels (fig. 2)
3. Particle Characterization and Contributions from Silicone Oil (fig. 3)

In the case of the traditional syringe with the high viscosity silicone oil plunger, 80% of the total particle count is due to silicone oil droplets. With the baked-on silicone on the barrel and the lack of free silicone oil migrating from OmniflexCP®, a dramatic reduction in silicone-oil-based particles is realized with the combined Gx baked-on RTF® syringe / OmniflexCP® system.

Extrusion Forces of the Baked-On RTF® Syringe / OmniflexCP® Plunger System



4

Conclusions

Since every component's particle levels are significant contributors to the total particle load in a prefilled syringe, a full systems approach is crucial in order to meet the increasingly stringent regulatory expectations for therapeutic proteins. Given the very low

particle load and highly consistent delivery forces of the system and the inert fluoropolymer barrier coating on the plunger, the Gx baked-on RTF® syringe / OmniflexCP® combination is well suited to meet the stringent requirements of biologic drug delivery.

The complete study can be found at: www.ondrugdelivery.com/products/current_issues.htm

Authors: Bernd Zeiss, Manager Technical Support Medical Systems, Business Development Gerresheimer Bünde GmbH | Susan Dounce, Senior Manager, Business Development & Innovation, Datwyler Pharma Packaging USA, Inc.

PLASTIC PACKAGING

Solar roof for Gerresheimer/Triveni Plant

Gerresheimer banks on photovoltaics in Kundli, India



Solar panels on the roof of the Gerresheimer Triveni plant

Being the leading global partner for the pharmaceutical and healthcare industries, Gerresheimer is committed to sustainability and environmental protection. The majority of Triveni Polymers in Kundli (India) belongs to the Gerresheimer Group since 2012. In order to meet its environmental and sustainability objectives the company put a

photovoltaic system into operation to enable the production of pharmaceutical plastic packaging with environmental-friendly energy.

As a start 80 solar panels have been installed with a capacity of 20 KW. In addition to the environment benefits Triveni will significantly reduce the monthly electricity expenses.

In the future Triveni is planning to install more panels and the target is to reach a level where at least 3 % of the total requirement of electricity is met by the use of solar energy. Gerresheimer/Triveni is aiming for 100 KW of solar power in the future.

With clearly defined objectives, the entire Gerresheimer Group is taking part in one of the world's biggest environmental initiatives, the Carbon Disclosure Project. This non-profit organization was founded in London, UK.

It checks and monitors greenhouse emissions of companies on a worldwide basis and also identifies the strategies companies implement in response to climate change.



A glimpse inside the clean room of the Triveni plant.

New injection moulding and injection blow moulding clean rooms

Gerresheimer optimizes clean room production at Brazilian plants



A glimpse inside the new clean room in Butanta, Sao Paulo (Brazil)

The Gerresheimer Group is one of the market leaders for plastic pharmaceutical packaging in Brazil. The three Brazilian production facilities in the Sao Paulo region collectively manufacture several hundreds of millions of plastic containers and closures for diverse health and well-being-related applications every year. In 2015, Gerresheimer modernized the clean rooms at its Brazilian plants to achieve sustainable improvements in production quality.

Back in July 2015, Gerresheimer optimized its injection molding production operations at the Butanta plant. Soon after the injection molding clean room had been modernized it was time to upgrade another clean room for injection blow molding in Butanta.

"Optimizing our clean rooms has enabled us to achieve considerable improvements in production quality and we're now setting new standards in the pharmaceutical pack-

aging market. The entire plant is profiting from the project, and our employees now enjoy vastly improved working conditions," said Jens Friis, Vice President Europe & Latin America at Gerresheimer Plastic Packaging. The three Gerresheimer plants in Brazil have a total production area of 28,000 square meters. All products are packaged and labelled in a clean room environment before they go to the warehouse. Product inspections also take place in the clean room. A brand new air-conditioning system is additionally contributing to improved working conditions at the plant.

