















Gempex[®] THE GMP-EXPERT



MT-Messtechnik



wezi-med produces biocompatible plastic components for surgical instruments

With the further development of its WG100, WG112 and WG160 specimen pouch models, medical technology manufacturer Espiner Medical provides surgeons with pioneering instruments for tissue and organ extraction. The use of innovative polyamides means that the specimen pouches are exceptionally safe and easy to use thanks to their improved stability and durability. Espiner Medical turned to wezi-med's comprehensive expertise when it comes to the production of biocompatible plastic components: The systems supplier of medical plastic products and parts developed a fully automatic, two-component injection moulding process that fully satisfies medical product manufacture requirements in accordance with Cleanliness Standard ISO 8.

Stable and durable thanks to innovative construction materials



The particular challenge lay in developing a multicomponent injection moulding tool that uses no oil or grease-containing lubricants and yet allows abrasionfree operation. The task also involved avoiding the use of hydraulics and compressed air in the production of plastic components, in order to ensure maximum cleanliness. "As part of the Weber Group, wezi-med looks back on over 50 years experience in the fields of research and development, injection moulding of plastics and mould making. The expertise from wezimould's mould technology division combined perfectly with our expertise in the production of medical plastic products," says Oliver Brück, Head of Technology, wezi-med division. "As a full service supplier for plastic components, we offered Espiner Medical not only a solution for the cost-efficient production of 2K injection moulded parts with shortened times to market, but we also met all of the requirements for the production of medical technology products." Following up on the

analysis of the ideal thermal, mechanical and rheological conditions, the development and design engineers built tools for the production of components that not only guarantee the best mould and surface quality, as well as ideal interior mould piece properties, but also the required reduction in particle emissions during the production and demoulding processes. As a result, for the lubrication- and abrasion-free production of the plastic components cavities made from corrosion-resistant steels are used. The release of ultra-fine plastic particles is completely avoided through the injection of two plastics via a thermally insulated, high-temperature gating system with valve gates. Only lubricantfree runs are used, too.

To produce the handle of the specimen pouch models, the so-called valve block, wezi-mould designed a complex injection moulding tool with two cavities and a collapsible core. The first work step involves injection of the hard part components into the lower cavity. Fol-

Stable and durable thanks to innovative construction materials

lowing the cooling process, the moulded part is transferred via a robot arm to the upper cavity. Once the tool is closed, it is completely surrounded by the contour-providing mould parts of the upper moulding cavity and the molten plastic is injected into it. During the same step, a further hard part component is produced in the lower cavity. "The production of the valve block using complex geometry as a 2-component-one-shot step makes the time-consuming assembly of the component unnecessary, thereby allowing us to cut unit costs. Possible component flaws can also be markedly reduced with this method," says Stefan Nix, Project Manager, wezi-mould division. In addition to developing and building the tools for the valve block, the company based in Dillenburg, Germany, is also responsible for developing injection moulding tools for two further plastic components in the triedand-tested specimen pouch models, as well as their serial production.

The use of innovative polyamides means that the sophisticated instruments, which are used to safely remove organs and tissue during minimally invasive surgery, offer more safety both for doctors and patients: While the hard part components of the valve block ensure the required stability and durability, the soft part components deliver an improved feel, optimized ergonomics and simpler and more intuitive handling of the specimen pouches.

Weber GmbH & Co. KG D 35683 Dillenburg



Oliver Brueck wezi-med



Stefan Nix wezi-mould





Pharmaceutical production must run extremely reliably and efficiently. The Excellence United Service Portal opens up new opportunities: five leading manufacturers of specialized machines for pharmaceutical and medical products are pooling their services with a new remote plat-form. Rapid response times and more efficient production processes are the goal.

Standardized Remote Servicing for Pharmaceutical Machines

Specialists at Bausch+Ströbel, Fette Compacting, Glatt, Harro Höfliger und Uhlmann have exploited the technological opportunities offered by modern communication electronics to create a new unified standard for remote servicing with the Excellence United Service Portal. Thomas Weller, Chairman of Excellence United, explains how far-reaching this approach is: "Many manufacturers of pharmaceutical equipment offer individual solutions. We are convinced that a new approach is required here that encompasses the entire service portfolio and standardizes remote servicing."

Direct Contact with Experts

That is why the partner companies in the Excellence United alliance are equipping their machines with the Service Portal. It enables users to contact the manufacturer's engineering experts directly via its Human Machine Interface (HMI) – for example, using online messaging, a webcam or by means of a whiteboard. A simple press of a button is all it takes to initiate a communication link over a secure data connection. Enquiries are answered exclusively by highly qualified service engineers over the alliance partner's hotline. They have access to the machine data and can produce a diagnosis. Many faults can be eliminated directly in this way.

Comprehensive Service Covering Several Links of the Process Chain

Large companies particularly benefit from this technology because the different processes of high-volume pharmaceutical production are generally interconnected in various ways. It is not always possible to tie a fault down to one particular machine. "This is where an additional strength of our service offering becomes clear," explains Weller. "Where necessary, experts from different companies can hold an online conference to clarify the cause of a production line fault - provided the equipment and machines concerned stem from the Excellence United network." If the problem cannot be eliminated by remote maintenance, an ideally prepared service engineer is dispatched, already equipped with the right spare parts. That saves time.

Much More than Just Rapid Assistance

However, the effectiveness of this approach goes far beyond providing rapid assistance in the event of a breakdown. Many production stoppages can be avoided long in advance. The Service Portal contains a comprehensive maintenance management tool that can recommend the replacement of wear parts in good time, for example, during

planned maintenance inspections. The exceptionally powerful nature of the system is also demonstrated in its optimization of production processes. If desired, the customer and manufacturer can scrutinize the entire life cycle of the machine and monitor and improve its effectiveness (OEE) at any time.

More Secure than Home Banking

Just how important the issue of security was for the developers is made clear by Jackson Heslop, Head of Customer Service, with a simple comparison: "The remote servicing provided by Excellence United is far better protected than any home banking." A connection can only be made if the machine client certificate matches the server's certificate.

Focus on Efficiency

Experts calculate that the Service Portal will significantly benefit customers as a result of less downtime for maintenance and repairs, a reduction of unplanned outages and complete OEE monitoring over the entire life cycle of a machine. "In the long term this service will deliver great advantages for customers," says Weller in conclusion and adds: "We are sure that comprehensive remote servicing will become a new standard in pharmaceutical equipment manufacturing."

Excellence United Marketing GmbH D 71573 Allmersbach im Tal



Dear readers, dear subscribers,

I look forward seeing you at the



NEW



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REINRAUM LOUNGE

Dynamic innovations for the spring season

Teaser for Automatica

o3rd - o6th June 2014: Automatica 2014, Munich (D)

From 3 to 6 June 2014, shortly before the World Cup kicks off, item Industrietechnik GmbH will be showcasing its latest product developments at Automatica. The company's presentation at the Munich trade fair will focus primarily on mechanical and factory equipment engineering. The MB spring products for dynamics include a new multifunctional Installation Column for industrial use.

The item building kit system – there's only one original

Taking centre stage at the item stand will be a range of dynamic components featured in state-of-the-art exhibits from the awardwinning Line XMS. Thanks to their particularly compact design, the new XMS profiles with a cross-section of 40x40 now harness the full functionality of the original Line XMS profiles launched in 2012 for even the smallest of installation spaces.

New: GSF is the latest Linear Unit to be added to the item portfolio of linear technology, and this light, quiet and high-performance innovation brings a whole range of benefits. What's more, its hollow shaft makes it incredibly easy to incorporate couplings.

The item Work Bench System: Now certified with the AGR seal

item has become the first and so far the only supplier of industrial work bench systems to be awarded the "Certified & recommended" seal of approval by the independent Campaign for Healthy Backs (AGR e.V.).

This achievement is further evidence of the leading role that the Solingen-based company is playing in the development of advanced ergonomic products.

The item Work Bench System is the first on the market to satisfy the stringent medical certification criteria laid down by the Campaign for Healthy Backs. This means it has been proven to help prevent potential health complaints and promote the wellbeing of employees in the workplace.

The latest factory equipment innovation from item – the item Installation Column

Multifunctional: Power, compressed air, data network access - all from a single, cen-



Linear Unit GSF: light, quiet and high-performance. Now with hollow shaft.



New: The Installation Column from item. The perfect connection point for power, compressed air and data.

tral point. The item Installation Column is a robust and versatile solution for routing supply lines in production halls, laboratories and industrial workstations. Unlike a cable conduit, the column also acts as an interchange or connection point for lamps, monitors, enclosures and work benches. It offers a smart solution for achieving a safe and versatile working environment.

item Industrietechnik GmbH D 42699 Solingen

About GOLLER Systems – Hubertus Goller GesmbH

Autor: Anna Egger-Piskernik

The company based in Klosterneuburg, Lower Austria (on the outskirts of Vienna), has approx. 60 employees and was founded more than 60 years ago by its name sponsor Hubertus Goller. Since then the enterprise has remained owner-operated, always combining tradition and vision.

Injection moulding and cleanroom production form the base for the broad range of services offered by GOLLER Systems. As original equipment manufacturer (OEM) the company has specialised in the fields of diagnostics as well as in the pharmaceutical and medical industries since 1990.

The range of products and services comprises the development and production of plastic components and customised system solutions (medical devices and primary packaging). The diverse competences of the committed team combine know-how in construction design, simulation, prototyping, injection moulding, cleanroom production, filling and packaging.

An integrated comprehensive quality management system ensures the compliance to all relevant legal requirements and regulations.

GOLLER Systems focuses on customer satisfaction, reliability and customised system solutions: from vision to realisation!

Innovation and Tradition

From its founding in 1948 until today GOLLER System has been following a continuous process of development and specialisation.

If you enter the premises in Klosterneuburg today, it is hard to imagine that the company's beginnings were in the production of tin toys. In the early 1950s, company founder and name sponsor Hubertus Goller started to work with the material "plastic". In the first few years mainly household appliances and toys were made of plastic, but soon he developed and manufactured innovative products, such as lip balm sticks or dosage pumps. From 1980 onwards, the company focused on the production of plastic components for diagnostics and the pharmaceutical industry. This development led to the expansion of the company's production area by building the first cleanroom in 1990. Meanwhile, the cleanroom production area has been multiplied and is still in process of being expanded.

Customised System Solutions

Today GOLLER Systems offers tailor-





made plastic components and customised systems, combining many years of experience and know-how in the field of plastics engineering with innovative solutions. This is the reason why the company holds various patents.

As a full-service supplier with a broad range of services - from construction design to serial production - GOLLER Systems ensures that its customers get "all in one" (i.e. everything under one roof). Thus, GOLLER Systems combines the professionalism of big players with the flexibility and speed of the smaller ones!

Expansion continues

The company's history reflects the stable pillars of the success of GOLLER Systems: continuous development, healthy growth and focusing on its core competencies are the basis of the solid owner-operated company.

In the future the path of ongoing development is pursued in the light of the increasing product requirements of the medical and pharmaceutical sectors. In order to be prepared to meet all these needs, GOLLER Systems has already expanded its warehouse capacity by investing in a high-way racking warehouse (incl. separate blocked storage area), which means that there is additional 600 m² warehouse space available. Thus, both the appropriate storage of raw material and finished items for diverse customised projects is ensured.

Furthermore, the existing cleanroom production area will be doubled in 2014. There will be four separate clean rooms certified acc. EN ISO 14644, class 6 & 7 (GMP class B/C).

The company continues to grow which is confirmed by GOLLER Systems' team members: "We look forward to the expansion and intensification of our activities as development partner and full-service supplier of customised system solutions for our customers. Very well-equipped for this challenge, we are looking ahead to the future optimistically!"

GOLLER Systems A 3400 Klosterneuburg

MEDTEC, Stuttgart/Germany, June 3 – 5, 2014, Hall 5, Stand 5E61

Spang & Brands combines know-how in new technology center

o3rd - o5th June 2014: MEDTEC 2014 Stuttgart (D)

Medical technology is not exempt from increases in customer requirements. Precision components are getting smaller and require ever tighter tolerances. Although medical devices are increasingly easier to handle and thus more patient-friendly, their complexity is yet becoming more and more demanding. The commitment, from design to products being ready-for-manufacture is on the rise. Components, such as, for instance, the miniaturized fix element (see photo, page 2), are to reach the production stage and be ready for market in the shortest possible time span. Over the past few years, Spang & Brands GmbH has been taking increased customer expectations fully into consideration with targeted investments in software as well as hardware.

