Industrial laundry Geiger Textil invests in new cleanroom

Cleaning and decontamination of clothing for highly sensitive areas

The family owned company Geiger Textil GmbH from Bad Säckingen is expanding its range of services with a new Cleanroom + service. The medium-sized company has invested in its own cleanroom and offers a full-service rental system for cleanroom clothing for the first time. The cleanroom textiles are collected after use directly at the location of the customer, they are then inspected in the new cleanroom system, restored, refurbished and securely repacked and delivered for further cleanroom use.

External view of the cleanroom system Cleancell4.0®. You can see the cleaning steps from the outside through the large cleanroom windows.

Not just clean but pure

The cleanroom operators in the field of pharmacy, microelectronics or the medical industry are perhaps the most demanding customers you can find in the field of work clothing. Surely the well-known advertising slogan „not only clean but pure“ fits nowhere better than to the cleaning of cleanroom textiles. Because there are significant differences between a cleanroom laundry and an industrial laundry. There are very strict guidelines for the control, quality and hygiene standards of cleanroom clothing. The number of particles and germs must be strictly monitored.

Patrick Wenger, responsible for the new cleanroom division at Geiger Textil, explains the difference between the cleaning of normal work clothing and the decontamination of the cleanroom clothing: „The sensitive production processes inside a cleanroom can be jeopardized even by the release of the smallest microparticles. Humans are the greatest source of danger. Special cleanroom clothing prevents particles from being released, for example, from the skin of the employee. After use, these garments must be carefully cleaned of particles and germs not visible by the naked eye before the next use. No new particles should enter the clothing even during drying and packaging. In order to prevent contamination during cleaning, the cleanroom clothing is treated in a cleanroom which corresponds to at least the same clean room class in which it is later used by the customer. In our case, this is a cleanroom of ISO class 5 in operation“

Modular cleanroom of ISO class 5

The cleanroom was integrated in the newly built production hall of Geiger Textil and is designed for a capacity of 20,000 articles per week. The cleanroom company SCHILLING ENGINEERING, which is also based at the Hochrhein, was commissioned with the planning of the 66 square meter cleanroom system. The CleanCell4.0® cleanroom is certified according to ISO Class 5 and is equipped with state-of-the-art technology and has been designed for the special requirements of the laundry. The cleanrooms are designed with recesses for the attachment of washing machines and drying units. The staff is safely routed into the cleanroom via an actively flushed personnel sluice. A self-closing gravity flap inserted in the clean room wall ensures the contamination-free output of the cleaned and packaged laundry. Two washing ma-

Cleaning and decontamination of clothing for highly sensitive areas

chines operated with specially treated water are connected to the rear of the cleanroom. The washing machines have a through-loading function for safe feeding of the textiles. They are filled outside the cleanroom and discharged in the cleanroom after cleaning. Drying, testing and packaging of the sensitive textiles are carried out within the cleanroom. A sample is taken from each wash cycle for which the remaining particle density is determined and documented using a Helmke-Drum test.

The tables and other furniture are made of clean-room compatible stainless steel. Large windows and a dimmable LED lighting create a balanced lighting and a proper external visibility. A counter-intercom system facilitates the communication between the individual areas.

The management of the new cleanroom team explains the special features of the system: „We have installed an ISO class 5 cleanroom in operation in our newly built hall. We are therefore in a position to meet even the most demanding requirements of our customers from the pharmaceutical industry or microelectronics. As we enter the market for cleanroom textiles, we have placed great importance on making the possible expansion of the cleanroom. The cleanroom has a modular design and has fully met our requirements. In close coordination with the engineers from SCHILLING ENGINEERING we have planned a cleanroom which exactly meets our requirements."

State-of-the-art technology, satisfied users

The newly developed CleanCell4.0® cleanroom system is equipped with the latest technology and can be operated more energy-efficiently than comparable systems. Sensor data are used to set and monitor components such as number of particles, temperature, air humidity and air pressure. The data flows into the CRControl® control system which is easily operated via a monitor installed next to the clean room door.

A low turbulence displacement flow ensures full compliance with the pure areas as per cleanroom class ISO 5. Flush mounted Laminar-Flow units operated with U15 ULPA high-performance filters introduce pure air into the working area. An air recirculation process within the cleanroom walls introduces the already cooled and filtered air into the air exchange cycle. This allows filters and air conditioning equipment to be operated much more economically.

A special feature of the cleanroom systems from SCHILLING ENGINEERING is the modular, expandable design. The wall elements are connected with a patented silicone-free GMP sealing clip system and can be flexibly dismantled or extended.

The employees have been specially trained for safe conduct inside the cleanroom. Here you can see the dryer unloading process.

Cleanroom system Cleancell4.0® of the ISO cleanroom class 5. The dimmable LED lighting ensures balanced light in the area of the spreading table.

Geiger Textil GmbH is very satisfied with the system: „The cleanroom has been running for several weeks now and works flawlessly. We can easily monitor and control the cleanroom just by using the touchscreen-controlled monitoring system. For example, the filter contamination is displayed and we can detect problems or perform maintenance early on. Previously this was not necessary. We especially like the dimmable LED lighting, which ensures very good light conditions for the workstations and saves energy."

With its investment in a high-tech cleanroom system, the third generation family owned company Geiger Textil has invested in the future and has raised its own benchmark for quality and hygienic standards. Opting for the module cleanroom CleanCell4.0® enhances the investment security for the newly developed service.

SCHILLING ENGINEERING
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Dear subscribers,

are your suitcases packed? You better get ready for the upcoming events.

Maybe you need a (used) cleanroom of class 5 with 40 m2 size? Then we possibly got something good for you. http://www.reinraum.de/forum.html?id=16005

Our content as well is remarkable this month. Maybe you want to take a closer look at „Turned upside down", „Cleaning is just the beginning" or „Closer to the µ than ever – Medical Devices in High-End Precision".

Looking forward, seeing you at the Cleanzone in Frankfurt.

Yours sincerely,

Reinhold Schuster

New cleanroom concept for high temperature applications

Turned upside down

Author: Dipl.-Ing. Helene Schöngruber Bsc, Dipl.-Ing. Christoph Lhota

High temperatures are not wanted in cleanrooms, however, in the injection molding process they are unavoidable. Research on the influence of mold tem-perature by laminar clean airflow underlines the significance of this subject and simultaneously lays the foundation for a completely new cleanroom concept with reversed airflow. The first industrial installations promise much potential for even higher cleanroom quality.

For injection molding of thermoplastics, the resin pellets are heated in the barrel until they have reached a viscous or liquid state and are then injected into the temperature-controlled mold. The temperature of the mold is a material-specific parameter with a direct influence on the process and in particular on the cycle time. The mold temperature also influences the air-flow, which is relevant to the injection molding process in cleanrooms. The hot air radiated by the mold rises and therefore moves in the opposite direction to the cleanroom airflow which conventionally runs from top to bottom (Figure 1). As the temperature rises, the particulate load increases which puts the cleanroom quality at risk. Uneven airflow in the mold area can cause particle deposits on the parts because there is not enough clean air coming in to re-move the contamination.

Influence measurable at 40°C

It was investigated for a thesis from which mold temperature use of a conventional filter fan unit (FFU) or laminar flow box is ineffectual [1]. The experiments were carried out in the cleanroom of the injection molding machine manufacturer ENGEL AUSTRIA in Schwertberg, Austria. The LMP type laminar flow modules were provided by Max Petek Reinraumtechnik (Radolfzell, Germany). They were developed in the size used specifically for injection molding machines.

Two system conditions were used for comparative purposes: one with normal cleanroom air-flow, and the other with the mold and ejector area encapsulated with an LMP. In both series of experiments, mist was added from above to the mold area to make the airflow visible for both systems. Mold heats were also held constant across both experiments.

It was established with the simple experiment that without an additional laminar flow module the mold temperature of 40°C already influences the flow of clean air through the mold area. This outcome shows how important this research work is because such a low mold tempera-ture can only be used for very few applications.

The LMP was used to achieve an even more constant flow from top to bottom. The air veloci-ty was set on 0.45 m/s in accordance with the EU GMP Directive. The mist tests in this en-capsulated configuration were recorded in a video. The still images clearly show that a con-stant airflow no longer prevails and turbulence occurs from a mold temperature of 90°C and above (Figure 2). The turbulence occurs primarily directly after opening of the mold; the air-flow settles again after four seconds and the flow through the mold becomes constant again.

The same measurement was repeated at a mold temperature of 140°C (Figure 3). Here four seconds did not suffice to disperse the turbulence. At this high mold temperature, the com-plete air in the mold area is very hot, and particles are emitted in increased number. An ade-quate laminar flow can only be shown again at an increased air velocity of 0.8 m/s.

Mold opening speed a further adjustment parameter

In addition to temperature, the mold opening speed also has an influence on the airflow. The airflows were investigated at opening speeds of 1100 mm/s and 220 mm/s. The tests showed that a slow movement of the mold mounting platen causes less turbulence than very fast opening of the mold. When, however, the extremes were tested, it was shown that excessive-ly slow opening intensifies the air turbulence as the air between the mold halves heats up again in the

The influence of mold temperature on cleanroom quality was investigated intensively in the cleanroom of ENGEL AUSTRIA in Schwertberg, Austria. The results of this work formed the basis for development of a completely new cleanroom concept. (Picture: ENGEL)

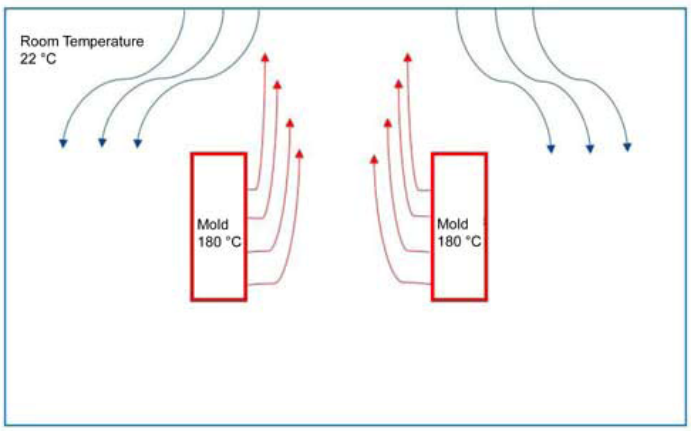

Figure 1. The clean airflow conventionally runs counter to the thermal flux. At very high mold temperatures the clean airflow does not even reach the mold. (Picture: ENGEL)

Turned upside down

long time of mold opening. In contrast to this, extremely fast opening can stabilize the airflow so that the mold and injection molded parts are constantly exposed to clean air. To depict these extreme speeds, mold opening times of 12 and 3 seconds were investigated. The optimal opening speed for the purposes of cleanroom reliability depends in each case on the manufacturing process and the mold. In practice, however, the flow effects cannot always be considered adequately when it comes to setting the opening speed. The medical technology sector is also subject to strong cost pressure and cycle time is a decisive factor in profitability.

The challenge of liquid silicone rubber

The previous experiments established an important baseline for further consideration of injec-tion molding processes in cleanrooms. The objective of a second thesis was, building on the above, to develop approaches on how to ensure a high class of cleanroom at high mold tem-peratures [2]. In order to be able to make assertions for extreme temperature conditions as well, further experiments were not conducted with thermoplastics, but with LSR (liquid silicone rubber). A special aspect of liquid silicone rubber is that the material is, unlike thermoplastics, cooled in the barrel, while significantly higher temperatures of 180°C prevail in the mold. Only at these high temperatures can LSR vulcanize and crosslink. In addition to the high mold temperatures, a further complicating factor is the fact that LSR outgasses during processing. At high temperatures silane is released, which can be seen as a cloud with the naked eye. These volatile components of the liquid silicone rubber are an additional contaminate to the cleanroom and in the course of production can quickly exceed the limit defined for the respective class of cleanroom. The cleanroom in the ENGEL technology center was set up in ISO Class 7 for the experiments for the thesis. Particle measurement after just a few cycles already showed an excessively high concentration of particles with a diameter of 0.5 µm.

