Award in the category product design

Filling and closing machine from Bosch honored with Red Dot Award

- AFG 5000 for the sterile filling of pharmaceutical powders
- Expert jury acknowledges functionality and machine design
- New feature: aseptic changeover of product-handling parts

The filling and closing machine AFG 5000 from Bosch Packaging Technology recently received the internationally renowned “Red Dot Award” from the Design Zentrum Nordrhein-Westfalen in the category product design. The assessment was carried out by a 40-member international expert jury based on criteria such as degree of innovation, functionality, formal quality, ergonomics and durability. Designers and manufacturers from 59 nations submitted more than 6,300 objects.

“We are very happy to receive this award. The independent jury verdict shows that our approach to focus on the customer right from the beginning proves successful,” said Dieter Bandtel, product manager at Bosch Packaging Technology, during the award ceremony at the Red Dot Gala in Essen, Germany. “The AFG 5000 was developed and designed according to customer requirements. The result is a machine with a compact and space-saving design, easy handling and a small number of format parts.”

Successful market introduction and ongoing development

In autumn 2017, the AFG 5000 was first presented to a selected audience. The flexible machine platform allows the exact dosing of both small and large amounts of powder with an output of up to 480 vials per minute. Customers can choose between statistical or 100% in-process control of dosing weights. While the vials are continuously fed into the filling machine, the transport system adjusts the feed rate to precisely match the rhythm of the individual workstations. Shuttle carrier
Dear subscribers,

a few days ago, I turned up the heat. Summer is over, it's autumn, then it's winter and very fast it's Christmas.

To help you plan your time until then, the calendar of events in this newsletter (written in german) is very extensive: 139 events by mid-December!

A few dates in advance for an overview:
25.9./26.09.2018: Lounges on Tour, Vienna (AT)
03.10./04.10.2018: ILMAC LAUSANNE, Lausanne (CH)
09.10./10.10.2018: Lounges on Tour, Berlin (D)
09.10./10.10.2018: Cleanroom technology and practice, Aschaffenburg (D)
16.10.2018: Cleanroom qualification and monitoring according to ISO 14644, Wattwil (CH)
23.10./24.10.2018: CLEANZONE, Frankfurt (D)
23.10.-25.10.2018: parts2clean, Stuttgart (D)
04.12./05.12.2018: 3rd Conference „Film Contamination“, Nuremberg (D)

We wish you an interesting and instructive autumn.

With kind regards
Reinhold Schuster
Efficient parts cleaning and process optimisation starts with the cleaning container

Today, parts cleaning mostly means to fulfil defined cleanliness specifications. In order to clean as economically as possible, the potential of the cleaning system needs to be fully exploited. This is often prevented by the cleaning container. With the MEFO-BOX system, Metallform has developed a solution whose well thought-out design offers key advantages.

When designing or optimising a cleaning process, much attention is usually spent on finding the appropriate machine, cleaning mechanics and agent. With this approach, it is frequently forgotten that the costly cleaning mechanics such as ultrasonic waves or spray jet as well as the cleaning media can only take their cleaning effect if they reach the parts to be cleaned. This is what the MEFO-BOX system with standard cleaning baskets and accessories is designed for.

Faster, better and more efficient cleaning

Thanks to the system's well thought-out design, open structure and its manufacture from stainless steels rounds with electrolytic polished surfaces, it ensures that the capability of the cleaning mechanics will be used at its best. Cleaning media as well as ultrasonic waves and/or spray jet have boundless access to parts and can take maximum effect. This yields to shorter cleaning processes with better results. Additionally, the easy accessibility of parts and good draining behaviour reduce the drying time required and enable uniformly dry parts – even in bulk material processes. Thus, the MEFO-BOX system enables increase in throughput without additional investments.

At the same time, the manufacture from rounds without closed edges and corners prevents the formation of dirt traps and residues in the container. As a result, process reliability is increased since re-contamination of parts is largely eliminated. The open basket design also minimises the carry-over of cleaning media, resulting in extended bath service life and thus improved system availability. Additional benefits of the MEFO-BOX system are compatibility to standard transport containers, a high stacking frame for safe transport and reliable separation as well as the integrated occupational safety due to completely welded joints without sharp edges, corners or wire ends.

A system for countless applications

The extensive range of standard components of the MEFO-BOX system and of the flexible workpiece holder system MEFO-VARIO - both available ex-stock - allow to fix approximately 85% of all parts in the cleaning basket for the cleaning process. If required, the MEFO-BOX standard components can be supplemented by part specific components. This kind of a flexible solution is suitable for parts which are manufactured in small numbers, which have simple geometries as well as if the throughput is uncritical and no upstream or downstream handling has to be considered. Another application for such a solution is a frequently changing range of parts. A solution with standard components is also useful to gain experience with the cleaning process and handling of baskets and then optimise the system for all top seller parts in a second step.

For all other applications in which parts with complex geometries and/or large quantities have to be cleaned, Metallform offers a technically and economically optimised solution with part specific workpiece holders. This is also the case when the workpiece holders have to be automatically loaded and/or unloaded, designed for maximum throughput or adapted to a packing (e.g. blister pack).
Industry 4.0 in the semiconductor industry

On July 17th the topic „Industry 4.0: The introduction of cyber-physical systems in the production facilities of the semiconductor industry“ attracted all interested parties to the AP&S International GmbH company's headquarters in Donaueschingen, Germany. The event was held as part of the Technology Mountains Tour 2018, a series of lectures organized by a German technology networking association. Practically, using the examples of company’s own Industry 4.0 solutions, AP&S presented the possibilities and challenges of cyber-physical systems (i.e. the combination of computer-aided software components with mechanical and electronic parts that communicate via a data structure, such as the internet).

AP&S IoT solutions are used for machine monitoring, machine control, maintenance, service assignments, spare parts deliveries and deployment, but also in the sales process for demonstration purposes and in the development phase. In the focus by doing so is always the benefit for the machine operator/customer. “Machine monitoring by humans, as we know them from the past, is no longer necessary and won't exist in the future,” says Christoph Kluge, Head Software Department at AP&S and Managing Director of the subsidiary tepcon GmbH. “In the condition monitoring area our solutions provide a configurable visualization of real-time data in tables, graphics or flow diagrams, monitoring of threshold values and timely alerting e.g. via email, SMS or WhatsApp. The customer can intervene flexibly from anywhere at any time, e.g. via his mobile device. Machine failures can be avoided in time. Process data analyzes enable the recording and tracking of recipes and incorrect operations as well as a comparison with historical data, which lead to an optimization of recipe sequences and efficient planning of service assignments.”

The topic of machine learning was explained on the example of an AP&S solution, which was developed for the in-house UHPW system and now operates with a great success. „A typical failure that causes unplanned shutdown in this type of water treatment system is a blocked filter. This was one of the starting points for our development. Now our solution predicts with 99% certainty whether the filter needs to be changed in the next 3 days. This leads to a reduction of downtimes and an optimal operating life.”

After the presentation session a company tour and a live demonstration of the AP&S Augmented Reality solution followed. In the last one the participants were able to interact virtually with the AP&S wet process machines by using the Microsoft HoloLens.

On the participant question, whether the risks of increasing digitization such as in particular the fear of job loss, which is often discussed in the public, is an issue at AP&S too, HR Manager Cäcilia Wegner answered: „No, there are several reasons for it: We are a technology company, many of our employees are tech-savvy, show a great interest in developments and enjoy the use of latest technologies. With a wide range of trainings and regular in-house seminars, we are optimally preparing our employees for the changes that new technologies could bring to their respective jobs.”

The conclusion of the evening: the cyber-physical systems provide a wide range of advantages to their users, are on the rise and will decisively drive and influence the world of special machine construction.

AP&S International GmbH
D 78166 Donaueschingen
Phillips-Medisize Enhances Integrated Connected Health Platform

Phillips-Medisize, a Molex company, announced the release of its third generation connected health platform, a service offering for its pharma and drug delivery device clients. The platform builds on the success of the company’s first connected health solutions, including the first FDA-approved combination product for medication adherence, and incorporates more than a decade of experience in developing connected health solutions.

Utilizing connectivity in drug delivery devices such as injectors and inhalers, connected health solutions help pharmaceutical companies, healthcare professionals and patients, improve how people take their medication. In addition to medication tracking, these systems support patients through reminders, incentives and peer communities to improve disease management, medication adherence and, ideally, outcomes.

Phillips-Medisize teamed with industry-leading healthcare IT providers to develop a platform that addresses the key challenges faced by the industry. The cloud-based third generation connected health platform is a secure, reliable and scalable medical device data system (MDDS). Using an industry-leading health integration engine combined with a rich analytics tool, it can integrate patient data with electronic medical records and other data from pharmacy and IoT devices, allowing customers to conduct insightful analysis focused on improving medication adherence.

“Phillips-Medisize is a leader in connected health systems for medicine currently on the market, supporting patients daily across the globe. This new, advanced connected health platform builds on our deep knowledge and experience,” said Bill Welch, Chief Technology Officer, Phillips-Medisize. “For us, connected health is a strategy for better serving our customers and their patients, not a buzz word. We are unmatched in the industry with our global innovation, development and manufacturing capabilities to create end-to-end systems.”

As connected health systems begin to demonstrate incremental improvements in adherence and patient outcomes, Phillips-Medisize expects the market to grow. The third generation platform further demonstrates the company’s commitment to meeting industry, provider and patient needs by building technology that is sensitive, scalable and cost-effective.

Covert-Hologram Seal offers Tamper Protection Conforming to EU Directive

Reliable First-Opening Indication and Tamper Evidence for Pharmaceutical Packaging

The Europe-wide Falsified Medicines Directive 2011/62/EU coming into force in February 2019 requires all pharmaceutical manufacturers to mark their prescription medicine packaging with a serial number and an additional tamper protection device. Schreiner MediPharm’s multifunctional Covert-Hologram Seal with an irreversible, holographic effect offers reliable first-opening indication and tamper evidence, plus counterfeiting protection, and complies with the requirements of the EU Directive.