Always looking at how to benefit customers, the company has taken further steps into the future of medical device innovation by increasing its efficiency and by combining its specialist know-how. During June, the MEDTEC month, the company will inaugurate a new technology center. Flat organizational structures, geared to maximize performance-driven expertise, can then flourish under one roof, a concentration of the entire range of core competences, including state-of-the-art hardware.

"Now we have an integral facility covering more than 2,500m². The performance chain begins with the initial idea, in other words product design, seamlessly moves to



the precision mould manufacture, then to trials with new materials or material blending and to special assembly methods. At the end of the development phase we reach production sign-off, including clean-room injection moulding technology, and final customer validation", according to Friedrich Echterdiek, managing director at Spang & Brands GmbH.

The CAD development and design division is located on the first floor of the new center. Here, new products are given their threedimensional shape. The precision mould making division occupies some 1,000m² of the entire facility. The adjacent mould trial section houses several injection moulding machines, including fully electric IMM with clamping forces of between 30 and 150 tons. Documented quality control routine, according to the strictest possible guidelines, is essential for product optimization, including the validation process. Special assembly can be found in the adjoining clean-room, mainly for manpower-intensive products which cannot yet be assembled fully automatically. "In this center the entire breadth of knowhow functions is concentrated in one facility - from the initial idea to the product and, finally, to the production process", emphasizes Echterdiek. Also incorporated is the department to thoroughly train the next generation of experts. For the first time, training to become a fully qualified product designer is available here.

Spang & Brands GmbH is a DIN ISO 13485 certified company. The new cleanroom conforms to GMP (Good Manufacturing Practice). "In a further expansion phase, we are planning to enlarge and upgrade our machine pool. That will be the second step following our move to the new center", explains the managing director. "With these steps the course is set to produce ever more sophisticated medical devices in the future. In accordance with this, we will be sustainably flexible, be that our know-how, manpower, our technology and capacity. At MEDTEC in Stuttgart customers can convince themselves of our capabilities."

During MEDTEC, Spang & Brands will exhibit a broad range of medical devices in Hall 5, Stand 5E61, ranging from precision and micro products in mono and co-injection moulding technology, moving on to disposables, syringes, cannulas, tamper-proof membranes and parts for implants, through to components for minimally invasive medicine. Furthermore, connectors, functional parts for intravenous drip solution bags and closure systems are on display, not forgetting assembly-intensive devices and ready-for-sale units.

Spang & Brands GmbH D 61381 Friedrichsdorf

MEDTEC, Stuttgart/Germany, 3rd to 5th June 2014, Hall 5, Stand 5B40

Phillips-Medisize – Anniversary during the MEDTEC Year

o3rd - o5th June 2014: MEDTEC 2014 Stuttgart (D)

For the areas of medical device technology and diagnostics at MEDTEC in Stuttgart, 3 to 5 June 2014, Hall 5, Stand 5B40, Phillips-Medisize will present solutions for the development and manufacture of medical devices made of plastics: From disposable insulin pens, blood glucose meters, inhalators, IV sets, peristaltic pumps, titre plates, mixing injectors, consumables for diagnostic components, all the way to complete MDD application sets. Phillips-Medisize offers their customers a complete service chain, from the idea to the finished solution, from the design stage all the way to the ready-to-use sterile-wrapped medical product. The company's strong point in the market is represented in particular by complex disposables, controlled across all processes through highly prioritised quality assurance measures compliant with ISO 13485 as well as with FDA standards and GMP (Good Manufacturing Practice).



Expansion of the Finnish production site for drug delivery devices.

Anniversary during the MEDTEC year: After having been around for 50 years, the Phillips-Medisize Corporation continues to concentrate on offering its customers an integrated chain of service with particular focus on GMP. The leading global outsourcing partner for product development and manufacture for the Medical and Pharma industry is determined, in cooperation with its customers, not only to maintain the standard of quality it has achieved, but also to expand it. As Matt Jennings, president and CEO, recently noted, the anniversary year 2014 represents a significant milestone in the company's development. "During the past 50 years, together with our customers, we established a cooperation based on fairness and partnership. Quality, innovation and service have always played a major part in this. The success of the partnership is based on sustainable investment in our employees, our processes know-how, our plants, and our equipment. This is how we were able to develop an outsource design, development and manufacturing business that is unequalled across the globe," Jennings remarked. This type of organisation made it possible for customers to integrate their own product designs into Phillips-Medisize's comprehensive injection moulding and assembly services.

Not too long ago, Phillips-Medisize substantially expanded its business in Europe. Moreover, overseas as well – especially in China and Mexico – the company made some strategic acquisitions. Through its expansion strategy, Phillips-Medisize essentially wants to help customers shorten and strengthen their supply chains. At the same time, uniform standards are to be established globally. Locally, there will be comprehensive engineering services and flexible manufacturing options. Providing the customer with a solid platform within reach, to be able to produce top-quality products together with a pool of competent and talented employees, is the objective of all activities. Particularly in the Netherlands, the Czech Republic, and in Finland, Phillips-Medisize continues to increase its presence further. In the Netherlands, the company enlarged a building complex for the



Pain Management IV-Set, tube line for pain management.



Peristaltic cassette

manufacture of medical and diagnostic devices in early 2014. Some 1,200 m2 of an expansion area of 1,600 m2 are reserved for various classes of cleanrooms. Here, 11 additional injection moulding machines – clamping forces between 35 and 260 tons – are taken on duty. In the Czech Republic, the company is expanding its production area by approximately 1,000 square metres – for clean room production, which is gaining in importance in Eastern Europe. The largest European investment was made in Finland, an expansion by an additional production area of 6,000 m2, to meet the increasing demand for drug delivery devices in Europe from a single source. For this purpose, the company built cleanrooms up to ISO class 8 and assembly halls for injection systems.

In January 2014, Phillips-Medisize announced that it had signed a cooperative agreement with Sanofi for the delivery of insulin pens – a significant success of its expansion strategy. The enlarged Finnish plant is manufacturing single-use systems for this long-standing pharmaceutical enterprise that are to be sold in Japan and must meet that country's strict quality requirements. Phillips-Medisize met these standards by virtue of its knowhow in assembly technology. The pens are being made using the injection moulding process with subsequent fully automated assembly. For Matt Jennings, this project is a typical example of innovative cooperation, based on the Phillips-Medisize premise of having everything, from mould making to automation technology, under one roof in order to provide the customer with comprehensive service.

Phillips-Medisize Corporation CH 8309 Nürensdorf

GMP-IT workstation – a mobile self-sufficient cleanroom workstation for the highest degree of flexibility and performance in pharmaceutical manufacturing

The new ready-to-connect mobile computer workstation Trolley light from Systec & Solutions GmbH is specially designed in uncompromising industrial design for use in regulated industries. The high-tech inner workings are protected by an easy-to-clean stainless steel housing which meets the requirements for IP65. The Trolley light cannot be harmed by dust, water or acids. In combination with e.g. the WAVE IPC with capacitive multitouch display, it generates entirely new possibilities for operation.

Mobile - thanks to powerful battery

The Trolley light is equipped with a very powerful and low-maintenance AGM battery pack as standard, enabling the mobile operation of a WAVE IPC system mounted on a Trolley light for up to 20 hours.

Inductive charging technology - convenient battery charging without any cables

The new Trolley light inductive with inductive charging technology uses a modern Li-Ion battery system with high power density. The induction technology-equipped base station is very quickly and efficiently charged without any cables whatsoever. The energy transfer for the integrated battery charging process takes place on an inductive basis. To this end the Trolley light inductive is docked to a charging station - mounted on the wall or on the floor. The charging and simultaneous operation of the IPC system are thus possible without any cable or plug contact. What is more, the charging process can be constantly monitored via computer software. Batteries can be changed during operation with the hot swap function.

High performance and modern display technology

The Trolley light can be equipped with display sizes of 19, 21, 24 and 32-inch with resistive touch or multitouch technology. The displays are especially bright if modern IPS panels and optical bonding technology are used. From the monitor, ultra-thin client right through to the Intel[®]Core™i7, almost any IT-needs can be met. A secure mobile data connection can be delivered by W-LAN,



GMP-IT workstation – a mobile self-sufficient cleanroom workstation

thus providing maximum system mobility while retaining wide coverage.

Complete GMP-IT workstation

The Trolley light is a complete computer workstation to which various peripheral devices can be added in modules.

- Hygienic keyboard available e.g. as glass keyboard or antibacterial membrane keyboard housed in stainless steel with torsional hinge for tilting
- Support bracket for bar code scanner
- Docking station mount optionally with direct power supply
- RFID reader for authentication

Satisfying GMP requirements

The Trolley light meets the highest demands for computer workstations in the cleanroom sector, in medical technology or pharmaceutical manufacturing. The absence of cables leaves you with great flexibility and a high level of operational and occupational safety, especially in confined surroundings.

Systec & Solutions GmbH D 76131 Karlsruhe







Figure 2: Trolley light inductive with WAVE 219 IPC

Raumedic AG, a member of the REHAU Group, is expanding its headquarters in Germany. Last week, the executive board and the project team celebrated the official laying of the foundation stone of the 26 million euro project together with public representatives, architects and representatives of the trades.

Laying of the foundation stone for Raumedic company expansion



Best wishes for a good construction project and a continued business growth with symbolic hammer blows (from left): Jobst Wagner, President of the REHAU Group, Martin Bayer, CEO of RAUMEDIC AG, building contractor Alois Dechant and RAUMEDIC project leader Martin Silbermann (picture: Michael Giegold)

With best wishes for an accident-free construction project and continued business success, Jobst Wagner, President of the REHAU Group, Raumedic chairman Martin Bayer, building contractor Alois Dechant and Raumedic project leader Martin Silbermann embedded a time capsule with current products, the daily newspaper, the construction plan and a few coins into the foundation of the new building.

"This is not only an investment for the future of the region, but also an investment in the future of our employees," said Martin Bayer.

The new building will be constructed directly next to the headquarters of this supplier of polymeric solutions for the medical and pharmaceutical industry. The 9000 square meters of usable area will have space for around 200 employees in clean room production, laboratory work, logistics and administration. The Raumedic campus will thus offer all types of possibilities for continued growth in the three areas of extrusion, injection moulding and assembly.

Raumedic AG D 95233 Helmbrechts

New product generation for mobile measurement tasks

Multifunctional hand-held meter with data logging

The new Omniport 30 from E+E Elektronik is a professional and robust hand-held meter that meets the highest requirements. Thanks to a wide range of interchangeable sensing probes, Omniport 30 can be used in various applications.

Up to 22 measurements, including humidity, temperature, dew point, air velocity, volumetric flow or air pressure can be accurately measured and logged. The Omniport 30 allows both continuous and single-point



data logging and is particularly user-friendly due to its touch screen and intuitive menu navigation.

Up to three physical quantities can be displayed simultaneously on the large TFT color screen. A selection between continuous and various long-term measuring modes is possible. Measured values can be displayed as graphs directly on the device screen.

Omniport 30 can store up to 2 million measurement values. The data can be transferred easily to a PC for further processing with its the free data management software. Firmware updates can be uploaded via USB interface.

An optional carrying case is available for



The Omniport 30 with sensing probes and accessories in the convenient carrying case.

the storage and transport of the hand-held, sensors and accessories.

E+E Elektronik GmbH Langwiesen 7 A 4209 Engerwitzdorf Telefon: +43 7235 605 0 Telefax: +43 7235 6058 E-Mail: info@epluse.at Internet: http://www.epluse.com

A dividend of EUR 0.70 per share was approved at the Annual General Meeting of Gerresheimer AG held today in Duesseldorf. The Company, a leading partner to the pharma and healthcare industry, presented a strong set of results for financial year 2013.

Annual General Meeting of Gerresheimer AG approves dividend of EUR 0.70 per share

- Dividend raised to EUR 0.70 per share

- Management Board and Supervisory Board given formal approval by large majority

- Dr. Axel Herberg new member of the Supervisory Board for shareholders

"2013 was a good year for Gerresheimer AG. We achieved all the goals we set ourselves and sharpened our organization's customer focus, thereby taking important steps in setting a course for the future. For 2014, we are counting on further growth in industrialized and emerging economies. We thus plan to further extend our leading position as global partner to the pharma and healthcare industry," said Uwe Röhrhoff, CEO of Gerresheimer AG, summarizing the strategy at the Annual General Meeting.

The dividend of EUR 0.70 per entitled no-par-value share will be paid out on May 2, 2014. In the prior year, a dividend of EUR 0.65 per share was distributed.

