



Life Sciences















MT-Messtechnik











## 'Cleanzone Campus'

Expanding cleanroom knowledge through research

23rd - 24th Oct. 2018: CLEANZONE 2018, Frankfurt am Main (D)

Universities and research institutes are drivers of innovation for industry – particularly in the highly dynamic field of cleanroom technology. Their findings give rise to new approaches, offer solutions to current problems and lay the foundation for future products and processes. With Cleanzone Campus at the Cleanzone trade fair on 23 and 24 October 2018 in Frankfurt am Main, Messe Frankfurt has created a platform where research institutes in the field of cleanroom technology can present their projects.

Ruth Lorenz, Vice President Technology at Messe Frankfurt, explains: "We initiated Cleanzone Campus as a way of highlighting the key role that research plays in driving innovation and securing the future viability of cleanroom technology. As an international and interdisciplinary event, Cleanzone is the platform that brings together everyone in the fields of science and research in one place." Universities present their projects not only as a way of sharing their findings and information, but also to make it clear just how important and necessary it is to foster exchange between research and industry. The list of institutions that have already signed on includes Albstadt-Sigmaringen University, Fraunhofer Institute for Manufacturing Engineering and Automation (IPA), Hermann-Rietschel-Institut (HRI) at the Technical University of Berlin, and OTH - Technical University of Applied Sciences, Amberg-Weiden.

#### Standardising the preparation of cleaning textiles

Albstadt-Sigmaringen University will be utilising Cleanzone Campus to present their current project from the field of cleaning and hygiene technology. The concept is to establish round robin tests as a means of standardising procedures for the preparation of cleaning textiles (e.g. wiping cloths and covers etc.). Another project addresses the potential offered by technical cleanroom systems for food processing. They will also be showcasing the possibilities presented by collaborations between universities and industry and anchoring the field of cleanrooms in the curricula of life sciences faculties.

#### Cleanliness and hygiene in the field of medical technology

Cleanroom technology is an important part of both instruction and research at OTH Amberg-Weiden, and that is why the university will be taking advantage of the opportunity offered by Cleanzone Campus to present its industry projects in the fields of cleanliness and hygiene. The university also operates an ISO class 7 cleanroom at the Weiden campus. Here, students in the medical technology faculty (bachelor's and master's) are given the chance to familiarise themselves with cleanroom technology on both a theoretical and practical level.

#### Mobile cleanroom tent and IT communication tool

Two innovations - a mobile and flexible cleanroom tent, and the 'FlexNote' IT communication tool - will be the focus of attention for the Fraunhofer Institute for Manufacturing Engineering and Automation (IPA). This year marks the first time that the Fraunhofer Institute will be providing a detailed presentation of the creation phase for a cleanroom at Cleanzone: It will be spotlighting the entire process, from the initial concept to the first drawings and construction of the prototype all the way to the final product. With FlexNote, Fraunhofer IPA has developed a mobile application that represents a significant step towards paperless cleanrooms and further reducing the sources of contamination. With the help of this mobile application, it is possible to quickly record various necessary observations or document pending tasks - resulting in targeted distribution and transparent tracking.

### Projects focusing on cleanrooms, operating theatres and special isolation wards

The primary focus of research at the Hermann-Riet-schel-Institut is cleanroom hygiene. In particular, the institute works to develop concepts for rooms with special protection requirements that make it possible to keep concentrations of chemically, physically or biologically active aerosols as low as necessary. Furthermore, experimental and numeric studies are undertaken to investigate the dispersal and sedimentation behaviour of particles in enclosed spaces. At Cleanzone, HRI will be presenting the findings from their most recent projects concerning cleanrooms, operating theatres and special isolation wards.

### **clean**zone

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## Lab Innovations returns to the NEC on 31 October to 1 November 2018

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#### Save the date for the UK's only lab-dedicated exhibition showcase

Lab Innovations, the UK's only trade show dedicated to the laboratory industry, returns to the NEC, Birmingham, on 31 October & 1 November 2018. Free-to-attend and supported by some of the UK's top scientific institutions, Lab Innovations is the nation's largest gathering of laboratory professionals, growing year on year, with almost a third more attendees in 2017. As well as an exhibition of products and services, visitors can also benefit from learning and business opportunities, with 98% recommending Lab Innovations as a "must attend" event.

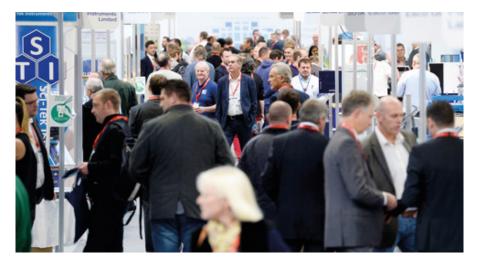
Covering a broad spectrum of industries, including the life sciences, pharmaceuticals, petrochemicals, materials science, food and drink, visitors can see the latest product innovations and services from companies such as: Perkin Elmer, SLS, VWR, Eppendorf, Shimadzu and Thermo Fisher Scientific.

Attendees will also be able to learn more about applications and hot topics in science. The Royal Society of Chemistry will again be hosting another fascinating lecture series in its dedicated theatre, and UK magazine Laboratory News will be organising the presentations in the "Insights and Innovations" theatre sponsored by Perkin Elmer. With over 35 hours of seminars and conferences on a broad range of the latest industry topics, everyone will have the opportunity to attend at least some of these talks.

New to 2018, an area dedicated to the "Sustainable Laboratory" will highlight environmentally-friendly products and examples of sustainable initiatives in the lab. Other new features include a "Cleanroom Pavilion" - focusing on cleanroom technology – the "Lab News Village" - dedicated to exhibitors not seen at previous shows - and a pavilion for SLS, the UK's largest independent supplier of laboratory equipment, chemicals and consumables.

Bethany McNamara, Lab Analyst at Sainsbury's, commented on her successful visit to last year's Lab Innovations: "Being from a small lab, our needs are quite niche and specific, so it was great that there was such a vast array of things to see and so many new technologies. It's given us some great ideas to take back..."

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Dear subscribers,

finding good specialists may sometimes be Sisyphean work. But it can also be difficult to get a job that fits one's own wishes and ideas. Cleanroom online wishes to improve the flow of information in the field of human resources. To do so, together with Jobware, we have optimized the search for cleanroom jobs. With one click on "Personalanzeigen" at cleanroom-online.com you will immediately have access to current job offers. Enterprises, which have to offer jobs, can publish these with Jobware and these offers will be presented optimally on cleanroom-online.com.

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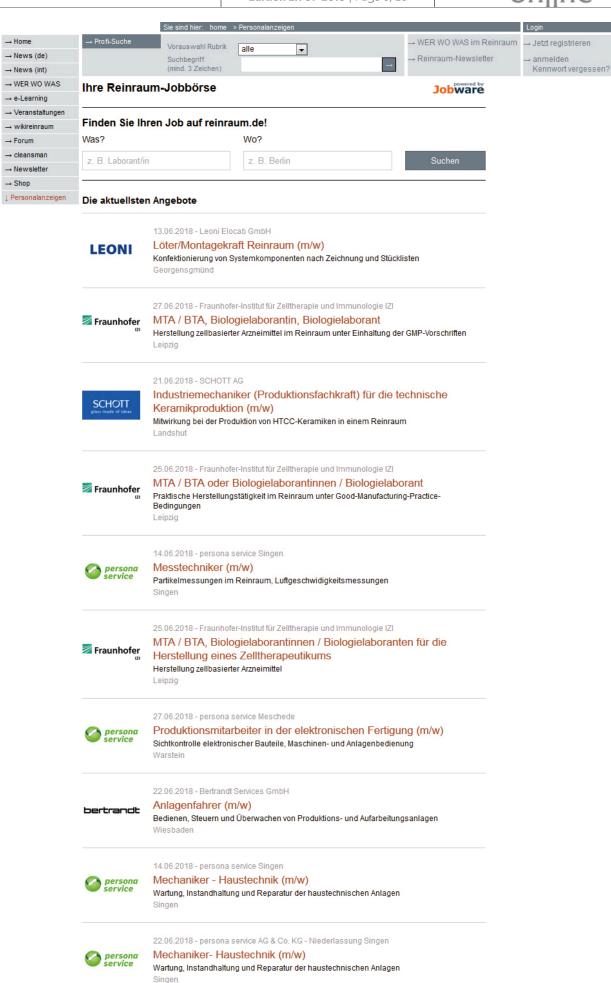
Otherwise, there are many novelties, several of which were presented at ACHEMA. We wish you many more nice summer days.



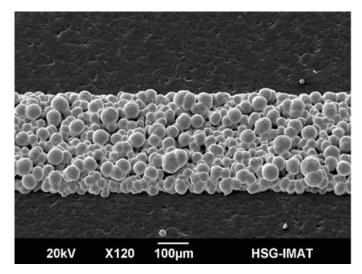
#### **NEWSLETTER**

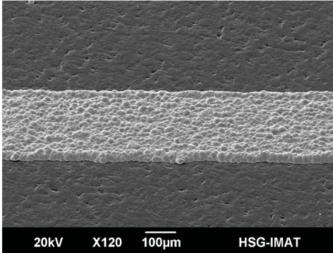
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Compared with common cleaning methods, such as ultrasonic or high-pressure washing processes, the quattroclean system has the advantage of smoothing rough laser structures at the same time (right). (Photo: HSG-IMAT)

## Cleaning with CO2 snow in a dry and residue-free process

#### Meeting growing cleanliness demands reliably and cost-effectively

Trends such as electromobility, lightweight engineering, miniaturization and Industrie 4.0 have given rise to new challenges in the field of industrial parts cleaning. With its quattroClean system, acp offers a solution capable of performing a wide range of cleaning tasks reliably, reproducibly and cost-effectively. In addition, the dry, residue-free and environmentally-neutral cleaning technology can be adapted to individual requirements, is highly compact, easy to automate and simple to integrate into production lines, Industrie 4.0 manufacturing systems and cleanrooms.

Whether it is the automotive or supplier industry, precision or micro engineering, medical technology, mechatronics, electronics or other industrial sector, current trends are changing requirements concerning parts cleaning. This also includes an increasing number of smaller and more complex parts and components. Shorter product life cycles, lower product volumes right down to the manufacture of single parts, the use of new materials and material combinations, for example for lightweight engineering applications, and new or modified production processes. Electromobility, autonomous driving and manufacturing environments designed



The CO2 snow jet technology selectively dry-cleans specific areas of components without leaving any residues, for example before or after laser-welding processes. (Photo: acp - advanced clean production)

for Industrie 4.0 are further developments which are influencing parts cleaning. There are cases where material combinations or surface structures are unsuitable for wet-chemical cleaning, or only certain areas of components need a specific degree of cleanliness, such as bonding, welding or sealing surfaces, or cleaning steps are performed on assembled components.

#### Scalable cleaning solution with CO2 snow

This is where the reliable and cost-effective snow jet technology from acp – advanced clean production GmbH comes into its own. The scalable cleaning system can be easily adapted to diverse component geometries to clean selective areas or whole components.

This environmentally-neutral technology uses liquid carbon dioxide as a cleaning medium which, as opposed to dry ice, is gained as a by-product from chemical processes and the generation of energy from biomass. It has an almost indefinite shelf-life and is supplied in cylinders or tanks.

#### Dry, residue-free and selective cleaning process

Liquid CO2 is guided through the non-wearing two-component ring nozzle of the acp system and expands on exiting to form fine CO2 crystals. These are then bundled by a circular jacketed jet of compressed air and accelerated to supersonic speed. The patented technology ensures uniform cleaning results - even on large surfaces where several nozzles are used.