A first approach to solve this problem consisted of encapsulating the mold area with an LMP in order to vaporize the silane cloud. Unlike normally, however, the clean air was not intro-duced into the mold area from above, but from below. The extraction downwards normal in cleanrooms up to this point in time was to be used to remove the silane particles. Although this experimental setup was unsuccessful, a lower concentration of particles was measured than in the previous measurement, even though it did not yet conform to the requirements of the cleanroom class ISO 7.

Simulation confirms empirical research

The idea of reversing the airflow was then implemented consistently in a second step. The clean air was not only passed from bottom to top, but the mist cloud was also sucked out of the mold area upwards (Figures 4 and 5). The thermal makes the mist cloud disperse and gain speed quickly.

A simulation of the experimental setup (Figure 6) was used to corroborate the test results using ANSYS software version R16.2 Academic. The calculations confirm the good result of the tests in the technology center and make it possible to predict the behavior when changes in the environmental conditions occur.

Max Petek Reinraumtechnik has developed a cleanroom solution with reverse laminar flow on the basis of these results. The air is sucked upwards out of the mold area.

First industrial system built

The results of the two theses cited in this article clearly show that

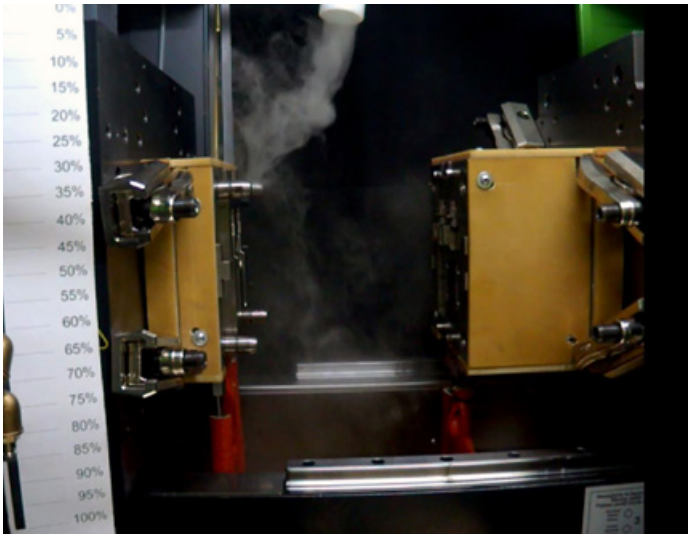

Figure 2. A constant airflow no longer prevails at a mold temperature of 90°C. The turbulence occurs primarily directly after opening the mold. The airflow settles again after four seconds. (Picture: ENGEL)

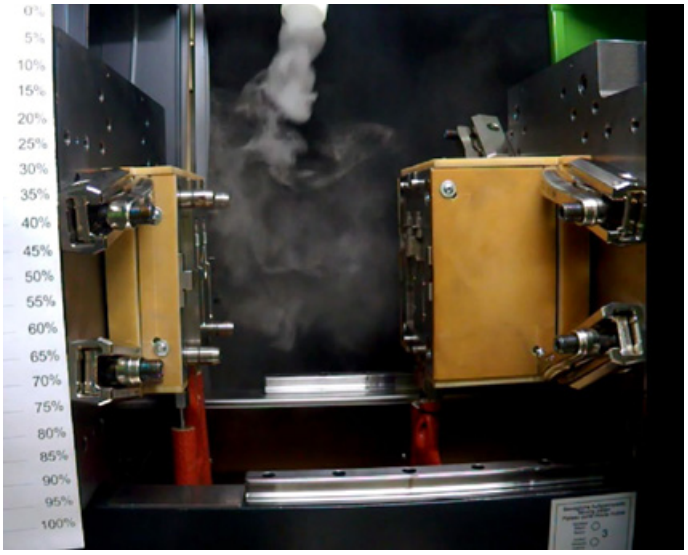

Figure 3. At a mold temperature of 140°C, it was only possible to achieve a throughflow by increasing the flow velocity, which, however, is not permitted in practice due to the fixed velocity of 0.45 m/s. (Picture: ENGEL)

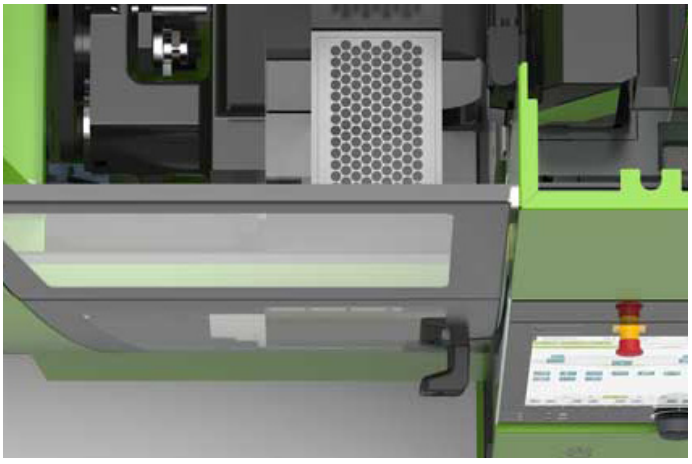

Figure 4. In order to keep the particle load low even at high mold temperatures, it is expedient to reverse the flow of clean air. ENGEL AUSTRIA and Max Petek Reinraumtechnik have already built a first industrial solution. A view into the mold area shows the air grille through which the cleanroom air is blown upwards. (Picture: ENGEL)

Turned upside down

the influence of mold tem-perature on reliable cleanroom operations cannot be neglected. The laminar flow is already disturbed at mold temperatures above 40°C. A mold temperature of 110°C was established as limit for a conventional clean airflow from top to bottom (without additional laminar flow module). Both empirical measurements and simulations prove that the particle load can be minimized by reversing the flow of clean air.

ENGEL AUSTRIA and Max Petek Reinraumtechnik have already implemented the results of this study industrially. The new solution has the potential to become standard for high temper-ature applications.

Figure 5: The cleanroom module with reversed airflow developed by Max Petek Reinraumtechnik fits space-savingly in the frame of the injection molding machine. (Picture: ENGEL)

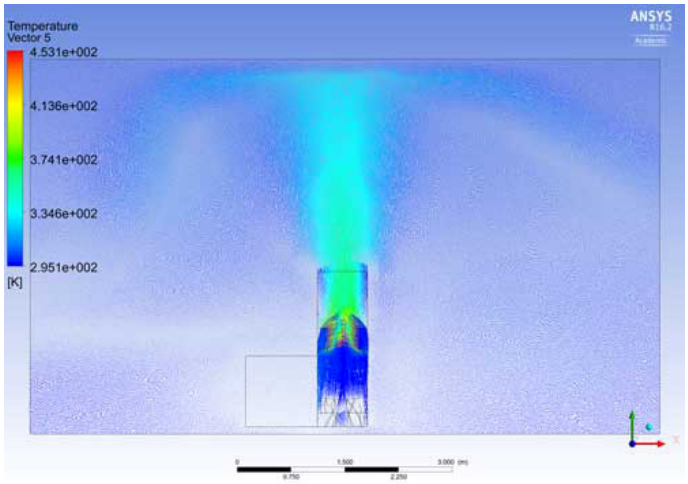

Figure 6. The simulation confirms the good result of the new cleanroom solution. The diagram shows the temperature distribution in the cleanroom. The mold has a temperature of 180°C, and the cleanroom air flows from bottom to top. It can be seen how the hot air moves up away from the mold quickly. The new cleanroom concept uses exactly this effect. (Picture: ENGEL)

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1. Denisa Costas, Analysis of the impact of process temperatures on the cleanroom airflow during the injecting moulding of medical grade high performance thermoplastics, thesis for the degree course in Medical Engineering at the University of Applied Sciences Upper Austria, Linz, Austria, 2015.
2. Helene Schöngruber, Identification and analysis of thermal flux in the cleanroom during liquid injection moulding, thesis for the degree course in Medical Engineering at the University of Applied Sciences Upper Austria, Linz, Austria 2016.

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The CIM med GmbH has a good reason for rejoicing. Over the past 10 years, the company, located in Munich, has grown from a small start-up to one of the leading suppliers of high-quality medical mounting solutions on the international market.

CIM med GmbH celebrates its 10-year anniversary

The success rate is something to be proud of: In 2007, Manuela Deverill and Manfred Rosa launched their company in Unterschleißheim with only four employees and a facility of 420 sqm. In the beginning, there was an innovative business idea – the development of ergonomic medical mounting solutions which are perfectly tailored to the requirements of the respective user and can be utilized in critical clinical areas such as operating rooms, intensive care units, emergency rooms, or examination rooms. Unique and almost revolutionary in the development of these mounting solutions was, and is the internal cable routing. CIM med® patented this system already in its year of founding. Since then the products, developed and manufactured in Germany, have been further improved. The same applies to the quality management systems which confirm the manufacturer's high demands relating mainly to hygiene and safety aspects. Since 2017, CIM med GmbH is one of the first suppliers on the market who meets the requirements of the new ISO 13485:2016 guidelines for medical devices.

Managing Director Manuela Deverill is not only proud of the previous development but looks also very optimistic at the coming 10 years. "We set the course for a successful future. Our production area expanded. Now, the CIM med® mounting solutions are utilized worldwide - in over 40 countries and more than 150,000 mounting solutions installed. With our extraordinarily demanding quality awareness, the high production flexibility, an expert team of - by now - 50 employees as well as short decision-making procedures we are also an attractive partner for big manufacturers of medical technology. This is especially true with regard to the development of specific solutions. Nationally as well as internationally."

Over time and specifically in the highly competitive international business it was possible for the Munich-based company to solidly establish itself. For the first time in 2012, the company succeeded in breaking through on the American continent. Additional prestigious major projects followed in 2013, such as in the Duke University Hospital in Durham, North Carolina, as well as in the Kitasato University Oriental Medicine Research Center in Tokyo. In 2016, CIM med's export rate was already round about 70 percent. The trend for growth continues.

CIM med GmbH D 80939 München

Extended consulting for biotech companies

Bosch subsidiary Valicare offers consulting in GMP-compliant development of cancer therapies

- Valicare customer polybiocept develops new forms of cell therapy
- International quality requirements call for high standardization
- Expert support for the reliable transition from laboratory to production scale

Valicare GmbH, a wholly owned subsidiary of Bosch Packaging Technology, has expanded its consulting services for Good Manufacturing Practices (GMP) to include biotech companies. Amongst others, Valicare is currently supporting the Swedish start-up polybiocept in establishing new cancer therapies. In a long-term project, the company ensures that all laboratory processes are standardized in compliance with GMP, the guideline for quality assurance of production processes and their environments. It plays an especially important role in the pharmaceutical industry, as quality defects in drugs can impact patients' health. Valicare also offers comprehensive qualification and documentation services for pharmaceutical research laboratories.

A high degree of standardization required

The polybiocept group develops new types of cell therapies for the treatment of pancreatic carcinoma and glioblastoma. Pancreatic cancer has the highest mortality rate with approximately 90 percent of all patients dying from the disease within five years and more than 70 percent within the first year following diagnosis. Glioblastoma represents approximately 15 percent of all primary, and the majority of all malignant brain tumors. Patients have an average survival rate of 14.6 months; 95 percent of patients die within five years.

Following successful approval, these cell therapies will be produced and applied at many different specialized centers. "For this reason, we recommended that polybiocept use a decentralized production concept," explains Dr Hans-Georg Eckert, senior project manager and GMP consultant at Valicare. It is especially important that the method of production complies with international pharmaceutical requirements. "The transfer of the cell-culturing processes developed at the research laboratory to a GMP-compliant manufacturing process requires an especially high degree of standardization. Biotech companies can profit from the long-standing experience of Valicare in GMP consulting for pharmaceutical companies," says Dr Eckert.

Ensuring rapid market availability for new therapies

In the approach developed by polybiocept, cells from the patient's own immune system are extracted from the tumor, isolated in a cell culture dish, multiplied and subsequently used to attack the tumor. "Our collaboration with Valicare is an essential building block to ensure that many patients are given the chance to benefit from these innovative therapies in the future," says Prof Dr Markus Maeurer, physician and chief scientific officer at polybiocept. Together with Dr Ernest Dodoo, neurosurgeon and chief development officer at polybiocept, he plays a decisive role in the clinical development of new cell therapies.