The actions of the Management Board

and Supervisory Board in financial year 2013 were approved by a large majority. Dr. Axel Herberg, Senior Managing Director of The Blackstone Group Germany GmbH, was voted in by a large majority at the Annual General Meeting as a new member of the Supervisory Board for shareholders. Amendments to the Articles of Association in relation to Supervisory Board remuneration were likewise passed by a large majority. The Annual General Meeting also approved amendment agreements to the Profit and Loss Transfer Agreement with Gerresheimer Holdings GmbH and a Domination Agreement with Gerresheimer Holdings GmbH. Deloitte & Touche GmbH Wirtschaftsprüfungsgesellschaft, Duesseldorf, was appointed as audi-



tor for financial year 2014.

71.79% of the capital stock was represented at today's Annual General Meeting. The results of the voting on all items of the agenda at the Annual General Meeting can be viewed at the below-mentioned link.

Gerresheimer AG D 40213 Düsseldorf

Leica Microsystems now offers Leica Steel

cleanroom onjine

Steel Analysis Software for Automated Non-Metallic Inclusion Rating Incorporates the Latest International Standards

Leica Steel Expert 2.0 Now Available as Upgrade or Full Package

Leica Microsystems now offers the latest version of the Leica Steel Expert 2.0 software module for fast, precise quality control in steel manufacture and processing as an upgrade. Customers already using Leica Steel Expert will benefit from the latest features of the new 2.0 version at an affordable price. Existing users of Leica Steel Expert 2.0 will benefit from an update of the integrated industrial standards, as the upgrade contains the latest version of each standard. Report templates for the respective Japanese and Chinese standards are also included.

"Leica Microsystems strives to continually improve the quality and efficiency of its products and services. Part of this effort entails providing frequent and industry-relevant upgrades so that our customers can keep their products up-to-date," says Thomas Locherer, Product Manager for materials microscopes and application software at Leica Microsystems.

Leica Steel Expert 2.0 software performs automated analysis of non-metallic inclusions in steel and provides precise, fast, and reproducible measurements of the purity of steel alloys, in compliance with many international standards. Leica Steel Expert 2.0 exactly matches the users' workflows, offering an easily mastered, intuitive



interface. With its new detection algorithm, the software reliably detects sulfides, oxides, and a wide range of carbonitrides. Analysis can be performed on the live image or the saved image. The position, area, length, breadth, and shape of the inclusions are stored as raw data.

Leica Microsystems GmbH D 35578 Wetzlar

Robolux Valves Are now Part of Bürkert's Element Product Family

Welcome to the Family



As part of a new actuator concept, Robolux valves can now be combined with Bürkert's Element control heads.

Robolux multiport valves ensure compact processes, facilitate excellent cleaning and increase overall process reliability. Now they can be combined with Bürkert's Element-Series of control heads to provide a comprehensive base for the decentralized automation of hygienic processes.

Hygienic processing places high demands on the reliability and cleanability of production facilities. These requirements are especially high in separation processes or when purity of media has to be ensured by maintaining sterile process conditions. The mixing of different media in the manufacture of nutrient solutions processes like fermentation demands absolute sterility. Common challenges related to tank installations in pharmaceutical and biotech facilities can be reduced by using Robolux multiport valves and complex multiport-based manifolds from Bürkert Fluid Control Systems.

Based on diaphragm valve technology these patented valves combine independent dual process switching functions in a single body with a single diaphragm and single actuator. The compactly designed multiport valve requires about 40 percent less space than traditional valve manifolds and can be sterilized more easily. A low internal volume and elimination of dead space supports faster cleaning and of course means better process efficiency and higher product yield from the process. The compact construction reduces installation and maintenance costs.

As part of a new actuator concept, Robolux valves can now be combined with Bürkert's Element control heads. As a new part of the Element family of products, Robolux becomes an integral part of a complete system approach to provide process solutions. The intelligent combination of Robolux multiport valves with Element control heads opens up a wealth of new possibilities for the decentralized automation of hygienic processes. The integration of all required automation functions in the control heads themselves allows for the valves to be equipped at field level with all required automation components including pilot valves, electrical feedback units and optical status indicators. By integrating an AS interface as a field bus interface, the entire range of advantages of this approach can be fully utilised. All that is required for power supply, feedback and communication is a two-wire line connecting the PLC with up to 62 valves. Within the framework of a decentralized automation concept the control head, as a central unit for the hygienic process valves, performs all pneumatic actuation, feedback and diagnostic functions, as well as bus communication.

Bürkert Fluid Control Systems D 74653 Ingelfingen

Market for packaging machinery in a period of transition

cleanroom

- New locations in Asia and Africa planned
- New markets to be opened up
- PA 2020 strategy unveiled

Bosch Packaging Technology aims to keep strengthening its leading position until 2020

Bv 2020, Bosch Packaging Technology aims to grow considerably faster than the market, and to further expand its leading position in the realm of process and packaging technology around the world. "We expect to see fundamental change in the market for packaging machinery. We not only want to react to this change, we also aim to help shape it," said Friedbert Klefenz, President of Bosch Packaging Technology, during the company's press conference at the Interpack trade show in Düsseldorf. On the basis of its PA 2020 strategy, the manufacturer of special machinery aims to continue expanding its business in the established markets, and to grow especially in Asia and Africa. In addition to this, the company intends to spur further growth by venturing into new fields of business.

"We are well on our way to realizing our plans," Klefenz said. Last year, Bosch Packaging Technology's sales exceeded the onebillion euro mark for the first time. In fiscal 2013, the company increased its sales by 22 percent, from 914 million euros to 1.1 billion euros. This was largely the result of the firsttime consolidation of companies such as Hüttlin, Manesty, and Eisai Machinery. After adjusting for consolidation effects, growth was 6.4 percent. Currency effects notwithstanding, Packaging Technology recorded internal growth of ten percent. According to VDMA, a trade association, the packaging machinery sector grew four percent in 2013. Including companies that were consolidated for the first time in the year under review, the company employed 5,600 associates at more than 30 locations, 12 percent more than the previous year.

Moving toward the next decade with the PA 2020 strategy

"We expect to keep up this pace of growth in the coming years as well. By the end of 2015, our annual sales are likely to reach the 1.5 billion euro mark," said Klefenz. "But our plans also go beyond 2015." Last year, the company defined its strategy up to the end of this decade with PA 2020. The strategy's central aim is to expand the company's current fields of business and markets and to venture into new ones.

Regional shift expected

At present, Bosch Packaging Technology generates around 40 percent of its sales in Europe, 30 percent in Asia, and a quarter in North and South America. However, for the coming years, a strong regional shift is expected. "Until the end of this decade, we aim to continue growing strongly in the established markets, such as Europe and North America. At the same time, we will generate far more than a third of our sales in Asia," said Klefenz. Africa and the Middle East are also gaining significance. "Markets in Europe and the Americas will keep developing continuously. This means that the overall market for packaging machinery will grow. However, in the coming years, there will be a shift in the importance of regional markets," said Klefenz.

Pharma segment growing strongly

The pharma segment is one of the drivers of Bosch Packaging Technology's growth. The company has benefited from the sector's dynamic global development. In the past year, it grew nine percent. In total, this field of business accounts for 52 percent of the company's sales. "This shows that a growing number of people have access to medication. It is also the result of the global growth of the generics business," said Klefenz. At the same time, more complex substances and the ever-stricter requirements of manufacturers and lawmakers have placed growing demands on the packaging industry. "This calls for major innovative strength," said Klefenz. In total, Bosch Packaging Technology spent around 4.5 percent of its sales on research and development in 2013.

Food sector: major order in Mexico

The equipment business for the food and confectionary industries also developed well. In 2012, Bosch Packaging Technology acquired the largest single order in the company's history. This year, the company will be delivering two packaging lines to a biscuit manufacturer in Mexico. Each line operates with six horizontal filling and sealing machines with fully automatic cartoning that can package more than 17,000 crackers per minute.

Alongside the sale of machinery for dry foods and confectionary, in the coming years Bosch Packaging Technology intends to significantly expand its business in the selected beverages and liquid food segments.

Service business continues to grow

Just like the entire industry, Bosch Packaging Technology expects to see the scope and nature of the service business change. "For this reason, comprehensive service is an important part of the PA 2020 strategy. Increasingly, customer expectations can only be met by companies with a broad range of expertise and a strong regional presence. We are one such company, and we offer a growing number of solutions that can be combined with one another in a flexible manner," said Klefenz. As a result, the company's customers can get everything they need from a single source. This includes process and packaging machinery, as well as technologies for product handling, automation, and inspection. "In short, we offer one stop shopping. The customer contacts us once and receives, if desired, a full turnkey solution for their project. This includes not only machinery and equipment, but also the planning and construction of packaging lines, as well as assembly, maintenance, and service," said Klefenz

Save Food

Better packaging also means that millions of people are gaining better access to medications and food. Today, a third of the world's food still goes to waste, often as a result of inadequate packaging and storage. For this reason, Bosch Packaging Technology is involved in the UN's "Save Food" initiative. The project was launched in 2011 at the last Interpack trade show in Düsseldorf. "We are proud to be making a contribution," said Klefenz. "Creating real value-added is also in line with the Bosch 'Invented for life' leitmotiv."

Bosch Packaging Technology D 74554 Crailsheim Quality has become a key issue for the pharmaceutical industry. On the one hand, increasing global demand for medical care is leading to new challenges in high-volume production; on the other, international regulatory authorities are defining increasingly stringent standards for the pharmaceutical industry. As a result, drug companies are more dependent on high-quality production chains than ever before – and this is true of all production locations and for all phases of production from development to manufacture to packaging. Excellence United – an alliance of five leading German manufacturers of specialized machines for pharmaceutical and medical products – offers production solutions for the entire value chain. Since its foundation in 2011 Excellence United has continued to successfully drive growth with numerous strategic and technological innovations.

Excellence United Aims for Growth through Quality

cleanroom

In its third year, the chief executives of Bausch+Ströbel, Fette Compacting, Glatt, Harro Höfliger and Uhlmann can report a very positive interim result. The five partner companies have continued to successfully drive growth in recent years. Excellence United's total turnover rose from roughly ϵ 800 million in 2011 to ϵ 965 million in 2013. The ϵ 1 billion mark is expected to be passed for the first time in 2014. More than 40,000 of the partner companies' machines are currently in operation worldwide. The five companies employ 6,000 people around the globe, including more than 600 service employees.

New Excellence United Marketing GmbH

In 2014 the partner businesses founded a joint marketing company to centrally coordinate combined marketing and press activities in the future. In addition to public relations activities, the new company will be supporting various project work groups on subjects such as technical cooperation, service, sales and quality management. In future, integrated project management is intended to ensure the smooth development of ambitious line projects – from planning to after-sales service. Information about Excellence United is also immediately available on the new website at www.excellence-united. com.

First Sales & Service Hub

Pharmaceutical production is highly complex. Faults, breakdowns and stoppages quickly lead to unwanted additional costs and quality defects. A great deal therefore depends on the service provided by pharmaceutical equipment manufacturers. Ideally, good service prevents production problems occurring in the first place. That is why Excellence United has set itself the task of establishing central points of contact with qualified sales and service teams worldwide. The first hub opened in Istanbul, Turkey, on 1 March 2014, and further sites are planned. Additional Excellence United centres are the joint sales and service office of Fette Compacting, Glatt and Harro Höfliger in Mumbai, India, as well as the joint offices of Bausch+Ströbel, Fette Compacting and Uhlmann in France. In Egypt, Akhnaton is the first sales representative of the corporate alliance.

Standardized Remote Servicing

Instead of lots of separate systems, Excellence United is relying on a standardized comprehensive service solution for pharmaceutical production. That is why the partner companies are equipping their machines with the Excellence United Service Portal. In the event of a fault, the user can reach a specialist engineer at the machine manufacturer directly via the Human Machine Interface (HMI) – for example, using online messaging, a webcam or a whiteboard. The maintenance management tool also ensures that wear parts are replaced in good time. Customers can even order spare parts quickly and easily using the system.

New Culture of Quality in the Pharmaceutical Market

The pharmaceutical industry is facing new challenges. More and more people have access to basic medical care, and this is leading to an enormous expansion of production and increases in the number of production sites. Additionally, there is increasing pressure on prices as a result of new competitors from emerging markets as well as the rush to produce blockbuster drugs as a result of expiring patents. Furthermore, the increasing importance of personalized medicine also requires the development of appropriate medicines and highly complex production processes. In light of the supply bottlenecks resulting from production errors, international regulatory authorities like the FDA, EMA and ISPE have taken wide-ranging measures to establish new quality standards in collaboration with the industry. Quality has therefore become one the key challenges for the pharmaceutical industry.