The innovative Covert-Hologram Seal is transparent, inconspicuous and thus appears like a simple packaging seal. However, the first time the seal is opened, an invisible effect becomes visible. A hologram emerges that shows various inscriptions and design elements in different colors depending on the viewing angle. The holographic effect is irreversible and the seal’s fully transparent original condition cannot be restored. Thus, manufacturers, suppliers, and patients can tell at first glance if the packaging has been previously opened or if the medicine is an originally packaged product.

Covert anti-counterfeiting features embedded in the specialty closure seal add extra security. Thus, the Covert-Hologram Seal effectively combines the reliable first-opening indication required by the EU Directive with additional counterfeiting protection in a single seal, enhancing security throughout the entire supply chain.
Swedish life science industry on an upswing

Autor: By Malin Anderson, Nordic Life Science June 13th 2018

The recent growth of the country’s life science industry is for example demonstrated in a new report by the Swedish Agency for Growth Policy Analysis and the fast growth of SwedenBIO, the national non-profit association for the life science industry in Sweden.

SwedenBIO has today 250 member companies and since the year end the association has grown by almost one member per week. This reflects that the industry as a whole is growing, states SwedenBIO, and refers to for example a recent report by the Swedish Agency for Growth Policy Analysis.

Increase and decrease

The report addresses two issues: How has the Swedish life science industry evolved in recent years and what are the prerequisites for innovation-driven growth among Swedish life science companies? And it shows for example that between 2014-2016 the number of small and medium-size companies increased by 12% while the number of large companies remained unchanged. The number of employees in small and medium-size companies increased by 8.4% while the number of employees in large companies decreased by 2.2% over the period.

Prerequisites for innovation-driven growth

Every year a large number of new life science companies are registered in Sweden. There is also a trend that global life science companies and digital giants are opening up their innovation processes and are looking for companies to acquire, says the report. Given this development it might be warranted to investigate the growth effects of governmental investments in life science more closely, it states.

The number of clinical trials of pharmaceuticals increased slightly between 2014 and 2016 but viewed over a longer period, the number of trials has decreased in Sweden while they increased in for example Denmark. This was also recently highlighted in this report.

The Growth report also shows how the governmental venture capital funds have come to invest increasingly in later phases. Here, there is a risk that governmental venture capital does not address market failures that create funding gaps in early phases. An international outlook shows that other countries are working to improve access to venture capital for life science companies in early phases.

A crucial interaction

Today, SwedenBIO’s member companies covers the majority of the business segments within life sciences, from self-employed companies within biotech and medtech to global life science giants and clinical trial companies, and from IP experts and law firms to science parks and funding agencies. The most recent addition to the association was SHL Group.

“We are a global medtech company with strong Swedish roots. Collaborations with the Swedish pharmaceutical industry has contributed to a foundation for our growth. It is crucial for our future development in Sweden to continue to identify local, innovative collaborations but also competence provision, how well we are able to attract the best engineers. Through our membership in SwedenBIO we hope to increase our visibility and at the same time support SwedenBIO’s goal to strengthen the life science sector in Sweden,” says Magnus Fastmarken, Global Director Marketing Medical at SHL Group.

VC2VC

And SwedenBIO says it aims to further strengthen this interaction between different players, both small and large, which they believe is crucial for the growth of the industry as a whole.

“We know B2B. We are working with this, both operatively by offering a platform for building business networks and collaborations, but also by spreading knowledge about the industry and giving it a strong voice. Now we are also working on something that we call VC2VC, a way to get international capital interested in Swedish life sciences and in particular, in our member companies,” says Jonas Ekstrand, Director General of SwedenBIO.

(* *) The pharmaceuticals industry has without doubt lost ground but probably also the medical devices industry states the “Growth in Sweden’s life science industry 2014-16”
ebm-papst builds new plant in China

Groundbreaking ceremony for the 30 million euro investment

With a groundbreaking ceremony, ebm-papst, world market leader for fans and motors, started the construction of a new plant in Xi’an, the Chinese capital of Shaanxi province. From summer 2019, fan solutions for the Asian market are to be produced on 27,000 square meters.

Stefan Brandl, Chairman of the Management Board of the ebm-papst Group: „Demand for our products in the Asian market is growing steadily, so that we need further production capacities in addition to our plant in Shanghai. With this new building, we are implementing a further step in our internationalization strategy „Structure 2020“ and the associated further localization in Asia“.

The decision for the new location near the city of Xi’an, with its 12 million inhabitants, is reinforced by the high availability of qualified specialists and excellent transport and logistical connections.

„In addition to China, we also have our sights set on the emerging markets which will in future be supplied with products from our new location,“ says Thomas Nürnberg, President and CEO of the ebm-papst China. „These include above all the Asean states with countries such as Indonesia, the Philippines and Thailand, which are on the threshold from a developing country to an industrialized state“, adds Nürnberg.

ebm-papst has been represented in China since 1996 and currently employs around 1,800 staff at the Chinese sites. The headquarters, which also houses the development center for products of the Asian market, is located in the free trade zone Waigaoqiao (Shanghai), the production plant in Nanhui (Shanghai). Two further locations are in Hong Kong and Qingdao.

The investment sum of the new building is estimated at around € 30 million.
The Röchling Group has completed another step in its growth strategy. Subject to approval by the Cartel Office, the plastics specialist from Mannheim has acquired FRANK plastic AG, a medical and industrial technology provider headquartered in Waldachtal, Baden-Württemberg. Just a few weeks ago, Röchling acquired U.S. medical technology specialist Precision Medical Products.

"With this acquisition, we are continuing to pursue our growth strategy in the medical and industrial segment. FRANK plastic AG perfectly complements our product portfolio, our production technologies, and our customer structure," explained Prof. Hanns-Peter Knaebel, CEO of Röchling Group, who is also in charge of the Medical division. He went on to note that in terms of size, focus, technical expertise and cultural qualities, FRANK plastic AG fits very well into the network of Röchling companies. "Its Waldachtal site will be the starting point for national and international success," said Knaebel.

Joachim Lehmann, BU Director Medical Europe for the Röchling Group is confident that the partnership will be beneficial for FRANK plastic AG and the Röchling Group. "With FRANK plastic we have the option of cultivating additional client potential, especially in the growing medical technology market," commented Lehmann.

FRANK plastic AG is a family company rich in tradition. It was founded in 1940 in Waldachtal near Freudenstadt in the Black Forest and was acquired in 2013 by Ferdinand Piëch Beteiligungs GmbH. In recent years, it has grown from being a provider for various industry segments to a being manufacturer that focuses on the medical segment and other select industrial segments. In the 2017 financial year, the FRANK Group had 260 employees and revenues of EUR 32.4 million.

FRANK provides medical technology for such segments as cardiology, infusions, angiography (CT/MRI), surgery and ophthalmology. The company's industrial business supplies select segments with extrusion profiles, complex injection molding parts as well as valves, flow meters, and fittings. In the future it will work closely with Röchling Industrial.

"We decided to sell our shares in FRANK plastic AG and partner with the Röchling Group because we feel this offers the absolute best outlook for the future and for further growth – not just for the company but for the location as well," said Ferdinand Piëch of Ferdinand Piëch Beteiligungs GmbH. In light of the changes in medical product approval requirements by the EU in 2017, it is becoming increasingly difficult for smaller companies to stay competitive on this highly regulated market and to continue their growth in the years ahead. "Our alliance with the international corporate network of the Röchling Group gives the employees in Waldachtal good prospects for the future," added Piëch.

The Medical division of the Röchling Group focuses on the areas of pharmaceuticals (primary packaging and drug delivery systems), diagnostics / patient monitoring, life sciences (dialysis and infusions) and minimally invasive surgery / interventional medicine. "FRANK's current product portfolio is a perfect fit for this market segment and is a complement to the product portfolio of the Röchling Group," said Knaebel.

Thanks to development partnerships with a number of customers in years past, FRANK has reinforced its own development activities and introduced an innovation management concept. The company has also acquired significant skills in the area of regulatory affairs (certification, registration, and approval of medical products). "This regulatory expertise and current innovation management concept are essential additions to the skill set for the Röchling Group's network of medical companies," explains CEO Knaebel.

FRANK plastic has been a family-managed company in the past decades and is very similar to the Röchling Group in terms of client focus. "We firmly believe that the collaboration will work very well in cultural terms," Knaebel continued. The CEO of FRANK plastic, Dr. Christian Holzherr, will continue to serve as the head of the company. According to Holzherr, "FRANK plastic would not be where it is today without the great dedication of our employees. I know that we will continue to succeed on the journey with the Röchling Group."

FRANK has impressive expertise and a broad spectrum of production technologies in the area of medical technology and industry. Injection mold manufacturing began back in 1960 and extrusion technology was added in 1970. Back in 1980, FRANK put its first clean room into operations for medical production. Alongside some 70 injection molding machines, 40 of which are in an ISO 8 clean room, there are some 18 extrusion lines in operation. There are also a number of machining centers installed. While the production technologies complement those of the Röchling Group, in some cases they provide key additional expertise. One example is clean room pipe extrusion.

FRANK plastic, as a new affiliate of Röchling Medical, will be a very important part of the global corporate network for the Röchling Group.
Safe media supply due to anti-static plant components

Electrically conductive designs of the GEMÜ PC50 iComLine multi-port valve blocks and the GEMÜ TubeStar tubes allow for the safe operation of plants, even with highly flammable media.

Plastics as valve material have an ever wider range of uses in the processing industries. Because of their good chemical and mechanical resistance, they are being used more and more frequently in processing corrosive media such as slurry. Even in solvent supply, the trend is increasingly toward the use of high-performance thermoplastics.

The handling of corrosive or highly flammable media such as solvents is risky because they are conducive to electro-static build-up and the development of flammable vapours. Uncontrolled and sudden discharge can ignite entire plants. Not only safeguarding against shortfalls but also ensuring the safety of the operating personnel is in focus during operation of the plants.