The plastic product portfolio includes dropper bottles for eye drops, spray bottles for nasal sprays, PE containers for tablets, plus a wide range of caps, closures and all kinds of accessories such as dosing caps, droppers, measuring cups, dosing syringes and applicators.

Gerresheimer also has a plant manufacturing insulin pens in Indaiatuba (also in the Sao Paulo region) in addition to the three pharmaceutical plastic packaging plants in Butanta, Embu and Cotia.

PLASTIC PACKAGING

Eye drop bottles adapted to new FDA requirements



In response to the FDA's warning about loose tamper evident rings on eye drop bottles, Gerresheimer has modified the closure system for its Type A drop bottle (LDPE). Now the tamper evident ring stays firmly affixed to bottle once it has been opened.

The tamper evident ring is important because it tells the user that the product hasn't been opened since filling. This guarantees that the bottle contains the original pharmaceutical and that nobody else has used it previously. Although that's important with all medications, it's particularly important with eye drops, which shouldn't be administered if they are contaminated. "Sometimes it's the little ideas that make a big improvement to a product," said Marek Mischczak, Head of Research & Development at Gerresheimer and primary packaging expert for ophthalmic applications. "Before the modification, the tamper evident rings were loose on the bottle neck after opening. Unless the user removed the ring, it constituted a potential hazard. That's why fixing the tamper evident ring in place is a good idea that improves safety." None of the other eye drop bottle specifications have changed.

Duma® Pocket 100 ml: handy and easy to use



As the name suggests, the Duma® Pocket tablet dispensers are ideal to carry around in your pocket because of their handy oval shape. A new member of the Duma® Pocket product family is being presented by Gerresheimer at CPhI in Barcelona: the Duma® Pocket with 100 ml filling volume.

The new Duma® Pocket design is so ergonomic that the user only needs one hand to hold and open the oval box. It has an integrated closure with dispensing aid, a tamper evident seal, and it is also senior friendly and child resistant.

So far Duma® Pocket was available in 30 and 50 ml sizes; the new tablet dispenser is sig-

nificantly larger. The side surfaces of the oval shape are useful for displaying consumer information, and they are also large enough for distinctive branding. The lid area can be used for customer-specific labelling.

A desiccant in the base reliably absorbs moisture. The maximum volume, not including the space occupied by the desiccant, is up to 100 ml. Like all other Duma® Pocket products, Duma® Pocket 100 ml is made of polypropylene (PP). The container can be manufactured in any color, even in translucent or transparent. It has the dimensions of 80.5 x 70 x 30 mm. The new Duma® Pocket is manufactured under clean conditions.

Duma® Pocket containers are suitable for high-speed filling processes, they can be compactly packaged and are easily stored. Filling sizes of 75 and 125 ml can be also manufactured using the same base.

Duma® Pocket is FDA registered, DMF type III, DMF no. 12077 and also satisfies European Regulations (EC) no. 1935/2004, (EC) no. 2023/2006 and EU no. 10/2011 on materials and articles intended to come into contact with food.



Duma® Twist-Off Protect –

the first US bottle with multilayer structure manufactured in an injection blow moulding process

At CPhI 2016 Gerresheimer is launching an extension to Duma® Twist-Off Protect, the new multilayer plastic container. Now the popular Triveni Round family has been extended by a 60 ml container with the multilayer design for the US market. The Protect features deliver enhanced protection against water vapor and oxygen to sensitive pharmaceutical drugs. It is the first plastic container with a multilayer sandwich structure manufactured in an injection blow molding process.

"Duma® Twist-Off Protect aroused much interest and proved its quality. Therefore, with US Triveni Round, we are extending our portfolio with this excellent feature for the US market," said Niels Düring, Global Executive Vice President Plastic Packaging at Gerresheimer. Pharmaceuticals are often susceptible to degradation caused by exposure to moisture vapor and oxygen. So these drugs need effective protection in the form of suitable packaging solutions.

U.S. Pharmacopeia MVT (WVP) USP 38 <671> and Oxygen Transmission Rate OTR: ASTM F 1307 tests confirm that the multilayer structure provides better barrier properties, so the container admits far lower levels of moisture vapor and oxygen.