An active role in the fight against cancer

For many years, the entire Bosch group has played an active part in the fight against cancer. In 2016 the Robert Bosch GmbH initiated the "Alliance Against Cancer" together with the Bosch Foundation and the Robert Bosch Hospital. The laboratory and manufacturing equipment from Bosch Packaging Technology is also suited for the development and production of anti-cancer drugs.

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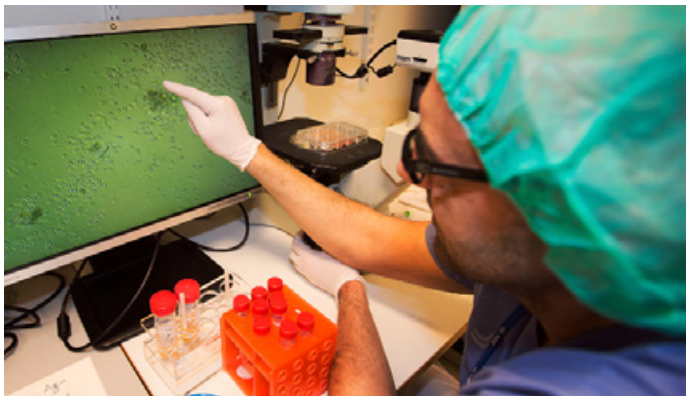
Developing new cancer therapies: Dr Ernest Dodoo, neurosurgeon and chief development officer at polybiocept, is catching up on the exact condition before the surgery of a tumor. Valicare supports the Swedish company in establishing new cancer treatments. (Picture: Bosch)



GMP-compliant manufacturing process: Valicare supports the start-up polybiocept in transferring the cell-culturing processes developed at the laboratory into a GMP-compliant manufacturing process. Prof Maeurer, physician and chief scientific officer at polybiocept, is looking at visualized cell cultures on the screen. (Picture: Bosch)

Linking up systems to a virtual network in order to make solar cell production in Baden Württemberg more efficient – this was the aim of the "InES" research project. With a cloud infrastructure developed by Fraunhofer IPA and both mobile and browser-based applications, the consortium is now able to share the use of machines at different sites. Remote monitoring of processes and automated test data transfers were also implemented.

Virtual technology center for efficient solar cells

The project partners, comprising Fraunhofer IPA and Fraunhofer ISE, the Institute for Photovoltaics of the University of Stuttgart (ipv) and the International Solar Energy Research Center (ISC), founded the "Solar Cells Technology Center 4.0" to pursue these plans. Fraunhofer IPA was given the task of establishing an IT infrastructure. To do this, the experts relied on the Virtual Fort Knox (VFK) platform and linked all of the technology center's systems to the cloud via a specified IT interface. Data from experiments is now automatically sent to VFK and can be processed directly.

Planning and conducting experiments via apps

The key element of the technology center is a mobile app developed by Fraunhofer IPA, which enables users to access individual machines and systems. Fraunhofer IPA Project Leader Martin Kasperczyk: »The app shows machine data and postings. This means that experiments can be planned and evaluated better.« Furthermore, the technology center sustainably improves solar cell production. With this connection to the cloud, manufacturers are now able to analyze previous machine data and identify weaknesses. The expert adds: »This means that experiments can be carried out more efficiently and systems and parameters can be sustainably optimized.«

Monitoring critical processes from your desk

In the technology center, solutions are also being implemented for tasks specific to the project partners. For example, the team of experts implemented the automated transfer of experiment data to the IT system for the ipv. Results and parameters were input manually into the IT system. With the cloud connection, documentation and transfer now occurs automatically. Employees can work more efficiently and input errors are avoided. The consortium implemented remote monitoring of cells in the diffusion tube for Fraunhofer ISE. This process is particularly critical in cell production and must be checked continuously, meaning that employees must start the process and monitor it in person in the cleanroom. As Kasperczyk knows, this is time-consuming as the employee must walk far and always change into the appropriate clothing. However, with a link to the cloud, it is possible for an employee to log into a system directly from their desk and check the values.

Plans to turn technology center into a self-learning factory

The Solar Cell Technology Center 4.0 will remain after the project has ended. Kasperczyk explains that the results can be expanded to other sectors and could be implemented in other laboratories and small-scale productions to increase efficiency. For their next step, the partners plan to build a self-learning factory on the basis of the technology center. This project, which is called "TechFab", is already in the application phase. The "InES" (Industry 4.0 used for future solar development and production) project received funding of EUR 2.4 million from the Ministry of Economic Affairs, Labor and Housing. The partners submitted their final report in July 2017.

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InES project Leader Maertin Kasperczyk transfers the final report to Günther Leßnerkraus, head of state ministry of economic affairs, employment and residential building together with the other project partners.
(© Photo Fraunhofer IPA, Rainer Bez)

For the cleanroom of Fraunhofer ISE, the consortium implemented a remote monitoring for cells in difusion tube.
(© Photo Fraunhofer ISE)

MULTIVAC Marking & Inspection invests around 2.5 million euros for an extension to the production hall

MULTIVAC is expanding capacity at its Enger production site

The production capacity of MULTIVAC Marking & Inspection in Enger is to be expanded with a modern extension to the production hall – and this will also enable the logistics and assembly processes to be optimised. The building work has already begun, and the planned date for putting the new production hall into operation is April 2018. The investment amounts to 2.5 million euros.

The business development of MULTIVAC Marking & Inspection is very positive: the number of machine orders increased by a total of 25 percent between 2014 and 2016, and last year the export share of the business was 77 percent. The growth is due to a rise in the sales figures for all types of machines, although the sectors of inspection systems and conveyor belt labellers showed the strongest growth. The core market continues to be the food industry, but the sector of healthcare and life sciences also registered a significant increase in turnover.

There are currently 197 staff in total employed at Enger. After the new building has been completed, the current operating area of around 5,800 m² will increase by approx. 1,600 m². Around 900 m² will be taken up by the new Assembly/Production and Logistics areas, while 300 m² will be made available for machining and welding. In addition to this, some 30 new office spaces will be created in an area of 370 m² on the top floor.

MULTIVAC is investing in total around 2.5 million euros in the new production hall, which, with its reinforced concrete supporting structure and its flat roof made of trapezoidal steel sheets, is being constructed in accordance with the latest energy-saving regulations and renewable energy legislation. Due to the current building foundations, it is necessary to install 20 drill piles, each with a length of 15 metres, under the existing building to prevent any subsidence of the new production hall.

The building work is due to be completed by the end of 2017. The internal work will follow in the winter, and completion is planned for the early part of 2018.

"With this extension to our production hall, we primarily want to expand our production capacity in the sectors of conveyor belt labellers and inspection systems, so that we can meet the constantly increasing demand for these solutions," explains Volker Gerloff, CEO of MULTIVAC Marking & Inspection. "Parallel to this, we will also use the opportunity after completion of the building work to further optimise our logistics and assembly processes". This will involve reorganizing all the process sequences in Goods Inward and Stores, as well as in the Machining, Assembly and Dispatch departments. With the introduction of new shopfloor management systems, there is also the expectation in Enger of more efficient planning and monitoring of operating processes, as well as a higher level of transparency, shorter reaction times and improved handling of re-sources.

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SKAN successful with glove leak testing system WirelessGT – number 1000 sold to GSK Singapore

The use of gloves to reach into and work inside of isolators is a common method, but also involves a risk of contamination that should not be underestimated. Therefore, it is crucial to check the tightness of the gloves. The Swiss isolator builder SKAN also knew this and launched the WirelessGT, a fully automated glove tester, in 2013. Since then it has been successfully used for isolators and RABS in the pharmaceutical industry. Now SKAN is very proud that GSK Singapore has purchased the 1000th WirelessGT (see picture). 83% of those thousand glove testing systems were sold for SKAN isolators and 17% for isolators of other manufacturers. 100 went to price-sensitive India, the rest to the US and Europe. In contrast to the pressure-retaining method used in the past, WirelessGT uses the so-called pressure-decay method. The system is closed during the test period and at the end of the time it is measured how much pressure has been lost. This leak testing method has proven successful.

Simon Keser, sales engineer at SKAN, is delighted at the success of the WirelessGT. He adds, „For users, however, it is not only important to know the hardware, a comprehensive risk analysis is also required. We show them how to best handle the gloves and inform them about the changing cycle. Bioburden control and the risks that the machine in the isolator bears regarding the glove are important aspects that need to be kept in mind".

SKAN AG CH 4123 Allschwil

Regulations are indispensable in cleanliness technology. They specify which cleanliness standards, test methods or threshold values must be observed for particular industries. Fraunhofer IPA is on committees all over the world and helps to shape groundbreaking guidelines. At the Cleanzone and Lounges on Tour trade fairs in Frankfurt am Main on October 17-18, Fraunhofer scientists will give information on new developments such as the expansion of the VDI 2083 set of guidelines to include nanoscale contamination and a calculation method to determine the degradation kinetics of hydrogen peroxide and the desorption kinetics of materials after hydrogen peroxide fogging.

New VDI standards established for cleanroom technology

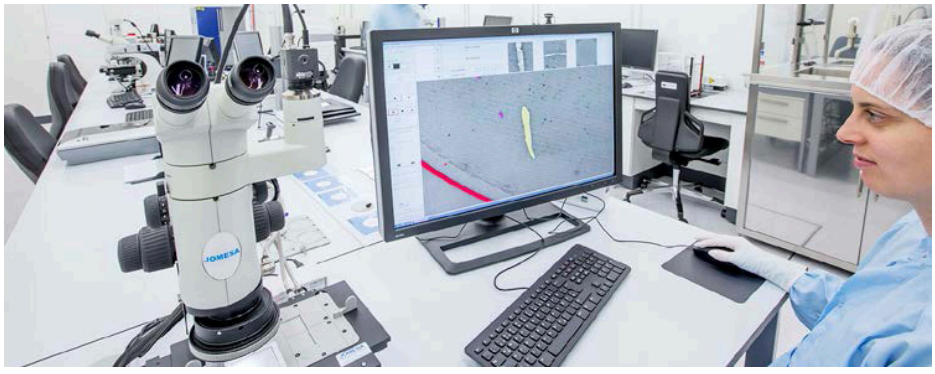
Dr. Udo Gommel, Head of the Department of Ultraclean Technology and Micromanufacturing, is responsible for the establishment of cleanroom and cleanliness technology regulations on several committees and in industry networks. He is Chairman of the VDI Expert Committee on Cleanroom Technology, which is made up mostly of industry representatives, and meets with the committee at least twice a year in order to examine over 20 guidelines on cleanroom technology (VDI 2083), modify them where appropriate and align them with the international ISO equivalents.

Basic standard for nanoscale particle contamination expanded

At previous meetings, the VDI Expert Committee on Cleanroom Technology determined the need for cleanrooms and cleanliness-technology-controlled areas to expand into ranges below 0.1 micrometers into the single-digit nanoscale range. The reason for this is that line widths are becoming ever smaller in the semiconductor and nanotechnology sectors. “Smaller and smaller components are required to produce microchips. Consequently, the size at which particle contamination must be controlled is also decreasing”, Dr. Gommel explains. VDI 2083/1, which the experts refer to as the “mothership” of VDI standards on cleanroom technology, covers particle sizes of 0.1 to 5.0 micrometers. The new forthcoming standard VDI 2081/1.1 relates to much smaller contaminants in the range of 5-100 nanometers. The VDI Expert Committee created a new classification system for this that specifies threshold values for compliance with product and process-specific specifications. Measuring techniques and procedures for characterizing clean areas and equipment were also determined. The new guidelines are to be adopted at the end of this year. Dr. Gommel will present the new developments in his lectures at Cleanzone and Lounges on Tour on October 18.

New calculation method determines the desorption time of H2O2

Another subject that the VDI Expert Committee on Cleanroom Technology took on is desorption kinetics, more specifically the degradation of hydrogen peroxide (H_2O_2) after applying it to surfaces in cleanliness-technology-controlled areas. To ensure that there is no contamination of pharmaceutical or medical technology products and surfaces where cleanliness is critical, for example in manufacturing tablets or implants, cleanrooms must be sterilized overnight. This is often done by hydrogen peroxide fogging, which kills off microorganisms. However, increased concentrations of H_2O_2 are harmful to humans and should not be inhaled, so cleanrooms are ventilated after sterilization until the H_2O_2 level has decreased to a non-critical value. In spite of this, the gas adheres to surfaces, meaning that degradation slows down and this delays the resumption of production activities in the cleanroom. For this reason, Fraunhofer IPA developed a procedure that can be used to determine the half-life of H_2O_2 degradation. Dr. Gommel: “This means that users know when they can resume production.” The new calculation algorithm was integrated into VDI guideline 2083/20. On October 18, Fraunhofer IPA expert Dr. Markus Keller will present the procedure to the public at Cleanzone.