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#### cleanroom onjine

#### Cleaning with CO2 snow in a dry and residue-free process

The jet of snow and compressed air has a temperature of minus 78.5°C and can be focused exactly where it is needed. When it impacts on the surface to be cleaned, a combination of thermal, mechanical, sublimation and solvent effects take place. These four cleaning mechanisms enable the quattroClean system to remove filmic contamination, such as residues of cooling lubricants, process oils, polishing pastes, separating agents and silicons, as well as particulate contamination, for example chips, dust and abrasion. Since the cleaning step with the non-combustible, non-corrosive and non-toxic CO2 snow is also gentle on materials, even delicate and finely-structured surfaces can be treated.

The aerodynamic force of the jet transports the detached dirt away. This is then extracted from the cleaning cell together with the sublimated CO2 in a gaseous state. The workpieces are dry on completion of the cleaning process, enabling them to be further processed or packaged straightaway.

#### Cleaning solution suitable for a wide range of products

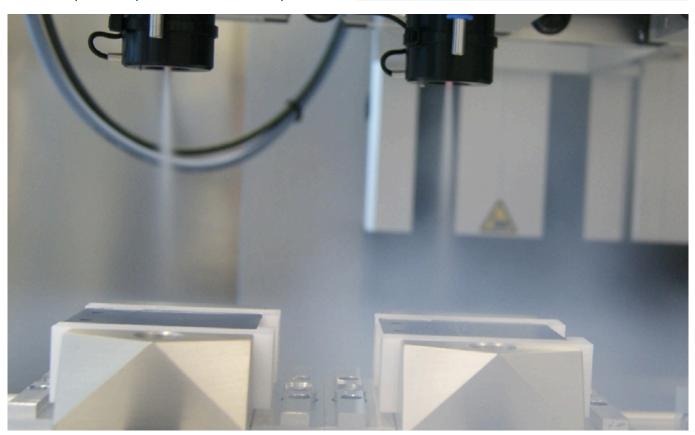
The quattroClean snow jet technology has proved to be effective in numerous applications in various branches of industry. For example, the cleaning system has been in use for several years now to remove ablation residues from injection-molded interconnect devices (MID) produced by means of laser direct structuring. Compared with common cleaning methods, such as ultrasonic or high-pressure washing processes, the quattroClean system has the advantage that the rough laser structures are smoothed at the same time, thus simplifying joining and assembly tasks. Laser residues also need to be removed when manufacturing batteries. Residues from laser processing cells, which could cause shorting, are removed selectively and reliably. A manufacturer of sensor systems uses

the snow jet technology from acp to clean off particles before sensors liable to damage are packaged. For this application, a hermetically-sealed cleaning cell was developed, which is integrated into a clean zone and fitted with a filter fan unit to supply clean air. The quattroClean system is also used in an inline application to clean engine pistons before their surfaces are optically measured. The parts are cleaned by a robot. The system works in the production system's one-piece flow and is capable of cleaning 11 cm2/sec. When it comes to die-cutting, an almost manual system removes production residues from strips immediately after cutting. This single-part cleaning step replaces the commonly-used wet-chemical cleaning process.

#### Compact, easy to automate and targeted control

Thanks to its modular design, the compact quattroClean system from acp is easy to adapt to specific customer requirements. This allows manual, partially-automated and even fully-automated cleaning systems to be developed and integrated into existing production, assembly and packaging lines. Cleaning tests are conducted at the acp technical center to accurately determine all the process parameters for the application concerned, such as volume flows for compressed air and carbon dioxide, as well as the duration of the jet. Material properties and the type of contamination requiring removal are also accounted for. These parameters can be filed as cleaning programs in the system control. Depending on the task at hand, systems for cleanroom use can be realized with their own local cleanroom system, including a specially-adapted extraction system.

acp – advanced clean production GmbH D 71254 Ditzingen



A jet of CO2 snow removes particles in a dry and gentle process after laser direct structuring MIDs. (Photo: acp - advanced clean production)

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cleanroom onjine

Gerresheimer expands production of pharmaceutical plastic packaging in Brazil

Gerresheimer produces plastic primary packaging at its production site in Anápolis (Goiás, Brazil)

Gerresheimer, the leading manufacturer of specialist packaging for drugs, is further ex-panding its strong presence on the South American market. The new Gerresheimer Anápolis plant has commenced production in the Bra-zilian state of Goiás in order to secure and support the continued strong growth.

"We are delighted about the strong demand for our plastic packaging in South America and with the additional plant we will be able to further expand our presence and support our customers's, "says Jens Friis, Vice President Europe & Latin America, adding that Gerresheimer's customers include both national and international companies.

Ten years ago, in 2008, Gerresheimer acquired Allplas, adding Vedat three years later. The company has thus steadily consolidated its position as Brazil's market leader with some strategically astute acquisitions.

"We're in a position to provide our customers with customized plastic packaging solutions. for their products," says Wellington Lentini, General Manager Brazil, detailing Gerresheimer's offering. However, its standard range of dropper bottles of various sizes, droppers, caps, vials for individual doses with corresponding caps, PET bottles, and closures for plastic and glass bottles also boasts a wide range of uses.

In future, Gerresheimer Anápolis will produce the entire range of plastic containers from PP, PE, and PET, along with the corresponding closures and caps. The produts will also be assembled and decorated in the plant providing customers with a complete concept solution.

The newly built plant will initially operate over 3,200 square meters and will be equipped with 30 machines during the course of 2018. The plan is to extend further to 20,000 square meters by 2021. Just like all the other Gerresheimer plants, the new one will be certified to ISO 9001 too. The requisite audit will be held in June.

#### Gerresheimer in Latin America

With its new plant, Gerresheimer has a presence in two Brazilian states. Alongside Goiás, Gerresheimer is also represented in the São Paulo region, where three plants (Butantã, Cotia, and Embu) provide the full range of pharmaceutical primary packaging made from plastic. The company also has another factory in Argentina (Buenos Aires). Gerresheimer produces insulin pens for South America in Indaiatuba, some 100 km north of São Paulo, and manufactures pharmaceutical ampoules and vials from glass in Querétaro, Mexico.

Gerresheimer AG D 40468 Düsseldorf



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## Chemicals Management

#### Handling with Confidence from A-Z

Heightened consumer awareness, industry initiatives such as ZDHC (Zero Discharge of Hazardous Chemicals) or the Greenpeace Detox campaign: they all pose new challenges for brands, retailers and manufacturers. The OEKO-TEX® Association together with Hohenstein as one of its founding members has developed a comprehensive product portfolio to provide everyone involved in the textile value creation chain with the best possible security and conformity regarding the use of chemicals. This provides transparent testing and certification systems, which build on and go hand-inhand with one another.

The aim of the OEKO-TEX® product family is not only the fulfilment of currently required standards and limit values, but also the efficient path towards this — individually for each company. Four OEKO-TEX® modules are available with this aim in mind:

- ECO PASSPORT by OEKO-TEX®: Independent testing and certification for textile chemicals, colourants and finishing agents.
- DETOX TO ZERO by OEKO-TEX®: A status report to evaluate established chemicals management and waste water and sludge quality, with the aim of compliance with the Greenpeace Detox campaign.
- STeP by OEKO-TEX®: Independent certification of production facilities with holistic analysis and evaluation of all relevant areas such as environmental management, environmental performance, social responsibility, chemicals and quality management, as well as occupational health and safety.
- STANDARD 100 by OEKO-TEX®: An independent certification system and label for textiles and accessories at any production level, tested for harmful substances.

From input of the raw material through production and output to brands and consumers: all channels can be seamlessly evaluated. With OEKO-TEX® and Hohenstein as a partner, every company can find its system solution.

#### **Using Tested Chemicals**

ECO PASSPORT by OEKO-TEX® tests chemicals, dyes and auxiliaries for harmful substances and environmental parameters. All limit values for ECO PASSPORT meet or exceed the requirements of the current ZDHC MRSL. A three-stage verification process evaluates whether chemicals are suitable for environmentally-friendly

production processes and use in textiles according to STANDARD 100 by OEKO TEX®. The certification process includes comparison with the OEKO-TEX® RSL and MRSL, conducting analytical laboratory tests for possible contaminations and an on-site verification. During the company visit, Hohenstein looks at both environmental management and the product responsibility measures. ECO PASS-PORT is closely linked to the STeP and STANDARD 100 OEKO-TEX® certification systems.

Providers of textile chemicals can enter their ECO PASSPORT certified products in the OEKO-TEX® Buying Guide, free of charge. Textile manufacturers use the Buying Guide to find and source system-compliant chemicals. Certification by Hohenstein protects confidential product data while simultaneously facilitating the transparency required by the market.

#### **Implementing Detox Objectives**

DETOX TO ZERO by OEKO-TEX® enables textile companies to check the status of their chemicals management and the quality of their waste water and sludge, and to use independent verification to provide credible documentation for external stakeholders. DETOX TO ZERO provides an annual status report that lists the chemicals used and assesses the handling of waste and waste water (with comprehensive MRSL screening, for example), as well as environmental protection measures. DETOX TO ZERO provides production facilities and their customers with a tool for continuous improvement, to reduce the amounts of harmful substances in the production process. The status report shows those companies that have pledged to meet the Detox objective by 2020 exactly where they stand regarding handling of chemicals along with specific suggestions for further implementation of the Detox objectives.

#### Safeguarding with Output Control

Product certification in accordance with STANDARD 100 by OEKO-TEX® helps companies stay ahead of worldwide legal regulations and industry and consumer demands. Annex 6 for the Standard contains tighter criteria and limit values, which have been specifically developed for companies that seriously intend to meet the Detox campaign targets.

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# Shrinking lot sizes and enormous volumes of data create opportunities for the pharmaceutical industry

Small lot sizes, reliable containment. The fact that these things are on the pharmaceutical industry's wish list is nothing new, but the growth of personalized medicine and high-potency drugs increases the sense of urgency. A number of exhibitors in "pharmaceutical and packaging Halls" 1 and 3 at ACHEMA have taken aim at these needs and offer efficient solutions which support the trend towards personalized medicine. Some companies are also positioning themselves as Industry 4.0 pioneers in areas such as services and software or simply by beginning to add an IT integration dimension to systems engineering and machinery manufacturing.

Growth in the pharmaceutical market remains modest. BPI reported that turnover worldwide was up 3.6% year-on-year in 2016. Growth rates were as high as 10% during the 1990's, but those days are gone for most pharmaceutical companies. Dieter Weinand, head of pharmaceuticals at Bayer, gave the keynote speech at the Handelsblatt pharmaceutical conference in Berlin in February 2018. During his talk, he stressed the need for the industry to "take a critical look at its business models and embrace new paradigms". Competition, often in the form of generics and biosimilars, continues to intensify, and the inevitable consequence is greater price pressure. More and more, yesterday's patent-protected blockbusters are being replaced by medication for individualized therapy.

These trends have an impact on the systems and machinery needed for production. More individualized medication, particularly for serious disease such as cancer, often goes hand in hand with biotechnologically produced, high-potency drugs and a very demanding requirements profile for the filling and packaging solutions. Increasing cost pressure, which is the second trend, primarily affects medication for the mass market. The response to this problem is solutions which make production more cost efficient. For years, packaging system manufacturers have taken the proven approach of increasing the level of automation and reducing manual intervention by the user. Another option, which has not been fully exploited by many users, is to significantly increase availability, ideally by enhancing overall equipment effectiveness (OEE). Among other things, that means less maintenance. When such work is necessary, then ideally with the aid of innovative, predictive maintenance strategies. In the future, the power of digitalization will help make production more efficient over the life cycle by reducing energy consumption or providing capabilities such as predictive maintenance and self-adaptation in response to process deviations without intervention by the operators.