Highest Quality from One Source

The five companies have responded to these challenges. The alliance offers stateof-the-art production technology of the highest quality along the entire value chain – from planning and product development to service and maintenance to the training of operators. By working together, the partner companies can ideally match individual interfaces in the process chain and orient quality standards to current and future requirements. As a result, they are pooling their expertise and developing common standards to optimize their customers' production and equip their new plants with machines ready for the future.

Excellence United Marketing GmbH D 71573 Allmersbach im Tal

Ground-breaking ceremony in Lossburg: Arburg expands central production plant

- New hall: Floorspace expanded by 18,600 m2 to a total of just under 165,000 m2
- More space: New building for assembly of large injection moulding machines and turnkey systems
- Commitment to the Lossburg location: Tens of millions of euros invested

On 28 April 2014, Arburg held the official ground-breaking ceremony for a new assembly hall in Lossburg, which will expand the central production location by 13 percent to just under 165,000 m2. Initial excavation work began in March 2014 and the completion date has been set for the autumn of 2015. With the new building section, Arburg is responding to the increasing demand for large injection moulding machines and complete production cells.

"Growth means preservation, means actively securing the future," explains Michael Hehl, Managing Partner and Spokesperson for the Arburg Management Team at the start of his speech, adding: "The capital investment for the new building section, to the tune of many tens of millions of euros, demonstrates our clear commitment to Lossburg as a production location and is an indicator of the long-term, targeted strategy for which Arburg has been famous for decades and makes us a reliable partner." Significantly more time and space is required for assembly and testing of the large injection moulding machines up to a clamping force of 5,000 kN and complete turnkey systems.

Modern facility management reduces energy requirements

During its construction activities, Arburg always focuses on functionality and aesthetics. Moreover, environmental protection and the conservation of resources and energy represent a permanent feature of Arburg's corporate culture. "With the new building, we are implementing highly integrated facility management, which will reduce the primary energy requirements to a minimum and therefore further expands our environmental protection activities," said Michael Hehl in this context.

The waste heat produced is utilised for heating the hall, for example. Collected rainwater is used by the gardeners and covers all the requirements for the sanitary facilities. Furthermore, its use as a buffer storage for the industrial cooling required in the building is a special feature. North-facing shed roofs reduce the thermal load and minimise the need for electric lighting. The natural cold of the ambient air is used for air conditioning purposes - e.g. via an ingenious facade design that employs natural ventilation instead of ventilation systems. Furthermore, extension of the photovoltaic plants to generate a further 340 kWp (kilowatt-peak) is also planned.

New hall ready for occupation by autumn 2015

The new two-storey building section with a floorspace of 18,600 m2 will increase the total area in Lossburg by some 13 percent to just under 165,000 m2. A few key figures illustrate the scale of the construction project: 22,000 m3 of earth are being excavated. A total of 8,000 m3 of in-situ concrete, 2,500 tonnes of reinforcing steel and 100 tonnes of pre-stressing steel are being used for the building. The glazed facade covers a surface of 3,800 m2. The new building will match the assembly hall built in 2000 as part of the ARBURG II plant expansion. At the time, Arburg was already thinking in forward-looking terms by employing a modular construction concept so that the new building section can be integrated into the existing building complex with relative ease.

ARBURG GmbH + Co KG A 72290 Loßburg



Official ground-breaking ceremony on 28 April 2014 for the new Arburg building section in Lossburg (from left to right): Arburg Partners Eugen Hehl, Juliane Hehl, Michael Hehl and Renate Keinath with Siegfried Schmelzle and Claus Matt (both from Schmelzle+Partner architect's office), the Mayor of Lossburg Christoph Enderle, Hans J. Theurer (Hans J. Theurer Hoch- und Tiefbau) and Mario Müller (A. M. Müller Tief- und Straßenbau). (Photo: Arburg)

Successful completion of CE performance evaluation study covering more than 400 patient samples Sales and Marketing Program Underway in Germany, Austria and Switzerland

Curetis Launches Unyvero™ i60 Implant and Tissue Infection Cartridge in Europe

Curetis AG, a developer of next-level molecular diagnostic solutions, today announced that it has launched its new Unyvero[™] i60 Implant and Tissue Infection (ITI) cartridge in Europe. The new cartridge for the Unyvero[™] system was developed to rapidly identify more than 90 pathogens and more than 20 resistance markers common in eight clinical indications. Commercial launch and roll-out has already begun in close collaboration with Heraeus Medical GmbH, the development and commercialization partner for the Unyvero[™] i60 cartridge. The Company has made first placements at major clinical centers in Germany, Austria and Switzerland (DACH market).

The i60 cartridge has been CE-IVD marked following the successful completion of a CE performance evaluation study involving more than 750 cartridges. Analytical sensitivity testing was conducted in 350 cartridges, while more than 400 cartridges were run with patient samples. Samples of various clinical indications were obtained for the trial, including periprosthetic joint infections, diabetic foot, catheters, surgical sites, skin and soft tissue and cardiology-related infections. The Unyvero[™] system analyzed challenging native clinical sample types such as swabs, synovial fluid, sonication fluid, tissue and catheters. Among others, the i60 cartridge detected several key pathogens with sensitivities in the range between 75% to 100% at an overall panel sensitivity of 67% and panel specificity of 97.8% for the 81 analytes that have been successfully validated so far. The i60 cartridge also identified 147 clinically important pathogens not found by standard microbiology culture. In particular, in every second sonication fluid and every third synovial fluid sample, i60 detected pathogens missed by microbiology culture. Pathogens most often overlooked by culture, yet identified by i60, were Enterococcus sp., Finegoldia magna, Corynebacterium sp., Enterobacter cloacae, and Acinetobacter baumannii. Resolution of these discrepant results is ongoing.

"We are delighted to have delivered the next highly multiplexed Unyvero application," said Dr. Gerd Luedke, Director Bio-Assay Development of Curetis AG. "It is gratifying to see the clinical value Unyvero can add in the many cases where classical microbiology culture fails to identify crucial pathogens, addressing a major shortcoming of established methods when pathogens are hard to culture and grow. Furthermore, we are pleased to see that the Unyvero Lysator allows us to process an extremely broad and diverse set of native patient sample types. Unyvero's unique lysis capabilities make the platform impressively versatile, especially in a point of care environment where clinicians might not always have the purest of native samples."

"The launch and commercial availability of the Unyvero i60 ITI Cartridge marks an important milestone in our collaboration with Curetis," said Dr. André Kobelt, CEO of Heraeus Medical GmbH. "In combination with our broad range of Heraeus Medical biomaterials for orthopedics and traumatology, i60 will enable us to offer comprehensive infection management solutions to our customers throughout Europe. This added capability will help foster teamwork in hospital settings between orthopedic surgeons, infectiologists, microbiologists and stakeholders in health economics."

"The i60 launch demonstrates our ability to continuously extend and expand our Unyvero platform to address unmet medical needs with unparalleled multiplexing capabilities and versatility in terms of sample types," said Oliver Schacht, CEO of Curetis. "By detecting not only pathogens, but also key antibiotic resistance markers, i60 for the Unyvero[™] system further builds our leading position in the marketplace. Initial customer response has been very positive and demand for this new cartridge has been building steadily over the past few months."

About the Unyvero[™] System

The CE-marked Unyvero[™] System is a versatile hardware platform for the detection of a broad panel of bacteria, fungi and antibiotic resistances from a single sample in one run. It processes a disposable cartridge providing the necessary reagents to complete the analysis from sample to result. It is marketed in Europe, Russia, the Middle East and various other non-European countries. In the U.S., Curetis is running a prospective multi-center clinical trial aimed at achieving FDA clearance registered under http://www.clinicaltrials.gov/ NCT01922024.

The platform enables the DNA-based testing of all clinically relevant samples in a fully automated, unsupervised analysis process requiring only few, quick manual preparation steps. The analysis thus can be performed with minimal operator time and without the need of skilled staff or special infrastructure.

Thereby, clinically relevant information is available within about four hours to support an informed therapy decision as early as possible.

The first CE-marked Unyvero[™] Cartridge, Unyvero[™] P50, focuses on pneumonia testing and simultaneously analyses 39 DNA targets. The second CE-marked application, the Unyvero[™] i60 ITI cartridge for implant & tissue infections, is also commercially available in Europe. Cartridges for additional indications are in various stages of development and preparation.

Curetis AG D 71088 Holzgerlingen Focus on customised polymers, new injection moulding processes and 3-D printing



Exhibitors display innovations at MEDTEC Europe 2014

o3rd - o5th June 2014: MEDTEC 2014 Stuttgart (D)

Up to 900 component suppliers of medical technology manufacturers will be exhibiting their innovations and services at MEDTEC Europe in Stuttgart. The central theme is innovative materials as well as product development and production processes. Amongst other things, Evonik Industries is showcasing customised plastics for the medical technology industry. The chemical specialist is appearing with its new VESTA-MID® Care ME-B product range, for example. The company is also exhibiting its biostable PEEK for long-term implants and biodegradable polymers for orthopaedic use on their stand. ARBURG, the acknowledged injection moulding expert, is bringing a new application to the leading trade fair. The machine construction company demonstrates the efficient manufacture of syringe bodies from Cyclic Oelefin Polymer (COP) with its electric Allrounder 370 A in a GMP-compliant stainless steel design. Concept Laser is showcasing a generative metal laser fusion solution at this industry gathering with its LaserCUSING® process. Using this method, components can be created from powdered metals layer by layer using 3D CAD data.

"Customised polymers are becoming more and more important", declared Christian Röhnke, Business Manager Medical Devices at Evonik Industries. The company is exhibiting one innovation in this area with its VESTAMID® Care ME-B product range. This plastic can adhere directly to specially modified, fluoridated ethylene-propylene copolymers. To do this, the bond is created by co-extrusion which considerably simplifies the manufacturing process. Innovative solutions will be the focal point on the ARBURG stand: "Our exhibits enable us to show the potential of our products and our expertise in the area of medical technology in a graphical form," said Sven Kitzlinger, a technical application consultant at ARBURG. With its electric Allrounder 370 A with 600 kN of locking pressure and the model 70 injection unit, the company gives an on the spot insight into the efficient manufacture of innovative plastic coating. 3D printing also provides undreamed of possibilities for the medical technology industry: "The shift away from intrinsic thinking to additive geometric freedom of components is now no longer a pipe dream," said Oliver Edelmann, partner and Sales & Marketing Director at Concept Laser. With the Mlab cusing machine solution the company will demonstrate the laser fusion process step by step on its exhibition area.



With a comprehensive exhibitor programme and a large number of innovation topics, MEDTEC Europe is underlining its claim to be the leading, largest trade fair for the medical technology component supplier industry in 2014 too. The latest trends and developments will be under the spotlight from 3 - 5 June in an area of more than 36,000 m2. Specialists from the areas of medical automation, clean room technology and materials and packaging will be exhibiting in Halls 3, 5, 7 and 9 at the Stuttgart trade fair. The exhibition is divided into nine clear focal areas and exhibition fora, such as

Exhibitors display innovations at MEDTEC Europe 2014

the i-Zone, where innovative start ups can exhibit for the first time on their own stage. In addition there is the matchmaking area for business contacts and discussions in a peaceful atmosphere and the networking area for interdisciplinary exchange between experts, industry representatives and all interested parties. The MEDTEC conference in Hall 9 is another addition to the leading trade fair. Here numerous experts will talk, for example, about progress in prototyping, in quality systems and production processes as well as changes to regulatory issues.

"The industry is on the move," said Fabienne Valambras, the organiser of MEDTEC Europe. "While regulatory authorities, for example, are setting stricter and stricter requirements, component suppliers are providing new solutions to current and future challenges. Anyone who wants to find out about the latest developments will find answers in Stuttgart. Once again, component suppliers and service providers will be showcasing innovations and intelligent solutions for the challenges posed by modern, efficient medical technology."

This year SÜDTEC, the industry gathering for the production industry in Southern Germany will be held again at the same time as MEDTEC. Visitors will find the trade fair in Hall 3.