Fraunhofer IPA helps to shape different regulations for cleanroom technology. The experts will present important new developments at the Cleanzone and Lounges on Tour trade fairs. (© Photo : ISS DEBEOS Studios)

From pure ambient air assessment to specific contaminants

Fraunhofer IPA also works with committees and industry networks to harmonize the various guidelines on cleanroom and cleanliness technology. In addition to the VDI 2083 set of guidelines, the international set of standards ISO 14644 and the European Cooperation for Space Standardization (ECSS) for the aviation and aerospace sectors also apply to cleanroom workers. For airborne contaminants, a trend can be seen: cleanroom environments are no longer just being assessed as a means to an end, with the products and their specific cleanliness requirements becoming ever more important. Dr. Gommel: “Previously, standards only focused on air purity, whereas now users can receive concrete guidelines on the requirements for surface cleanliness, component specifications or production environment qualities. This applies to particulate, chemical, film-type and microbiological aspects that are required for production processes, such as for manufacturing satellites, car components or even implants.” Dr. Gommel will explain this topic in more detail at Lounges on Tour on 18 October.

Fraunhofer IPA

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Pfeiffer Vacuum and its new subsidiary ATC present a wide range of CCIT technologies for pharmaceutical packaging

- Leak testing with Mass Extraction (air)
- Leak testing with tracer gas
- Optical emission spectroscopy

CCIT application examples

Pfeiffer Vacuum ASM 340 multipurpose leak detector

Leak testing with patented Mass Extraction technology: ME2 from ATC

Pfeiffer Vacuum AMI 121 Integrity Test System

Since February 2017, ATC is a 100% subsidiary of Pfeiffer Vacuum, a global leader in vacuum and detection solutions. With this merger, Pfeiffer Vacuum can offer its customers a complete range of leak testing and leak detection solutions. At the Pack Expo trade show, Pfeiffer Vacuum and ATC will present a wide range of CCIT (Container Closure Integrity Testing) technologies for pharmaceutical packaging.

ATC's patented Micro-Flow technology and Mass Extraction technology ensure product sterility and comply with regulatory expectations and USP standard for container closure integrity testing. The non-destructive, deterministic leak testing uses Mass Extraction technology to detect defect sizes as small as 1-2 micron (microbial challenge). With short cycle times, high sensitivity and repeatability these systems are very cost-effective.

Pfeiffer Vacuum will present its helium tracer gas leak detection solutions as well as the AMI non-destructive integrity test system which conducts qualitative and quantitative leak measurements in real time without using any specific tracer gas. This self-calibrating method offers the widest test range in the market and has higher sensitivity than conventional methods.

For all leak testing solutions, Pfeiffer Vacuum offers FDA 21CFR Part 11 compliant software as well as IQ/OQ qualification support.

Leak testing with Mass Extraction technology (air)

At Pack Expo Pfeiffer Vacuum will display products from its new subsidiary Advanced Test Concepts (ATC) from Indianapolis, Indiana, USA. The leak testers that will be exhibited work on the basis of leading leak testing technology using air, and therefore do not require any special tracer gases.

The devices operate according to patented Micro-Flow and Mass Extraction technology. The USP 1207 recognized Mass Extraction thereby works on the principle of rarefied gas flow. Testing takes place in vacuum conditions to attain higher sensitivity. This type of testing is particularly suitable for packaging or enclosed objects, such as pharmaceutical packaging as for example IV-bags or glass vials. Defect sizes smaller than 2 µm respectively leak rates of down to 5 • 10-6 mbar l/s can be detected with this method. The method is thereby suitable for laboratory applications as well as for the use in production environment allowing stability control as well as automated 100% testing.

Leak detection with tracer gas

The ASM 340 leak detector delivers very good performance for tracer gas leak detection using helium (or hydrogen) as a tracer gas. The device combines high performance, reliability and repeatability with fastest time to test. This leak detector is easy to use thanks to its user-friendly and intuitive color touch control panel.

The ASM 340 is the leak detector for MALL (Maximum Allowable Leakage Limit) testing within the packaging development process, e.g. for syringes. Pfeiffer Vacuum also supplies corresponding adaptions for specific test parts as well as process support.

Optical emission spectroscopy

The Pfeiffer Vacuum AMI integrity test systems measures leak tightness using a patented process that does not require a tracer gas. Instead, this method uses the existing

Pfeiffer Vacuum and its new subsidiary ATC

gas mixture in the cavities inside the packaging to perform high-sensitivity testing over an extended measuring range. The procedure offers great flexibility: a variety of different packaging types such as blister packs, pouches, vials, plastic bottles, and sealed parts such as battery casings, can be tested in this way.

A big advantage of the AMI is its wide measuring range that also offers higher sensitivity than conventional tests, down to 1 µm respectively leak rates of down to 1 • 10-7 mbar l/s. As a result, the AMI device provides gross and fine leak test in just one device. The procedure delivers deterministic test results with high repeatability, irrespective of the user, and with reliability and accuracy that comply with USP 1207.1. It can be used in laboratory testing as well as IPC (In Process Control) during production testing. Depending on the packaging the simultaneous testing of multiple parts at the same time is also possible.

Pfeiffer Vacuum GmbH
D 35614 Asslar

Investments in quality leadership and production optimization

Raumedic gears for Industry 4.0

Raumedic AG is introducing a new IT-based quality-assurance and production-control system as a way of raising its high quality standards and further boosting the efficiency of its production process. Under the company's plan, the system will be installed in all Raumedic production locations in Germany and the United States by 2019. The medical technology manufacturer reached an agreement on this goal with the software provider Guardus Solutions, the company that will design the machine link for both existing machinery of Raumedic and for future investments in October.

Increased transparency thanks to digitalized production

The manufacturing execution system (MES) is designed to take the transparency of the production operation of the international polymer processor to the next level. With the help of the new system, the status of machinery, production data and necessary work documents will be available at all times on a single platform. MES can help reduce potential sources of error, identify savings potential and increase it. The solution also offers standardized, cross-location performance figures as well as reporting and analysis data in real time.

Step by step, MES will eliminate decentralized island systems, Excel lists and paper documents in a way that will simplify the lives of production employees in particular. Digitalized, paperless processes are designed to perfect manufacturing.

Quality and customer benefits are critical

The solution will also make significant improvements in quality management: Individual products cannot just be tracked all the way back to the raw material. They can also be digitalized, cross-linked, managed and documented from the time of their development to their delivery. The MES covers the entire product cycle. In addition, integrated training and qualification systems ensure that employees have the very latest knowledge at their disposal.

"The use of digitalized processes will not just open up undreamed of possibilities. Above all, it will boost the value that we can and will generate for our customers," said Martin Schenkel, Head of Operations at Raumedic.

The basis for sustainability and competitiveness

"Medical technology and pharmaceuticals are sensitive business areas that have extremely high quality requirements," CEO Martin Bayer said. Bayer noted that not only the company's customers, but also government regulators place strict demands on the documentation of product and process data. As a result, a central standardized data management system will create significant improvements, he added.

Florian Pöhner, Head of IT at Raumedic, is overseeing the implementation of the IT solution. "The system creates an optimal link between our quality control and production units," Pöhner said. "The MES is a consequential step for us and will enable us to take on future projects in terms of Industry 4.0." He added that the company selected Guardus Solutions because the IT provider had an excellent reputation in the area of medical technology and offered a solution with a high level of usability.

Raumedic AG
D 95233 Helmbrechts

Working together: Ulrich Poblotzki (Head of Sales at Guardus Solutions), Florian Pöhner (Head of IT at Raumedic), Michael Frankenberger (Senior Purchasing Manager at Raumedic), Simone Cronjäger (member of the Executive Board of Guardus Solutions), Bernhard Kernen (CFO of Raumedic) and Raumedic CEO Martin Bayer (from left).

Customized for manufacturers and users

Gx® InnoSafeTM

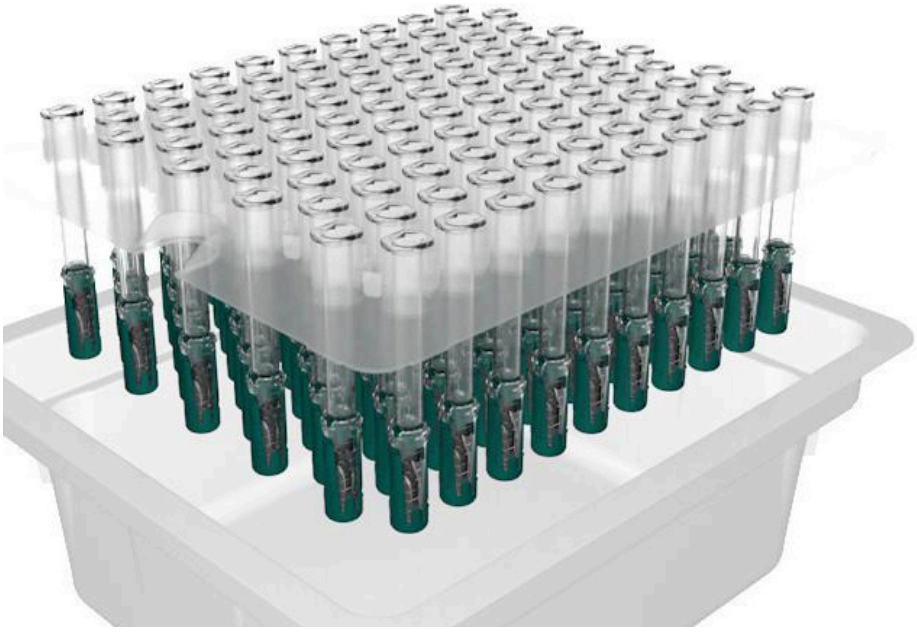
With their exposed cannulas, used syringes are an omnipresent source of danger in medical practices, labs, or hospitals. Existing needle protection systems reduce the risk of injury for the user, but require additional effort for filling on the part of the pharmaceutical companies and with respect to the use of the syringe by medical personnel. With Gx InnoSafe, Gerresheimer introduces a syringe with an integrated safety system for the avoidance of needlestick injuries that fulfils the current requirements of the pharmaceuticals industry and of users equally.

One careless movement is enough for medical specialists to injure themselves on unprotected, used syringe cannulas or come into contact with aggressive active ingredients. In the most adverse case, this can result in serious infections. There is also a danger that already used syringes may accidentally be used a second time. Gx InnoSafe provides reliable protection against needlestick injuries and eliminates the possibility of reuse. In contrast with many existing solutions, the needle protection mechanism is thereby activated automatically and requires no additional actions. This thus involves a so-called passive needle protection system. Also of advantage to the pharmacists is the processing of the Gx InnoSafe syringes, which can take place on existing lines in the nested state without significant changes. An additional installation step of a safety system, as is usual on the market, is dispensed with.

The user wishes a safety system that leaves the familiar injection procedure unchanged, is intuitive and can be operated ergonomically, and which requires no additional manual activation to secure the cannula prior to disposal. The Gx InnoSafe safety system is installed like a standard seal in the clean room on Gx RTF glass syringes in the context of the manufacturing process. The syringe body itself remains completely visible, so that the presence, filling level, and state of the active ingredient, as well as the injection procedure can be inspected without obstacles. The injection itself is administered as usual. Following the removal of the ergonomically optimized sealing cap with the integrated flexible needle shield, the syringe is positioned at the injection point, the cannula inserted into the tissue to be administered and the active ingredient injected as with a conventional syringe. An accidental triggering of the safety system isn't possible, as the mechanism is completely relaxed prior to the injection. The system is first activated with the pricking of the cannula and then automatically ensures when removing the syringe from the injection point that the safety mechanism is permanently locked. In this way, the cannula is reliably covered and renewed use of the syringes is impossible.