Conductive multi-port valve blocks of the GEMÜ PC50 iComLine series and GEMÜ TubeStar tubes reduce the risk of any such ignition to a minimum. Carbon is added to the fluoropolymer during the production process to make the components conductive and to discharge the electro-static build-up specifically over these conductive components.

GEMÜ designs the specified multi-port valve blocks on a case-by-case basis and manufactures them according to customer requirement. The conductive valve body made of PTFE makes it possible to combine various connections in different nominal sizes with each other. In addition, manual or pneumatic actuator versions and sensor systems can be integrated optionally.

The GEMÜ PC50 iComLine multi-port valve blocks can be safely operated in the conductive design at an operating pressure of 4.2 bar and ensure an optimal capability to dissipate electro-static charges in conjunction with the conductive GEMÜ TubeStar tubes. The conductivity ranges between 105 and 108 ohms. The tubes referred to are available made of PFA and PTFE material. On request, the version made of PTFE can also be offered as an FDA-compliant design. The tubes made of perfluoralkoxy (PFA) are available in both media-wetted and non-media-wetted design. The media-wetted version is black and non-transparent due to its carbon content like the multi-port valve blocks themselves. In the non-media-wetted design, a special procedure introduces a conductive strip to the surface only. This makes it possible to monitor the medium inside the tube visually on the one hand and ensures a high degree of freedom from particles on the other because the medium comes in contact only with the ultra-pure PFA. The anti-static tubes are available in sizes from 1/4" to 1 1/4". Further sizes or wall thicknesses are available according to customer requirements.

GEMÜ Gebr. Müller Apparatebau GmbH & Co. KG
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Life sciences startup LenioBio GmbH and the Fraunhofer Institute for Molecular Biology and Applied Ecology IME announced today the signing of an exclusive license agreement that allows LenioBio to utilize Fraunhofer’s proprietary vector solution and technology for the cryopreservation of cell lysates. In March 2018, LenioBio obtained an exclusive license from Dow AgroSciences LLC to commercialize its proprietary eukaryotic cell-free protein expression technology. The optimized vector solution and cryopreservation technology from Fraunhofer IME has been specifically developed to meet the wide application areas LenioBio is targeting.

With the addition of the Fraunhofer IME license, LenioBio is extending the patent family covering this innovative cell-free system and will soon launch its expression kit under the brand name ALICE™, targeting novel protein developers.

The development of ALICE™ was a collaborative effort between Dow AgroSciences LLC and Fraunhofer IME under a long-standing strategic alliance, and the system has been used by where Fraunhofer IME contributed some of the unique materials that made the system best-in-class among all cell-free protein expression systems. Fraunhofer IME has applied this system for the expression of many different protein classes, including those that are known to be difficult to express, such as human growth factors and full-size antibodies.

Professor Stefan Schillberg, Ph.D., a member of the Institute Management (provisional) and Head of Division Molecular Biotechnology at Fraunhofer IME, stated, “Cell-free biosynthesis allows the rapid screening and production of even difficult-to-produce proteins. In addition, the high productivity of ALICE™ opens new fields of applications for cell-free technology that we will develop further together with LenioBio.”

Dr. Remberto Martis, CEO of LenioBio, added that “ALICE™ is a unique and innovative platform for the expression of proteins for all kinds of applications. It has proven to be able to overcome several deficiencies of conventional expression systems currently used in the biotech field. In addition to delivering higher amounts of proteins than any other systems of its kind, ALICE™ has the capability to express a broad range of proteins while remaining cost effective”. The ease of use of ALICE™ will vastly simplify the work of our customers. We will launch the ALICE™ platform this quarter initially as an expression kit, which yields on average higher amounts of proteins compared to other cell-free protein expression kits.

Dr. Martis also noted that “Going forward, we anticipate launching the unique “Enterprise Kit™”, that will allow biotech companies to develop and produce larger amounts of their protein candidates in-house.”

About LenioBio

LenioBio GmbH is a life sciences start-up company committed to the advancement of transformative technology platforms for the development and synthesis of ‘difficult-to-produce’ proteins across all industries, including biomedical, industrial, and agricultural. LenioBio was established in September 2016 with offices in Düsseldorf and Bocholt and R&D and production facilities in Aachen.

About Fraunhofer IME

The Fraunhofer IME conducts research in the field of applied life sciences from the molecular level to entire ecosystems. Our interdisciplinary organization and laboratories with state-of-the-art equipment, including GMP facilities and complex facilities for environmental simulations, allow a wide spectrum of research and development services in the divisions “Molecular Biotechnology”, “Applied Ecology and Bioresources”, and “Translational Medicine”. The strength of Fraunhofer IME lies in this broad spectrum of scientific and methodological expertise, enabling us to develop innovative and comprehensive solutions to the enormous challenges confronting society in areas such as sustainable agriculture, health, and the bioeconomy. Fraunhofer has over 300 employees working at the locations in Schmallenberg, Aachen, Münster, Gießen, Frankfurt/Main, and Hamburg.

LenioBio GmbH
40231 Düsseldorf
Gerresheimer produces primary packaging for drugs in China and India in accordance with global standards

Gerresheimer has a total of 13 sites across Asia for its range of glass and plastic products. The company was attending Medipharm Expo at the Saigon Exhibition and Conference Center from August 2 to 4, 2018, showcasing its glass primary packaging for drugs. The exhibit will feature standardized and specially manufactured products made in accordance with the stringent requirements of the FDA and well-known pharmacopeias, following uniform certified processes defined at global level.

As a traditional material, glass has proved time and again to be the perfect choice for storing drugs. Gerresheimer boasts three specialist glassworks in China and two in India, meaning it is ideally placed to meet international and local demand for premium-quality primary packaging for all manner of different liquid and solid drugs.

Tubular glass containers for dry and liquid drugs

At its three Chinese sites, Danyang I and II and Zhenjiang, and at its most recent production facility for tubular glass containers in the Indian city of Kosamba (Gujarat), Gerresheimer produces ampoules, injection vials, cartridges, laboratory (threaded) vials and specialty products made from type I and II clear and amber glass.

Certified production in China and India

All Chinese sites are certified to the ISO 9001 standard for quality management, ISO 14001 for environmental management and to the ISO 15378. Suppliers of primary packaging for pharmaceutical products benefit from the fact that ISO 15378 incorporates all the relevant GMP requirements and facilitates compliance with international, European, and national law. The new Kosamba plant also holds certification in various international standards, including ISO 9001:2015, U.S. Drug Master File (DMF) type III, Health Canada (DMF), and ISO 15378. Gx Rhoc, the camera inspection system developed by Gerresheimer, ensures exceptional dimensional quality for vials. Several HD cameras detect every flaw.

Neutral Glass – clear and amber moulded glass

Kosamba-based Neutral Glass is Gerresheimer’s moulded glass production site in India, where various different types of glass can be manufactured at the same time, such as clear and amber glass infusion and injection bottles made from type I borosilicate glass. The company also produces type III glass containers for a large number of drugs. The production line in Kosamba is certified in accordance with ISO 9001 and DMF type III requirements.

Quality from the word go – cleanroom monitoring at the cold end

A new furnace for type I glass has significantly improved product quality at Neutral Glass this year. Thanks in particular to improved temperature monitoring during processing, the quality of the glass is now far more consistent. In combination with construction and upgrade work on the new furnace, a cleanroom inspection area complete with camera inspection systems has also been introduced at the cold end. Finished products are now guaranteed a full check before being packaged.

A standardized approach around the world

State-of-the-art global machinery standards and employees who are trained in the production process ensure that all the workflows at all the plants meet the same standards.
Access control, monitoring and traceable products – safety first!

Cleanrooms = Safety in its purest form

This includes rules governing personal access and the items taken into cleanrooms, as well as the prevention of counterfeit products. A key principle underlies all such efforts: Tracking. Current possibilities in this field will be on display for visitors to the cleanroom trade fair Cleanzone on Tuesday and Wednesday, 23 and 24 October 2018, in Frankfurt am Main.

Cleanrooms are classified according to the threshold values for particulate and micro-biological contamination, yet the interfaces between cleanrooms and the ‘impure’ areas surrounding them, as well as between various cleanroom zones, are especially sensitive. This is where airlocks have an important role to play. It must be possible to strictly define those who enter and exit here, and this process must be traceable.

**Access control and traceability of objects**

There are various ways in which to control access, with examples including decentralised systems with control elements located directly on the doors, and central systems in which the doors are equipped with simple operating terminals. These can take the form of touch displays or even RFID systems incorporating touch-free employee identification. In the latter case, it is particularly easy to modify individual access authorisations or implement specific restrictions. For example: Only a certain number of people can be working in Zone X simultaneously, and these people must comprise defined and practised teams.

One of the challenges here involves the ability to trace which employee took a particular implement into and/or out of the cleanroom (e.g. shoes, overalls, caps, mops, wiping cloths).

Currently, one of the basic measures being used for this purpose involves ensuring that each employee is only provided with precisely what they require each day – nothing more and nothing less. Once work has finished, the items of clothing and equipment are then placed in specific compartments or cupboards, from where they are picked up for cleaning and/or decontamination. This can be done by the cleanroom operator themselves, or they can utilise an external service provider.

Unless there are additional controls, experience has shown that residual risks remain – such as those posed by items accidentally brought into the cleanroom, and objects left there unintentionally. Implementation of an inventory management system designed especially for cleanrooms can help here. A basic version might involve employees recording mops, wiping cloths etc. when they enter/exit, with everything being entered in lists. This helps employees monitor their own actions.

In order to help eliminate any remaining risks (e.g. carelessness), the cupboard system can be supplemented in more complex systems with incorruptible robotics: Here, a gripper with a suction cup provides each individual employee with the items they require. For facilities in the highest security category, these processes are recorded digitally (e.g. in the cloud).