Of course answers also have to be found for existing challenges. Counterfeit protection, serialization and traceability are still significant challenges for pharmaceutical product packaging. "Local and international laws are a major factor in serialization," reported Davide Brancaleoni, Packaging Segment Leader EMEA at Rockwell Automation. There is market demand for both integrated and open serialization solutions. On top of that, personalized medicine crea-

tes new challenges. "Each and every product must be filled and packaged correctly and associated with the correct data record which contains the batch and production history."

#### Living cells in mini batches

Personalized medicine does not necessarily mean lot sizes of one. However, "the same treatment plan fits all" approach will play a less important role in the years ahead. Small to very small lot sizes for specific doses of a particular medication are already a necessity for some types of treatment in combination with state-of-the-art diagnostics including gene diagnostics. Stratified medicine, where for example tumor patients are divided into subgroups which respond, or do not respond, to a specific active ingredient is also part of the picture. This leads to therapy targeted at individual patients who are given the best medication in what for them is the most effective dose. The medication is often based on living cells. That naturally places stringent demands on the filling operation. The most suitable type of packaging such as vials or syringes made of plastic or glass, which does not cause problems during storage (possibly in liquid nitrogen), handling and administration, must be selected. In most cases, large shear forces must be avoided during filling of ATMPs (Advanced Therapy Medicinal Products) which are used in new forms of therapy.

All of the processes needed for that are currently available, claimed Dirk Bauernfeind, Product Manager at the Romaco Group: "We can already deliver the format flexibility and special packaging sizes which the industry needs. For one of our reference customers in Northern Ireland, we have developed an innovative packaging solution for orphan drugs." He explained that the packaging has a special feature, namely the inclusion of a desiccant in the individual blister cavities. For many pharmaceutical manufacturers, flexible filling and packaging solutions such as the Bosch MHD for aseptic filling of biopharmaceuticals are the preferred choice. With the aid of robotics, different types of packaging can be filled in the isolator. In response to the trend towards smaller and smaller batch sizes, Romaco offers a mid-range line for primary, secondary and tertiary packaging of pharmaceutical solids. "The line is highly flexible, and it is also very rugged and compact," reported Bauernfeind. He

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argues that the increased expectations for track & trace create the need for packaging designs which offer the same capacity but take up less space.

Gerhard Breu, who is head of the pharmaceutical business at Optima, said that the company will use robotics technology to meet the need for greater flexibility. It is his expectation that "life cycles will become much more dynamic and that new production variants and containers will be frequently added to the portfolios. In response, he intends to market systems with exceptional format flexibility to handle very small lot sizes. Optima will present a suitable solution at ACHEMA featuring multi-use design for variable filling of vials, syringes and cartridges. The system is based on an adjustable transport system which eliminates the need for format sets. Manufacturers of high-cost active ingredients such as ATMPs will undoubtedly welcome solutions which reduce product wastage, for example by using short tubing, 100% process control and post-dosing on demand.

Andreas Häußner, Marketing Director at the Rommelag Group, is also fully focused on the need to offer customers high flexibility and process reliability. ACHEMA visitors who are looking for flexible packaging solutions capable of producing very low quantities and very small batch sizes at an affordable cost and with built-in traceability should stop by the Rommelag booth. Häußner mentioned a "disposable filling system which we have already used in initial trials aimed at personalized medicine".

Bauernfeind pointed out that the importance of Industry 4.0 differs worldwide. In industrialized countries with high labor costs, Industry 4.0 will soon be very tangible, whereas in emerging markets it is something that is more likely to be relevant in the medium to long term. "Suppliers of packaging machines must be prepared for different scenarios," said Bauernfeind and he added: "There is no other way for us to offer solutions which meet actual needs."

#### Single-use containment minimizes validation costs

Containment systems and fill & finish are inextricably linked. They protect the operator from high-potency products and vice versa. Single use strategies are also a very effective way of preventing cross-contamination. Pilot solutions which combine containment and single-use design were on display at ACHEMA 2015. In 2018, additional suppliers will exhibit systems which have reached an advanced development stage. However Bauernfeind advised caution: "What is needed is close cooperation with pharmaceutical manufacturers to ensure that the systems are tailored to customer needs without costly over-engineering". He cites continuous manufacturing as a way of protecting machine operators from high-potency substances.

Pharmaceutical machinery manufacturers should also provide risk analysis advice to customers.

Rommelag's Flecotec system is a bit out of the ordinary. All sampling, weighing, filling and decanting processes can continue as normal. They are literally wrapped up with the aid of a single-use containment system. The entire system is then disposed of. "Our solution is to intelligently package the existing process, so there is no need for re-validation," explained Häußner.

Bosch takes a different approach, namely washable containment. It is used in a capsule filler for small batches. Product changeover can be done quickly. The manufacturer promises short cleaning times and low water consumption. The machine makes it easy to handle high-potency solid dosage forms. Some market researchers predict double-digit annual growth for HPAPIs (High Potency Active Pharmaceutical Ingredients) over the next five years. For this market segment, Fette Compacting offers reliable containment solutions and Containment Guard, a quality certificate based on a test process which complies with SMEPAC (Standardized Measurement for Equipment Particulate Airborne Concentrations) guidelines. It documents the OEB level of the containment tableting systems and makes set up easier for customers. They can select the right containment system with greater confidence and reduce the risk of installing a solution which is inadequate or too expensive.

There is also room for innovation in standard isolator technology. Metall+Plastic, which is part of the Optima Group, will exhibit a sterility testing isolator (STISO) which was unveiled for the first time at Interphex in the middle of April 2018. The Stiso is very user-friendly, and the decontamination process has very short cycle times. This is achieved through catalytic air circulation and a special decontamination system which distributes hydrogen peroxide very quickly in droplets that are much smaller than on conventional nebulization systems.

#### Individual services and Industry 4.0

Gerhard Breu from Optima emphasized that customer-specific solutions are the be-all and end-all for the pharmaceutical sector. Last year, the Group presented an end-to-end strate-gy for services in each phase of the lifecycle, and the strategy is equally suitable for the pharmaceutical business. Factory Acceptance Tests with simulation and start-up support, re-qualification following upgrades, calibration services and comprehensive maintenance services are just some examples from the Total Care portfolio. Optima's goal is very similar to what Bosch intends to deliver with its after-sales services. "Throughout the entire machine lifecycle, we help our customers improve overall equipment effectiveness (OEE) and reduce downtime," reported Uwe Harbauer, head of pharmaceutical products at Bosch.

This goes hand in hand with a high degree of transparency in production, which is one of the features which Bosch plans to deliver with its Industry 4.0 solutions. In the future, live information services will supply all of the data which customers need to monitor machine states and process parameters. Browser-based software captures, stores and visualizes machine data and helps analyze the information to improve system availability.

Davide Brancaleoni, a packaging expert at Rockwell, reiterated that the basic framework must be in place which enables access to all of the pertinent data: "It is vitally important for companies to build up convergent IT infrastructures which support system connectivity and data transfer." Many automation system suppliers can now meet this need, ideally with industry-specific solutions. Rockwell Automation, for example, offers modules from its FactoryTalk portfolio such as Pharmasuite MES and Factory Talk Historian to log data and highlight trends and changes. Brancaleoni argues that correct use of the data forms the backbone of track & trace solutions. "In that respect, Industry 4.0 plays a vital role in phar-maceutical production." Rockwell solutions create the link between production technology and the IT and enterprise systems.

Suppliers of filling and packaging systems must also show that they have the necessary expertise in data networking, data integrity and cyber security. This is especially the case with filling and **Edition EN 07-2018** | Page 9/26



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packaging lines for large pharmaceutical corporations. To an increasing extent, the systems must be integrated into the overall corporate IT ecosystem, for example MES and Historian systems. Integration solutions with real potential which pave the way to big data, data analytics and Industry 4.0 already exist, and there are even some initial projects. Breu from Optima remains vague, but he is convinced of one thing: "None of this will happen without integrated digitalization. Digitalization will be indispensable for managing the production process of the future." Suppliers of phar-

maceutical filling and packaging systems will not be able to put any solutions on display at this year's ACHEMA. However pharmaceutical manufacturers who are willing to embrace new paradigms and align their business models with Industry 4.0 should not hesitate to make inquiries.

DECHEMA Ausstellungs-GmbH D 60486 Frankfurt am Main

## Collaboration between KRÜSS and LINSEIS for high-temperature contact angles

- Combined wetting and thermal expansion measurements for metallurgy, energy recovery and high-temperature coating
- Precise temperature control, high-quality image recording and analysis as well as and comprehensive documentation of the measurement

Collaboration between two specialists: KRÜSS GmbH, global market leader in the field of contact angle measurement, and LINSEIS, as experts in thermal analyses, have established a new cooperative venture. With immediate effect, the two owner-managed family companies will be following a common path in the field of high-temperature contact angle measurement.

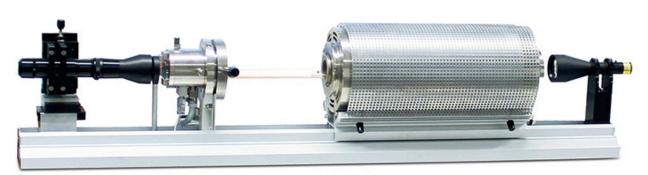
High-temperature contact angle measurements are of interest, for example, in energy recovery with mineral fuels, for investigating slag for blast furnaces or in the production of robust enamel coatings. With such coatings in particular, synergies can be utilized by combining the contact angle method and dilatometry. Wetting between carrier material and coating is just as important for their stability as the thermal expansion of the different phases.

Concentration will be on the marketing of the Drop Shape Analyzer – DSA High Temperature for analyses at up to 1550, 1700 or 2000°C. The instrument, which is also capable of measuring thermal expansion and deformation, provides everything needed for accurate wetting analyses at high temperatures with the help of the contact angle. This includes precise and stable target temperatures, the accurate control of temperature ramps, the simple introduction

of samples as well as contactless optical measurement with high-resolution CCD camera and powerful image analysis software. Simultaneous measurements of the contact angle and thermal expansion along with the melting deformation are particularly meaningful thanks to the continuous recording of the entire measurement in a video image with documented temperature characteristic. The system is also extremely flexible in the choice of ambient conditions. Measurements can be carried out in air (oxidizing atmosphere) or equally under inert gas, in reducing atmosphere or in vacuum.

As a result of the collaboration, LINSEIS will benefit from KRÜSS' expertise and market knowledge in the field of wetting analysis, while KRÜSS will be able to call upon LINSEIS' expert knowledge in high-temperature analyses and extend its market presence to new industrial and research fields. Both companies will be represented at ACHEMA from 11 to 15 June in Frankfurt and will each be available as a point of contact for the link between contact angle measurement and dilatometry.