For the pharmaceuticals company, Gx InnoSafe offers advantages for the filling process of ready-to-fill syringes. The safety system is positioned fully automatically in the RTF process and visually inspected with an X-ray check to 100 percent for correct positioning. The syringes, including the safety system, are packed in perforated trays and tubs and then sterilized with ethylene oxide gas. They can be processed on existing filling lines without additional preparation and assembly steps. Here too, the design of the safety mechanism ensures that unintended activation while filling, packaging, and transport is avoided. With the introduction of the new product line, Gx InnoSafe is available for the 1.0 ml long RTF glass syringe with a ½" cannula. Additional syringe variants will follow.

Gerresheimer AG
D 40468 Düsseldorf



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Gx® InnoSafeTM - integrated passiv safety system for the prevention of needlestick injuries.

Cleanzone : **Energy efficiency in cleanrooms requires engineering expertise and state-of-the-art measurement technology**

17th - 18th Oct. 2017: CLEANZONE, Frankfurt/Main (D)

Energy optimisation in cleanrooms is a very demanding process, for it is essential that the energy-saving measures do not lead to a reduction in the precisely defined threshold values. Visitors will be able find examples of this at the cleanroom trade fair Cleanzone on Tuesday and Wednesday, 17 and 18 October 2017 in Frankfurt am Main.

Since a key factor is always the precise tasks at issue, the fundamental process is best demonstrated using an example from actual practice. For the case depicted here, the cleanroom experts began by taking note of the most important factors. For a pharmaceutical facility in which production is taking place under GMP conditions, the task was to set up cleanrooms of various classes (A/B, B, C, D) in an area of over 1,500 square meters while ensuring that there would be no cross-contamination, and also satisfying high cooling load requirements.

The external engineers worked closely with the future user to develop a range of concepts. During this process, the focus was on process-optimised planning that incorporated profitability analysis, with particular attention being paid to the ventilation and air-conditioning technology.

In the end, it was decided that it would be best to ventilate the cleanrooms using individual recirculation units with integrated heating and cooling registers. The intention was to install these in the intermediate ceiling area and equip them with terminal HEPA (High Efficiency Particulate Air filter) filtration systems. The individual recirculation units were to be fed proportionally with pre-treated fresh air. The plan also included a clever air-conditioning concept that incorporated heat recovery in the central ventilation unit while allowing for "free cooling" with the generation of cooling. In other words, when it is cold outside, this cold is utilised for cooling the air.

As a result, the cooling units can be turned off for a number of months each year – ensuring that the necessary pumping operations continue is all that is required. The concept that was implemented also made it possible to reduce the size of the central air conditioning unit by approx. 70 percent in comparison with a system in which the cleanrooms are ventilated and aerated directly. The use of individual heating and cooling units for each cleanroom makes it possible to regulate usage to suit requirements – and therefore helps optimise the energy use of the entire system. Due to the fact that such finely tuned control of the pressure differentials between 'clean' and 'unclean' areas is subject to continuous monitoring and adjustments, cross-contamination is precluded right from the start / i.e. is only possible as a result of gross negligence.

Energy savings such as those described here can generally be achieved in all industries where production is carried out in cleanrooms. After all, the overall cleanroom system can be viewed as a single unit – with numerous possibilities for fine tuning at various locations and points in the process. Regardless of the potential savings that can be achieved through ventilation and air conditioning technology, however, the size and class of the cleanroom are the primary determinants of the energy consumption. Because of this, process-optimised planning is necessary right from the start.

Johann Mößlacher, Professional Engineer at DITTEL Engineering, Ried, explains: "Here, optimisation involves a process of carefully determining where the limits lie. In cleanrooms in particular, this entails such things as reducing the air exchange rates, lowering the pressure differentials between individual zones, and defining processes for a lower cleanroom class. This can quickly give rise to a fear that certain standards, regulations and the threshold values mandated therein are being violated, and this often results in a tendency to over-engineer systems and facilities in order to be certain that all requirements are satisfied. Yet it is an engineer's job to question these very assumptions, so that they can design systems that comply with all necessary threshold values without exceeding them needlessly. That is the correct approach for optimising the energy consumption."

Retroactively modifying existing cleanroom systems can also be a successful approach – as in ointment production, for example: a recirculation unit for low-turbulence displacement flow makes it possible to lower energy consumption by 32 percent by reducing the air flow speed from 0.45 to 0.20 metres per second during times when production is not taking place. The one-off costs of 11,000 euros for tests and qualification can lead to annual cost reductions of 6,000 euros – meaning the move pays for itself within two years.

It all comes down to making good use of the leeway that is almost always available. This entails continuously comparing target and actual figures and taking new technological possibilities into account. And it is critical to remember that conventional energy meters are not enough. In order to properly record the relevant data in cleanrooms, specialised cleanroom expertise is a must, for when this is done, it is possible – to give an example – to achieve savings of ten to twenty percent with existing systems and, in comparison with conventional 'off the rack' designs, as much as fifty percent for a brand new design that is precisely tailored to requirements.

The industry will be offering a clear demonstration of the fact that energy efficiency and high quality standards in cleanrooms do not have to be mutually exclusive at the Cleanzone trade fair on 17 and 18 October in Frankfurt am Main. For example, the "Measurement Technology: Equipment + Project Validation/Qualification" module of the Cleanzone Congress will be focusing on state-of-the-art measurement processes. Visitors to the Cleanzone trade fair this October will be able to obtain an information advantage and return to their own operations with concrete concepts and impressive examples from actual practice.

cleanzone

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parts2clean 2017: **Providing the key to reliable, efficient component cleanliness**

- Leading trade fair to showcase numerous innovations and refinements
- Presenting wide-ranging expertise on the cutting-edge optimization of cleaning processes

24th - 26th October 2017: parts2clean, Stuttgart (D)

In virtually every sector of industry, parts and surface cleaning has developed into a quality criterion and competitive factor, while at the same time creating added value. "This year's parts2clean features the world's most extensive range of products and services for reliable and efficient components cleaning," remarks Olaf Daebler, Global Director of parts2clean at the event producer, Deutsche Messe, adding: "Our guided tours, our new special display titled 'The Process Chain for Quality Analysis in the Cleanroom' and our speakers' presentations at the expert and innovations forum will provide visitors with additional, targeted information on a wide array of topics covering parts and surface cleaning."

Display sectors to showcase numerous product innovations and refinements

Over 230 companies from 14 different countries will be represented at this year's parts2clean, which runs from October 24th to 26th at the Stuttgart exhibition center. With a total of some 7,100 square meters of display space, this 15th edition of the flagship show will be the biggest ever. The companies exhibiting there will be showcasing cross-industry, "cross-material" products, solutions and services for all segments of industrial parts and surface cleaning. "Numerous exhibitors will be taking advantage of the international forum provided by the event to unveil their latest innovations and product refinements," reports Daebler. This includes a new, continuous process for cleaning parts using water-based media as well as several innovative cleaning systems using solvents like hydrocarbons and modified alcohols. Another first at parts2clean will consist of a new ultrasound generator which can be fitted with a second resonator attachment, allowing two similar or different processes, for example cleaning and rinsing in two separate basins using different agents, to be performed with a single generator. A further innovation in the field of ultrasound cleaning consists of the first-ever waterproof generator.

The visitor can also expect to see additional innovations in the area of automating cleaning processes, including the first manipulator specially developed for deployment in robot cells. Apart from its robust design and protection rating of IP 69, this product is compelling based on the ease of programming and operating it using the CNC control system of the cleaning cell. The event will also feature a number of solutions for integrating cleaning processes with the Industry 4.0 environment. Other display segments include cleaning agents, bath monitoring and care, corrosion protection and packaging, systems for particulate and film cleaning control as well as cleaning and transport containers, with participating firms showcasing their new and improved solutions in all of these areas.

Supporting program features special display, guided tours and expert forum

The supporting program for this year's parts2clean will unveil all the latest developments, including at a special display titled "The Process Chain for Quality Analysis in the Cleanroom", where visiting professionals can get a close-up look at the process steps necessary not just to comply with strict cleanliness standards, but also to verify and document this compliance.

The guided tours will allow visitors to find out all the latest developments, being led by a specialist guide who will take them directly to the key segments of industrial cleaning.

Coordinated by the Fraunhofer Cleaning Technology Alliance and the Industrial Parts Cleaning Association (FiT), the three-day expert forum at parts2clean has long been considered one of the world's leading sources of inside knowledge. At this integrated forum, high-caliber speakers from industry, science and research will share their expertise on process optimization as well as special industrial parts and surface cleaning themes, innovative developments and the interface between cleaning technology and Industry 4.0. Attendance at the parts2clean expert forum is free of charge for all trade fair attendees.

Deutsche Messe AG
D 30521 Hannover

Parts2Clean 2017: Fraunhofer IPA presents details of the process chain from cleaning through analytics all the way to packaging in ultra-clean environments.

Cleaning is just the beginning

It is more complicated than many might think to clean components for industry. Expert knowledge is required in selecting the correct cleaning process, cleanliness analysis and packaging. Moreover, industry-specific regulations and the requisite infrastructure are additional factors involved. Fraunhofer IPA is the only institution in Germany to offer the entire process chain in an ultra-clean environment. Experts will present details of this at Parts2Clean, an international trade fair for industrial parts and surface cleaning, which is being held October 24–26, 2017 in Stuttgart, Germany.

When component parts require cleaning, there is no uniform procedure to be followed. The most suitable cleaning process must be determined, which all depends on the material, industry and application at hand. For workshop components, it is often sufficient to remove organic residues such as fats and oils with a solvent. Aeronautic applications, in contrast, require extremely delicate cleaning procedures, for example with CO_2 snow. Occasionally, a component has different, sometimes unknown materials or a complex geometrical design. This requires a combination a different procedures which must be conducted in a specific order.

Trial and error often helps

IPA scientist Max Metzmacher explains: "Here is where the majority of service providers fail, because they tend to either specialise in coarse cleaning or fine cleaning. However, Fraunhofer IPA possesses both the knowledge and the tools to also find a solution to this issue." Some examples of these tools are an ISO category 1 cleanroom CO_2 snow nozzle and highly efficient ultrasonic immersion bath with several compartments. A particular challenge is presented by cleaning prototypes or individual component parts. Here, the process is not integrated in manufacturing, as is the case for serial production. Threshold values and suitable processes must instead be ascertained first of all. Fraunhofer IPA is able to conduct complex tests and lab experiments as well as guaranteeing the required level of safety. "When the original idea doesn't quite work, we simply try something new out", Metzmacher explains.

Fraunhofer IPA is the only institution in Germany to offer the entire process chain, from the cleaning itself through cleanliness analysis all the way to transportation in an ultra-clean environment. (© Photo Fraunhofer IPA, Rainer Bez)

Validating cleanliness

The actual cleaning is only part of the process. The level of cleanliness must also be verified and validated. In some industries standards have already been defined which stipulate specific test methods and threshold values. For example, VDA Volume 19.1 regulates the automotive industry whereas the ECSS (European Cooperation for Space Standardization) regulates the aerospace industry. Fraunhofer IPA has the instruments to conduct the analyses required here. Measurements using an electron microscope, gas chromatography or infrared spectroscopy are all possible, for example. If no regulatory framework has been established, the scientists support their partners in defining suitable standards. Furthermore, the scientists form committees in order to establish norms for various industries. These include the industry association "Cleanroom Suitable Consumables (CSC)" for consumable supplies in cleanrooms or Adhäsa, an association for adhesive cleanliness.

Clean packaging for clean transportation

Cleaned and validated components are not easily packed and dispatched in boxes. As Metzmacher explains, "The majority of components require a cleanroom in order to remain unsoiled. If they are taken outside of this environment and carried down the corridor, the threshold values will already have been exceeded." Instead, the components must be wrapped in certified sheets and transported in a clean environment. In cases where the components are exceptionally large with complex geometrical designs, IPA scientists design suitable packaging to safeguard the clean status of the components.

Metzmacher summarizes things by concluding: "Our USP is that we are able to carry out the whole process chain, from cleaning through analytics all the way to packaging in ultra-clean environments." It is because of this that the team has years of experience working for companies using components which are subject to the strictest cleanliness requirements. "Our customers include, for example, the aerospace company OHB Systems AG and the European Space Agency,«" the expert explains.