According to Benedikt Fischer, CTO of Dittel Cleanroom Engineering: “From a technology standpoint, these solutions are ready to be used. In fact, cleanroom utensils with integrated chips can even be tracked in detail throughout the cleanroom, and camera systems make it possible to create movement profiles for employees. However, there are certainly two sides to the use of such measures. On the one hand, tracking makes it possible to improve the efficiency of cleaning procedures, yet this gives rise to ethical questions regarding just how far employee monitoring should be taken, questions that must be answered. Whereas these ethical matters are already being addressed in Germany, in some other parts of the world, the focus is solely on maximising the utility of the available data.”

**Counterfeit-proof and suitable for cleanrooms**

Tracking also means being able to trace products and avoid counterfeits – as set out in the ‘Falsified Medicines Directive’ (FMD; EU Directive 2011/62/EU). This directive is of particular importance right now, as it must be implemented by 9 February 2019.

Basically, under the terms of this directive, the pharmaceutical manufacturers can assign their products unique identification codes (including printed barcodes) and record these in a central data hub (for German manufacturers this would be the industry’s securPharm initiative). This gives wholesalers, pharmacies and hospitals the ability to perform a check when distributing/administering these medications: Is the pharmaceutical recorded as an original preparation, or is it possible that it is a counterfeit?

A scan reveals the answer in milliseconds, allowing counterfeiters to be immediately removed from stocks available for sale or use. Furthermore, special security measures integrated in the packaging make it possible to distinguish between originals and counterfeits.

Dr. Heinrich Prinz from PDM-Consulting in Groß-Zimmern explains: “One good method, for example, involves using a combination of two adhesives, a hot adhesive and a cold adhesive, to seal the packaging. If the secondary packaging has been opened, this ensures that this is immediately evident and makes it clear that counterfeiters may be involved.”
Access control, monitoring and traceable products – safety first!

Such measures can also be implemented in the field of logistics, but it is important to remember that products without secondary packaging must have primary packaging that is counterfeit-proof – such as when filling directly in the cleanroom.

Furthermore, the goal of seamless tracking means that cleanroom-suitable packaging and printable packaging are both becoming increasingly important. This not only impacts primary packaging for pharmaceuticals, but also applications involving chemicals and implants.

Visitors to the Cleanzone trade fair will be able to gain an overview of all the latest trends regarding the security of cleanrooms on October 23 and 24 in Frankfurt am Main.

Cherwell Publishes Guide on Environmental Monitoring Processes and Validation

Supporting EM programs in preparation for proposed EU GMP Annex 1 changes

Cherwell Laboratories, specialist supplier of products for environmental monitoring and process validation, has drawn on its in-depth pharmaceutical and related industry knowledge to publish an eBook titled, “The Environmental Monitoring Processes and Validation Guide.”

Available to download from Cherwell's website, the new guide has been created following the release of the revised draft of EU GMP Annex 1 – Manufacture of Sterile Medicinal Products. It is intended to assist sterile product manufacturers with reviewing and improving their environmental monitoring (EM) programs in preparation for the proposed changes to Annex 1.

The comprehensive guide highlights the most business-efficient EM measures organisations can take to comply with the latest iteration of the EU GMP Annex 1, and practical steps they can take to create the ideal EM process. It also addresses and summarises the key changes proposed to Annex 1 and covers: Why the EU GMP Annex 1 draft has been proposed; how it helps all industries move closer towards a global standard; how to prepare for compliance; examples of best practice for EM programs and the right tools needed for an effective and compliant program.

Andrew Ramage, Cherwell Laboratories' Microbiology Product Specialist comments: "The draft copy of the new version of EU GMP Annex 1 has considerably more detail on the expectations of designing and implementing an environmental monitoring regime. It remains to be seen how much will change following the public consultation. Regardless of what changes are made, our in-depth guide will help the end user to interpret the new guidelines and to create and implement a robust environmental monitoring regime for their cleanroom, whatever the size of their facility."

With over thirty years' insight and experience with environmental monitoring applications, Cherwell has intricate insight and expertise that ensures they continually deliver high calibre products and services to their clients. Their ability to offer bespoke solutions to match customer needs not only applies to their range of Redipor® prepared media, but also the SAS range of air samplers and EM accessories which they specialise in.
Higher international character, clear trends, satisfied exhibitors, but fewer visitors: these are the keywords to summarize ACHEMA 2018.

From 11 to 15 June 2018, 3,737 exhibitors from 55 countries presented the latest equipment and innovative processes for the chemical, pharmaceutical and food industries on more than 132,000 m² at the world’s leading trade fair for the process industry.

Exhibition groups

By far the strongest growth was recorded by the Pharmaceutical, Packaging and Storage Technology exhibition group, where two additional halls were rented due to strong demand. In view of the strong trend towards digitization and automation, it is not surprising that the „Instrumentation, Control and Automation Techniques“ group was also able to grow. However, „traditional areas“ such as mechanical process engineering and safety technology also occupied slightly more space, while other groups such as plant construction or laboratory technology recorded slight losses.

Internationality

Behind Germany (1,644 exhibitors / 78,909 m²), China (342 exhibitors / 5,694 m²) and Italy (307 exhibitors / 12,366 m²) showed the largest number of exhibitors, both with significant growth compared to the previous event in 2015. The number of exhibitors from India and the Russian Federation also increased, as well as from Poland, South Korea and Turkey. The number of exhibitors from the Netherlands, Belgium and France remained constant, while the number of exhibitors from the USA, Austria and Great Britain declined. The proportion of exhibitors from abroad rose again to 56 %, which is higher than ever before.

Atmosphere

The products and technologies presented aroused great interest among the audience. „The exhibitors we talked to and we ourselves had a very successful fair,” said Jürgen Nowicki, Chairman of the ACHEMA Committee and Member of the Linde Engineering Board. Uwe Harbauer, Member of the Board of Management of Bosch Packaging Technology and Head of the Pharmaceuticals Product Group at Bosch Packaging Technology, shares this impression: „Achema has proven once again, that it is the most important international trade fair for Bosch Packaging Technology in the field of pharmaceutical and process technology. Our booth was very well attended throughout the week and we had many qualified discussions with trade visitors from all over the world.”

A very eye-catching trend this year: the numerous booths where visitors could experience systems and equipment in „Augmented Reality“ with the help of special glasses or even test their skills in completely virtual environments. The three focus topics were very well accepted. Numerous exhibitors presented modular solutions and intelligent components for the factory of tomorrow under the label „Flexible Production“. „Biotech for Chemistry“ included process development and plants from the laboratory to the fermenter that integrate biotechnological processes into the chemical industry. „Chemical and Pharma Logistics“ made the progressive integration of the supply chain visible and appealed to new target groups that are increasingly no longer „only“ service providers but system partners of the process industry.

„We have been participating at ACHEMA for more than 60 years - and the fair is still a highlight for us. Our approach of focusing even more strongly on consulting services in solid/liquid separation has proven its worth. Many discussions revolved around possible attempts to enable us to offer the respective company a tailor-made filtration solution. In the pharmaceutical industry, the focus is shifting more and more to the modular configuration of systems for use in various applications,” says Detlef Steidl, Director of Sales Filtration Technology at BHS-Sonthofen. „Compared to previous years, the number of visitors has decreased slightly. This was particularly true on the first day of the fair. At the same time, internationality continues to rise: in 2018, exhibitors and visitors from Asia in particular increasingly shaped the image of the fair.

Visitors

A drawback for the organisers was the drop in visitor numbers to around 145,000, which the organisers attribute primarily to the more complex registration procedure, due to the increased security requirements for major events.

Congress

The ACHEMA Congress covered the entire spectrum of chemical process technology and biotechnology. The presentations allowed insights into current research and the latest scientific results. On the first three days of the fair, current topics in particular were dealt with on a separate theme day: Resources, digitization and energy and climate. Above all, the digitisation topics, but also the lectures on the subject of energy, aroused particular interest. The concept of the PRAXISforums, which was introduced in 2015, was very well received; the events in the immediate neighbourhood of the halls, which are primarily intended to bring exhibitors and users together, were well attended throughout.

The two panel discussions were also very well attended. The question „Plastic-Free Europe - is a plastic-free Europe possible and sensible?“ was debated controversially. The panelists agreed that plastic is indispensable and that a combined approach is needed to address the problem of plastic waste. Of course, it is particularly efficient to avoid plastic waste wherever possible.

On the topic „Digitalization meets process Industry“, experts from industry and science discussed the challenges facing industry. Do companies have to change their business models in view of digitization? With regard to the right approach for the digitization of the process industry, the panelists agreed that every company should have a digital strategy that focuses on the customer.

Perspective

The next stop for the process industry is AchemaAsia, which will be held for the first time in Shanghai from May 21 to 23, 2019. As the „International Expo and Innovation Forum for Sustainable Chemical Production in China“, the „little sister of ACHEMA“ focuses on the current trends in the process industry in China and Asia.

Final Report ACHEMA 2018

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

ACHEMA Ausstellungs-GmbH D 60486 Frankfurt am Main
ISCC’18 announces final programme

From 23 to 26 September 2018 VCCN, the Dutch contamination control society, hosts the International Symposium on Contamination Control and cleanroom technology in the Hague. ISCC’18 is pleased to announce the final symposium programme, including our keynote speakers.

The symposium starts with a social programme, followed by a two day conference programme, including tutorials and workshops. The symposium closes with technical visits to companies as Philips, ASML and ESA/ESTEC/Space-Expo. The total conference programme consists of 4 keynote speakers and 27 speaker sessions with 72 speaker sessions.

- Opening keynote speaker prof.dr.ing. Dave Blank - on Monday 24 Sept. from 9.15h - 10.00h
- Health Care keynote speaker dr. Bas Zaat - on Monday 24 Sept. from 17.00h - 17.45h
- Micro Nano Technology keynote speaker prof.dr. Vadim Banine - on Tuesday 25 Sept. from 08.30h - 9.15h
- Closing keynote speaker Peter Ross - on Tuesday 25 Sept. from 15.00h - 15.45h

The symposium is intended for people that are new in the field of contamination control and for people that are experienced.

ISCC’18 welcomes all contamination control professionals to exchange knowledge while meeting old and new friends. With more than 500 participants from all over the world, ISCC 2018 offers an excellent opportunity to learn all about new applications and inventions concerning the improvement of quality in cleanrooms.