About MEDTEC Europe

MEDTEC Europe has been one of the most important fairs for medical technology in the world since 2002 with visitors from almost 60 countries. Every year exhibitors from about 30 countries showcase their latest products and innovations to the international public. MEDTEC Europe will be held on the Stuttgart trade fair site in Halls 3, 5, 7 and 9 from 3rd - 5th June. At the same time the cross-industrial component supplier trade fair, SÜDTEC, will take place. This focuses on the South German production industry (Hall 3).

MEDTEC Europe is organised every year by UBM Canon, which is based in London. The leading organiser of trade fairs and publisher of print and online publications for the international production industry employs some 5,500 people throughout the world.

UBM Canon SE1 9UY London Vereinigtes Königreich Großbritannien und Nordirland

Frankfurt takes advantage of interfaces to leading international trade fairs

Cleanzone exhibitors are already making plans to return

21st - 22nd October 2014: Cleanzone 2014 Frankfurt am Main (D)

On 21 and 22 October 2014, Cleanzone – international trade fair and congress for cleanroom technology – will be taking place for the third time, further solidifying its status as a must-attend event for the in-ternational cleanroom industry.

With its interdisciplinary and international approach, this young specialist event has successfully forged links between highly specialised providers of cleanroom technology and the ever-expanding range of areas in which it is applied. This means exhibitors in Frankfurt encounter not only visitors with many years of cleanroom experience, but also potential new customers dealing with the field for the first time who have come to Cleanzone with concrete investments in mind.

That is why many exhibitors have already decided that they will be back again in 2014. Friedhelm Rickert, Managing Director of Spetec, is one of them: "Cleanzone 2013 was a resounding success for us, and we were particularly satisfied with the quality of visitors. That is why Cleanzone is an absolute must for us this year as well." Other Cleanzone exhibitors who have already decided that they will be back in 2014 include ASSA ABLOY Entrance Systems, CAS Clean- Air-Service, Cleanroom Competence CRC, Decontam, DITTEL Engineering, Dycem, Hydroflex, KEK, Lechleiter, Particle Measuring Systems Germany, PPS Pfennig Reinigungstechnik, Profi-con, ReinraumAkademie and Vieira Lopes. Messe Frankfurt will also be welcoming a number of new faces, including measurement technology specialists TSI and PMT Partikel-Messtechnik.

International expertise and the right interfaces

In 2014 Cleanzone will be taking place in Hall 1.1 of the Frankfurt exhibition grounds. Exhibitors and visitors alike benefit from the global links of this international trade fair venue. Messe Frankfurt is also known worldwide for its leading technology trade fairs ISH, Light + Building and IFFA, which cover such fields as climate control technology, building automation and food technology. Its long-standing expertise in these areas creates ideal interfaces for Cleanzone. This young event is also benefiting from Messe Frankfurt's decision to increase its strategic focus on new event themes. This means the company will be making even greater use of its international network, which boasts a presence in some 150 countries around the globe, for its sales efforts for Cleanzone 2014. It will also be increasing its international marketing, including joint efforts with the afore-mentioned trade fairs.

New partners for Cleanzone

Cleanzone's continued positive performance is generating increased interest both within the cleanroom industry and among the industries in which it is used. As of this year Cleanzone is not only a member of the reconstituted German Cleanroom Institute (DRRI), but has also welcomed Fachverband Gebäude-Klima e.V., a trade association for the building climate control sector, as a new Cleanzone partner. Numerous associations and organisations were also Cleanzone partners in 2013, including ICCCS, IVAM, SEMI, SPECTARIS, VDI and DECHEMA Ausstellungs-GmbH.

Book your stand for Cleanzone 2014

Since the beginning of the year it has been possible for exhibitors to book their stand and select their ideal location for Cleanzone 2014 conveniently online. The direct link to the online registration is: www. cleanzone.messefrankfurt.com/registration

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The innovation award for cleanroom technology is in its third year

Cleanroom Award 2014

Cleanzone, the international trade fair and conference for cleanroom technology, is already going into its third edition and so the Cleanroom Award of the ReinraumAkademie will be given for the third time. The competition is open to companies or individuals with innovations that go beyond further developments of already existing products or services. The search is on for pioneering progress in the clean room industry, in connection with renewal, sustainability and efficiency. An international jury will be selecting the five best entries that are presented at Cleanzone on the 21st and 22nd October 2014 in Frankfurt/Main. The visitors of Cleanzone will then choose the winner by voting.

"The fact that the Cleanroom Award 2014 will once again be given at Cleanzone is a gain for both events. The specialist visitors of Cleanzone can find out about the outstanding technological innovations of the premiered projects and even choose their favourites. For the winners of the award this gathering for clean room technology presents an ideal opportunity to present their concepts to an international expert audience," says Ruth Lorenz, Head of Department for New Events at Messe Frankfurt.

Any innovation that drives the cleanroom industry forward can be submitted: for example, surfaces that no longer become dirty, gloves in which one no longer sweats, or perhaps even an innovative project that has been implemented – there are no limits to the ideas.

Both companies and individuals can still enter until 15 August 2014 at the ReinraumAkademie in Leipzig.

The Cleanroom Award is endowed with a cash value of 3,000 euros. But the real prize for the finalists is the attention of the specialist audience and a wider public during Cleanzone, as well as publications in ReinraumTechnik and CLEANROOM.MAGAZIN. These aspects in particular also led to the entry of the prize-winner for 2013: "Following the release of Blautouch, the interactive workbench for laboratories and cleanrooms developed and patented by Laborial, Cleanroom Award was identified and strategically defined as an imperative for the recognition and the market success of that innovative solution." emphasises Tânia Fernandes, Director of the Marketing Department at Laborial.

ReinraumAkademie GmbH bestows the Cleanroom Award in order to pursue the aim of promoting exchange regarding new deve-



lopments and ideas within the clean room industry. The intention is to motivate the providers of cleanroom products and services, but also the operators of cleanrooms, to report about their projects and ideas in order to push forward the interdisciplinary transfer of knowledge. The ReinraumAkademie is also supported in this by other multipliers in the market: "A healthy culture of innovation is important for an industry. That is why we support the Cleanroom Award," explains Dr. Roy T. Fox, Chief Editor of Rein-RaumTechnik.

ReinraumAkademie GmbH D 04103 Leipzig

Mitigating the environmental impact of cleaning processes in GMP regulated facilities

An "eco-friendly" assessment of cleaning agents in GMP regulated facilites

Autor: Elizabeth Rivera

There is a growing awareness and concern in today's society about the "long-term maintenance of biological diversity for human well-being," also known as environmental sustainability. This concern is growing due to a variety of factors, including global climate change, limited natural resources, human health issues, and increasing population, among others. This global issue has led to resurging demand for 'green' chemistry solutions for cleaning and microbial control challenges.

The origin of green chemistries

The 'green chemistry' concept dates back to the mid 1990's when two chemists established 12 principles for designing chemical products and processes to reduce or eliminate the generation of hazardous waste [1]. These principles have been applied to various industrial processes including pharmaceutical, medical device and cosmetic manufacturing, and other regulated industries [2, 3]. The following discussion focuses specifically on cleaning chemistries.

The green chemistry concept focuses on the intrinsic hazard of a chemical or chemical process, and seeks to minimize that hazard to reduce personnel and environmental concerns. So, green chemistries can be viewed as risk mitigation tools.

The meaning of 'Green'

So what exactly does 'green cleaning' mean? Does this term imply that the chemi-

stry is safe for the environment; for humans and animals; in any concentration? Possibly. It may also mean that a product is made from plants and not petroleum. What about biodegradability? Recyclability?

In industry practice, 'green' could mean any or all of those things, and more. But a green formulation must also be effective and suitable for its intended use. A cleaning product that cannot efficiently clean (e.g. requires a high concentration, or a very long contact time to be effective) is a potential waste of resources, and is therefore the antithesis of environmentally sound.

The focus of this article is on cleaners as they relate to cleaning processes for GMP applications. A brief overview of several standards is presented to assist in understanding environmentally friendly cleaners. Next there is a discussion to answer some of the common concerns regarding current chemistries used for cleaning processing equipment in GMP regulated industries. The focus is given to relevant issues in minimizing pollution, reducing waste, managing personnel hazards, and complying with local regulations.

The current state of GMP cleaning

Cleaning procedures are required in cGMP (current Good Manufacturing Practices) industries for maintaining safe and optimally performing manufacturing equipment and facilities. The use of cleaning products to effectively remove process residues, dust, allergens, and infectious agents may be crucial to preventing product contamination that could adversely affect patient safety. But the use of cleaning products may also present health and environmental concerns. They may contain chemicals associated with skin irritation and corrosion, inhalation risks, and other human and animal health problems.

Additionally, the concentrated forms of some cleaning products are environmentally hazardous, containing ingredients that must undergo significant treatment (e.g. pH adjustment) before they can be safely discharged. Since the use of some products creates potential handling, storage, and disposal issues for users, these use factors are increasingly becoming components of the selection criteria when new or current cleaning processes are being evaluated.

Beyond consumer endorsements

Definitions of green chemistries and processes rely primarily on local legislation. However, environmental organizations, public information, and company policies regarding the environment are also influences.

Green certification is also feasible for some categories of cleaners. Government agencies and non-profit organizations offer voluntary programs such as the U.S. EPA Design for the Environment (DfE) and the Green Seal[™]. These are renowned programs dedicated to the development of green products standards. However, most of these programs focus primarily on household (consumer) and janitorial type cleaning products [4 -7], which may not be optimized for use in critical GMP cleaning.

The effectiveness of cleaning procedures used in GMP regulated facilities is affected by multiple factors like temperature, action, concentration, chemistry, and contact time. Other factors affecting cleaning are soil type and conditions, type of equipment surfaces, equipment design, and others [8, 9]. Because of the many process variables and the critical nature of this cleaning, consumer-focused 'green' guidance may not adequately address the effectiveness of cleaning products for GMP cleaning processes.

Another potentially problematic aspect of household and janitorial products is that because of their consumer focus, the formu-

Table 1. Green Products Voluntary Programs

Name	Reference Standard (s)	
Green Seal™	GS-37 Cleaning Products for Industrial and Institutional Use	
United States (U.S.) Environmental Protection Agency (EPA) Design for the Environment	Standard for Safer Cleaning Products	
Canada's Environmental Choice Program (EcoLogo®)	CCD-146 Hard Surface Cleaners	
INFORM, Inc.	Cleaning for Health: Products and Practices for a Safer Indoor Environment	
Consumer Specialty Product Association	Cleaning Products Compendium	
ECOCERT® Group	Natural Cleaning Product Standard	
EU Ecolabel	Commission decision on Establishing ecological criteria for the award of the Ecolabel to all-purpose cleaners and sanitary cleaners	
GREENGUARD [®]	Indoor Air Quality Standard for Cleaners and Cleaning Maintenance Systems	

An "eco-friendly" assessment of cleaning agents in GMP regulated facilites

Table 2. Regulations that impact cleaning agents

Bureau	Regulation	Description
U.S. Environmental Protection Agency	Toxic Substance Control Act	Lists ingredients used in non- exempt products.
U.S. Occupational Health and Safety Administration	Occupational Safety and Health Act	Provides regulations and guidance for labeling, material safety data sheets and hazard communication.
Health Canada	Hazardous Products Act and the Controlled Products Regulations	Provides cautionary labeling of containers of controlled products, the provision of material safety data sheets, and worker education and training programs.
European Parliament	Regulation (EC) no. 648/2004 on detergents	Controls the use of surfactants in cleaning products. Establishes biodegradability criteria for surfactants.
European Chemicals Agency	Registration, Evaluation Authorization and Restriction of Chemicals	Requires that all chemical manufacturers identify and manage risks linked to the substances they supply.

lations are regularly changed to maintain their "New and Improved!" status in the market. This may appeal to consumers, but it presents validation nightmares for GMP cleaning.

Moreover, voluntary programs may support the use of bio-based renewable ingredients that include plant, animal, and marine mass derived materials [10, 11]. These types of ingredients may not be appropriate for GMP industries because they may pose risks associated with variable bioburden, prion contamination, and other related issues [12, 13]. The variety of manufacturing equipment, complex soils, and unique applications in these highly regulated industries makes cleaning product selection even more difficult. For these reasons, each GMP regulated site might be best served by defining their own specific 'green' goals.

However, some of the fundamental pollution prevention and hazard reduction principles might still be useful to GMP sites when they are developing an eco-friendly cleaning program. Table 1 provides a list of references.

This article does not intend to assess the requirements of any of the aforementioned standards or to establish criteria for green cleaning processes in the pharmaceutical and related industries. Rather this discussion addresses common issues regarding cleaning

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products and procedures used by GMP industry participants, and offers assistance in the selection of cleaning chemistries to ease major environmental and health concerns.