24th - 26th October 2017: parts2clean, Stuttgart (D)

Fraunhofer IPA

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2. Trade Fair for Deburring Technology and Precision Surfaces, 10th - 12th October 2017 with around 150 exhibitors

DeburringEXPO – a wealth of innovations and information covering all aspects of deburring and precise surfaces

From 10th to 12th October 2017 at the trade fair center in Karlsruhe in Southern Germany, around 150 exhibitors at DeburringEXPO will be showcasing an extensive spectrum of solutions to the wide-ranging tasks of deburring, rounding and manufacturing precision surfaces. In addition to the products presented by companies from 16 different countries, a three-day expert forum will also be held. This will give professional visitors the opportunity to find out about innovative developments, practical examples and benchmark solutions in simultaneously-translated (German <> English) presentations.

10th - 12th October 2017: Deburring Expo, Karlsruhe (D)

In its second year, DeburringEXPO is expecting a plus of over 40 percent more exhibitors compared to its first fair in 2015. The trade fair for deburring technologies and precision surfaces is also becoming significantly more international, with approximately 22 percent of the 150 exhibitors coming from abroad. “Of course we’re really pleased to have aroused such interest among so many foreign companies. We are even more pleased to be able to offer the most comprehensive range of solutions to professional visitors from the fields of automotive, drive and transmission technology, aerospace and space travel, mechanical engineering and medical products, as well as the sanitary, watch-making and tool industries, fluidics, hydraulics, precision engineering, microtechnology and many other sectors. They will be able to obtain all the information they need within the space of just one day”, explains Hartmut Herdin, CEO of the organizing company fairXperts GmbH & Co. KG.

Cross-technology solutions with many innovations

The fact that exhibitors view DeburringEXPO as a platform for their industry is further underlined by the numerous new and further developments being showcased at the fair in all areas of the exhibition. These include robot-deburring systems for machining die-cast parts, for example. Specially-designed cutting tools produce uniform and narrow deburring edges on aluminum cast parts. An energy-efficient and automated blasting system for processing small components will be presented. An innovative ECM plant, specially designed to finish the surfaces of 3-D printed metal parts and remove microburrs, will also be on show. A new planetary finishing machine with a freely-controllable gearing mechanism will be showcased, as well as a teachable plug-and-play grinding system for finishing defined areas of single parts in an automated, high-precision process that is easy to integrate into production lines. Novelties also await exhibitors in the deburring tool sector, such as a tool that uses a machining process to automatically deburr intersecting boreholes with a defined edge. The new tools are designed to cope with increasingly complex geometries, as well as new materials and material combinations. New and further developments are also being presented in the areas of brush deburring, thermochemical deburring (TEM), abrasive flow machining, (flow grinding), plasma polishing, cryogenic and ultrasonic deburring, as well as process monitoring and quality control.

The solutions on display are extended by the theme park “Cleaning parts after deburring”. This gives an overview of current technologies for optimally removing deburring residues.

Bilingual expert forum – Basic and Expert Knowledge

With the integrated three-day expert forum, which already proved to be highly popular among visitors last year, DeburringEXPO also provides a platform for transferring knowledge and exchanging experiences. “We have realized that the global demand for informa-

DeburringEXPO – a wealth of innovations and information

tion and know-how on deburring technologies and generating precision surfaces is very high. For this reason, the 29 talks given at this year's fair will be translated simultaneously (German <> English). Visitors can attend free of charge", says Hartmut Herdin. The technical contents of the program have been coordinated by the Fraunhofer Institute for Production Systems and Design Technology IPK. Covering a wide range of topics, it kicks off on the first day of the fair with a general lecture on deburring technologies. The remaining speeches on this day revolve around mechanical deburring. These include, for example, high-speed deburring (HSD) with mechanical tools in highly-automated processes, machine deburring components and belts, the possibilities and restrictions of robot-based deburring, as well as burr-free boreholes drilled using an innovative drill spindle technology. The focus of the first block of talks on Day 2 of the fair is on abrasive deburring. Among others, topics include cryogenic deburring and cleaning parts made from rubber, non-ferrous metals and technical plastic molded parts, the main aspects of plasma polishing, and PECM as a gentle solution to the toughest tasks. The second session is devoted to measurement technology. Lectures on this agenda include digital multi-wave holography for measuring precision surfaces and residual burrs with micrometer accuracy in an inline process, optical high-accuracy measuring techniques for inspecting precision-machined surfaces and analyzing edge preparation, as well as scattered light measuring devices for conducting fast inline surface measurements. The third day of the trade fair starts with a block of talks on surface treatment. Among other things, the information imparted in these lectures ranges from Plasma electrolytic Polishing (PeP) – applied technologies and current challenges faced when deburring metals, through developments and trends related to precision-machining surfaces right up to generating precision planar surfaces. The final session is devoted to technologies for cleaning parts after deburring. These talks focus on industrial cleaning media capable of transporting high quantities of particles from a wide range of metals, targeted processes for cleaning inner contours/geometries with strict cleanliness requirements, as well as aqueous cleaning and deburring methods for medical and micromechanical precision parts.

fairXperts GmbH
D 72639 Neuffen

STC Standard Technology Corp. Taiwan becomes new distribution partner of AP&S. Partners celebrated the cooperation at a joint booth at SEMICON Taiwan 2017.

AP&S International GmbH and the new partner STC Standard Technology Corp. Taiwan started into the cooperation with a common booth at the upcoming SEMICON Taiwan event, which will take place from 13th to 15th September 2017 in Taipei, Taiwan.

"Taiwan, as one of the world's major producers of electronic products, belongs to the most important regions for the semiconductor industry globally. Correspondingly high is the interest for advanced wet process solutions in this market. The goal of our new partnership with this local player is to cover this demand efficiently", stated Oliver Pohl, responsible for the international distributor network at AP&S.

"Since 2016 we have already successfully cooperated with the company CLC Tech, who was and will remain the exclusive Taiwanese distributor for our cassette, box and foup cleaner CB II and CB III. With STC, as a new distributor for our single wafer and wet bench product portfolio, our Taiwanese customers and prospective business partners have a reliable contact person right at their front door. STC is well established in the market since 1988, is an expert in his field and is familiar with the specific needs of the local market. Together we offer convenient access to required information for interested parties and achieve short distances between the customer and equipment provider, who can be quickly on-site on request."

At the SEMICON Taiwan event AP&S and STC presented the full range of AP&S wet process solutions. Highlights of the single wafer area were the unique AP&S SpinLift-off tool, which processes with DMSO (an EH&S uncritical substance) and the SpinMask tool, which provides outstanding mask cleaning results.

Within the wet bench portfolio the partners emphasized the A-Series wet process tool, which is available with 100 wafer half-space feature for high volume production and the AP&S Vulcanio bench, a fully automated e-less plating tool. Both wet benches are capable of handling up to 300 mm wafers.

12th - 14th September 2018: SEMICON, Taipei (Taiwan)

AP&S International GmbH
D 78166 Donaueschingen

High-tech for more comfort and personalised applications

13th. - 16th November 2017: COMPAMED, Duesseldorf (D)

COMPAMED 2017: **Medical technology is the most important market for micro systems**

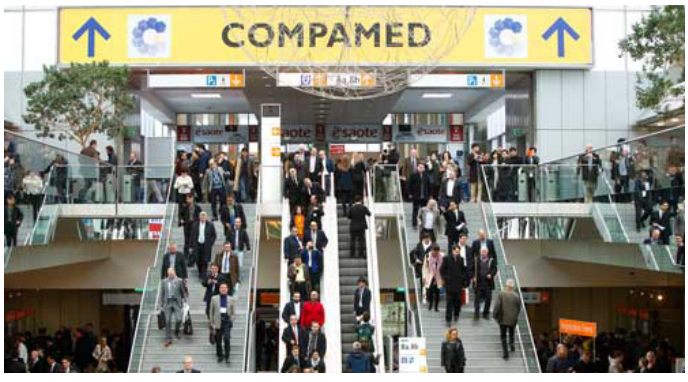
The trend towards personalised medical care, demographic developments and digitalisation constitutes an important driver towards technological advances in the fields of medical technology and healthcare. Health policies and cost pressures are also pushing progress forward. The field of medical technology has in particular given the micro-technology industry a huge boost with its demand for corresponding solutions. Nearly two-thirds of micro-technology companies in Europe supply products, technologies and services to the medical technology and healthcare sectors … they represent the most important sales market for almost 20% of these firms. The share of companies that supply primarily to the market for medical technology will increase by another 5% in the next three years. This is what the IVAM Fachverband für Mikrotechnik (IVAM Association for Microtechnology) has found in its annual survey of economic data from companies and research institutions operating in the field of microtechnology in Europe.

Microtechnology will therefore also be playing a major role at the COMPAMED 2017, which is the leading international trade fair for supplies to the medical-manufacturing sector. It will be taking place in Düsseldorf alongside the MEDICA 2017 – the world's leading medical trade fair – from 13 to 16 November. "Besides digital transformation that has affected all sectors, the miniaturisation of components for creating increasingly handier and lighter product applications also constitutes an overarching technology trend," says Joachim Schäfer, Managing Director at the Messe Düsseldorf. Since its launch 25 years ago, COMPAMED has developed into the No. 1 platform for suppliers to the medical technology industry and will this year again be counting almost 800 exhibitors in Halls 8a and 8b (MEDICA: approximately 5,000 exhibitors) at Düsseldorf's exhibition centre.

The 'High-tech for Medical Devices' product market with around 700 square metres and more than 50 companies and institutions (Hall 8a) is again fully booked and is being organised as in every year by the IVAM Fachverband für Mikrotechnik as a special showcase for microsystems destined for medical technology applications.

Measuring blood pressure without cuffs

One important application is the field of so-called 'wearables', mobile, almost entirely concealed and very comfortable systems for recording and analysing vital parameters in everyday situations and transferring them to medical experts. The continuous recording of so-called peripheral photoplethysmograms will in future provide valuable information about a person's health. The information recorded includes the pulse and arterial oxygen saturation, heart-rate variability, respiratory rates and data about vascular stiffness and signs of rising or falling blood pressures. Elevated blood pressure is currently one of the most serious risk factors for cardiovascular disease which – according to the Deutsche Hochdruckliga (German Hypertension League) – affects around 35 million people in Germany alone. The disease is often detected too late because its symptoms are not always apparent. The consequences are in particular stroke, heart disease, kidney failure and dementia.



Against this backdrop, the possibility of tracking blood pressure continuously without the need for cuffs is one of the most important innovations at this year's COMPAMED. A team of scientists around project manager Dr Hans-Georg Ortlepp at the CiS Forschungsinstitut für Mikrosensorik (CiS Research Institute for Microsensors) developed the sensor for this application along with the sophisticated method of analysis. "The necessary raw data is taken from the shape of the pulse wave and its behaviour over time. It is essential in medically relevant applications that the sensor signals are of a high quality and that suitable mathematical algorithms are employed for data analysis," explains Ortlepp. CiS has already been working for a good decade on miniaturised multispectral photoplethysmography sensors that are integrated into silicon. The tiny sensors are placed in the outer ear canal and are individually adapted to patients. It is very important that the high-tech components are comfortable to wear as it is this aspect that decides acceptance by users. It is possible to equip the sensors with up to four LEDs that utilise different wave lengths to enable additional vital parameters and data from different depths of tissue to be measured besides blood pressure thus making it possible to eliminate movement artefacts from the signals.

Administering active ingredients into instead of under the skin

The Hahn-Schickard-Gesellschaft für angewandte Forschung (Hahn-Schickard Association for Applied Research) has also dedicated itself intensively to researching, developing and manufacturing in the field of technology for microsystems. It cooperates with the Verapido Medical GmbH spin-off in the development and production of equipment, systems and technologies that allow active ingredients to be administered into instead of under the skin. Studies have shown that active ingredients introduced intradermally are available at considerably faster speeds than those administered subcutaneously and are consequently able to develop a more efficient effect. It has also been proved that such biotech molecules as insulin, antibodies, proteins and hormones are absorbed into the body much more quickly when they have been administered intradermally.