Contamination control

Contamination control is essential to all high-tech industries and research facilities where ‘cleanliness’ is a precondition for the quality of the product and for the safety and health of the users or employees. Contamination control enables new technology. New research results and innovative technological applications make it possible to keep improving our control over air purity. Sharing this knowledge worldwide significantly accelerates the developments in this field. The ISCC plays a prominent role in doing so.

Theme

The theme of the symposium will be “The world behind Contamination Control” and includes the following areas:
- Health Care
- Life Sciences
- Micro-Nano Electronics
- Photonics
- Micro Assembly
- Food
- Space

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automatica beats all records again

- Exhibitor, visitor and area records
- More international than ever
- The tangible Workplace 4.0

automatica 2018 (June 19 to 22) set new records: more than 46,000 visitors (+ seven percent) and 890 exhibitors (+ seven percent). Trade Fair Managing Director Falk Senger: “automatica addresses the future topics of human-robot collaboration, digital transformation in production, and service robotics. The strong results show: The history of automation and robotics is being written here in Munich!” Mr. Senger considers the growing internationalism of the trade fair as particularly impressive. “There was a 20 percent increase of visitors other countries. This shows that the automatica is becoming increasingly important on a global level.”

Industry Representative Dr. Norbert Stein, Chairman of the Board of VDMA Robotics + Automation and Managing Director of VITRONIC GmbH, is convinced by the trade fair concept: “automatica has once again set standards. It shows the future of automation and provides knowledge for orientation at the highest level. Visitor quality and quantity: outstanding!”

Per Vegard Nerseth, Managing Director of ABB Robotics, explained the importance of automatica for his company: “automatica has once again set standards. It shows the future of automation and provides knowledge for orientation at the highest level. Visitor quality and quantity: outstanding!”

Networked production is already a reality today

New names, products and concepts enriched the exhibition portfolio. The motto is: Digitalization, easy operation and greater flexibility in production with the aim of opening up new application areas.

Ralf-Michael Franke, CEO of the Factory Automation Business Unit at Siemens AG, commented on the trade fair premiere of his company: “Our digital enterprise portfolio fits ideally to the automatica motto ‘Optimize your Production’. Siemens provides end-to-end software and hardware solutions, with which the entire value chain can be integrated and digitalized. As a result, machine manufacturers and users can already use the benefits of Industry 4.0.”

Wilfried Eberhardt, Chief Marketing Officer of KUKA AG, sees a decisive advantage for the trade fair in the networked production world: “The topic IoT is part of intelligent automation. automatica is the only trade fair in the world that focuses on it. That is why it stands quite clearly for innovation. Trade visitors get a glimpse into the future here.”

Highlight: IT2indusry

With new exhibitors, specialist lectures and demonstrations, the topic “IT” plays a central role at the trade fair. Fifty-four companies exhibited from the IT environment within the framework of the IT2industry area. Dr. Christian Schlögel, CEO of connyun GmbH, stated: “automatica 2018 has shown the technological opportunities that companies have for implementing their digital transformation. It is impressive to see the great range of industrial IoT developments and which potential is still available.”

Machines speak a common language

A major growth driver for the future: the connectivity between machines. The decisive factor for this is the standardization of communication interfaces. The importance of collaboration between industry participants was demonstrated by the OPC UA
Demonstrator from the VDMA Robotics + Automation Association, in which three companies are participating. “Interoperability is the key to differentiating our products in the networked world of Industry 4.0. OPC UA is the designated standard to let machines speak the same language in the intelligent factory of the future,” Dr. Horst Heinol-Heikkinen said, Chairman of the VDMA OPC Vision Initiative.

Collaboration—the dominant topic

Collaborative robotics is conquering the market at rapid pace and opening up almost unlimited automation possibilities. From the sensor via the cobot to a complete installation, direct interaction between man and machine is gaining increasing acceptance. The technological developments are thanks to close collaboration between science and industry. Munich is the international meeting point for this. Prof. Oussama Khatib from Stanford University explained: “automatica, this year, opens a wide window on the emerging applications in the robotic industry. Robots with increased capabilities working in closer proximity with humans are being built for real world applications, a testimony to the fruitful collaboration and technology transfer between research and industry.”

People in the Smart Factory

The question that goes beyond the trade fair: How will people work in the future? With the special exhibition “People in the Smart Factory”, the professional association VDMA Robotics + Automation made the work world tangible: digital assistance systems as supporters in manual assembly, augmented reality, gesture control, exoskeletons and wearables that simplify interaction between man and machine. Patrick Schwarzkopf, Managing Director of VDMA Robotics + Automation, explained: “Jobs will be more attractive and ergonomic. The respective strengths of man and machine are complementary! This opens up a great opportunity for a better workplace design. This topic sets the tone of automatica as hardly any other fair.”

What lies ahead—Artificial Intelligence

Artificial Intelligence (AI) is the next technological leap. automatica communicated relevant expertise with numerous talks on this topic. AI-based data analyses can give industry an enormous increase in growth. Interdisciplinary dialog is crucial here. “To use business potential successfully, automation and IT providers must collaborate much more closely together with AI experts in future,” Ralf Backsch said, Technical Executive of Watson IoT Europe, IBM Sales & Distribution, Software Sales.

Start-ups and the promotion of young people

Twenty-three young entrepreneurs from all over the world presented themselves at the Start-up Arena. With that, automatica promotes exchanges in the industry and supports young entrepreneurs on their way to success. With the Makeathon, Integration Islands and Escape Game formats, the trade fair addresses young people in a targeted manner. More than 120 Makeathon participants and 200 students brought a breath of fresh air to the industry. Trade fair Managing Director Mr. Senger sees an important issue in this respect: “The shortage of skilled workers is unfortunately a daily reality in industry and SMEs now. To address this problem, we will continue to strengthen our commitment in the area of promoting young, talented people.”

Top grades from visitors and exhibitors

The positive mood in the industry could be felt everywhere: Ninety-six percent of the exhibitors and 98 percent of visitors evaluate the trade fair as excellent, very good or good. automatica is the business platform for making concrete investments, and 97 percent of the visitors confirmed this.
Top themes medical technology

Germicidal surfaces, new systems engineering capabilities and innovative software for hygienic and efficient pharmaceutical production

Nikolaus Ferstl, Technical Director at University Hospital Regensburg, will be discussing ‘Innovations in the field of cleanroom technology’ and their importance for hospital operations at the Cleanzone Conference. He offers a preview of his presentation here in our interview.

In what areas does University Hospital Regensburg operate cleanrooms?

“University Hospital Regensburg operates cleanrooms in various areas, including the pharmacy, in the José-Carreras Centre for Somatic Cell Therapy, where it is used for the production of cell therapies and pharmaceuticals for Advanced Therapy Medicinal Products (ATMP), and in transfusion medicine.” (Nikolaus Ferstl, Technical Director at University Hospital Regensburg)

Medicinal Products (ATMP), and in transfusion medicine.

What sort of investments are planned in cleanrooms over the next few years?

“In the field of cleanroom technology, we are investing in renewing our ventilation and air-conditioning systems, including the measurement and control technology, to satisfy hygiene requirements and reduce energy costs. We have also begun implementing a CATO project, and are in the process of creating the technical framework in which this can proceed. CATO® is a comprehensive software solution for chemotherapy that supports the entire process, from long-term therapy planning and therapy support to the actual production of the cytotoxic drugs. State-of-the-art database technology allows for its utilisation both as a standalone application in smaller pharmacies, as well as in networks for large hospitals with station integration.”

With the growing number of multi-resistant germs in hospitals, what is the importance of cleanroom technology?

“Cleanroom technology has a huge role to play here. We are trying to deliver the necessary improvements in every area. These include the aforementioned new systems engineering capabilities, systematically structured quality improvements within the framework of re-validation and re-qualification activities / requirements, additional training for employees, and achievement of GMP production certification in all areas, including in production in pharmacies.”

Your presentation at the Cleanzone Congress is entitled ‘Innovations in the field of cleanroom technology’. Which innovations are particularly important for hospital operations, and what are some of the other factors that you will be addressing in your talk?

“The following innovations are particularly important for hospital operations: Hygienic and germicidal surfaces and materials, due to the high footfall, and the CATO solution I discussed, because it offers the potential for tremendous cost savings. Medications that have been opened do not have to be disposed of immediately, and can potentially be used for the preparation of medications for other customers. Other aspects of my presentation including current requirements mandated by law and GMP guidelines, while I will also be addressing the topics of digitisation, cleanroom technology 4.0 and BIM.”
Rising Demand for Plastics and Plastics Processing

Fakuma Profits from Positive Trend in the Industry Sector

Plastics are booming. But not only is demand on the rise, quality requirements specified for materials and processing are becoming stricter as well. The Fakuma international trade fair for plastics processing will present modern solutions for high-quality plastics processing in Friedrichshafen from the 16th through the 20th of October, 2018.

Good Mood, Rising Demand

The mood amongst European manufacturers of plastics and rubber processing machines is excellent. Production has increased to an estimated €53 billion since 2009, which corresponds to 99% growth over the last eight years. In 2017, production output of the industry sector organised under the Euromap umbrella association experienced above average growth amounting to 7%. And thus it’s no wonder that plastics processing companies are doing well, because plastics are not only being used in automotive and packaging technology more and more frequently, efficiently and diversely. Fakuma will also present application options in the construction sector. For example, BASF recently increased production capacity by 40,000 tons per year for Neopor, which is used as an insulating material. The grey successor to conventional Styrofoam is lighter and more efficient than its white predecessor.