The multilayer containers are fully compatible with the Duma® Twist-Off family and the Triveni Round family.

PLASTIC PACKAGING

Gerresheimer Zaragoza:

Gerresheimer Zaragoza in Spain to optimize the production of PET pharma bottles



The Gerresheimer plant in the Spanish town of Zaragoza optimizes the manufacturing of pharmaceutical bottles and closures. All processes are being thoroughly analyzed and adapted to a new, more customer-oriented strategy so that the plant can better meet the pharma market's long-term requirements as a total solution provider.

"All the staff at the plant have been working very hard to facilitate the optimization of Gerresheimer Zaragoza into a competence center for pharmaceutical bottle and closure production," commented Niels Düring, Global Executive Vice President Plastic Packaging. The optimization of the production processes, all the associated technical modifications and the construction of a new ISO class 7 clean room have already commenced. The product portfolio has also been adapted to reflect customer requirements.

Gerresheimer has decided to roll out new technology for pharmaceutical bottle production in Zaragoza. The new, high-performance machines manufacture PET bottles in higher quality, both as a result of the optimized machine technology and due to improved material distribution. The bottle top design has been modified so that the bottles can be

fitted with any kind of closure system, from tamper-evident and child-safe closures, at one end of the scale, to simple stoppers, on the other. Production of PP128/PP28 standard closures and accessories has now commenced in Zaragoza. The plant offers a total solution with tamper evident closures. In other words, Zaragoza is evolving into a system supplier of high quality PET pharmaceutical bottles.

The new clean room

By October 2016 construction work will be finished and the new ISO 7 clean room will be ready. The new 600 square meters clean room is designed to house nine injection stretch blow moulding (ISBM) and injection moulding (IM) machines, and another six can be successively installed before the maximum capacity of fifteen in total is reached.

LIFE SCIENCE RESEARCH

Gerresheimer to sell Life Science Research business

In line with its strategy of focusing on packaging and device solutions for pharmaceutical customers, Gerresheimer announced on September 12, 2016 that it is to sell its Life Science Research business to Duran group, a portfolio company of One Equity Partners. "We are a leading global provider of pharmaceutical packaging and medical devices. Producing laboratory glassware is not a core business for us and synergies are very limited. Together with our joint venture partner Chase Scientific Glass, Inc., we have decided to sell the business," said Uwe Röhrhoff, CEO of Gerresheimer AG.

Kimble Chase Life Science and Research Products LLC is based in Rockwood, Tennessee, USA. It is a leading producer of laboratory and scientific glassware. The product portfolio includes reusable laboratory glassware for research, development and analytics, such as beakers, Erlenmeyer flasks and measuring cylinders as well as disposable laboratory products such as culture tubes, pi-

pettes, chromatography vials and other specialty laboratory glassware. Kimble Chase has approximately 760 employees worldwide. It has manufacturing facilities in Rockwood, Tennessee, USA, Rochester, New York, USA, Queretaro, Mexico, Meiningen, Germany, and Beijing, China. Kimble Chase's annual revenues in financial year 2015 amounted to EUR 100.7m with the majority of sales in



North America. Kimble Chase was established in 2007 as a joint venture of Gerresheimer (51%) and Chase Scientific Glass, Inc. (49%) contributing their respective laboratory glassware businesses.

Revenues of the Life Science Research division, Kimble Chase, declined by 2.6% in the first six months of 2016 to EUR 47.8m. At EUR 6.5m, adjusted EBITDA for the first half of 2016 was slightly down compared to the prior-year period.

The total enterprise value for the transaction is USD 131m. The transaction will be an all-cash acquisition. Its closing is subject to regulatory approvals.

RECOMMENDED READING

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.

Lubricious Coatings for Substantial Reductions in Silicone Oil Droplets and Total Particle Loads in Prefilled Syringes for Biologic Drug Delivery**Bernd Zeiss, Gerresheimer and Susan Bounce, Datwyler Inc. in OnDrugDelivery October 2016.**

For a summary of this article see pages 4–5 in this Update newsletter.