Active ingredients that are injected into the skin are also able to influence the immune system more efficiently and specifically. "Clinical studies have shown that up to 90% of the injected dose can be saved with intradermal administration while achieving the same or even better effect than injecting into muscle," emphasised Dr Markus Clemenz, Managing Director at Verapido Medical. The company is working on micro-needle technology and micro cannula that are injected precisely into the dermis – a layer of skin that is located just under its surface. Only the top layer of skin is penetrated which makes it a minimal invasive procedure. "Our scope of developments range from patch-based micro-needle arrays through intradermal administration equipment with fixed or variable depth settings for injections and infusions to drug-metering systems for (time-delayed)

COMPAMED 2017: Medical technology is the most important market for micro systems

chronotherapy without the need for any electronics," says Clemens. Verapido is anticipating that intradermal injections will become clinical state-of-the-art in the future.

CorTec is going to be exhibiting at the COMPAMED for the second time. This young company that specialises in medical technology is working on the next generation of active implants. It is developing and producing implanted electrodes for drain-outs and stimulation in the central and peripheral nervous systems. CorTec is also manufacturing encapsulated casings to support high-channel applications. Electrodes and encapsulated casings will possess between 32 and more than 200 channels and thus more drain-outs than comparable products. "CorTec's technology combines innovative solutions for design, layout and working with materials that are already tried-and-tested in the field of medical technology – particularly with high numbers of channels. We are thus making applications and therapies possible that were previously impossible to address in this way," explains Dr Martin Schüttler, CTO and CEO at CorTec.

Its patented 'AirRay' electrode technology has enabled CorTec to overcome the current limitations when working with electrodes through innovative and highly precise manufacturing conditions. This makes smaller dimensions for contact diameters from up to 25 µm possible which in turns means that it is possible to significantly increase packing densities in electrode arrays. This will allow the quality of data acquisition to be improved many times over. The electrodes also possess excellent electrochemical properties. Platinum-iridium or MP35N (nickel-cobalt alloy) may be used to make the electrodes, optionally with high-performance coatings, to further improve the delivery of stimulation impulses to the biological tissue. It is also possible to adapt the electrode's mechanical properties to individual needs.

Communicating with implants via high-frequency or infrared technologies

In addition to its 'AirRay' electrode technology, CorTec's portfolio also includes such other products for manufacturing active implants as a ceramics-based hermetic encapsulated casing. The use of thick-film technology here allows hundreds of electrical throughputs to be realised – entirely in contrast to conventional encapsulated casings. The ceramics-based encapsulated casings by CorTec are also permeable to electromagnetic waves which in turn means that it is possible to communicate with implants using high-frequency and infrared technologies and to transmit energy wirelessly. The ceramic encapsulated casings have been optimised to the extent that they are able to withstand the mechanical loads that have, for instance, been specified for cochlear implants. CorTec Brain Interchange has combined all these components into a single system that is able to measure and analyse neuronal activity and so is able to stimulate the nervous system as required. This so-called closed-loop functionality opens up a wide range of possible applications for individual and needs-based neural treatments. The system's scope of applications range from controlling assistance systems for paralysed patients through needs-based deep-brain stimulation to rehabilitation for stroke patients and epilepsy intervention. The first system prototypes are currently undergoing preclinical trials. Initial clinical pilot studies are in preparation.

Additive procedures for personalised implants

Another topic that has been becoming more and more important at the COMPAMED are additive procedures. The IKTS Fraunhofer Institut has developed 'bone from the printer'. It has been designed to be used to repair defects in facial areas or bones damaged by tumours that have metastasised. In such conditions, the patients' quality of life is considerably restricted because the bones can suddenly break without the application of any external forces. Ceramic bone implants that have been adapted to the precise millimetre to the patient's anatomy would be able to potentially alleviate patients' suffering. The ceramic implant by IKTS is being manufactured in two stages: The ceramic casing is printed in 3D which is then filled with a ceramic foam. The additive manufacturing of the shell allows the piece to be adapted to the patient's specific skeletal structure and the porous foam filling enables porosity to be adapted specifically to the patient. The foam facilitates cell growth while it is also biologically active and resistant to pressure. It is this combination of procedures and materials that create the great benefits that the new solution delivers. "We work with such commercially available materials as hydroxylapatite and tricalcium phosphate and are now initiating the biological testing phases for our substances," explains Dr Matthias Ahlhelm, Project Manager at IKTS.

Microstructures from 3D printers

Multiphoton Optics is also active in the field of 3D printing. This company is producing a high-precision 3D printing platform ('LithoProf3D') and software ('LithoSoft3D') for the additive and subtractive manufacturing of randomly shaped structures that are realised either in the full or on surfaces of materials. The technology supports the high-precision manufacturing of optical 3D interconnects, aspherical or free-form microopitics as well as biomedical products such as scaffolds for tissue engineering, microfluidic cells and drug-delivery structures. Multiphoton Optics only recently demonstrated the opportunities presented by 3D printing platforms by manufacturing this stack of microstructures. The stacks resemble the optical component of an endoscope and they consist of five different individual freely shaped lenses and other structures thus creating a total of 10 differently shaped surfaces. "Microoptical structures are increasingly becoming the core components for highly integrated technical medical systems. We shall be presenting exhibits at the COMPAMED that will also demonstrate how well our process performs in this area," says Felix Kiesel, Director of Sales at Multiphon Optics.

The 'Cobra' line of products by Silicon Microstructures (SMI) Inc. – the first commercially available pressure sensor with a connected cable that fits into instruments with a French-scale diameter – will be another highlight at the COMPAMED 2017. The French scale is used in the field of medicine to indicate the outer diameter of cannula and catheters where three on the scale is equal to one millimetre. The sensors are small (220 micrometers wide), stable and smart as well as temperature-compensated; digital and amplified analogue versions are available. SMI will be presenting how this sensor array is able to reduce risks with urodynamics, endourology, cardiology, emergency surgery, brain-pressure monitoring and other processes.

The world of small and smallest solutions for medical technology therefore remains a subject that will remain important to the COMPAMED in Düsseldorf and, as previously, it is also going to be presented and explored within the scope of the IVAM's COMPAMED HIGHTEC FORUM in Hall 8a. Besides microsystems technology, the focus this year will be on nanotechnologies, production technologies and process control. Specialists will also be presenting parallel talks about current developments along the entire process chain of medical technology at the COMPAMED SUPPLIERS FORUM, which is being organised by the DeviceMed magazine in Hall 8b. This year, the event will be focusing on digitalisation, wearables, 3D printing and regulations.

Messe Düsseldorf GmbH
D 40001 Düsseldorf

Machines and plants for injection molding (thermoplastics and elastomers)

Electric TE series

- Precise, clean and fast
- Optimum cycles achieved through parallel machine movement
- Fast cycles with outstanding process reliability

"Precise, clean and fast" is Woojin Plaimm's trade fair motto for Fakuma 2017. A fully electric injection molding machine from the TE series will be on display at the GKV/TecPart Verband Technische Kunststoff-Produkte e.V. stand. (Hall A5, Stand A5-5106). At the same time, Fakuma 2017 will also be the premiere for the company's new German sole agency, Nortec Maschinentechnik from Soltau (D), which assumed the new machine business and after-sales for Woojin Plaimm as of 1st May 2017.

Production will be realised using a fully electric TE110 with a clamping force of 1,100 kN where the tie bar distance is 410 x 410 mm (h x w). Screw diameters from 22 to 32 mm are on offer as the injection units for the TE110. The TE110 is powered by high performance servo motors. The TE series can provide high cycle speeds thanks to movements which occur in parallel. Peter Nellen, the CEO of Nortec: "The use of a single independent servo motor for each operation in the machine enables every movement to be controlled in parallel, including the removal of the part during the dosing for the following cycle." The TE series is ideal for demanding uses with maximum precision in the areas of electronics, packaging and medicine. When operational, the machines from the TE series are very quiet, clean and energy efficient, they emit very little heat, they function without the expense of oil recooling and they offer better environmental and working conditions.

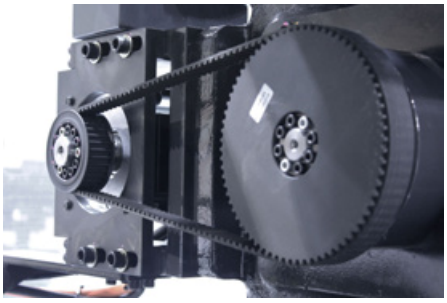
A finite element analysis enables the optimum distribution of forces

The toggle lever system in the TE series has been developed on the basis of a finite element analysis for the optimum distribution of forces. The clamping force is derived from the typical concentration points at the edges of the mold to the centre. The toggle level principle enables the creation of a uniform clamping force envelope curve around the cavity. The efficiently applied clamping force lowers the energy requirements in general and allows for greater injection and internal pressure in the mold. A separate drive motor ensures the adjustment of the clamp to various mold installation heights. A solid linear guide enables the precise movements of the clamping unit. The TE series provides a clamping force range from 300 to 8500 kN with the corresponding injection units supplied from the factory.

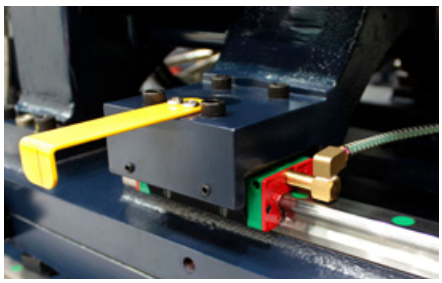
The electric high-precision injection unit

The TE injection units by Woojin Plaimm stand equally for precision and speed: The in-line injection unit in the TE series, combined with the closed control loop, is optimal for high precision injection molding. The TE110 is also equipped for injection molding with very short cycle times, where very fast and precise position control is required.

The fully electric TE series by Woojin Plaimm: Precise, clean and fast. (Photo source: WOOJIN Plaimm GmbH)



High performance servo drives enable optimum cycle times by means of parallel machine movements. (Photo source: WOOJIN Plaimm GmbH)



A ball screw (RAM box) with a high load capacity has been used in order to ensure a long service life and high availability for the TE series. (Photo source: WOOJIN Plaimm GmbH)

Peter Nellen, the CEO of Nortec (photo source: Nortec Maschinentechnik)

The PP580 intuitive controller

The TE100 is controlled using the PP580 controller with a real-time operating system. The 15' TFT colour monitor, which is directly connected to the controller, enables highly user friendly and transparent operations via a touchscreen (1024 x 768 mm) and robust plastic covered keys. The fast signal processing time of less than 0.4 ms enables the TE110 to provide high performance during time-critical operations. The PP580 unit's comprehensive energy monitoring informs the operator of the current energy consumption in the process. The PP580 unit enables the central monitoring of the extraction systems and other ancillary equipment. The integrated interface programs such as Euromap 67 enable a robot interface and the management of the temperature control units. It is possible to remotely monitor the machine in real time using a VNC server function. A large number of molds and parameter data can be acquired and saved via the USB interface in order to enable a fast production start-up and reproducibility. The PP580 controller also provides the option of embedding up to 250 Woojin Plaimm machines in the factory data capture (FDC).

17th - 21st October 2017:
FAKUMA,
Friedrichshafen (D)

Woojin Plaimm GmbH
A 2544 Leobersdorf

Closer to the µ than ever – Medical Devices in High-End Precision

The investment into the new technology center (TC) at Spang & Brands, Frie-drichsdorf/Germany, could not have been more future-oriented. Here, all new customer pro-jects from the medical device, pharmaceutical and dental technology sectors enter the process chain – from design and product feasibility right through to pilot series. Not until the quality as-sessment department has given approval, the CAD/CAM product data are transferred to the manufacturing plant: for multiplication of a given medical device in multi-million batches. Al-ways with one and the same high quality. Background: latest technological feature in the TC is a software package called CATIA Mold&Die. It is the basis for guaranteed consistency of the CAD mould data and highest possible precision during CAM of the moulds for medical devices: "… with a precision level up to the last µ", says Technical Director Alexander März.

During COMPAMED, Spang & Brands will exhibit more than 100 different medical products in hall 8a, stand M33 – component groups, precision and micro products manufactured in mono or multi-component injection moulding technology. Among the exhibits are syringes, cannulas, push-through membranes, implant components and those for minimally invasive medicine, fastening/joining elements, functional parts for infusion solution bags and closure/sealing systems, as well as assembled units and ready-for-sale devices where accuracy and structure must be – and is – exemplary.