New Materials, High-Tech Processing

However, not only the latest materials and their possible uses will be showcased in Friedrichshafen. Simultaneously rising demand for better and better performance, as well as top quality, necessitates an unrelenting innovative spirit and new developments. Whether injection moulding, extrusion, thermoforming, foaming or 3D printing is involved – raw materials producers, machine builders and manufacturers of precision parts will present all they have to offer in the way of innovation throughout the entire value chain at the exclusive industry meet. The trade fair with continuously growing international recognition is taken advantage of by numerous exhibitors in order to unveil their new products to a broad-based audience for the first time. There’s no end in sight to the success of the industry sector (or Fakuma as its representative trade fair). Due to the persistently good order situation, Euromap is expecting turnover growth amounting to 2% this year. Propensity to invest in new machines and systems remains high, which is affecting lead-times for materials and machine. At the same time, steady growth is being impeded by the lack of qualified personnel. "This fact may well provide additional impetus for the automation solutions exhibited at Fakuma", surmises Fakuma project manager Annemarie Schur.

Plastics In Demand All Over the World

Plastics are long since not just a German or European business factor. This is demonstrated by the expert visitors who have travelled from distant countries to attend the industry event in recent years. Expert visitors, specialists and decision-makers journeyed to the last event in 2017 from more than 120 countries. 48,375 expert visitors accepted the invitation of the roughly 1900 exhibitors to attend the event in Friedrichshafen on Lake Constance where Germany, Austria and Switzerland meet – and the numbers continue to rise. In addition to innumerable participants from Germany and elsewhere in Europe, above all the number of visitors from Asia is increasing. And the Asians are profiting from international growth of the industry sector as well. In particular Chinese competitors have become stronger according to Euromap. In 2017 they produced machines and systems valued at €1.1 billion – 180% more than in 2009.
FANUC’s 450 ton all-electric IMM comes to Europe

FANUC at Fakuma 2018 in Friedrichshafen, Germany, in hall B3, stand B3-3211

FANUC Europe will exhibit several all-electric ROBOSHOT injection moulding machines (IMM) during Fakuma 2018 – in hall B3, on stand B3-3211. One of the main highlights is the new a-S450iA. Latest machine developments led to the 4500kN clamping force IMM the market has been expecting for years. Furthermore, a production cell, incorporating a 100-ton ROBOSHOT, will produce technical parts in engineering grade plastics under “Variotherm” mould process. The system literally works hand-in-hand with a six-axis FANUC LR Mate robot and a CR-7iA robot for parts assembly and handling. ROBOSHOT machines fulfil strict user requirements aimed at low energy consumption and flawless injection moulding quality, combined with stable repeatability and maximum process security. In the so-called IOT corner FANUC and TIG demonstrate Euromap 77 for plastics processing according to industry 4.0. Last, but not least, ROBONANO builds a bridge between injection moulding and mould manufacturing: the 5-axis CNC machining centre excels in ultraprecision five-axis machining in freeform surfaces with 0.1 nanometre command resolution. This machine tool demonstrates automated, predictable and repeatable optical-quality finishing of high-accuracy mould inserts.

ROBONANO a-NMiA demonstration

“Of course, injection moulding experts will come to the FANUC booth to see the new 450-ton IMM”, admits Gianluca Tristo, FANUC’s ROBONANO expert, “however, I am sure that they will be also inspired by having their eyes on ROBONANO a-NMiA outstanding capabilities.” This new ultraprecision machine tool has been developed by FANUC specifically for five-axis diamond machining of freeform surfaces. This fits pretty well in the injection moulding industry since FANUC can now offer a quite extended line-up of products, particularly for the polymer-based process chain. As a matter of fact, FANUC ROBOSHOT customers can now use tools where high quality mould inserts prepared by ROBODRILL and fine-finished by ROBONANO are assembled to precise components wire-cut by ROBOCUT. To this specific industry, ROBONANO – with its 0.1 nanometre command resolution – offers a robust alternative to manual polishing of mould inserts. And of course, FANUC ROBOTS can also be exploited in order to automate processes even further. At the exhibition, ROBONANO a-NMiA will demonstrate real machining of a mould insert for the automotive industry, with a complex shape. Besides the demonstration, examples of different applications will be presented, such as surface texturing with holographic visual effects, finishing of high-precision optical-quality surfaces and processing of different materials, including mould steel.

ROBOSHOT a-S450iA finally in Europe

Its debut was celebrated in Japan last year following the introduction into the U.S. market on the Milacron booth during NPE Orlando – the all-electric FANUC ROBOSHOT a-S450iA, 4500 kN clamping force precision injection moulding machine will start its European market success from Fakuma 2018. Higher cavity numbers and bigger moulds require larger platen sizes and tie bar distances which demand a larger/stronger machine with higher clamping forces. Beyond automotive, the medical/pharmaceutical device markets and other precision parts branches want more precise and fast output. "That is how the market works", agrees Wolfgang Haak, FANUC’s Product Manager ETS Europe Roboshot, “and FANUC was aware of that – deciding to develop a bigger machine based on the same performance and reliability as the other six models between 150 and 3000 kN clamping force. Now we have 4500kN clamping force, a tie bar distance of 920 mm by 920 mm, a clamping stroke of 900 mm, a 1300 mm by 1300 mm platen size and a maximum die height of 1000 mm. Four different screw sizes for the two basic injection units achieve high flexibility." The a-S450iA on stand B3:3211
FANUC’s 450 ton all-electric IMM comes to Europe

demonstrates the machine's productivity potential: connection pieces for infusion components are produced using a 32-cavity medical device mould provided by KEBO/Switzerland. Complex geometries, as produced in very large quantities in the medical device and pharmaceutical industries, require maximum precision – particularly pertaining to surface quality, contour accuracy, weight stability and reproducibility. State-of-the-art CNC technology in the ROBOSHOT provides a unique electric moulding solution. The machine is equipped with efficient energy recovery control function, reliable torque plasticise control – Precise Metering Control (PMC) 283 – as well as backflow monitor and highly efficient AI mould / ejector protection. The results are high-end process performance and product quality.

**Hand in Hand with robots**

Using the example of a compact production cell, FANUC demonstrates a high-tech / high-batch production concept demanding clean machines, cleanroom environments and robotized activities, promoted today by e.g. the medical device and technical branches. Robotec PLASTICMATE and FANUC ROBOSHOT a-S/one.OSFiA/zero.OSFiA interact in a compact and flexible production cell. Demonstration of the integrated “Variotherm” function: in-cycle mould temperature changes improve the mechanical properties of the parts. The controlled cavity surface temperature does not only maintain low viscosity up to complete and immaculate mould filling it also allows special surface effects. Parts removal is carried out by a six-axis FANUC LR Mate robot combined with a linear axis. Subsequently, the top and bottom parts are deposited in a trace buffer before they are assembled automatically. The cooperation between the LR Mate robot and the collaborative CR-7iA robot ends at the delivery station where visitors can receive the finished parts.

**Industry 4.0: FANUC ROBOSHOT LINKi & Euromap 77**

In one section of stand B/one.OSFiA/two.OSFiA/three.OSFiA – called IOT corner – FANUC shows the new Euromap 77 OPC UA interface in cooperation with the TIG “Authentig” MES system. Visitors can see real-time quality, machine and job status monitoring of all machines and the Robot cell in compliance with Industry 4.0 requirements. FANUC ROBOSHOT LINKi will be demonstrated.
The laboratory of the future: smartLAB III in the starting blocks

smartLAB/Lab of the future

21st - 23rd May 2019: LABVOLUTION, Hannover (D)

If you’ve ever wondered what tomorrow’s intelligent laboratories might look like, chances are you will find the answers you’re looking for at the LABVOLUTION smartLAB showcase, which has been at the forefront of the latest laboratory technologies and trends since 2015. A key part of smartLAB’s unique appeal has been the way it combines market-ready applications with forward-looking vision.

Good things come in threes: smartLAB will be back for a third season at LABVOLUTION 2019. Germany’s Lower Saxony state government has given confirmation of funding, paving the way for a 2019 edition this immensely popular showcase on the intelligent laboratories of the future. While the government decision marks the official start of the project, preparations for the showcase have been ongoing for some time, and the organizers can now announce that smartLAB 2019 will put the spotlight squarely on integration and interactivity, both with respect to the technologies on display and the visitor experience.

If you’ve ever wondered what tomorrow’s intelligent laboratories might look like, chances are you will find the answers you’re looking for at the LABVOLUTION smartLAB showcase, which has been at the forefront of the latest laboratory technologies and trends since 2015. A key part of smartLAB’s unique appeal has been the way it combines market-ready applications with forward-looking vision. Supported by a core group of regular partners and several new ones, next year’s smartLAB III will take the “intelligent laboratory of the future” theme to the next level. The showcase has become a mainstay of LABVOLUTION, Europe’s flagship fair for innovative lab equipment and laboratory workflow optimization. A joint project by science and research organizations and industrial companies, smartLAB has built a worldwide reputation as a forum for dialogue and a driver of digitization in the lab sector.

“We are delighted at our partners’ unwavering commitment to seeing this very special project continue,” said Dr. Andreas Gruchow, a member of the Managing Board of LABVOLUTION’s organizer, Deutsche Messe. “And now we also once again have the financial backing of our state government. This fantastic support gives us added confidence as we continue our preparations for LABVOLUTION 2019, which will have lab automation, digitization and integration as its keynote themes.”

Sabine Johannsen, Lower Saxony’s State Secretary at the Ministry of Science and Culture: “We are very pleased to support the smartLAB project for the third time running. It’s a model example of a multi-stage research project that achieves the all-important linkages between fundamental research, applied science and communication. smartLAB also shows how an interdisciplinary approach can help science-based industries, such as the chemicals industry, come to grips with the challenges and opportunities of digitization. All this makes the project an important catalyst for the future development of the lab technology sector as well as a key driver of added value.”

Preparations for next year’s smartLAB are already in full swing. The Institute of Technical Chemistry at the Leibniz - University Hannover (TCI) will once again head the joint initiative. “smartLAB III will feature many innovative new elements,” explained Sascha Beutel, smartLAB Project Coordinator at TCI. “We will make full use of the latest technologies – basically everything from interactive media and AR applications to the latest generation of VR headsets and drones – while ensuring that we meet our objective of creating a fully functional ‘Lab 4.0’ at LABVOLUTION.”