Minimizing water and air pollution

The most controversial environmental problem related to formulated detergents is the surface active agents, or surfactants [14] used as ingredients. In the European Union most of this concern has been alleviated by restricting the use of less biodegradable materials, such as tetrapropylbenzene sulfonate and certain alkyl phenol ethoxylates, through legislative ban or voluntary action. Even so, surfactants are still considered by many to be an environmental risk because they are in large-scale use by both industrial and consumer-focused manufacturers.

The overall biodegradability of surfactants has improved, in part due to legislation such as Detergent Regulation EC 648/2004, which demands stringent tests for biodegradability. This has led to the withdrawal of several surfactants from products sold in the European Union. In addition, the Organization for Economic Cooperation and Development (OECD) is developing standards for testing aquatic biodegradability of organic ingredients in products, and some have been adopted by several of the organizations listed in Table 1.

Waste water regulations are often the starting point for determining the type of cleaning agent a facility should use. Local limits may be established for some chemical species and these must be addressed before implementing a cleaning procedure. For example, the general feeling in the late 1960s was that U.S. lakes and streams were getting more polluted each day, and phosphate detergents were the primary reason. Furthermore, the presence of hypochlorite has been demonstrated to form trihalomethanes if the amount of chlorine and the nature of organic residues in the waste stream created the right conditions. Consequently, local authorities may establish limits for both phosphorus and chlorine, which necessitates limits on the amount of discharge from cleaning agents containing these materials [15, 16]. Also there may be limitations on levels of mercury, lead, cadmium, and other heavy metals.

Chelating agents may also have potential environmental drawbacks. These are substances that improve the effectiveness of formulated cleaners by preventing free metal ions in solutions from interacting with surfactants. The most frequently used chelating agents are EDTA (ethylenediaminetetraacetic acid) and NTA (nitrilotriacetic acid). The first is biodegradable (but it does so slowly) [17, 18], and the second is listed as a possible human carcinogen by the IARC (International Agency for Research on Cancer) [19].

There has also been resurging discussion about phosphates, because of the widespread use of STPP (sodium tripolyphosphate) which is a common ingredient used in the formulation of cleaning products. Since STPP is an inorganic substance, biodegradation studies are not applicable. However, STPP can be assimilated by algae and by microorganisms, and thus ends up being assimilated into the natural phosphorus cycle. Restrictions in the use of certain chelating agents are in place or are evolving in some countries. For this reason, the industry continues to search for cost-effective alternatives [20].

The pH of a formulation is another environmental factor to consider. Many municipalities have established pH restrictions in the discharge stream from industrial users. Facilities that use alkaline or acidic cleaning solutions must discharge the waste waters within acceptable discharge pH limits. If not controlled through neutralization prior to discharge, industrial users can incur substantial fines.

Cleaning agent suppliers should be able to supply charts or supplemental information to help these users establish neutralization processes. Usually, neutralization is

An "eco-friendly" assessment of cleaning agents in GMP regulated facilites

done in specialized systems to allow mixing and temperature control. Most residues in GMP manufacturing are soluble in either a high or low pH cleaning solution. Neutralization of waste solution should not be performed in the cleaned vessel because a shift in pH may cause precipitation and re-deposition of residues onto vessel surfaces and, consequently, more cleaning steps.

Water pollution concerns are also addressed by other tests to demonstrate that substances are not toxic to aquatic life. In some U.S. states - California for example - acute aquatic toxicity would normally be determined using a fish 96-hour LC50 (lethal concentration) as required per California's Title 22 Code of Regulations. The BOD (biological oxygen demand) and COD (chemical oxygen demand) of waste effluents are relevant in this regard. BOD is a measure of the content of biologically degradable substances in sewage while COD is commonly used to indirectly measure the amount of organic compounds in water. Generally, it is desirable to send low level BOD and COD directly to the municipal or plant wastewater system and divert high level BOD waste to a field recovery or holding tank. As in the case of LC50, BOD and COD are often governed by regulatory agencies.

Phthalates are a class of widely used industrial compounds based on esters of phthalic anhydride. There are many phthalates with many uses, and just as many toxicological properties. Phthalates are used as emulsifying agents and suspending agents in a large variety of products, from enteric coatings of pharmaceutical pills and nutritional supplements to detergents and surfactants. Despite the variety of uses, phthalates are primarily linked to plasticizers in polyvinyl chloride (PVC) piping and packaging materials. Even so, there is a growing demand for phthalate-free products after a U.S. bill was signed into law in 2008 banning the use of six types of phthalates in children's products [21]. The ban is permanent for the use of children's toys or childcare articles that contain more than 0.1% of di (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or benzyl butyl phthalate (BBP). Environmentally conscious industries are demanding cleaning products with no hazardous phthalates and using phthalate-free PVC or stainless steel pipes in their GMP processes.

Certain VOCs (volatile organic compounds) released into the atmosphere may pose a threat to both air and water quality. VOCs are hydrocarbon compounds that have low boiling points, usually less than 100° C, and therefore they evaporate readily. Since 1990 the U.S. Clean Air Act requires abatement of a list of solvents that are hazardous

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air pollutants; a majority of these are toxic VOCs. Many VOCs can become a major concern for ground-water contamination because large environmental releases can be toxic to humans. Some VOC compounds can persist in ground water and migrate to drinking water supplies. Acetone, methanol, toluene, ethyl acetate and other solvents are volatile organic compounds that are used in solventbased cleaning processes in pharmaceutical production. While not all VOCs are hazardous air pollutants, handling large quantities for cleaning processes poses a concern because the spent solvents are not easily disposed of. They require solvent recovery, treatment, or incineration. For this reason there is a growing pressure in the pharmaceutical industry to move away from VOC solventbased cleaning to aqueous-based chemistries or less hazardous solvents.

Ease of disposal and waste reduction

The term "ease of disposal" is often applied only in reference to the cleaning agent in a GMP process; unfortunately, this is a gross oversimplification. The GMP industry deals with a wide range of process residues, including active ingredients and excipients, rouge and water scale build-up, and processing aids. Even when a cleaning agent is 'eco-friendly,' the spent solution may contain environmentally un-friendly residues like potent drugs and metal fines, among other things, that would not allow it to be disposed of directly into municipal sewers. Drug products manufactured at GMP sites are likely to be toxic in nature or otherwise bioactive and bioavailable (e.g. endocrine disruptors) and restrictions may be imposed on the amount of such residues that might end up in water effluents. This is where technologies like chemical and/or biological water treatment and stripping systems may need to be available on-site to ensure that waste streams meet required standards [22].

Therefore, a spent solution's ease of disposal would not only depend on the cleaning agents, procedures and tools that were used, but also on other residues collected in the spent solution. However, selecting a cleaning agent that poses minimal environmental impact should lessen the number of steps and resources necessary for water treatment.

Some residues may be easy to remove and some others can be tightly adhered to surfaces due to manufacturing steps that involve heat or steam. Complex residues like biopharmaceuticals may have an altered polymeric structure, which can make them more difficult to clean than their original state. Typically, parameters such as time, action, chemistry, concentration, and temperature (TACCT) determine the cleanliness achieved by a process for a specific soil or group of soils [23].

Choosing the right cleaning chemistry and parameters can help maximize productivity and reduce waste. Performing a laboratory simulation using representative materials of construction and manufacturing process soils is a good starting point to help determine the right cleaning chemistry and the optimum cleaning parameters. With this information in hand, a company can decide on the cleaning option that requires minimal raw material and utilities, and consequently produces less waste. Controlling these parameters effectively results not only in consistent cleaning performance but also reduces waste by avoiding repeated cleaning steps due to unacceptable results.

Another way of reducing waste is by recycling and reducing packaging. Most packaging of cleaning products and tools, are made of recyclable material. Plastics like HDPE (high density polyethylene), and PP (polypropylene) are mostly recommended for liquid chemistries because of their excellent chemical resistance and recyclability. Cleaning agents that are offered in bulk sizes can accommodate large, industrial consumption while also reducing the overall amount of packaging that must be dealt with. In addition, concentrated formulas can maximize the use of each unit container, which also reduces the number of empty containers.

Personnel safety management

Environmental organizations are encouraging the industries to opt for innovative systems that reduce the potential for inhalation exposure and meet other environmental goals. For example, packaging and delivery systems can be designed in such a way that they reduce operator exposure to the cleaning product.

Another great example is CIP (clean-inplace) systems, which allow for cleaning of a great deal of equipment without the added steps of dismantling it. This reduces operator exposure to potent drug residues and hazardous cleaners. It also minimizes the risk of damaging process equipment, since the assembly and disassembly of the equipment is subject to human error. If not executed correctly, it can lead to malfunction or serious damage to the equipment, and can result in spills into the environment. Moreover, CIP systems may obviate the need for personnel to get inside the vessel to clean sharp parts like agitator blades or hard-to-clean locations, and reduce the added risk of personal injury.

A cleaning process in a facility must also

An "eco-friendly" assessment of cleaning agents in GMP regulated facilites

consider the safety of the personnel who perform the procedures and who handle the chemistries. This is of special importance in manual cleaning processes where the personnel have a higher risk of exposure. In theory, a cleaning agent used in manual applications should not contain toxic VOCs or be corrosive to skin. Unfortunately, this may not always be feasible since the majority of organic residues are most efficiently cleaned with alkaline chemistries. Therefore, if cleaning agents that are corrosive to skin or are flammable are considered, then proper PPE (personal protective equipment) and training are essential.

Regulatory compliance

In North America and Europe, cleaning agents are regulated by one or more agencies. Each agency has an impact on the type of cleaning agents that are available and on their applications. Table 2 offers a description of some global authorities and cites their reference guidance.

Even though biocidal agents are not within the scope of this document, it is worth mentioning them in this context. From a regulatory perspective, antimicrobial agents used in GMP facilities are often considered separately from cleaning agents. Overall, there is no widely accepted definition or criteria for "environmentally preferred" antimicrobial products. For example, "non-toxic" may be an unrealistic criterion for biocidal agents since, by definition, they must be effective at killing microorganisms, especially in highly regulated environments like aseptic GMP processing areas. Environmental and health impacts can be reduced by using proper application and worker protection techniques, making appropriate choices about which antimicrobial product is necessary under what circumstances, and substituting less toxic alternatives whenever feasible.

Conclusion

In the past, the topic of 'green' in critical production industries has emphasized products rather than considering the whole picture, which also includes the processes. This focus on only one aspect of a complex process is not only limiting, but potentially harmful to personnel and the environment.

In the GMP industry, cleaning agents vary in type. They include formulated detergents, commodity chemicals, and solvents, and can be selected based on a variety of "green" criteria. When deciding on a cleaning process, the overall best approach takes into account performance, price, availability, regulatory requirements, and environmental impact.

As regulations continue to evolve and vary from region to region, being 'green' may be 'in the eyes of the beholder.' GMP regulated sites should evaluate, define and establish cleaning processes that best suit their individual cleaning and 'greening' goals.

About the Author

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Virtual Injection Molding Machine reduces costs in rubber injection molding

SIGMASOFT® Virtual Molding at Maplan Days of Technology 2014

In a 40 minute presentation the application and potential of SIGMASOFT® Virtual Molding for rubber injection molding industry will be presented. Shortened time-to-market, improved mold tempering, optimized cold runner design, reduced energy consumption and reduced cost-per-part are some of the achievable advantages.

4th - 05th June 2014: Maplan Days of Technology Ternitz and Vienna (A)

Between the 4th and 5th of June 2014, Maplan will host their in-house show "Maplan Days of Technology", an exchange platform on the topic of elastomer injection molding. The event will take place in Ternitz and Vienna, Austria, with technical presentations and booths exhibiting solutions for automatization, quality control, application engineering, energy efficiency and cost reduction.

"We are proud to be invited to this prestigious event, to share with existing and potential customers our latest technological developments for the rubber industry", explains Dr. Marco Thornagel, Executive Director at SIGMA Engineering GmbH. "With SIGMASOFT[®] Virtual Molding we have developed a unique tool to support quality assurance, to reduce energy consumption and to minimize costs in elastomer injection molding".

On the first day, Wednesday 4th at 14:00, SIGMA Senior Engineer Tobias Mansfeld will give a presentation on the topic "Virtual Molding of Elastomer Parts" in the English session. On the second day, Thursday 5th at 16:00, the same presentation will be repeated in German under the title "Virtueller Spritzguss von Elastomerformteilen".