Krüss GmbH Wissenschaftliche Laborgeräte D 22453 Hamburg



## Bosch Packaging Technology with stable sales development in 2017

#### Prepared for the future

9

- Bosch Packaging Technology achieves sales of 1.3 billion euros
- Higher order volume from the pharmaceutical industry
- China, Middle East and Africa as growth drivers

Robert Bosch Packaging Technology GmbH reports a stable business development for the past fiscal year. With 1.3 billion euros and 6,300 associates, the most important corporate figures of 2017 were



Uwe Harbauer: Uwe Harbauer is member of the managing board of Robert Bosch Packaging Technology GmbH as well as head of business unit pharma. (Picture: Bosch)

on a par with the previous year's level, as Uwe Harbauer, managing director of the Bosch subsidiary, announced at Achema 2018, the leading global trade show for the processing industry. A higher order volume was achieved in the pharmaceutical sector. "The market is continuing to develop positively, and we were able to win market shares in several segments," Harbauer, who is also head of the business unit pharma, explained. The company expects a good sales development for the pharma division in 2018. In comparison, the food business unit could not entirely match the results of the previous year. "We have introduced individual restructuring measures to concentrate our activities and optimize our competitiveness," Harbauer said.



Partner during the entire machine lifecycle: Bosch supports its pharmaceutical customers with comprehensive service and industry 4.0 know-how. (Picture: Bosch)

The developments in China are highly satisfactory for the business unit pharma: despite growing competition, Bosch was able to further expand business in the region. This is, amongst others, due to the establishment of an own organization in 2001, which today has nearly 350 employees. This way Bosch managed to build an extensive customer base at an early stage. Middle East and Africa also saw some forward-looking projects – both in equipping new manufacturing facilities and in expanding existing ones. The order intake was doubled compared to the previous year.

#### Partner during the entire machine lifecycle

Bosch supports its pharmaceutical customers in fulfilling the high demands regarding safety, speed, flexibility, sustainability and competitiveness. "We rely on our strength of understanding and accompanying the entire lifecycle of a customer's product," Harbauer explained. "There is more to it than delivering excellent equipment or complete systems. We also support our customers in the planning and development phases, and are at their side during start-up and operations, as well as maintenance and modernizations." To do so, Bosch combines its expertise in mechanical engineering and pharmaceuticals with comprehensive service and software know-how.

#### Higher transparency thanks to Industry 4.0

Industry 4.0 solutions account for an important part of the overall portfolio. They can be seamlessly combined with single machines, lines or other services. For instance, Bosch shows how the machine data from the new processing system SVP and the

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## cleanroom

#### Bosch Packaging Technology with stable sales development in 2017

ALF filling machine is harmonized in a single system and enables optimum production planning. The new Pharma i 4.0 Starter Edition ensures higher production transparency by storing, visualizing and analyzing machine conditions, process parameters, availability and events.



Xelum R&D: At Achema 2018, Bosch Packaging Technology introduces its latest R&D device for the continuous production of oral solid dosage (OSD) forms. (Picture: Bosch)

#### Safety for processes, products and operators

Safety is also at the heart of all Bosch solutions. The new capsule filling machine GKF 720, for example, provides for highly safe handling of toxic products thanks to its washable containment. The new freeze



Bosch freeze dryer: Before (left) and after lyophilization (right): the new Bosch freeze dryer makes sure that thermolabile, liquid pharmaceuticals are reliably stabilized.

dryer makes sure that thermolabile pharmaceuticals are reliably stabilized. "At Achema, visitors can expect numerous further exciting developments. They all have one goal in common: to facilitate efficient, productive and safe processes, which lead to a fast time-to-market of their products," Harbauer said.



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## **Interface Agrees to Acquire Nora Systems**

## Acquisition of Rubber Flooring Leader Will Expand Interface's Resilient Flooring Portfolio, Extend Reach into the Performance Flooring Category, and Is Expected to Accelerate Growth.

Interface, Inc. (Nasdaq: TILE), a leading global commercial flooring company and worldwide leader in sustainability, today announced it has signed a definitive agreement to acquire nora systems in a stock purchase transaction valued at approximately \$420 million. Nora, a global leader in performance flooring and worldwide share leader in the rubber flooring category, is a privately held company that is majority owned by investment firm Intermediate Capital Group (ICG). Nora's annual revenues are approximately \$280 million. Interface expects to close the transaction during the third quarter of 2018, subject to regulatory approvals and other customary closing conditions.

This acquisition will expand Interface's rapidly growing resilient flooring portfolio and increase its penetration into high growth segments including healthcare, life sciences, education and transportation. Nora is the leader in the nearly \$1 billion rubber flooring category of the \$34 billion global commercial flooring industry. Rubber flooring is ideal for applications that require hygienic, safe flooring with strong

chemical resistance, and it is extremely durable compared to other flooring alternatives. Nora is considered the leading premium brand and has built a specified selling organization that provides reach into approximately 80 countries around the world.

"We believe our value creation strategy is working in the marketplace as we better serve our customers with an expanded product portfolio and an enhanced selling system. Customers want a single flooring solution provider that can deliver a range of options that meet their requirements in different commercial applications. The nora acquisition is expected to accelerate our growth strategy by expanding our product portfolio and extending our reach in the performance flooring category of resilient flooring," said Jay Gould, CEO of Interface. "More importantly, we believe the nora team has put the right focus on design, sustainability, and performance of their products, which aligns with Interface's brand, purpose, and values. We are excited to combine the nora team with the Interface family so that together we can continue to create value for our key stakeholders including our customers, employees, investors, and the environment."

The nora acquisition, when completed, is expected to be accretive to Interface's margins and adjusted earnings per share. Nora is anticipated to increase the company's adjusted EPS, a non-GAAP measure, \$0.03 to \$0.06 in 2018, and \$0.15 to \$0.20 in

Bank of America has committed to finance the transaction through a term loan facility. "We will expand our net debt leverage ratio to approximately 3x EBITDA at closing, and our goal is to decrease that ratio to 2x EBITDA by mid-2020," said Bruce Hausmann, CFO of Interface.



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#### cleanroom onjine

## FINAT Awards: Schreiner MediPharm and Schreiner ProTech Each Win Recognition for Two Developments

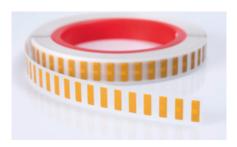
#### **Jury Recognizes four Products from Schreiner Group**

Several entries submitted by the Schreiner Group high-tech company convinced the FINAT judging panel this year: The Schreiner MediPharm and Schreiner ProTech business units each received two awards for their developments for the pharmaceutical and engineering-based industries respectively. The accolades were presented on the occasion of the European Label Forum in Dublin in early June. For nearly two decades, Schreiner Group with its innovative solutions has been among the annual award winners of the FINAT Label Competition, an international competition of the European association for the self-adhesive label industry (FINAT).

"Receiving awards for four products is a sensational success for our two business units Schreiner MediPharm and Schreiner ProTech, and tremendous confirmation of our continuous striving for innovation. Without the dedication and focused commitment of our employees these awards would not have been achievable. That is why my sincere appreciation goes to everyone involved in this success," says Roland Schreiner, President and CEO of Schreiner Group.

### Schreiner MediPharm: FINAT Award for Incontinence Sensor and Functional Label

First place in the "Innovation & Electronic Printing" category went to Schreiner



Chip protection film: The award-winning protective film prevents small sensors on microchips being damaged by solder splash during the solder bath and reflow process.



Incontinence sensor: The delicate conductive lines measure and document moisture and wetness due to incontinence.

MediPharm's newly developed incontinence sensor. Extremely delicate and highly flexible printed conductive lines are attached to the inside of adult diapers, thus enabling moisture due to incontinence to be indicated and tracked. The analysis of the data captured this way assists nursing homes and hospitals in providing the best possible care to patients and optimizing the related processes.

In the "Pharmaceutical Products" category, the Pharma-Comb functional label with ten detachable label parts came out on top. It simplifies documentation and tracing of medications in the patient's medical records. The label features a sophisticated multi-layer design and is suitable even for medicine containers with small radii. It offers ample space for product information, while the detachable labels may be supplemented with handwritten information as needed. Convenient starter tabs facilitate peeling off the label parts even with gloves.

### Schreiner ProTech: Chip Protection Film and CLF with Fingerprint Effect

As the best product in the "Innovation"



CLF with fingerprint effect: Lumogens partially embedded in the label's adhesive, for instance in the form of a logo, migrate into vehicle paint. An unauthorized attempt to remove the label can be proven under UV light. Wird das Label unbefugt entfernt, lässt sich dies unter UV-Licht nachweisen.

category the FINAT judging panel recognized Schreiner ProTech's Color Laser Film, a label for tamper-proof vehicle identification featuring a fingerprint effect. Embedded in the label's adhesive are lumogens—for instance in the form of a logo or word trademark—that migrate into a vehicle's coat of paint. Illegal removal of the label from a vehicle can be proven under UV light.

First place in the "Security" category went to a protective film for microchips on printed circuit boards. It prevents damage to the small sensors by solder splash during the solder bath or reflow process. The protective film resists short-term exposure to temperatures of 260° C and can be non-residually removed after the reflow process.

Schreiner MediPharm D 85764 Oberschleissheim



Pharma-Comb label: The innovative functional label features a sophisticated two-layer label construction.

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## Multifunctional dosing system for combining natural fibres with polymers

The University of Rosenheim has built a system – a pilot plant unique across the whole of Germany – for developing climate and resource-friendly procedures and materials for automotive applications, timber construction and furniture manufacture as well as a wide range of other applications. The aim of this investment project is to combine the advantages of wood fibres with those of polymers in order to develop technologically innovative products made of natural fibre-polymer composites and to develop appropriate manufacturing technologies for producing the same.

### MUNACU – an inter-faculty research collaboration

The interfaculty research collaboration project "MUNACU - Multifunctional Natural Fibre & Synthetics Composites" was sparked by an announcement by the Federal Ministry of Education and Research (BMBF). This announcement detailed the fact that the BMBF is offering help to uni-

versities of applied science seeking to expand their research profile or a research focus through investment projects with the acquisition and application of research equipment through its "FHInvest" funding initiative.

"Initially, we were going to combine classical wood processing methods with proven and efficient one-shot injection moulding technology", explained Peter Karlinger, professor at Rosenheim University, about the project's origins. Karlinger's specialist area is injection moulding and he conducts research in the area of injection moulding process technology, lightweight construction and clean room technology. Karlinger designed the "Multifunctional lightweight construction using raw or natural materials, with an emphasis on renewable fibres" project together with his colleagues Dr.-Ing. Michael Schemme, who specialises in fibre composites, and Dr. Andreas Michanickl from the faculty of wood technology and construction.



In designing the pilot system, the researchers pursued an integrated concept that simultaneously meets the objectives expressed by the superordinate principle of "from the raw material to the fibres and the final component". This means that the system is correspondingly complex and comprises a number of components that are located in different departments:

- Refining system inside the university's Wood Materials & Engineering Laboratory for producing specific natural fibres
- DCIM direct compounding injection moulder in the Polymer Processing Centre
- Gravimetric synchronous dosing and blending station with four dosing modules for supplying the compounder
- Vertical clamping unit that can simultaneously be used as a stamping press
- Additional injection moulding unit (bolton unit)
- IMC injection moulding compounder with a continuous gravimetric dosing system
- Six-axis robot, experimental tools and test equipment

### Material preparation and processing using DCIM technology



The modular dosing system comes with four different dosing modules and can be quickly and easily adapted for feeding granulate, micro granulate, powder, grinding stock and liquids and various dosing tasks. (Image: motan-colortronic)

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## cleanroom

#### **Multifunctional dosing system**

ding (DCIM), the raw material is both prepared for processing and then moulded in a single production step.

This is achieved by employing a single-screw compounding extruder that continuously feeds material to a standard plasticizing and injection moulding machine. The tip of the extruder is fitted with a switch valve for controlling the material feed to the plasticizing and injection moulding machine. There is no need for a melt reservoir; and the injection process itself is not changed.