Good things happen when competitors join forces

Apart from TCI and Deutsche Messe, the regular smartLAB partners are Eppendorf, Labfolder, Köttermann, PreSens, Schmidt+Haensch, Sartorius and Fraunhofer IPA. New partners this year include Mettler Toledo, I GO 3D.com, Advus, Noack Laboratorien, Qiagen, Realworld One and Ostfalia University of Applied Sciences.

The list of partners highlights another key benefit of the joint project: its role as a catalyst for collaboration – as a platform that allows competitors to come together to jointly drive digital transformation of laboratory technology. Open collaboration between partners from research and industry fosters the development of integrated and interoperable lab solutions. This touches on another key objective of the project: to establish shared standards. For 2019,
The laboratory of the future: smartLAB III in the starting blocks

The project team is planning to standardize the lab's IT infrastructure even more, to further optimize its modular, integrated design and to introduce interactive communications solutions, such as touch projectors and Amazon Echo.

Getting even closer to trade visitors

One thing that is clear from past LABVOLUTION shows is that the visitors like to interact with the exhibits. That's why the project team is planning to expand the interactive sections of the smartLAB display in 2019. The team is likewise significantly expanding the scope and duration of smartLAB's use case demonstrations. About 50% of the trade visitors who attended LABVOLUTION 2017 visited the smartLAB display at least once during the show, and about 20% returned to the display three or more times.

Unlike the other LABVOLUTION displays, the smartLAB showcase didn't cease operations on the final day of the show. Instead, it was transferred straight to the on-site Deutsche Messe Technology Academy, where it has attracted numerous delegations and served as a venue for numerous industry and political events ever since. The smartLAB II display's final event will be a function by the German high-tech industry association SPECTARIS at the end of July. Straight after the function, the lab will be dismantled and moved to Leibniz University where it will be transformed into smartLAB III.

LABVOLUTION

The next LABVOLUTION will be held from 21 to 23 May 2019, in Hannover, Germany. LABVOLUTION is Europe's flagship fair for innovative lab equipment and laboratory workflow optimization. It covers every aspect of laboratory work, from the life sciences to analytical chemistry. Its displays feature the full spectrum of equipment and infrastructure for research, analysis, production and training laboratories in the chemicals, pharmaceutical and life sciences industries, as well as in the environmental, food, bioanalytics and R&D sectors. LABVOLUTION grew out of and replaces the long-established BIOTECHNICA show, and several areas of its lineup, including, most notably, the BIOTECHNICA Forum, have a strong focus on biotechnology and biotech research. LABVOLUTION is an international platform for discussion on current themes and trends, including Lab 4.0, laboratory workflows and bioanalytics, and delivers further added value with an array of knowledge-transfer, networking and continuing professional development events. LABVOLUTION is staged in Hall 19/20 (adjacent to the NORD entrance) at the Hannover Exhibition Center.

French representation celebrates 50-year partnership with BOY

On the occasion of the 50-year partnership, Alfred Schiffer, Managing Partner of BOY (in the picture on the left), visited the owner of BMS France, Antoine Bidet (2nd from the left) and Thierry Roche, National Sales Director at BMS (2nd from the right). Wolfgang Schmidt, BOY Export Manager (in the picture on the right), also congratulated BMS on the successful 50 years of common cooperation.

50 years ago, the German family business BOY started its success story. As a German manufacturer of Injection Moulding Machines, the company founder Max Schiffer soon found a competent partner organization in France – the company BewePlast. An agency contract was signed, which remains valid until today. Rudolf Weber, founder of BewePlast, continuously expanded his market position in the French plastics industry. During five decades of successful cooperation BewePlast has sold numerous BOY Injection Moulding Machines into the emerging market. In addition to sales, the company has also been responsible for the service of the BOY Injection Moulding Machines in France and gained a very good, reliable reputation among its customers.

Today, BewePlast works successfully far beyond the French border within the BMS France Group - in the French-speaking Switzerland and in the French-speaking North African countries as well. As an independent company within the group, BewePlast is still the sales and service organization of BOY Injection Moulding Machines in these markets. Much of what Rudolf Weber had started at that time is still integrated in the philosophy of the BOY partner.

In addition to the successful Sales and good Service of the BOY Injection Moulding Machines, the company is also very successful as a full-service provider with versatile peripherals. Equipped with its own demonstration room in Argonay - near Oyonnax, the center of the French injection molding industry - , BewePlast offers its users a comprehensive product range. The positive market trends in France offer both companies the best prospects for the future.

Dr. Boy GmbH & Co. KG     D 53577 Neustadt-Fernthal
When top decision-makers in the healthcare business meet in Düsseldorf in the middle of November at the world's leading medical trade fair, MEDICA 2018, (date: 12 – 15/11/2018; Monday to Thursday), over 5,000 exhibitors from at least 70 countries will meet them once more, as consistent partners who are enthusiastic about innovation and offer tailored solutions for outpatient and clinical care. Digital transformation remains at the top of everyone's list this year. It is shaping the health economy worldwide and changes both processes and business models alike.

This prevailing trend will not only be represented by exhibitor innovations at the MEDICA, but is also reflected in the programmes of the accompanying conferences and forums.

These conferences and forums include the MEDICA HEALTH IT FORUM (on IT topics such as big data, artificial intelligence and cyber security), the MEDICA CONNECTED HEALTHCARE FORUM (hardware and software solutions for connected healthcare) and the MEDICA MEDICINE & SPORTS CONFERENCE, held entirely in English, which takes a look at the use of applications which are used in close proximity to the body and wearables for monitoring vital signs.

A significant strength of the MEDICA is that it not only presents solutions for individual medical specialist disciplines in one place over a few days, but also takes on the complete workflow of patient treatment. The individual focal points are clearly structured according to hall and include: Electromedicine / medical technology (approx. 2,500 exhibitors), laboratory technology / diagnostics, physiotherapy / orthopaedic technology, commodities and consumables, information and communication technology, medical furniture and specialist furnishings for hospitals and practices.

This year, the COMPAMED will be taking place for the 27th time, in parallel with MEDICA, with just under 800 exhibitors (in Halls 8a + 8b). A while ago, the items presented here would generally include simple parts, components and equipment for technical devices and medical products, but today, COMPAMED is a hotspot for complex high-tech solutions such as innovative materials, microtechnology and nanotechnology.

Over the previous years, MEDICA and COMPAMED have regularly received between 120,000 and 130,000 visitors between them annually, with around 60% of these visitors coming from outside Germany. This year, Federal Health Minister Jens Spahn will also be among the visitors. On November 12, he will open MEDICA 2018 and the parallel 41st German Hospital Conference.

This globally unique combination means that both MEDICA and COMPAMED will reflect the entire process chain and present a comprehensive range of medical products, devices and instruments. Together, they occupy the entire space at Düsseldorf’s exhibition centre.
Statement by Horst Giesen, Global Portfolio Director for Health & Medical Technologies at Messe Düsseldorf GmbH, regarding MEDICA 2018 in Düsseldorf (12 – 15 November)

For years, almost no other industry has been shaped so much by sustainable growth as the medical technology industry and its suppliers. Furthermore, there are practically no other industries in which it is so imperative to remain at the cutting edge of progress and gain information on new products, trends and technology, which are presented at the MEDICA in particular, a world-leading industry platform in this area. The structure of the market is changing constantly. Even within specific regions of the world, the market situation can be radically different, depending on the nation in question, and the approval processes for medical technology systems and products can also differ from each other dramatically.

Taking a look at Europe proves this remarkably well. In Spain, Ireland and Romania, the sales curve for medical technology is on the up, thanks to widespread economic recovery and a need for investment that built up during the years of the credit crunch. Demand is also high in the Netherlands, Austria and Switzerland. However, in Germany, Italy and France, progress is slower than it could be - the key word here is “investment slowdown”. While austerity is creating obstacles within the healthcare systems here, the current political developments and subsequent currency depreciations in some places put the brakes on access to the market and businesses in Turkey and Russia. The upcoming Brexit also produces more obvious limitations.

One challenge that is faced across regions is increasingly strict regulation for product approval. This concerns both manufacturers and their suppliers equally, although smaller and middle-sized companies also have to put up a good fight against the obligation to fill out increasingly complex and comprehensive documents and create reports, which results from a multitude of EU directives and guidelines, for example the Medical Device Regulation or the REACH (Registration Evaluation, Authorisation and Restriction of Chemicals).

A market-influencing factor such as this throws up many questions for visitors and exhibitors at our internationally organized MEDICAAlliance specialist trade fairs. They need to know how to set their own businesses on the right track internationally and come together with the right partners. We also offer you the communication and information platforms, which have been tailored to meet specific needs.

In addition, the innovation cycle demands that we consistently remain up to date. For medical technology and products, this cycle is incredibly short. To give an example of its effects, German manufacturers gain a third of their turnover from products that are less than three years old. This means that MEDICA in Düsseldorf, the top international event, is a hotspot for the latest products and developments for service providers every year, all within the scope of current trends.

Digital transformation is also shaping the world of medicine

Currently, digital transformation is the primary force shaping the health economy and radically changing processes and business models worldwide. Our programme of events for MEDICA 2018 (12 - 15 November) takes this into consideration, both in presenting product ranges from over 5,000 exhibitors from 70 countries once again, and in the spectrum of topics covered at the accompanying conferences and forums. We stay on the ball for these high priority topics and illuminate them from different perspectives, ensuring that we consider the different target groups carefully. The communication and information platforms, MEDICA HEALTH IT FORUM and MEDICA CONNECTEF HEALTHCARE FORUM (including the MEDICA App Competition), organized within the scope of MEDICA, drew over 8,000 visitors on their own last year, and will definitely constitute another of the people-magnets in the Düsseldorf trade fair halls this year.

The discussions, presentations and speeches in these forums will focus on essential digitalization and IT trends such as opportunities to implement artificial intelligence, big data analysis via algorithms or cyber security measures. Equally, innovative products and technology will be presented, from the wearable technologies, telehealth and robotics and apps sectors, to name a few.