SIGMASOFT[®] Virtual Molding was first presented at the past K-Show in Düsseldorf, in October 2013. Following a unique approach, it reproduces the complete injection molding process, including all mold components with their complete thermal and physical interactions over several cycles, to predict the real mold performance and its effect over part quality, cost and cycle time.

"The result is that you can now try all iterations virtually, instead of doing it on a real mold", explains Dr. Thornagel. The conventional approach when developing a new rubber part is to design the injection point, the runner geometry and the tempering layout in the mold based on previous experiences. This approach, however, normally requires iterations; when the mold is ready,



SIGMASOFT® Virtual Molding reproduces the complex thermal interaction between all mold components during several cycles in rubber injection molding. As a result the exact thermal behavior of the molding system, and its effect on productivity and part quality, can be predicted.

it is mounted on the machine for its first trials, and usually undesired results are found, requiring tool tweaking and rework. As SIG-MASOFT[®] Virtual Molding reproduces exactly all the phenomena appearing in real injection molding, it can show the outcome of each iteration. Several mold configurations and process set-ups can be tried upfront. "This way, the machine is used for producing, and not for fine-tuning", explains Dr. Thornagel. "You only produce a mold once you are sure to have the optimal configuration, as on the computer you can now visualize how a mold will work in real life".

Early adopters of SIGMASOFT[®] Virtual Molding have revealed overwhelming results: they get first-shot success on the molds produced, with no further iteration required. "A team can now virtually try different configurations, and decide based on physical results whether they will work or not and, most importantly, why", explains Dr. Thornagel. "Possible issues compromising part quality can be early identified and corrected, and the team can gain confidence to compromise with new projects, as they have now a powerful tool to back them up", he adds. "We have built a smooth and easyto-use interface, with language familiar to process-skilled people and an automatic intelligent meshing system, so that the software works for the rubber process engineers, and not the other way around".

With SIGMASOFT[®], SIGMA Engineering has been attending the needs of rubber injection molding since its very beginnings in 1998. "We know that rubber molding is a science by itself, and deserves targeted material models, able to reproduce complex material interactions. We are committed to excellence in rubber molding, knowing that only through continuous technological investment we can aid our customers increase their competitive edge and profitability. This is why our offer complements the one of our prestigious partners at Maplan Days of Technology", declares Dr. Thornagel.

SIGMA Engineering GmbH D 52072 Aachen

Hans-Peter Endress, Thomas Kraus and Antonietta Pedrazzetti join the administrative body of the Endress+Hauser Group

Changes to the Supervisory Board

Changes are taking place to the Supervisory Board of the Endress+Hauser Group. The Annual General Meeting elected Hans-Peter Endress, Thomas Kraus and Antonietta Pedrazzetti as new members of the Group's controlling body. In turn, Dr George A Endress, Dr Hans Fünfschilling and Willi Ruesch have duly retired from the board.

Klaus Endress, President of the Supervisory Board of Endress+Hauser AG since the beginning of 2014, thanked the retiring Supervisory Board members for their many years of service. They had been members of the independent body since its creation in 2002. "Throughout this long period they have given critical and constructive support to the work of the management team and thereby played key roles in ensuring the good development of the Endress+Hauser Group." At the Annual General Meeting Hans-Peter Endress, Thomas Kraus and Antonietta Pedrazzetti were appointed new members of the Supervisory Board.

Hans-Peter Endress (67), eldest son of company founder Dr Georg H Endress, is a Swiss citizen. He graduated from a commercial traineeship and a management program at the renowned private business school IMD in Lausanne, Switzerland. In 1980 he joined Endress+Hauser's British business as financial director, managing the company from 1985 to 2011 in the role of Managing Director and, as Chairman, is still involved with their development today.

Thomas Kraus (47) is an internationally experienced CEO. He spent a large part of his career at the logistics service provider TNT Express. Besides positions as Director of Marketing and Sales and head of the group's marketing strategy committee he also was in charge of TNT Innight. From 2007 to 2013 he was CEO of TNT Express Deutschland. The German citizen is chairman of the association granting Germany's most prestigious quality management award ('Initiative Ludwig-Erhard-Preis') and advisor of German foodbank ('Bundesverband Deutsche Tafel').

Antonietta Pedrazzetti (51) graduated from her studies in business administration majoring in finance at the University of San Diego in the United States. Since 1992 the Swiss citizen has worked for the Diagnostics division of the pharmaceutical corporation F. Hoffmann-La Roche Ltd and has been responsible for business development with a focus on mergers and acquisitions as well as strategic projects since 2003.

Additional members of the Supervisory Board are Dr Georg Bretthauer, professor of applied IT and automation engineering, the finance expert Dr Klaus Eisele, as well as the former Chief Financial Officer of the Endress+Hauser Group, Fernando Fuenzalida. Dr Heiner Zehntner, a member of the Group's Executive Board, is the Secretary of the Supervisory Board.

Endress+Hauser AG CH 4153 Reinach BL 1



The Supervisory Board of the Endress+Hauser Group (from left): Dr Heiner Zehntner (Secretary), Fernando Fuenzalida, Thomas Kraus, Klaus Endress (President), Hans-Peter Endress, Antonietta Pedrazzetti and Dr Georg Bretthauer. Not pictured: Dr Klaus Eisele.

In a joint booth in the Metal-Ceramic-Plastic (IMKK) innovative cluster, BOY presented its new BOY 60 E with 600 kN clamping force. Eveline Lemke, Minister of Economic Affairs of Rhineland-Palatinate, was impressed by the production of transparent polycarbonate beer glasses, which were also automatically filled.

Automated, energyefficient BOY 60 E at Hannover Messe 2014

Produced, lasered, tapped and provided

The glasses, which were produced on the BOY 60 E, were removed from the mould by a BOY 30 SL handling system and labeled by a laser that was provided by Bluhm Systeme GmbH, Rheinbreitbach / district of Neuwied. Afterwards, the empty glasses were placed on a conveyor belt and filled with an outstanding exhibition drink, a tasty product from Westerwald-Brauerei H. Schneider GmbH & Co. KG.

The BOY 60 E was equipped with the new BOY SL 30 handling system, which recently was added to the BOY sales program. The four axes industrial robot with integrated rotating and swivel function, has load bearing capacities up to 5 kg and conforms to CE protection housing requirements. It transforms a conventional injection moulding machine into an automated production cell.

The multi-patented multi-touch Procan ALPHA [®] 2 control and the newly developed EconPlast optional heating system, which can reduce the energy requirement during plasticizing of plastics up to 50 %, completed the equipment package on the BOY 60 E.



Handling gripper arm removes finished injected beer glass from the mould

Promising potential

The many talks that were held in the well-attended joint booth caused Dirk Steinbach, local BOY Sales Staff, to expect promising sales results in the future. Mr. Steinbach summed up the exhibition by stating, "We left a very good impression with many trade visitors with the compact automation on the BOY 60 E.

Harald Schmillen, organizer of the joint booth of the IMKK and Managing Director of SME promotion in the district of Neuwied GmbH, agrees with the BOY Sales Staff: "According to the host, more than 180.000 people visited the HMI 2014. It felt like 10% of them visited our joint booth, which pointed out the successful cooperation between the fields of materials metal, ceramic, plastic and composite materials. We are pleased that the co-exhibiting companies experienced such great success. When the good response from the visitors then leads to further contacts and orders, the work has paid off."

Top marks with saving energy

A high part of Steinbach's positive exhibition conclusion certainly included the new BOY EconPlast technology. In combination with the servo-motor pump drive, the BOY 60 E achieves the energy classification 9+ according to Euromap 60.1. The Euromap norm compares the energy consumption of injection moulding machines and permits the user to compare results with other injection moulding machines. Since 2013 BOY has set very high standards in the implementation of Euromap 60.1 and achieves top marks throughout its entire clamping force ranges.

Dr. Boy GmbH & Co. KG D 53577 Neustadt-Fernthal



Minister of Economic Affairs Eveline Lemke in front of the new BOY 60 E

International exhibitors demonstrate efficient and interdisciplinary solutions for the processing industry across a wide range of sectors

Leading suppliers exhibit at SÜDTEC 2014

cleanroom

03rd - 05th June 2014: SÜDTEC 2014 Stuttgart (D)

Numerous large and small successful companies make South Germany and the region around Stuttgart into a powerhouse of the German economy. The processing industry benefits from a dense network of innovative companies and specialists with the great scope for the exchange of ideas that this closeness can deliver. An important contribution to this process is made by the leading trade fair for the region, SÜDTEC at the Landesmesse exhibition centre site in Stuttgart. For the sixth time, from 3 to 5 June a large number of suppliers will be presenting their solutions for the processing industry. The exhibitors will include providers from the sectors of plastics production and process, raw materials and semi-finished goods as well as metal processing and machining. As part of an ongoing process of internationalization, of both the region and the trade fair, this year will once again see numerous companies visit from Switzerland, France, Italy, Lithuania and Spain. In particular, suppliers of stamped parts, sub-assemblies and components made from a vast array of materials will be exhibiting their wares. Their portfolio will be complemented by a vast array of other providers, including from the sectors of CAD/CAM systems, precision tools or coatings. The local industry association, the Wirtschaftsverband Industrieller Unternehmen Baden e.V. will be active at this trade fair, as a regional services association, to promote the networking of regional companies.

"For the processing industry, the exchange of ideas about new developments and intelligent solutions in an international context is a decisive success factor", explains Fabienne Valambras, Event Manager of SÜDTEC. "In the globalized world of business, new ideas arise all the time and innovative processes get implemented. At SÜDTEC, processing businesses from the region can inform themselves and can exchange ideas with other leading specialists. This meeting with the manufacturers is proving increasingly attractive to providers from around the globe, a fact ably demonstrated by the already high number of registrations from international exhibitors."

From 3 to 5 June, SÜDTEC will once again be the platform for suppliers and the processing industry in southern Germany. In Hall 3 at the Stuttgart trade fair centre, the organizer is expecting up to 120 exhibitors on a surface area of 5000 m2. At the same time, MEDTEC Europe 2014 will be taking place, the showcase event for medical product suppliers at the Stuttgart trade fair centre. Here, up to 900 providers from around the globe will be exhibiting their innovations for the development and manufacture of modern medical products.

About SÜDTEC

Since 2009, SÜDTEC has been an important trade fair for regional suppliers from South Germany. On an annual basis, regio-



nal and international exhibitors showcase their products from the sectors of plastics production and processing, metal processing and machining, design and construction services as well as IT services and research. From 3 – 5 June, this year's SÜDTEC will be held in Hall 3 on the premises of the Stuttgart trade fair centre. Parallel to this, MEDTEC Europe, the largest European trade fair for medical products, will also be being held. Visitors can use their ticket to visit both trade fairs at no additional cost. This also helps to promote cross-fertilization between the general manufacturing industry and the medical products sector.

SÜDTEC is organized on an annual basis by UBM Canon, a company based in London. The leading organizer of trade fairs and a publisher of print and online publications for the international manufacturing industry, employs about 5500 people worldwide.

UBM Canon SE1 9UY London Vereinigtes Königreich Großbritannien und Nordirland



Greater efficiency and process stability thanks to intelligence for surface technology as a standard feature

SONOPOWER DIGITAL 3S

The new SONOPOWER DIGITAL 3S is Weber Ultrasonics' response to stricter requirements in the field of surface technology in terms of both process stability and profitability. The 3 kW ultrasonic generator has a whole host of innovative features and a control system based on a 32-bit processor architecture that lends it intelligence. This intelligence enables it to automatically make numerous settings, which in turn provides greater stability and reliability, while maintaining maximum performance and efficiency. The device is supplied ready-to-connect and is available with the frequencies 25 kHz and 40 kHz.

Efficient and stable processes that guarantee consistent results are a key prerequisite for profitability and competitiveness in the fields of industrial component cleaning and electroplating. Weber Ultrasonics, one of the world's leading manufacturers of ultrasonic components, has reacted to these requirements and designed the all-new SO-NOPOWER DIGITAL 3S. The 3 kW ultrasonic generator is equipped with various innovative features. It is controlled via a modern 32-bit processor architecture, similar to the kind used in smartphones. The SONOPO-WER DIGITAL 3S is fully digital and excels through its exemplary ease-of-use. Even under difficult operating conditions, it secures maximum process stability and performance. Employing the frequencies of 25 kHz and 40 kHz, which are frequently used in the fields of component cleaning and electroplating, it is suitable for a broad range of applications.