Optimized Siliconization in Prefillable Syringes, functionality, analytical methods and trends,**Bernd Zeiss, in Technopharm 5/2016.**

The optimal siliconization is an extremely important aspect in the production of sterile, prefillable glass syringes, as the functional interaction of the glass barrel and the plunger stopper is crucial to the functionality of the entire system. Low, unevenly distributed, inadequate or excessive siliconization can cause problems in syringe functionality. In this article the author discusses different ways of minimizing the amount of free silicone oil.

Failure to Launch – How difficult it is to develop a drug.

Taking a promising drug all the way through to regulatory approval is a long, difficult process – and successes are rare. Most drugs fail before they reach the clinic, and most drugs that reach the clinic fail before approval. Diving deeper into the problem, the Biotechnology Innovation Organization (BIO) teamed up with Amplion (a biomarker business intelligence company) and BioMedtracker (a service that tracks a drug's likelihood of approval by the FDA). BIO examined clinical trial success rates from 2006 to 2015, and 9,985 clinical and regulatory phase transitions were recorded and analyzed from 7,455 development programs, across 1,103 companies in the BioMedtracker database.

<https://themedicinemaker.com/issues/0616/failure-to-launch/>

PEOPLE

**Primary Packaging Glass****Jens Heymann has been appointed as Senior Vice President Europe & Asia Tubular Glass**

Jens Heymann has been appointed as Senior Vice President Europe & Asia Tubular Glass effective from June 1, 2016. In this function and further to his responsibility for Europe and India, he assumes additional responsibility for China. His global responsibility for Finance & Controlling Tubular Glass re-

mains unchanged. In his most recent function Jens Heymann was Chairman Europe & India and Global Vice President Finance & Controlling for Tubular Glass. He joined the Gerresheimer Group in May 2014 as Head of Finance & Controlling Tubular Glass in the Headquarters.

**Primary Packaging Glass****Julie Ruble has been appointed US Sales Director**

Julie Ruble has been appointed US Sales Director for the Primary Packaging Glass Sales Organization, effective August 15, 2016. She most recently held the position of Key Account Manager at Gerresheimer. Julie formerly worked at Nemera

(previously Rexam Healthcare) as Key Account Manager. Until her accounts are re-assigned, she will remain as key commercial contact. Julie holds a Bachelor of Arts Degree, Communications from the University of Illinois.

**Primary Packaging Glass****Rick Kassal has been appointed as Senior Plant Director Chicago Heights Moulded Glass**

Rick Kassal has been appointed as Senior Plant Director Chicago Heights Moulded Glass, USA, effective from August 22, 2016. Rick Kassal first joined Gerresheimer in 2003 as Engineering Manager in Tubular Glass Tubing in Vineland, New Jersey, USA. In 2008 he

was promoted to Global Engineering Manager for Tubular Glass and left the company to join Corning Incorporated as part of the sale of Tubular Glass Tubing in 2015. Prior to joining Gerresheimer he was a Project Manager for Alcan Packaging in Millville, USA.