Directly processing material at a uniform temperature has both technical as well as economic advantages. This includes better material quality thanks to the fact that the material is not put under any significant thermal or mechanical stress (lower shear stress). This process also, for example, makes it possible to gently and uniformly integrate longer fibres, which is very important when working with natural fibres. Forgoing the production of a semi-finished product also saves costs and energy. The DCIM technology was jointly developed by KraussMaffei, Motan-Colortronic and the compound developer Exipnos.

### Quadruple Labline dosing system – Precision component dosing

The compounding extruder is supplied with material by a Graviplus-series gravimetric synchronous dosing and blending station from Motan-Colortronic, Germany.

Graviplus-series gravimetric synchronous dosing and blending station with four Labline dosing modules, one of which can be automatically supplied with material by a Metro conveying unit, while the other three have to be manually filled. (Image: motan-colortronic)

The dosing system features four Labline dosing modules. One of these dosing modules can be automatically filled with material by a METRO conveyor, while the other three are designed to be filled manually. The dosing modules are equipped with dosing screws that are suitable for materials with a range of different flow properties (free flowing, average and poorly flowing). One of the dosing units has been retrofitted with a twin dosing module.

The dosing system is modular and can be quickly and easily adapted to a range of different dosing tasks, which makes it perfect for use in the planned research project. The different modules include modules for dosing granulate, micro granulate, powder, grinding stock and liquids. The dosing system also includes dosing modules with twin screws and mixers for dosing materials that do not flow easily or not at all.

The Graviplus uses the differential weighing method, which is also known as Joss-in-weight' feeding. This is because loss-in-weight feeding is significantly more accurate than batch dosing as demonstrated by dosing tests conducted during a previous project. This aspect is particularly important when working with materials that are difficult to feed. The fact that the material is fed directly to the compounding extruder also means that it is near impossible for material to separate, which, in addition to the required level of dosing accuracy, was another reason for choosing a continuous gravimetric dosing system.



The dosing system is controlled by a Gravinet GP control unit, which is operated using a menu displayed on a 12.1 (Picture: Motan-Colortronic)

During operation, the control unit compares the actual with the specified nominal throughput rate, which means that deviations are instantly identified. These deviations are then compensated for using the dosing modules' feed speed. The material is continuously and synchronously fed into the storage container, where it is mixed to form a homogeneous blend that is then fed into the compounder's material feed. This process ensures that the material does not separate.

Thanks to the fact that the material flow is constantly monitored and controlled on the basis of its weight, bulk density fluctuations, particle size differences or changes in flow behaviour only have a marginal affect on the differential system's dosing accuracy. This aspect is also an important factor for the research project that is going to be conducted in Rosenheim, because dosing and conveying natural fibres is considered a serious challenge.

The dosing system is controlled by a Gravinet GP control unit, which is operated using a menu displayed on a 12.1" TFT touch screen. The control unit displays messages and alarms in plain text.

"Apart from needing a system with a high level of dosing accuracy and that would allow us to reproduce results, we also needed one that is easy to use. With this system, changing the test set-up and the material only takes a few minutes" explained Karlinger.

#### **Research aims**

The technologies now available to us in wood and polymer materials processing allow us to research a wide range of different material and process technologies. This research is primarily aimed at investigating and developing new materials and lightweight construction methods that will allow us to produce components from natural fibres in a more resource-friendly and cost effective way, and such that they are suitable for a wide range of applications. The researchers are also planning to conduct comparative tests with the DCIM and classical parallel double screw extruders with reference to the IMC injection compounder, which is also equipped with a Motan-Colortronic continuous gravimetric dosing system.

motan-colortronic gmbh D 61381 Friedrichsdorf **Edition EN 07-2018** | Page 15/26

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## Screwdriving and feeding technology from a single source

Effective system solutions for reliable assembly

– Standardised modular components build the perfect ensemble

Production downtime, assembly errors, product recalls – Who is not eager to avoid these horror scenarios for industrial series production. Contamination, defect parts or faulty screw joints are all examples of small issues creating major problems. Significant financial damages and loss of reputation lead to dramatic consequences which can be avoided if the utmost reliability is guaranteed.

Industrial screwdriving and feeding assembly systems are composed of a variety of complex components, the sound interplay of which, is of decisive relevance for the reliability and productivity of the unit as a whole. In order to avoid interfacing issues between screw feeding and the screwdriving tool, DEPRAG SCHULZ GmbH from Amberg, Germany, provides a wide spectrum of requisite system components from a single source. With over 40 years of experience, the standardised modular design of their components enables wide-ranging and versatile combination options with fast delivery times which ensure the perfect ensemble.

As well as ergonomic handheld screwdrivers for manual application, the DE-PRAG portfolio also comprises stationary screwdriving tools for easy integration into automated PLC-driven systems. EC-servo technic tools can be used for maximum flexibility. Integrated sensor controlled

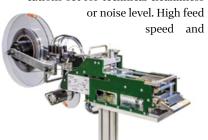




torque and angle measurement enables precise control and regulation of the screw tightening procedure. The freely programmable applications allow a consistently high degree of flexibility. Furthermore, the comprehensive documentation and evaluation options for the processing parameters, guarantee the highest precision and security of processing sequences. The brushless EC-motors play an essential role in ensuring maintenance-free operation. Depending on the application area, EC-motors can be supplied with torque measurement based on power consumption as well as pneumatic screwdrivers. All screwdrivers are available in straight design, in angular design for restricted environments or pistol grip design for horizontal use. A torque range of between 0.008 Nm and 500 Nm can be achieved subject to tool and application requirement. Even difficult to reach positions can be accessed for screw assembly using the DEPRAG Feed Module DFM, which provides screwdriver vacuum hold for screws or nuts until processing begins.

The selection of the most suitable screwdriving technology is the first step on the way to optimised screw assembly. Smooth functioning feeding technology is vital for high system reliability, productivity and the efficiency of manual work stations.

DEPRAG has a range of feeding technologies available depending on the specifications set for technical cleanliness





high production quantities can be realised using vibratory spiral feeders (also called oscillating conveyers). In a vibratory bowl, the feed product is set into motion by targeted vibrations so that each fastener is propelled up the spiral and fed into the separator system. Incorrectly positioned elements fall back into the bowl. In their "eacy feed" vibratory feeder, DEPRAG have developed a modern generation, sustainable, innovative feeding system. Thanks to the 24 V oscillatory magnets, power consumption is significantly reduced, resulting in an energy saving of around 80 percent. Furthermore, "eacy feed" is Industry 4.0 capable and due to the 24-volt technology, can be operated smoothly and safely worldwide, even with a poor mains power supply. The vibratory bowls, available in fill sizes 0.15 l, 0.75 l, 1.2 l and 2.5 l, can be loaded with a variety of feed products, such as screws, nuts, O-rings and other fasteners.

Segment or sword feeders are used when feed parts need to be handled particularly gently, quietly and with low abrasion. The feed products are lifted out of a storage container by a pivoting segmented rail and slide into the separator by gravity. This feed system is particularly suitable for applications which must conform to high technical cleanliness specifications. The use of hardened wear-resistant materials as well as specific coating procedures ensure the consistently high quality and efficiency of the DEPRAG sword feeders. The standard machines can be used to process screw sizes from M2 to M6. Sword feeders are ideal for screws up to 25 mm in length and balls of a diameter of 1 to 12 mm.

Linear conveyors are an optional link between the feeder and screwdriving tool. They function in the same way as vibratory spiral feeders with mini pulsing movements and can be used to span wide distances within assembly systems, supply part buffers or split the material stream. Because the linear conveyor supplies parts much more quickly than the feeder provides them, a gripper can for example, be used to safely and simply pick up the fastening elements. There is no chance of a backlog of parts in

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#### Screwdriving and feeding technology from a single source

the feed bowl and there is no pressure accumulation when sorting parts in the feed bowl.

Fasteners are primarily fed to the screwdriving tool for processing via a feed hose from the feeding system. It is however, sometimes not possible to feed screws with a very short shaft, rivets with a large collar diameter or parts with particularly complex external geometry by feed hose. In this case the best option is the Pick-and-Place procedure in which the screws are "picked" using vacuum, gripper or magnet system. After each fastener is removed, the next part is automatically prepared.

Integrated refill and storage systems, such as the classic hopper, supply parts to the feeder securely and optimally throughout the entire process. A fill level sensor signals when the volume has fallen below the pre-set minimum fill capacity of the vibratory feeder or sword feeder and prompts the conveyor to supply a refill. A constant low fill level enables gentle handling of feed products with long refill intervals. Furthermore, the hopper can be simply integrated and flexibly utilised for the most varied of products without the need for modification.

Single or double-sided adhesive com-

ponents such as seal rings can be supplied for processing on tape reel feeders. Components are fed on a tape and then removed from the tape by a blade. A combination of highly precise sensors and fast fixation ensures that the DEPRAG tape reel feeders attain exact positioning of parts with high repeatability.

In many branches technical cleanliness is increasing in relevance and becoming an important quality specification in the entire process chain. Equally, in the production of electronics, the reduction of dirt particles is particularly vital and consequently feeding must be particularly gentle. DEPRAG has met this challenge by designing a universal concept, also for use in cleanrooms: the CleanFeed concept. It is based on specifically designed Clean-Feed components, developed and produced in-house by DEPRAG. They range from specially adapted feeding technology and expressly designed screwdriving function modules for underfloor screw assemblies, to particle suction by the "particle killer". These fulfil the requirements for technical cleanliness: avoid, reduce and remove particles - throughout the entire screwdriving assembly process.

The extensive DEPRAG product and service portfolio can provide components for every requirement enabling flexible and reliable assembly. Beginning with the inquiry and project work, DEPRAG customers receive comprehensive technical support and guidance with outstanding engineering work throughout the entire system design process. A great variety of tried and tested standard modules can be called on for the layout of the assembly system. All screwdriving automation components such as screwdrivers, feeders, controller and process monitoring equipment have been developed to be perfectly coordinated with one another and have proven themselves over many years. One of DEPRAG's core competencies is the realisation of customer-specific requirements. Top quality is assured by a continuous test before delivery. The customer receives comprehensive documentation relating to the commissioning and operation of the system. If servicing is required, all wear parts are available with very short delivery times.

DEPRAG SCHULZ GMBH u. CO. D 92224 Amberg

## GEMÜ strengthens its industrial business and acquires new sales markets

When we think about GEMÜ, we often – justifiably so – have a picture in mind: Aseptic stainless steel diaphragm valves. The family-owned enterprise from Baden-Württemberg in Germany has enjoyed a prominent position as market leader in sterile applications for the pharmaceutical and biotechnology industries for many years. GEMÜ is very much at the cutting edge of these sectors worldwide. However, the manufacturer's expertise in valves, measurement and control systems goes far beyond this.

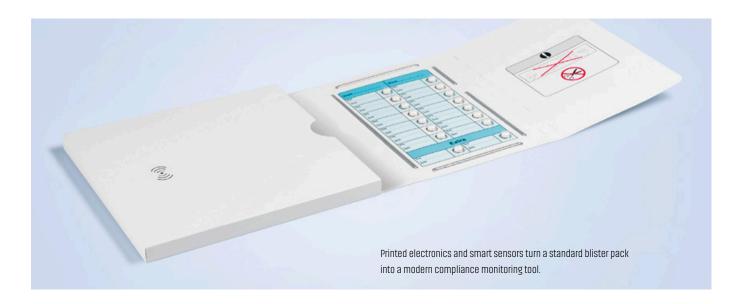
Plastic valves are inextricably linked with GEMÜ. One of the first valves was made from PVC and has proven to be extremely resistant for over 50 years. Even if the robust range of products, comprising butterfly valves, ball valves as well as globe and diaphragm valves, was rarely at the forefront, it was always there in the background: GEMÜ products have been working reliably in the broad industrial market too for decades – all around the globe.