Automatic settings and adjustments

Thanks to the new Weber SONOSCAN, the generator automatically determines and sets its operating frequency. This is already performed before any ultrasonic output and thus increases the process reliability for cleaning and electroplating applications. The continuous monitoring and automatic adjustment of the frequency also ensures that the system always uses the optimum output, even when operating conditions change - for example in the case of temperature fluctuations, when switching over from cleaning to rinsing medium, or when replacing a transducer. Thanks to this new technology, the generator also detects whether a transducer system is connected at all. This prevents damage to the generator due to "dry running".

Of course, conventional generators are also capable of detecting when they get too hot. However, they then simply switch off, which leads to an interruption in the process and requires manual intervention. The new SONOPOWER DIGITAL 3S is quite different in this regard, as it independently adapts its fan speed in accordance with the prevailing situation. The parts can then continue to be treated with no loss of performance/quality and without the generator overheating.

In addition to this, the SONOPOWER DIGITAL 3S is capable of independently de-

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tecting the mains voltage and then adapting to this – and not only during installation. It continuously measures the mains voltage and reacts promptly to any overvoltage or undervoltage, as well as to voltage fluctuations. This also contributes to consistent quality of the cleaning or electroplating process.

Programmed for the future

On the SONOPOWER DIGITAL 3S, the sweep function and the power output can each be individually adjusted in 1% steps, allowing users to set up various modes exactly as they wish and integrate these into parts-specific treatment programmes. This in turn allows easy adjustment of the ultrasonic treatment to various or varying ranges of parts. At the same time, the new 32-bit processor architecture makes it possible to further extend the intelligence of the generator, thereby offering flexibility for resolving future tasks.

The new power section of the SONOPO-WER DIGITAL 3S also makes a valuable contribution in this regard, as its output stage is twice as powerful as those used in previous generators. This offers high power reserves for greater safety and reliability, in particular when handling tasks for which previous generators were forced to operate at their limits. Not least thanks to Weber SONOSCAN, it is also more tolerant with regard to transducer systems and supply lines. As such, the generator reacts less critically to differences in transducer systems caused by material tolerances, ageing or wear.

Another plus point of the new 3 kW generator is its IEC-compliant PLC interface. This makes it fully compatible with the programmable logic controllers (PLCs) typically used in the field of automation. The optimum communication between the generator and the PLC that results from this not only simplifies commissioning, but also any potential troubleshooting.

Attractive price-performance

Using the latest technology and innovative modules not only lends the new SONO-POWER DIGITAL 3S exemplary intelligence, it also renders many components that were previously required to operate ultrasonic generators superfluous. This ensures the same, unparalleled price-performance that the generator itself offers.

Weber Ultrasonics will be presenting the innovative SONOPOWER DIGITAL 3S at Stand C14 / D13 in Hall 5 at the parts2clean fair in Stuttgart which takes place from 24 - 26 June 2014.

Weber Ultrasonics GmbH D 76307 Karlsbad-Ittersbach



Thanks to its use of innovative equipment, the new SONOPOWER DIGITAL 3S provides increased process reliability for ultrasonic applications in the field of industrial component cleaning and electroplating, and impresses both through its maximum output and ease-of-use.

Bürkert develops pneumatic technology for high-precision dosing

Every drop counts

The tasks involved in industrial process dosing are very diverse, but they all have one thing in common: high precision requirements. These requirements have to be fulfilled regardless of environmental influences. Bürkert now presents a new pneumatic system as a compact solution for this purpose.

Bürkert's patented pneumatic dosing system for fluids can be used in all applications that require dosing of defined sample quantities with maximum repeatable accuracy. Examples of dosing applications include vaccines, chemicals in industrial washing machines, flavourings in the beverage industry, pharmaceutical raw materials and dosing tasks in filling machines. The high precision is made possible by the use of pneumatics. The dosing system is actuated by means of pressure and vacuum, which provide substantially more power than conventional actuating systems. This power makes it possible to control the defined dosing quantity with a precision of ± 2 %, largely independent of temperature and viscosity. The size of the dosing chamber defines the dosing volume per stroke. It can be between 150 and 750 µl.

Few components, many possibilities

The system, which features a high level of flexibility and numerous options for adaptation, consists of a controller and an exchangeable dosing chamber, which can either be attached to the controller or positioned freely. The dosing chamber consists of two media-contacting components, a plastic housing and a separating membrane. The use of high-quality materials such as PEEK and FKM or FFKM also makes it possible to convey very aggressive media. The chamber is self-priming and easy to flush. The controller supplies the membrane above the chambers alternately with either pressure or vacuum. This conveys a pre-defined quantity of media through the dosing chamber. Media can be conveyed in both directions. This makes the recovery of expensive media, for example, as well as mixing processes possible. Due to the separation of the controller and dosing chamber it is easy to replace the chamber. For single-use applications the dosing chambers are made of inexpensive materials. Depending on requirement, the are also available in sterile versions.

The controller of the pneumatic dosing system contains the on/off valves and the electronics. The system requires external compressed air. In the case of unpressurised media, vacuum must also be supplied. On request, the controller is also available with a completely integrated pressure and vacuum supply.

Bürkert Fluid Control Systems D 74653 Ingelfingen



In the pneumatic dosing system the size of the dosing chamber – between 150 and 750 µl – determines the dosing volume per stroke.

Engel med.con 2014 six times in Europe

Engel continues successful medical conference series

Uncompromising cleanliness, maximum product safety, economic efficiency – Engel med. con 2014 provides answers to current and future challenges in medical technology. Between June and November, Engel invites to the medical conference at six venues in Europe. The programme includes specialist lectures, expert panel discussions, live demonstrations, a partner fair, as well as manifold networking opportunities.

Since the first Engel med.con four years ago, the medical conference has become an integral part of the injection moulding machine manufacturer's event calendar. Worldwide it is among the Engel events that attract the largest attendance. "The Engel med.con has established itself as a kind of networking event for plastics manufacturers in the field of medical technology," explains Christoph Lhota, Head of the Business Unit Medical at Engel in Schwertberg. "Our customers and partners use this platform to exchange ideas and to keep informed about current trends and strategies, as well as innovative products and methods. Participants often tell us that many of these ideas can be implemented straightaway."

Process integration reduces cost per unit

Process integration and peak performance – this year Engel med.con focuses on these two topics with two live exhibits. Engel will produce drip chambers for transfusions with an integrated filter on an Engel e-victory 160 combi injection moulding machine with an integrated Engel easix multi-axis robot in a single work step. The highly developed manufacturing process, which was developed by Engel in cooperation with Hack Formenbau, celebrated its world performance at K 2013. Engel med.con now offers the opportunity to analyse the efficiency potential of the new method in detail. "We expect this process to revolutionise the production of multi-component hollow bodies with or without inlay," states Lhota. "Starting with plastic granulate and the prefabricated filters, we receive ready-to-use drip chambers within 12 seconds. In the past, several independent work steps and at least two machines were necessary for this." The exhibit further demonstrates how process integration reduces the risk of contamination in medical technology. At Engel med.con, the energy-optimised, tie-bar-less hybrid machine will be presented in its clean room design.

Scale-up with maximum reliability

In a second highly-automated manufacturing cell, needle holders for pens will be produced on an all-electric Engel e-motion 160 injection moulding machine. Together with partner companies, Braunform and Hekuma, Engel demonstrates how cavity numbers can be increased also in medical technology without risking process stability and component quality.

The process for manufacturing of needle holders is hard to beat when it comes to process reliability. The cores of the 96-ca-



Engel med.con offers not only specialised information, but also plenty of networking opportunities. (Photo: Engel)

vity-mould have a diameter of just 0.3 mm, but the manufacturing cell still works with a cycle time of about 4 seconds. To counter deformation of cores effectively, the premium version of the electric injection unit is equipped with a direct drive, which allows for dynamic injection movements and an injection time of up to 500 mm/s. If, however, there is a problem with a manufactured part, the camera-based monitoring system immediately picks up on this. Thanks to cavity-specific handling, reject parts are automatically separated and the injection mould can carry on producing without deactivating the cavity.

Engel has consistently adapted the machine series Engel e-motion to the meet requirements of high-performance applications in regulated manufacturing areas also when used with high-clamping forces. "The increasing cost pressure leads to the use of larger and larger multi-cavity moulds," says Christoph Lhota. "The injection moulding machines employed in medical technology applications therefore constantly increase in size."

Specialist lectures, partner fair, and room for networking

During the specialist lectures, experts from Engel as well as from partner companies and the processing industry will delve into the topics of safety, precision, and efficiency. They will discuss current challenges, success factors, and market opportunities and will also draw upon their own experience.

At the partner fair, companies from the fields of mould manufacturing, automation, peripheral units, raw materials, and clean room technology will show their know-how.

At the end of the event, Engel will invite all participants to an evening soiree with buffet and entertainment. "It is important to us that Engel med.con participants have a chance to talk," says Christoph Lhota. "The key to success in medical technology lies in cooperative partnerships between the companies along the value added chain. Over the past years, Engel med.con has inspired many new joint ventures."

Engel med.con 2014:

- Stuttgart/Germany, June 2
- Lyon/France, June 18
- Hannover/Germany, September
- Mirandola/Italy, September 17 and 18
- Copenhagen/Denmark, November
- Warwick/Great Britain, November

Further details and registration: medical@engel.at

ENGEL AUSTRIA GmbH A 4311 Schwertberg

Toshiba and SanDisk Sign Memorandum of Understanding

Toshiba to Replace Fab Z at Yokkaichi Japan for Transition to 3D NAND Technology

Toshiba Corporation (Tokyo: 6502) announced in May 2014 that it will demolish the No. 2 semiconductor fabrication facility (Fab 2) at Yokkaichi Operations, the company's NAND Flash memory plant in Mie prefecture, Japan, and replace it with a new fab on the same site. Toshiba also entered into a non-binding memorandum of understanding with SanDisk Corporation (NASDAQ: SNDK) to invest jointly in the new facility. The primary purpose of the new wafer fab is to secure space for converting existing Toshiba and SanDisk 2D NAND capacity to 3D NAND beginning in 2016.

Demolition work on the current Fab 2 will start in May with construction beginning in September 2014, with a target completion date of Summer 2015. The clean room within the new fab will be built in phases to align the clean room investment with the timing of conversion of 2D NAND capacity to 3D NAND. Construction of the initial cleanroom will be complete in time for 2016 output. Decisions on capacity conversion ramp and equipment investment, the start of production, and production levels in the new fab will reflect market trends.

The new fab will provide a supplementary facility for processes mainly dedicated to 3D NAND memory production, and work in close cooperation with Yokkaichi's other facilities. Toshiba and SanDisk will support 3D memory production with leading-edge ma-



Artist's impression of the new fab, Yokkaichi Operations.

nufacturing equipment for lithography, deposition and etching through joint ventures.

Yasuo Naruke, Corporate Senior Vice President of Toshiba Corporation and President and CEO of Semiconductor & Storage Products Company, said, "Our determination to develop advanced technologies underlines our commitment to respond to continued demand of NAND flash memory. We are confident that our joint venture with SanDisk will allow us to produce cost competitive next generation memories at Yokkaichi. "

Sanjay Mehrotra, President and Chief Executive Officer of SanDisk, said: "We are pleased to continue our long-standing collaboration with Toshiba in this new wafer fab, which will advance our leadership in memory technology into the 3D NAND era."

The new fab will have a quake absorbing structure and an environmentally friendly design that includes LED lighting throughout the building. It will also be equipped with the latest energy saving manufacturing equipment, which will secure productivity advances while lowering power consumption. Highly efficient use of waste heat will help to lower fuel consumption and cut CO2 emissions by 15% compared to Fab 5, currently the most advanced fab on the Yokkaichi site.

Toshiba and SanDisk will, through joint ventures, maximize investment efficiency in the transition to 3D NAND by making full use of the Yokkaichi site. Going forward, the companies will continue to jointly develop advanced process technology, and make investments to meet market requirements.

About SanDisk

SanDisk Corporation (NASDAQ: SNDK), a Fortune 500 and S&P 500 company, is a global leader in flash storage solutions. For more than 25 years, SanDisk has expanded the possibilities of storage, providing trusted and innovative products that have transformed the electronics industry. Today, SanDisk's quality, state-of-the-art solutions are at the heart of many of the world's largest data centers, and embedded in advanced smart phones, tablets and PCs. SanDisk's consumer products are available at hundreds of thousands of retail stores worldwide. For more information, visit www.sandisk.com.

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