**Plastics & Devices****Jens Fernis has been appointed as Vice President Sales Medical Systems**

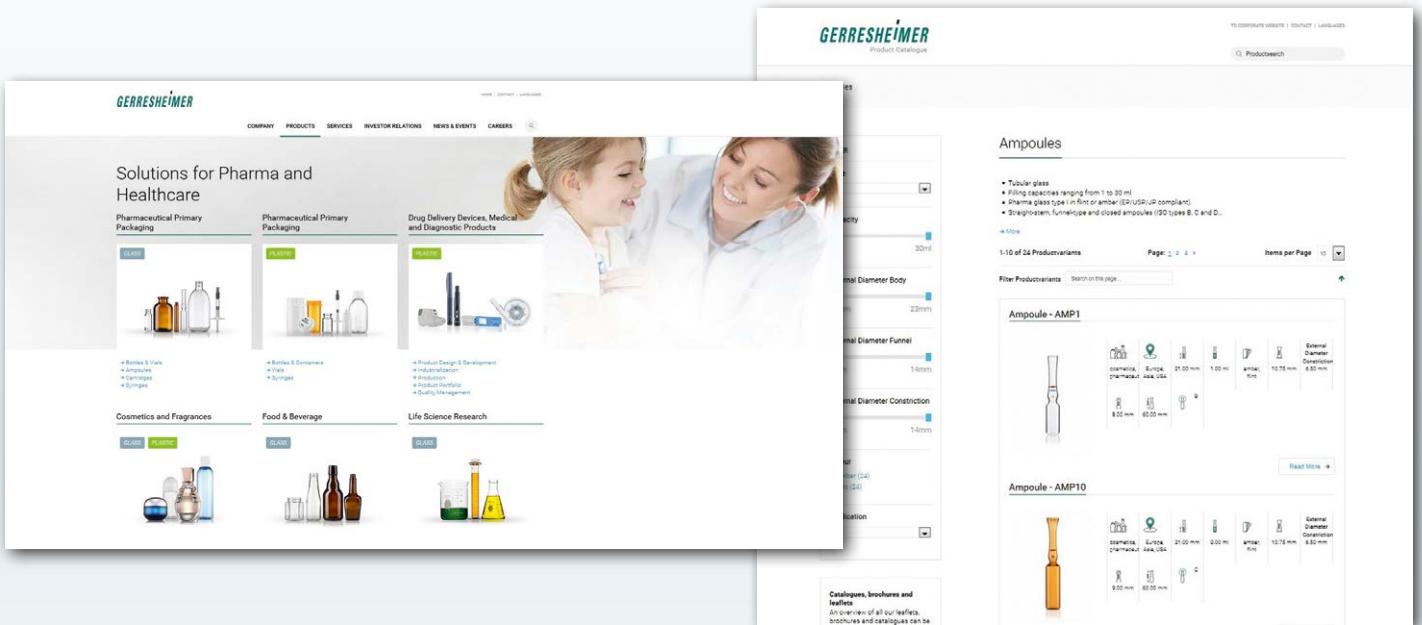
Jens Fernis has been appointed as Vice President Sales Medical Systems effective from September 1, 2016. He is responsible for the Bünde production plant and sales of syringes and insulin cartridges. He reports to Jürgen Kaiser,

Vice President Sales Medical Technology & Pharma Americas & Asia Medical Systems. Jens Fernis joined Gerresheimer in 2014 as General Manager Life Science Research with the focus on Sales at the Meiningen plant in Germany.

WEB & EVENT

www.gerresheimer.com:

A new look and a responsive design



We regularly update the Gerresheimer website and upgrade its technology because the internet is a key information and communication platform. Our customers confirmed this in the 2016 Customer Survey. These days, people don't just use their desktop PCs to access the internet. They also use many other devices such as smartphones and tablets. That's one of the reasons why we decided to modernize the website and make it more user friendly across all devices.

The Gerresheimer Group website went live way back when the internet was still a new phenomenon. Since then we've continually adapted it, added new information, modified navigation structures and introduced technical improvements. The last relaunch took place in 2007 at the time of our IPO. Now we have made some comprehensive changes, the main ones being the switch over to responsive design and the restructuring of our product and service section. The website visuals have also been enhanced by modern design modules.

Responsive design

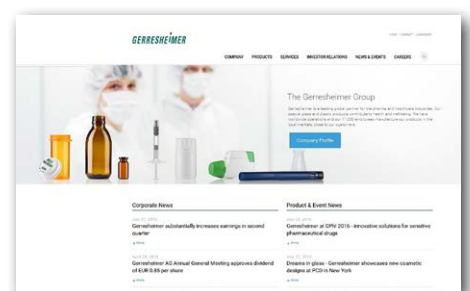
Responsive design enables the website to automatically identify which device is accessing it and optimize the viewing experi-

ence for that device. Both the content and navigation elements change depending on screen size and resolution. Our corporate website is now flexibly programmed so that information is displayed quickly and in the correct format for desktop, tablet and smartphone users.