With an advanced, international growth strategy and associated goal to acquire new sales markets in the area of industrial applications, GEMÜ has therefore undergone organisational restructuring. "Our orientation in the market – starting with sales, but also covering product advice right through to product management – has in the past not been sufficiently focused on the industrial market. However, this has now changed," explains Joachim Brien, Head of the Industry Business Unit. "Since 2017, we have been pooling our

strengths into one business area in order to be able to better meet our customers' various requirements. By interlinking our sales activities with the specialists from the application and engineering areas, we are creating a competence centre for customer-orientated valves and controls solutions."

But what does this mean specifically? If we want to offer genuine advantages, we need to put ourselves in the customer's situation. Only in this way can we offer application-specific, integrated solutions. This is why an international team of 100 engineers and developers, design engineers, product managers and sales employees are working closely together in the Industry Business Unit and specializing in new markets. Industrial water treatment, the chemical industry, surface finishing, mechanical engineering as well as power generation and environmental engineering are the key sectors in which GEMÜ will increase its attention in the medium and long term. All activities here revolve around professional project monitoring by specialists in technical advice and sales. The Industry Business Unit team knows both the markets and the requirements of the customers and uses this knowledge to lay the foundations for innovative, intelligent valve solutions.

GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG D 74653 Ingelfingen Edition EN 07-2018 | Page 17/26



## Schreiner MediPharm Develops Smart Blister Pack for Clinical Trial

#### **Digital Compliance Monitoring**

For a multinational pharmaceutical corporation, Schreiner MediPharm developed a smart blister pack for digital patient compliance monitoring to enhance medication adherence by clinical trial participants. Schreiner MediPharm implemented the smart packaging solution together with the Dutch technology company ECCT (Experts in Communications and Connectivity Technology). Employment of this electronic tool to manage and track processes during clinical trials marks a milestone for the pharmaceutical manufacturer.

Clinical trials are normally conducted on an international scale and require high accuracy, reliable workflow, efficiency, speed and flexibility. Conventional, non-automated processes are frequently error-prone. Medication adherence by participating patients, however, is a key factor for the successful outcome of clinical trials, but often difficult to track. For instance, based on a rule of thumb, 20 percent of patients do not adhere to the therapy. Accordingly, an increase of the patient population by 60 percent is necessary to compensate for the lack of clarity in the results.



Printed electronics and smart sensors turn a standard blister pack into a modern compliance monitoring tool.

To address these challenges, Schreiner MediPharm, in cooperation with ECCT and the pharmaceutical corporation, developed a smart packaging solution for patient compliance monitoring: Pressing a tablet out of the blister pack generates data in real time such as the type of medication, the time of extraction and the respective cavity. This information is automatically stored in the smart package and transmitted to a database via a smartphone app or reader. Compliance of the respective patient is thereby tracked. Additionally, it is possible to send the patient a reminder to take the medication, to adjust the dose and to assist trial participants with interactive communication between the physician and patient in the interest of medication adherence.

The smart packaging solution includes printed electronics without impacting the packaging design. A database platform enables diverse data transfers and analyses. Schreiner MediPharm supplies the required expertise in innovative printing technology and ECCT the smart sensors.

The utilization of the digital patient compliance monitoring tool significantly reduces the manual documentation for the pharmaceutical corporation. Complex therapies and trial processes can be adapted with greater flexibility, the delinquency rate due to proven non-compliance reduced and data quality optimized. In addition, the smart packaging solution can shorten the overall trial period and accelerate the approval process for new medicines.

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## In India, Gerresheimer produces bottles, vials, and ampoules in accordance with globally recognized standards

Gerresheimer's Indian plants produce glass vials, ampoules, and bottles that are specially designed for storage of high quality drugs. These are all examples of primary packaging, which means they come into direct contact with their contents. For pharmaceutical applications, they must therefore be manufactured in line with the stringent requirements of the relevant pharmacopeias. After all, the packaging must allow drugs to be stored safely until their use.

Gerresheimer has two plants at its site in the Indian city of Kosamba: The recently constructed Gerresheimer plant manufactures vials and ampoules for the pharmaceutical industry using tubular glass, while Neutral Glass makes moulded glass products for pharmaceutical applications and only very recently put a new high-performance furnace into operation.

### Quality from the outset: clean room control at the cold end

"The technical features of our new furnace for type I glass has significantly enhanced our quality levels to meet growing demands of pharmaceuticals worldwide," says Sachin Sule, Head of Sales & Marketing. Most importantly, he explains, the glass is considerably more uniform thanks to an improved electrical boosting control during processing. The state-of-the-art furnace has also a higher pull rate, he adds. To coincide with the construction and upgrade work on the new furnace, a clean room inspection area was also built at the cold end, complete with new camera inspection systems to guarantee a comprehensive ex-

amination of the finished products before "safe packing".

#### Various types of clear and amber moulded glass

Neutral Glass is set up to produce different types of glass at the same time. Here, for example, Gerresheimer manufactures clear and amber glass infusion and injection bottles from type I borosilicate glass. The company also produces type III glass containers for a large number of drugs. The production line at this factory is certified in accordance with DMF (Drug Master File) type III requirements.

### Tubular glass production in line with internationally recognized standards

"Our new plant in Kosamba produces ampoules and vials made from borosilicate glass to the same high quality standards as apply in Europe or the Americas," says Director Sales Saibal Sengupta. "All of our production and inspection processes are internationally standardized and certified." The new plant is certified in accordance with the following standards: ISO 9001:2015, US DMF Type III, Health Canada (DMF),

and ISO 15378. Gx Rhoc, the camera inspection system developed by Gerresheimer, ensures exceptional dimensional quality for vials. Several HD cameras detect every flaw.

#### Gx vials made from glass

Vials are amongst the world's most popular pharmaceutical packaging solutions and Gerresheimer produces versions in clear and amber glass that can hold between 1 and 50 ml. The range of tubular glass vials on offer in Asia includes clear and amber glass type I. All manner of different shapes are available, either with or without blowback and compliant with either international standards or the customer's own specifications.

#### Gx ampoules made from glass

Gerresheimer's wide range of high-quality pharmaceutical ampoules made from pharmaceutical glass type I includes ampoules made from clear and amber glass that can hold between 1 and 30 ml. Among these products are straight-stem, funnel-type, and closed ampoules that comply with the relevant ISO standards (types B, C, and D) with various break systems such as OPC (one point cut), CBR (color break ring), and score ring. Customer-specific requirements can also be implemented alongside the major ISO standards.

#### An end-to-end range

Gerresheimer's full global range encompasses all classes of glass used for pharmaceuticals – types II and III sodium silicate glass as well as type I borosilicate glass. This enables the company to supply the perfect glass packaging to suit drugs of any shape or size. Its extensive glass range means that appropriate packaging solutions can be found for even the most sensitive pharmaceuticals. With its Duma and Triveni brands, Gerresheimer also offers plastic containers in line with international requirements.



Gerresheimer has two plants at its site in the Indian city of Kosamba: The recently constructed Gerresheimer plant manufactures vials and ampoules for the pharmaceutical industry using tubular glass, while Neutral Glass makes moulded glass products for the pharmaceutical industry.

#### **NEWSLETTER**

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## **Pure safety**

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23rd. - 24th October 2018: CLEANZONE 2018, Frankfurt am Main (D)

Mikrobiologische Verunreinigungen stellen die hauptsächliche Herausforderung für Herstellungsprozesse in den Life-sciences dar. Biolumineszenzbasierte Verfahren könnten luftgetragene Keime in Zukunft schneller erfassen helfen – bis zum Echtzeit-Monitoring. Aber auch partikuläre Verunreinigungen erhalten aktuell eine größere Bedeutung. Einen Überblick gibt die Reinraummesse Cleanzone, Dienstag/Mittwoch, 23./24. Oktober 2018, in Frankfurt am Main.

In cleanrooms in the fields of medicine, pharmaceutical manufacturing and medical technology, it is necessary to satisfy a plethora of requirements, all depending on the particular circumstances. These can be 'ranked' as follows: Medical products are typically manufactured in an environment corresponding to cleanroom class D and then sterilised, while pharmaceuticals requiring subsequent sterilisation are produced in an environment corresponding to cleanroom class C. Sterile, aseptic filling requires cleanroom class A; and, in keeping with the 'onion principle', this area must be surrounded by a cleanroom of class B.

#### Two primary criteria for a clean environment

Every cleanroom system must be adapted to suit the specific process. It is possible to work with clean workbenches, for example. Here, the desired level of purity might be achieved through such measures as the horizontal or vertical laminar flow of filtered air, or one can work using gloves in an isolator, i.e. a hermetically sealed glove-box. In this case, ampoules can be filled in sterile production lines, or both can be combined to create an isolator with various filling modules.

The two cleanliness criteria are compliance with the maximum permissible particle concentration and the maximum permissible microorganism level, or more specifically, the number of colony-forming units (CFU). In the fields of medicine, pharmaceuticals and biotechnology, the latter value is significantly more important than it is in cleanrooms intended for the production of semiconductors, for example. The CFU value is generally determined by taking a sample and placing it in a culture medium (usually an agar plate). One the sample has been cultivated, the number of colony-building units is counted.

### Agar plates and fluorescence-assisted detection of airborne microorganisms

When it comes to identifying/quantifying airborne molecular contamination (AMC), microbial air samplers are a particularly useful tool. These samplers collect the bacteria and fungus found in the ambient air on filters or directly on agar plates. Even so, it can take as long as five days' cultivation before growth becomes visible on the plates (or plates cultivated from filters). A great deal can happen during this time, and it may even be necessary to dispose of entire batches. That is why a number of researchers have already developed processes that make it possible to immediately identify fluorescent molecules that could be indicative of the presence of micro-organisms.

Dr. Martin Klingmüller, Quality Manager at PNS GmbH, Melsungen and a specialist in the field of patient-specific parenteral nutrition, explains: "Today, there are systems that can identify cell wall components from bacteria and fungi in real time using florescence. However, these systems are still unable to distingu-

ish between viable and non-viable components, which means that they cannot take the place of the colonyforming unit counts mandated by regulations." In future, we expect realtime measurement methods to move ever closer to the capabilities required to satisfy pharmaceutical standards.

#### For heat-sensitive materials, transplants and grafts

Aseptic production is especially important for thermolabile substances (e.g. pharmaceutical agents) when is not possible to perform a final sterilisation using heat. This means that to prevent the entry of ambient micro-organisms, the environment in which manufacturing takes place must be practically free of micro-organisms, something that is achieved by the appropriate disinfection of the area, sterile tools and materials, and ventilating the area with air that has been filtered to the maximum possible degree (class A in accordance with EU-GMP).

Personalised medicine can result in even stricter requirements – it is one of the top themes of this year's Cleanzone. Autologous tissue transplants are one such area – an example from the field of tissue engineering can be summarised as follows: The patient's own cartilage cells are to be multiplied in the patient's own serum with the goal of creating cartilage cells that can be transplanted to replace tissue in the knee joint. The thermolabile transplant material is handled in an isolator corresponding to cleanroom class A. Thanks to a patented process, it is possible to carry out the glove change from the exterior room even while operations are ongoing – something that is also a major advantage in economic terms. Furthermore, this form of cartilage generation means that antibiotics and growth factors can be done away with entirely.