On the whole, Spang & Brands uses very particular plastics blends, including resomere materi-als, those that can only be processed using state-of-the-art high-performance moulds: "For the past 30 years or so, we have specialised in precision and cleanroom injection moulding for the medical and pharmaceutical industries …," states CEO Friedrich Echterdiek, and continues "… for just those special ISO 13485 relevant projects, we employ the right technologies with CAD-3D development and MoldFlow analysis. We have more than 65 active injection moulding ma-chines – including all-electric machines. Most importantly, we take full advantage of our contin-uously growing engineering know-how." In Class 8 (100,000) clean-rooms, fully automatic and manual assembly takes place, not forgetting the packaging of components and assembly units ranging from pilot/preproduction series and just-in-time produced batch sizes right through to runs of many millions. Strategically positioned checkpoints and 3D precision metrology support the company's stringent quality surveillance and assurance system.

"The demand for smaller, more complex and more accurate functional components with an emphasis on patents' safety is continuing to rise – this is particularly relevant in medical technology. During COMPAMED, we will demonstrate that we master the corresponding technologies, those regarding, among others, the development of components, mould making, injection moulding technology, the topic of cleanroom production, and assembly, in other words the complete range of production processes within the entire value-added chain", concludes Jürgen Mader, Director at Spang & Brands.

13th - 16th November 2017: COMPAMED, Duesseldorf (D)

Spang & Brands GmbH
D 61381 Friedrichsdorf

Two-component cap with rated breaking point (Foto: Spang & Brands)

Die Spang & Brands Geschäftsführer vor dem neuen Technologiezentrum, v.l.n.r.: Alexander März, Friedrich Echterdiek (CEO, Vorsitzender), Jürgen Mader (Foto: Spang & Brands)

Pencil point spinal needle with magnifying glass (Foto: Spang & Brands)

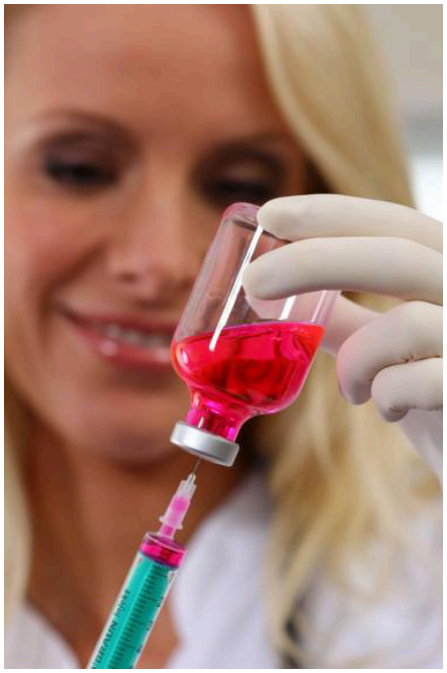
Life Sciences 2018 Exhibitions of Turkey for International Trade Opportunities in Rapidly Developing Market

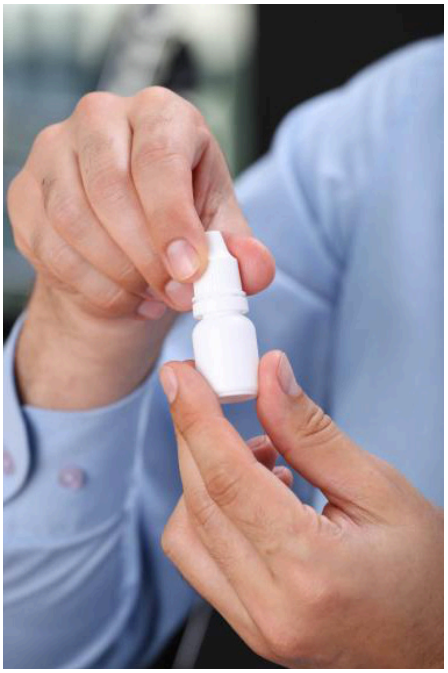
The manufacturers who supply advanced technology and special services for Life Sciences in different industrial fields will come together at the "one and only" Life Sciences Exhibitions of Turkey in İstanbul,on 19th - 21st April 2018. The key players of ; biotechnology, OTC, pharmaceuticals and laboratory industries will wecome the professionals from all concerned sectors of Turkey and the neighbouring countries covering a huge market.

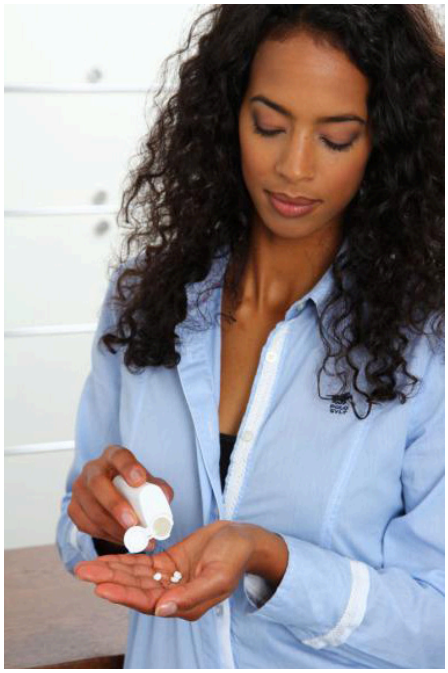
This new concept of "Life Sciences 2018 Exhibitions of Turkey" includes 4 industries and 4 special exhibitions in one hand..Analytech 2018, Biotecnica 2018, PharmaNEXT 2018 and NutriVISION 2018 Exhibitions will be organised at the same time, in the same venue in order to create "synergy" and "absolute concentration" We invite the concerned industries to take place in Life Sciences 2018 Exhibitions of Turkey" in order to establish new business contacts in this rapidly developing field and to take a place in the future-oriented market of Near Asia and entire Middle East as well as the Eastern Mediterranean area.

19th - 21st April 2018:
Life Sciences 2018 Exhibition of Turkey,
Istanbul (Turkey)

AntExpo Org. ve Dan. Tic. Ltd. Şti
Ümraniye, İstanbul
Turkey







Pack Expo Healthcare 2017 : **Gerresheimer's plastic packaging for the healthcare industry**

Gerresheimer's debut at the Pack Expo trade fair in Las Vegas from September 27 to 29, 2017 will focus on new safe and patient-friendly drugs packaging made from plastic such as its Duma Twist-Off and Triveni US-type containers, eye drop bottles with fixed US TE-ring, Duma Pocket containers, and COP monolayer and MultiShell vials. Gerresheimer will begin manufacturing a wide variety of US containers in US in September.

"We can supply the right type of packaging for virtually any drug," states Franck Langet, Business Development Manager North America, who will be advising existing and potential customers in person at booth N-638 in the Las Vegas Convention Center together with his team.

Gx MultiShell – leak-tight, shatterproof, and transparent

"The kind of powerful active ingredients that are being developed nowadays need shatter-resistant packaging and an oxygen barrier," Franck Langet says, explaining the properties of the Gx MultiShell vial. With its innovative multilayer structure made from COP and PA, this transparent vial is a unique packaging product that meets all these requirements. Gerresheimer also provides monolayer versions of its COP containers.

Eye drop bottles – now even safer

"Sometimes, the devil is in the detail," reveals Franck Langet, adding that Gerresheimer is among the world's largest suppliers of eye drop bottle systems. The TE-ring now remains firmly attached to the bottle after it is opened in line with new FDA requirements.

Triveni plastic containers with induction seal

Made specially for the U.S. market and primarily in white, the plastic containers manufactured under the Triveni brand are available in round and square versions, with some also equipped with a black lining for particularly light-sensitive drugs. All containers are fitted with an induction seal. The containers are available in various sizes and designs. All models are FDA-approved.

Duma Pocket 100 ml: handy and childproof

The Duma Pocket 100 ml has an ergonomic design that enables the oval-shaped box to be held and opened in one hand. Boasting an integrated closure and a dose dispenser, it is tamper- and childproof and easy for elderly people to handle.

Gerresheimer has several sites in the Americas that make pharmaceutical packaging products out of glass and plastic, including those of Centor – the leading manufacturer of plastic containers that meet the regulatory requirements for prescription drugs in the US.

Ultra-modern production processes – worldwide standards

Gerresheimer employs the world's latest techniques and monitoring technology from the development stage right through to production and packing for delivery. Gerresheimer uses cutting-edge clean room technology to guarantee optimum cleanliness for its products in terms of particles and germs. With bases in Europe, Asia, and the Americas, Gerresheimer specializes in manufacturing primary packaging for pharmaceuticals in line with the relevant pharmacopeias. All its factories are currently certified to standards including ISO 9001.

Gerresheimer AG
D 40468 Düsseldorf

**The EE220 can be equipped with intelligent, interchangeable probes.
Separate humidity and temperature probes enable highly accurate loop calibration.**

Humidity and temperature transmitter with interchangeable probes

The EE220 transmitter from E+E Elektronik measures relative humidity and temperature in the range from -40 °C to 80 °C (-40 °F to 176 °F) with a high accuracy of ±2 % RH and ±0.1 °C (±0.18 °F). The basis unit can be fitted with various pluggable and interchangeable sensing probes. Separate probes for humidity and temperature enable highly accurate loop calibration. The easy-to-clean metal enclosure and stainless steel probes are ideal for clean room applications and use in the pharmaceutical and food industry.

Probe exchange in a matter of seconds

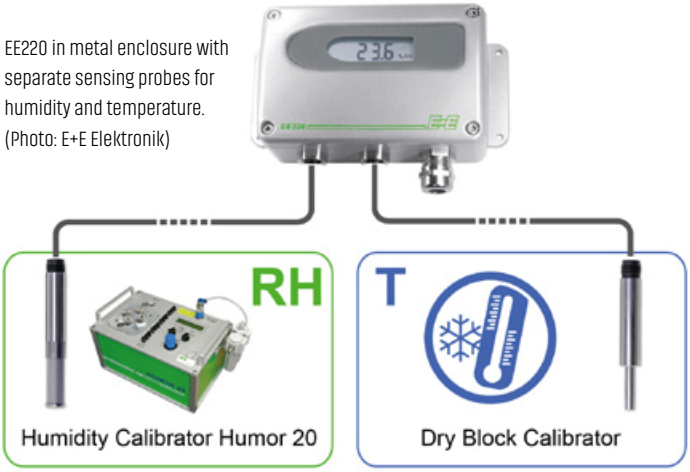
The EE220 basis unit can be equipped with a combined humidity and temperature probe or two separate probes, one for humidity and one for temperature. The EE07 probes can either be plugged directly onto the basis unit or mounted up to 10 m away using extension cables. Thanks to the plug-in system, the sensing probes can be exchanged in just a few seconds. As the calibration data is stored in the intelligent probes, the transmitter does not need to be re-calibrated after a probe replacement.

Loop calibration according to FDA recommendation

The use of separate stainless steel sensing probes for humidity and temperature enables most accurate loop calibration, as recommended by the FDA (Food and Drug Administration) for the pharmaceutical and biotechnology industry. Using extension cables and without dismounting the EE220 basis unit, the humidity probe can be placed in a portable humidity calibrator and the temperature probe in a dry block calibrator. Thus, the entire measurement chain from the probe to the controller can be calibrated on-site (loop calibration).

The probes can be individually adjusted with buttons on the E220 electronics board. Adjustment and calibration is particularly comfortable using the optional display, which can be simply plugged onto the EE220 board for this purpose.

EE220 in metal enclosure with separate sensing probes for humidity and temperature. (Photo: E+E Elektronik)



The EE220 enables separate calibration of the humidity and temperature probe (loop calibration). (Photo: E+E Elektronik Ges.m.b.H.)

Accuracy check with reference probes

Two reference probes can be used instead of the regular probes to check the correct functioning and accuracy of the EE220 basis unit. The reference probes simulate defined humidity and temperature values which can be compared with the EE220 outputs.

Optimum sensor protection

The optional E+E proprietary coating is brings relevant benefits in harsh ambient conditions. It protects the sensing elements from dirt, dust and corrosion, thereby considerably improving the long-term stability and lifetime.

Options and accessories

The EE220 basis unit and the EE07 sensing probes are available with polycarbonate or stainless steel enclosure. The current measured data is available locally on the optional display. The EE220 is suitable for wall mounting and rail installation according to DIN EN 50002. A duct mounting kit is also available.

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