Product and service area

We also completely revised our navigation concept for the Products & Services section to make it more user friendly for the relaunch. Now all our glass and plastic products are clearly presented on the homepage so that the user can go straight to the relevant product group. It is also just a few clicks to our new, interactive online catalog and detailed information about customer-specific

products and services. The new Services section includes information about business innovation, quality management, engineering, business excellence and global production.



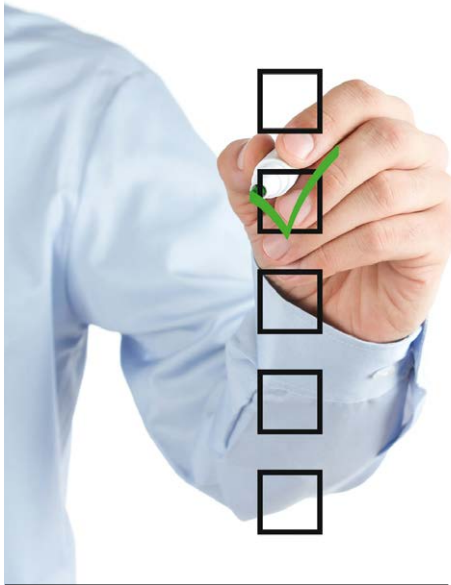
Take a look for yourself!

Visit our website at www.gerresheimer.com to see what has changed!

WEB & EVENT

Gerresheimer Customer Satisfaction Survey 2016

Thanks for your feedback!



This March we invited more than 3,000 customers to take part in our global online customer satisfaction survey. It was our third large-scale survey after the first in 2011 and the second in 2013. The Moulded Glass, Tubular Glass, Medical Systems, Plastic Packaging and Syringe Systems business units were all involved. This latest survey was also implemented by the renowned TNS Infratest market research company, the same independent service provider that has assisted us in previous surveys.

We have received a great deal of constructive feedback on all of the areas covered by the survey, most notably on our development work, our product portfolio and our customer-specific systems, our order processing and logistics processes, our expertise and the performance of our sales teams, as well as technical support in complaints processing. You have shown us which attributes are particularly important to you, which aspects of our performance you are satisfied with and where improvements are necessary. The results show that Gerresheimer has improved somewhat since the 2013 survey.

We have now given the relevant employees access to the survey results and they have been explained and discussed in various constellations of personnel at all organizational levels. Teams of experts from all divisions are now developing the first action plans and catalogs of measures. Over the next few months, these will be elaborated in more detail and implemented.

Your opinions help us to optimize our products and services, so thanks very much for taking part in our study. We're making good progress and thank you for your confidence in us!

Gerresheimer explains the German training system to the Governor of Georgia



During his visit to Germany the Governor of Georgia/USA, Nathan Deal, stopped by at Gerresheimer AG in Düsseldorf to find out about the successful German dual training model that combines an apprenticeship with a study program. Gerresheimer has a fast-expanding plant and Technical Competence Center in Peachtree City, Georgia/USA.

Governor Nathan Deal and the US State of Georgia are very interested in supporting the training initiatives of successful US and foreign companies in Georgia. Around 120 people currently work at the Gerresheimer plant close to Atlanta, with further employees being recruited in subsequent years. Gerresheimer particularly needs skilled employees with good qualifications. This is a problem, though, because the USA doesn't have the dual training system as a source of qualified personnel. Now Gerresheimer is teaming up with the State of Georgia and local education providers to make some positive changes to the training system there.

GERRESHEIMER

EVENT-CALENDAR 2016

**OCTOBER, 04–06**

CPhI Worldwide
Barcelona, Spain
Fira de Barcelona Gran Via
Booth 2H28

OCTOBER, 17–18

Universe of Pre-filled Syringes
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OCTOBER, 26–28

MedTec China
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NOVEMBER, 14–17

Compamed / Medica
Düsseldorf, Germany | Fair Düsseldorf

NOVEMBER, 21–23

CPhI India
Mumbai, India | CPhI India

NOVEMBER, 22–25

Pharmtech
Moscow, Russia
Crocus Expo IEC

DEZEMBER, 05–08

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

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