(Source: Messe Frankfurt/Sandra Gätke)

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## cleanroom online

#### **Pure safety**

### Particulate contamination increasingly important for point-of-care medical products

In addition to micro-biological contamination, particulate contamination is also becoming ever more important. Guido Kreck, Fraunhofer Institute for Manufacturing Engineering and Automation (IPA): "They are currently a major area of focus in the area of medical technology. If particles enter the bloodstream with an infusion, for example, they can cause thromboses." Furthermore, the currently valid version of DIN EN ISO 13485 now mandates that particulate contamination be controlled for sterile medical products. Kreck: "In recent years this has led to us receiving an increa-

sing number of enquiries here at IPA regarding how to deal with such requirements in actual practice."

Another example is offered by implants, including dental and hip implants. Their surfaces are roughened to facilitate adhesion to the bone, a process known as osseointegration. Thanks to the fact that there is close contact with human tissue at the interface between the implant and the bone, it is essential that the product does not have any microbiological, particulate, chemical or film impurities, such as residues of auxiliary substances.

As a result, when manufacturing medical products it is imperative that a suitable and practical cleanliness concept be established, and that this concept account for the production environment (cleanroom, conventional production etc.), cleaning, production process, personnel and logistics.

## The future belongs to real-time methods for determining micro-organism counts

Micro-organisms continue to pose new challenges for the cleanroom industry. Dr. Christian Raiss, Director of Testing Laboratory and Hospital Hygiene at the Hygiene-Institut AYSID GmbH, will be discussing the latest methods for determining micro-organism counts at the Cleanzone Conference 2018. He offers a preview of the topic here in our interview.

HDr. Raiss, you are the Director of Testing Laboratory and Hospital Hygiene at the Hygiene-Institut AYSID GmbH. What types of tests and requests do you deal with in your everyday work?

"For one thing, our institute plays an active role in measuring and monitoring hygiene on site in both cleanrooms and hospitals. Our institute is also affiliated with a microbiological testing laboratory accredited by DAkkS, Germany's national accreditation body. As the Director of Testing Laboratory and Hospital Hygiene, it is my re-



As the Director of Testing Laboratory and Hospital Hygiene, it is my responsibility to ensure that measurements and analyses of samples are performed in accordance with applicable standards and QM guidelines. (Dr. Christian Raiss, Director of Testing Laboratory and Hospital Hygiene at the Hygiene-Institut AYSID GmbH)

sponsibility to ensure that measurements and analyses of samples are performed in accordance with applicable standards and QM guidelines. I also provide expert consultation for planning and implementing construction projects in compliance with hygiene requirements."

#### What topics will you be addressing at the Cleanzone Conference?

"I'm always fascinated by the ways in which micro-organisms manage to find entry into even the cleanest areas – and actually survive there. Even NASA must find and combat extremely resilient, hygiene-resistant bacteria in their cleanrooms. Finding, identifying and eliminating these micro-organisms, be they bacteria or mould, is an exciting job, and one that always confronts me with new challenges. Among other things, I'll be taking advantage of Cleanzone to provide some tips on how companies can keep their cleanrooms sterile and combat contamination through

the application of custom hygiene management"

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What is it that fascinates you about cleanroom and hygiene technology? What innovations in the field of determining micro-organism counts and cleanroom technology do you expect to see within the next few years?

"I always work to ensure that I'm upto-date on the very latest technologies and processes, and I'm certain that real-time methods will be playing a major role in future. I'm fascinated by bio-microchips some of these are even suitable for on-site use in real-time, providing readings directly without any need to send samples into the lab. Thanks to the fact that I've worked on these chips myself, however, I also know that it will still be some time before these innovative tools can be manufactured for a reasonable price. I will be delving into these and other themes, such as new methods for determining micro-organism counts, in greater detail my presentation."

### cleanzone

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## cleanroom

## pacprocess India, indiapack and food pex India now open for registration

#### Large German presence planned – leading companies have already committed

Registration is now open for the interpack alliance trade fairs pacprocess India, food pex India and indiapack (organised by the Indian Institute of Packaging). All three trade fairs will be held at the Bombay Convention & Exhibition Centre (BCEC) in Mumbai from 24 to 26 October, supplemented by a parallel event, drink technology India, held by Messe München. The trade fair quartet, which celebrated a much acclaimed première in New Delhi last year, is set to alternate between New Delhi and Mumbai each year. The exhibiting companies responded extremely well to the concept of trade fairs supplementing one another from the packaging sector and the processing industry (i.e. the interpack alliance trade fairs) together with the areas of beverage technology, dairy and liquid food (i.e. drink technology India, held by Messe Munich).

The trade fair quartet has a leading role in this industry in India, covering the entire bandwidth of food, beverages, baked goods, confectionery and pharmaceuticals, cosmetics as well as non-food and industrial goods. In all, 212 exhibitors occupied around 11,000 square metres of exhibition space in New Delhi last year and attracted around 10,000 visitors to the exhibition centre, including a large number of decision-makers. Considerably higher numbers are now expected for the main venue of the trade fairs, Mumbai. The precursor of the current trade fair quartet in 2016 featured around 300 exhibitors and was attended by over 12,000 visitors.

In 2018 there will again be an official presence of the German Ministry for Economic Affairs and Energy, and several large companies have already registered, including SMC, Multivac and Bizerba. Exhibitors will benefit from numerous perks, including a reduced participation fee, a wide-ranging trade fair package, central meeting and hospitality facilities and special (on-site) support. The registration deadline for German companies wanting to participate is 23 July 2018.

Italian companies will also have a major presence in Mumbai. Several members of the association PROCESSING AND PACKA-GING THE HIGH-TECH ITALIAN WAY have already registered, including Cama, Ronchi, Clevertech and Makro Labelling. Moreover, an official Italian presence has been applied for, supported by the association UCIMA.

The Indian trade fair quartet is also attracting companies from the Far East, and exhibitors in 2018 will include a Chinese market leader, Hangzhou Youngsun Intelligent Equipment Co. A Chinese group stand is also being planned. Furthermore, this is the first year that an important Indian market leader will be represented: Pakona Engineers Pvt. Ltd.

The packaging sector is one of the fastest growing in India. This process is driven by dynamic economic growth, rapidly growing middle classes, rising levels of income and a steady increase in urbanisation - elements which are causing changes in consumer patterns as well as a growing demand for packaged food, beverages and commodities.

24th - 26th October 2018: pacprocess India, indiapack + food pex India, Mumbai (India)

alliance

Messe Düsseldorf GmbH D 40001 Düsseldorf



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#### cleanroom onjine

## **Bosch presented new Xelum R&D**

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#### The shortest way from the lab to continuous production

- From the development of new products through to production
- Precise dosing of smallest amounts of API
- Integrated dry blender with up to four loss-in-weight feeders
- Direct 1:1 transfer from Xelum R&D to Xelum production equipment

At Achema 2018, Bosch Packaging Technology introduced its latest R&D device for the continuous production of oral solid dosage (OSD) forms. The platform ensures a short time to market and optimum dosing of APIs. "The new laboratory device is based on our Xelum production platform that we presented last year," said Fritz-Martin Scholz, product manager at the Bosch subsidiary Hüttlin. "The separated process steps of batch production take place one after the other and without interruption. This leads to shorter cycle times, lower production costs and high flexibility." With the Xelum R&D, Bosch offers a platform that offers an ideal start to continuous manufacturing.

#### Precise and reliable dosing

As opposed to the common complex mass flow rate, excipients and active ingre-

dients are dosed as a discrete mass in the Xelum R&D. This makes it possible to dose even smallest amounts of APIs of less than one percent. The system doses, mixes and granulates individual packages, so-called X-keys, which continuously run through the process chain and are removed successively from the machine as packages into bins. "This way we reduce not only process complexity, but also the system's failure susceptibility, while increasing both accuracy and quality of the end product. Moreover, the product is traceable at all times," says Scholz. Depending on requirements, up to four loss-in-weight feeders can be used.

Since the Xelum R&D uses the same components for dosing, mixing and granulating as the Xelum production platform from Bosch, process parameters are identical and can be directly transferred 1:1. "Scale-up becomes obsolete, which reduces development time and API usage,

since elaborate tests are no longer necessary," Scholz explains. Material flow from dosing to emptying takes place in a closed process (bin-to-bin) to ensure the highest safety.

#### The benefits of the fluid bed

Current continuous production systems for wet granulation mostly use twin screw granulators. The Xelum system relies on fluid bed processors - based on a proven technology developed by the Bosch subsidiary Hüttlin. In the fluid bed, granulation and drying take place in the same process chamber. "This eliminates the need to transfer wet granules, which in turn has a positive effect on the system's reliability," Scholz emphasizes. Pharmaceutical manufacturers obtain granulates with the desired characteristics - including unimodal particle size distribution, as well as excellent flow and tableting properties combined with high production yields.

The controls of the Xelum R&D correspond to a modern production system. All relevant process parameters are continuously recorded. Both the production and the product transfer, as well as the cleaning process are recipe-controlled and ensure reproducible results. The user-friendly handling of the system is complemented by a DoE (Design of Experiment) software support.



Xelum R&D by Bosch: The new R&D device for the continuous production of oral solid dosage (OSD) forms ensures short time to market and an optimum dosing of smallest amounts of API. (Picture: Bosch)



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cleanroom onjine

## Reliable quality with low unit costs

The exhibition booth of ENGEL at Interplas 2018 in Thailand was focused on medical technology. Pipette tips were produced in the cleanroom version of an automated production cell. This sophisticated application illustrates how extremely quality-sensitive products can be manufactured at the lowest possible price per unit. Also in Bangkok: The intelligent assistance systems from ENGEL's inject 4.0 programme, which make it easy for the operator to maintain a high degree of parts quality without expert knowledge.

The medical technology sector in Thailand is developing very dynamically. One strong driver of this development is medical tourism from neighbouring countries, which is continuously raising the capacity of medical practices, clinics and medical service providers. The government support investments that help to develop Thailand to become a medical hub for Asia and to produce medical products in the country. Equipment suppliers are benefiting accordingly. In particular, consumables and diagnostics accessories such as pipette tips are already manufactured locally.

Because the pipette tips are used in fully automated analytical systems, reproducible product quality is the highest priority. As mass-produced parts, however, they are also under especially high cost pressure. In order to combine a stable process with high efficiency, the integrated and fully automated production cell at ENGEL's exhibition booth utilises various efficiency factors. With an extremely compact footprint, it integrates a tie-bar-less ENGEL e victory

170/80 injection moulding machine featuring 800 kN of clamping force, a hydraulic clamping unit, and an electric injection unit, with a 32-cavity hotrunner precision mould by Wellmei (Dongguan, China), and a high-speed automation by Waldorf Technik (Engen, Germany).

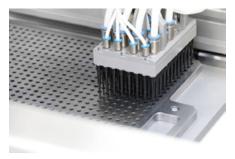
#### Tie-bar-less technology optimally utilises efficiency potentials

The tie-bar-less technology, which is unique to ENGEL, above all contributes to a high degree of total efficiency. Since there are no tie-bars in the way, the mould mounting platens on ENGEL e-victory machines can be fully used up to their edges. This allows for the installation of large multi-cavity moulds on comparatively small injection-moulding machines, keeping the cost of investment and operation low. In addition, the tie-bar-less technology allows for an especially close fitting of the automation to the clamping unit, thus reducing the system's footprint.



When producing pipette tips, the unhindered access to the mould area of the e-victory injection moulding machine allows for an especially close fitting of the automation to the clamping unit. (Picture: Engel)





Because the pipette tips are used in fully automated analytical systems, reproducible product quality is the highest priority. (Picture: Engel)

The high-performance automation is another key to high efficiency. In the rhythm of the injection moulding process, 32 pipette tips at a time are removed from the mould and cavity-specific groups of 96 pipette tips each are placed in racks. Every 18 seconds, 96 pipette tips are discharged from the production cell, which is enclosed to create a cleanroom environment.

The design of the tie-bar-less e-victory injection moulding machine already ensures a high ratio of good parts. The patented force divider enables the movable mould mounting platen to follow the mould in precise parallelism while clamping force is building up and ensures that the generated clamping force is distributed evenly across the platen face. On the injection side, the electric injection unit is responsible for the extreme precision when injecting the plastic melt.

To additionally compensate for fluctuations in the ambient conditions and raw material, iQ weight control is used. The assistance system from ENGEL's inject 4.0 programme analyses the pressure in real time during the injection process and compares the measured data with a reference cycle. For every shot, the injection profile, the switchover point and the holding pressure profile are automatically adjusted to the current conditions and the injected melt volume kept constant throughout production. This is a proactive way of preventing rejects.

In order to integrate other peripheral units and moulds alongside its own automation solutions and process technologies, ENGEL has established a worldwide network of system partners. The production cell for the production of pipette tips is the result of a European-Asian collaboration. ENGEL, Waldorf Technik and Wellmei Mold have combined their know-how and experience with medical technology precision parts in order to tailor the system solution to the specific requirements of the Asian processors. By working with local suppliers, ENGEL can also guarantee high cost efficiency for challenging applications

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## cleanroom

#### Reliable quality with low unit costs

and keep the delivery time short for the complete plant.

#### Self-optimising injection moulding machine

Intelligent assistance systems such as iQ weight control provide an important contribution to making even complex applications manageable for the operator. Since the machine optimises itself with the help of the assistance systems, a consistently high quality of parts can be ensured without any expert knowledge. While iQ weight control automatically maintains consistent injected melt volume throughout the injection moulding process, iQ clamp control monitors the mould breathing in order to calculate and automatically adjust the optimal clamping force.

iQ flow control is the newest iQ assistance system and connects the temperature control units to the injection moulding machine in order to adjust the speed of the pumps based on actual requirements. The results are a significantly reduced power



iQ weight control compensates for process fluctuations before rejects can occur. The intelligent assistance system is available for both electric and hydraulic injection moulding machines. (Picture: Engel)

consumption and a stable temperature control process. iQ flow control is capable of actively regulating the temperature difference in all individual circuits and to automatically adjust the required flow amount for each temperature control circuit.

The growing intelligence of the machine control is a key feature of the smart factory,

the goal of Industry 4.0. The systematic use of machine, process and production data and the networking of production machines all contribute to increasing the productivity, quality and flexibility of production.

ENGEL AUSTRIA GmbH A 4311 Schwertberg

## **Successful ACHEMA closes in Frankfurt**



At the most important trade show for the process industry, more than 3,700 exhibitors from 55 countries showcased the latest equipment and innovative processes for the chemical, pharma and food industry.

Whether in the classic process technology hall, the pump exhibition or in the plant engineering section, many stands were so crowded that visitors had to take some time to pass through the halls.

"The exhibitors we talked to as well as we ourselves, had a very successful show", said Jürgen Nowicki, Chairman of the ACHEMA Exhibitors' Committee and Speaker of the Linde Engineering Board. "Exhibitors' feedback has been very positive", agrees Dr. Thomas Scheuring, CEO DECHEMA Exhibitions. "The first results from the exhibitor and visitor survey also show that both sides were highly satisfied".

A very visible trend this year: At many stands he visitors could experience plants and equipment in "augmented reality" with the aid of special goggles or even test their aptitude in completely virtual surroundings.

The three focal topics were very well received. Under the motto "Flexible Production" numerous exhibitors showed modular solutions and intelligent components for the plant of tomorrow. "Biotech for Chemistry" comprised process development and equipment from the lab to the fermenter that integrate biotechnological methods into the chemical industry. "Chemical and Pharma Logistics" put a spotlight on the advancing integration of the supply chain

and attracted new target groups that are increasingly not "only" service providers but systemic partners of the process industry.

A certain drawback for the organizers has been the decrease in visitors to about 145,000. The organizers explain this partially by the more complex registration procedure that had to be introduced due to the increasing security requirements for large events. "That certainly prevented some spontaneous visits", says Dr. Thomas Scheuring. "Nevertheless, we will analyze the numbers very diligently."

In the congress programme, especially digitalisation, but also presentations on energy drew large crowds. The PRAXISforen that were introduced in 2015 have been received very well; the events that are located closely to the respective halls that bring together users and suppliers attracted many visitors.

Next stop for the process industry is AchemAsia that takes place from 21-23 May 2019 for the first time in Shanghai. The "International Expo and Innovation Forum for Sustainable Chemical Production in China" focusses on the current trends of the process industry in China and Asia.

14th - 18th June 2021: ACHEMA 2021, Frankfurt am Main (D)

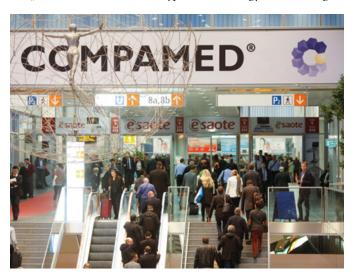


# The 12th COMPAMED Spring Convention was devoted to innovative implant technology - an important research field in medical technology.

Messe Düsseldorf and the IVAM Microtechnology Network hosted the 12th edition of the COMPAMED Spring Convention, offering a sneak preview of the trends at COMPAMED. With almost 800 exhibitors at last count, COMPAMED is the leading international specialist trade fair for medical technology suppliers, taking place annually in Düsseldorf. This year, COMPAMED takes place from 12 - 15 November 2018 (in parallel with the MEDICA). The Spring Convention had 45 participants from companies and institutions from eight different nations and was held on 3 May at the Airport Center Frankfurt, under the title "Implants in Medical Technology", and examined this topic in four areas: "Technology for Manufacturing Implants", "Packaging of Implants", "Materials for Implants" and "Microtechnology in Medical Applications".

The significance that the global market for medical implants has taken on is indicated by the findings of the International Trade Administration and BCC Research: The market researchers value the sales volume at 30 to 60 billion Euro, of which active implants constitute around 15 billion Euro. "Active" here means any implant that is fitted with an energy source, which is generally a battery. However, other types of power supply, such as induction, are also possible.

"The new combinations of types of technology and the integra-



tion of electronics, smaller and smaller components, high frequency and wireless technology as well as monitoring, recording and control systems are market drivers for implants at the moment", explained Dick Molin, the Medical Market Segment Manager for Specialty Coating Systems (SCS).

Active implants are some of the most technically tricky and risky medical products, and place very high requirements on the research, development, production and approval undertaken for them. Innovations must always be developed in consideration of patient safety, reliability throughout their entire lifetime, biological compatibility and biostability as well as compatibility with other medical technology devices.

#### Active implants: It all started with pacemakers...

The development of active implants began before 1958, when the first pacemaker was implanted at the Swedish Karolinska Institute. Since then, a huge range of devices for electric stimulation, improving hearing, delivering medication or for use as dental prostheses have become common. Orthopaedic implants for distraction osteogenesis among other things, implants for supporting cardiac function and various sensors which measure intracranial and intraocular pressure, bladder pressure or blood sugar levels are also devices of this nature.

Neuroprosthetics constitutes an important field for the application of active implants. In this sector, CorTec has developed a closed-loop system for measuring and stimulating brain activity for long-term use. "The driving premise behind our work is the realisation that these kinds of therapies need to be personalised" said Dr. Martin Schüttler, founder and CEO of CorTec. The Brain Interchange concept consists of three components: Electrodes for recording and stimulating the nervous system, a telemetric unit for optical communication with both the implant and the computer unit that evaluates the brain signals in real time in order to determine the level of stimulation that the patient requires at that point in time. CorTec manufactures the electrodes itself. They consist of five layers which are created using ultrashort pulse lasers and microfabrication methods. Consequently, the electrodes can be produced in any geometric shape (three dimensional or in a cuff design), with

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#### The 12th COMPAMED Spring Convention was devoted to innovative implant technology

high contact density and for a wide variety of applications. CorTec thus manufactures both components and complete active systems.

#### Biodegradable materials for reabsorbable implants

Many implants need to have a lifespan that is as long as possible, but for others, it is important that they do not remain in the body long-term. At the IFAM (Fraunhofer Institute for Manufacturing Technology and Advanced Materials) in Dresden, a biodegradable magnesium implant with a fibrous structure has been developed as a solution for treating major bone defects. This serves as a guiding structure for the bone while it is growing, with this growth being particularly stimulated by the well-suited biomechanical properties of the implant. This structure also stimulates blood vessel growth simultaneously. The implant degrades as the healing process progresses. Up until now, major bone damage has mainly been treated by grafts taken from the patient's own bones. This is, evidently, only possible to a limited extent. In addition, harvesting the graft, which generally comes from the iliac crest, harbours additional risks for the patients. Synthetic bone replacements represent an alternative here, but often these can only withstand little mechanical stress and are unsuitable as a result of the disruptions they cause in imaging in the long-term. Biodegradable materials therefore represent the ideal solution; they are used to create implants that disappear once the healing process has been successfully completed, such as the innovative magnesium implant from the Fraunhofer IFAM in Dresden, which was discussed at the COMPAMED Spring Convention. The starting point for technological development is the manufacturing of short magnesium fibres via extraction from the melt. These



fibres are then homogeneously deposited and bonded to each other and densified via heat treatment. Implants manufactured in this manner have excellent mechanical properties and, most importantly, stellar corrosion properties, which are particularly well suited to the physiological feats required of them. In the animal model, slow corrosion was thus first measured after 12 weeks, and after 24 weeks the majority of the metallic component had disappeared. Osteosynthesis and cardiovascular stents are considered the most significant commercial applications for this technology.

#### "Sword catheters" for easy puncturing of blood vessels

Puncturing blood vessels is often a part of the daily routine in the medical sector. It also constitutes the first step for inserting catheters into vessels, which then in turn feed medication, perfusions and other elements into the patients, and is indispensable for all emergency cases that require blood transfusions. Generally, the Seldinger technique, which was published in 1953, is performed for opening larger blood vessels when puncture systems are used. This technique takes up a lot of time, space and uses a lot of material, and the doctor performing it also needs an assistant for standard cases. The Seldinger technique has many individual steps and the procedure can last up to approximately 30 minutes. With this in mind, Ebnet Medical has come up with a remarkable new development: the "SWORDCATH" is a puncture system that already contains all the necessary components and is packed in a user-friendly manner. "Our system uses a puncture technique that is new and can be learned intuitively. It also combines a small puncture needle with a large catheter", reported Dr. Jens Ebnet, founder and CEO of his eponymous company. The new solution, which has now been registered for patents in many countries, enables the time for the procedure to be cut down significantly and for it to be completed by one person without additional assistance.

New materials, innovative procedures and the combined application of electronics and microsystem technology are not only typical for modern implants but are also fundamental main themes at COMPAMED. COMPAMED 2018, held from 12 - 15 November in Düsseldorf (alongside the world's largest medical trade fair MEDICA), will not only tackle the latest developments in this field but will also present many other fields of research, such as digitalisation and miniaturisation in medical technology.

12th - 15th November 2018: COMPAMED, Duesseldorf (D)

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Impressum

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