The main strength of MEDICA is that it does not limit itself solely to clinical and practice IT and the fairly rigid framework of the national telematics infrastructure. It shows us digital trends and best practices for connecting from stakeholders in the health industry that have swept across many nations. Already, it has become apparent that the theme of “Patient Empowerment”, i.e. the management of healthcare data being considered the responsibility of the patient, is becoming more significant this year.

You are your own doctor: E-Files are coming soon...

Following the enactment of the E-Health Act, applications for electronic patient files are being planned in Germany, in conjunction with an electronic health card; however, the first solutions developed by health insurance agencies, namely the electronic health records (eGA) for use on smartphones or PC, are already ready to be launched and tested out, and are slated to be rolled out for all members who hold the appropriate insurance. At the same time,
leading technology and software groups in the smartphone sector are chomping at the bit. They want to expand the health apps in their operating systems by adding health record applications (for example, the Health Records app in iOS).

At MEDICA 2018, lively discussions will be had on topics, and this should result in an answer to the question of how available the service providers in the health industry will make these types of digital solutions to patients. Aspects which are linked to this, such as the new HL7 FHIR - the standard for mobile communication in healthcare, or the economy platform’s attack on healthcare data, will thus be dealt with in the MEDICA HEALTH IT FORUM, for example.

**AI for optimal cooperation between humans and machines**

Another concept on everyone’s tongue is artificial intelligence (AI). The long-held fear concerning AI, namely the suspicion that doctors and healthcare staff would be replaced by learning, automated working systems and robots in the future, has long been refuted. MEDICA exhibitors are proving that this fear is unfounded with their innovations. Instead of replacing workers, these modern working methods are best described instead as “advanced intelligence”. Here, humans and machines work hand in hand to ensure that the best of both worlds is merged together. Examples of this are seen in diagnostic imaging. Here, AI ensures that the radiation zone in CT scans can be delimited optimally, or that data recorded in MRI or CT systems can be pre-analysed before the actual findings are determined by the radiologist, no matter whether the subject studied is a fracture, tumour or an infection point. AI acts similarly in fully automated calculation of care cases, which means that the human workforce can concentrate primarily on following up abnormalities and more complex cases.

**MEDICA START-UP PARK – A platform for creatives**

The premier of the MEDICA START-UP PARK met with approval from our professional audience in 2017, and this is why this new platform for the creative start-up scene has made a firm fixture in MEDICA’s program. Here (in Hall 15), young companies can present their ideas, primarily those for the digital health sector, and meet potential business partners. Magnosco from Berlin will be among the attendees this year. The development team will present an application for early detection of skin cancer which uses a combination of laser technology and artificial intelligence.

NUVOAIR from Stockholm has also registered as a participant at the MEDICA START-UP PARK. They want to use their presence to introduce their Air Smart Spirometer. Last year, they laid excellent foundations at MEDICA by participating in the MEDICA App COMPETITION, and coming away with a respectable second place. The “Air Smart Spirometer” enables lung capacity to be measured easily at home, using a combination of hardware and an app, for asthmatic or COPD patients.

**Blockbuster themes in medical practices**

The MEDICA ACADEMY sets its course for blockbuster topics in medical practice once more. Following its premier in 2017, it will be held again this year, as a certified further education event for doctors from various specialities. In addition to practical courses “on devices” (e.g. ultrasound) and updates on general medical diagnostics and therapeutic issues, digital topics are also on the program, in the form of best practices for telemedicine. Given the backdrop, that the telemedicine prohibition is set to be relaxed in Germany, this session should definitely be followed with close attention.

Other program highlights at MEDICA 2018 include the DImED conference for disaster and military medicine and the MEDICA MEDICINE: + SPORTS CONFERENCE (respectively on 13 and 14 November 2018 / Congress Center Düsseldorf South) that will be focusing on prevention and sports medical treatment concepts. The conferences will be held in English and are geared towards an international audience.

The 41st German Hospital Conference (12 - 15 November), a leading communication platform for decision makers from hospitals, specifically seeks to address a German specialist audience, as does the MEDICA PHYSIO CONFERENCE. With its treatment-oriented presentations, it is directed towards the professional scene of physiotherapists, sports medicine specialists and orthopaedists and is taking place this year on 14 and 15 November (Congress Center Düsseldorf South).

Other forums that are integrated into the MEDICA trade fair include the MEDICA LABMED FORUM (trends from the medical laboratory sector), the MEDICA ECON FORUM for discussions on healthcare policy between industry, political entities, insurance bodies and patient representatives, and the MEDICA TECH FORUM for market-relevant topics ranging from the medical industry to science and legal conditions.

**The whole diagnostic and therapeutic workflow in one place**

The MEDICA specialist trade fair is oriented around a broad diagnostic and therapeutic workflow in medical care, and has the following clearly defined focal points: Electromedicine / medical technology (approx. 2,500 exhibitors), laboratory technology / diagnostics, physiotherapy / orthopaedic technology, commodities and consumables, information and communication technology, medical furniture and specialist furnishings for hospitals and practices.

COMPAMED 2018 will also take place alongside MEDICA 2018, on all four days (12 to 15 November) in Halls 8a and 8b. With around 800 exhibitors, COMPAMED is the leading international market platform for suppliers of the medical technology industry.

**The German Federal Minister of Health, Jens Spahn, will attend the opening**

Last year’s MEDICA and COMPAMED counted a total 123,500 trade visitors from 130 countries.

The German Federal Minister of Health, Jens Spahn, will be among the top decision makers travelling to Düsseldorf this November. He will open MEDICA 2018 and the German Hospital Conference on 12 November.
Statement by Horst Giesen, Global Portfolio Director for Health & Medical Technologies at Messe Düsseldorf GmbH, on COMPAMED 2018
– High-tech solutions for medical technology

12 – 15 November 2018 in Düsseldorf

The market for medical technology and products is characterized by sustainable growth. The innovation cycles are short. However, approval procedures differ widely from country to country and are very complex as a whole. Restrictions due to trade policies and exchange rate fluctuations are further challenges that providers have to face. That is why they require competent and flexible partners by their side to give them significant additional clout. Regardless whether in product development, manufacturing individual components, complete end products or sales and after-sales services: suppliers in the medical technology industry meet these high requirements. This year, they will once again impressively demonstrate these abilities at their leading international information and communication platform, the COMPAMED 2018, which will take place from November 12 to 15 in Düsseldorf.

Once more, we can expect a future-oriented exchange with an eye to innovative solutions to ensure better healthcare among the over 800 COMPAMED exhibitors and their customers, who are made up of, for example, the over 5,000 exhibitors at MEDICA, the world’s largest medical trade fair that takes place alongside the COMPAMED. Exciting trends are currently setting the pace. For quite some time now, ‘dematerialization’ and ‘digitalisation’ or ‘networking’ have been buzzwords that quite fittingly describe the events around medical technological product development and are still extremely current.

Providers are turning to suppliers to seek ever more delicate, lighter and at the same time more advanced components such as sensors, chips, wireless modules and even accompanying energy savers or information savers. These then can be installed in wearables used for diagnostics of vital signs. These devices are in high demand. Another large application is the field of active implants. Participants in this year’s COMPAMED Spring Convention have already learned why these are among the most technically sophisticated medical products with particularly high research, development, production and approval requirements and which are currently the most interesting innovations in this area.

Miniaturised components are among these innovations as well as developments in coating technologies. Experts, for example, describe parylene coatings as multi-talents. Due to their organic compatibility and other characteristics, these progressive, plastic-based coatings are particularly well suited for encapsulated casings for implants. In addition, they can be made into ultra-thin products, which is why they are used in stent technologies, neurostimulation or infusion technologies.
Statement by Horst Giesen on COMPAMED 2018

Durability is in demand – or is it the exact opposite?

So whilst certain materials require extreme durability, other usages require the exact opposite. And exhibitors at COMPAMED have the right solutions up their sleeves for these, too. Take applications to treat bone defects, for example. The IFAM (Fraunhofer Institute for Manufacturing Technology and Advanced Materials) recently presented their ideas and developments in this field, in particular a magnesium implant that dissolves after a certain period of time. The ingenious twist in this process: The fibrous structure of the implant supports the bone during growth and stimulates blood vessel growth. This allows the bone to grow, whilst the implant practically breaks itself down at the same time.

Of course, there are also products with a limited lifetime that can be used outside of the body. Despite their disposable nature, they are designed to achieve maximum validity for (diagnostic) purposes and represent high-tech in a miniature format. ‘Lab-on-a-chip’ technologies are a good example. At last year’s COMPAMED, the Fraunhofer Institute of Applied Optics and Precision Engineering (IOF) presented a pocket-sized lab. Ideally, this can be used in future to locate disease indicators in the bloodstream at the patient’s home. This will do away with the need for specialist physicians. All that is required is a disposable fluorescence chip and a smartphone. A drop of blood applied to the chip will then be sufficient to receive a diagnosis via app within minutes.

Print your own pocket-sized lab

This chip, which is based on optical methods, is produced using a fairly low-priced production method that comes across as just as sensational as its effects. The chip contains extremely fine channels and is equipped with a tiny lamp and a miniature photo detector. Both are printed onto the chip using a conventional ink-jet printer that has been only slightly modified. The trick: This is done using special ink. It is populated with fluorescent molecules and nanoparticles. Furthermore, anchor molecules that are typical for a certain disease marker (e.g. gluten intolerance) are added. When the blood containing the disease marker comes into contact with these special molecules and the fluorescent dyes during analysis, the printed lamp stimulates the dye and causes it to light up. As a result, the photo detector triggers an alarm and proves the presence of the disease.

It is difficult for laymen to understand just how such innovations work exactly, however: With their know-how and strength in development, suppliers in the medical technology industry make a valuable contribution with regard to systems and products that are both economic and offer high benefits to doctors and patients.

For providers exhibiting at the MEDICA, which takes place in parallel, they offer tailor-made innovations and are able to adjust the depth of development according to customers’ requests.

Hand in hand throughout the entire value chain

Every year, this cooperation between COMPAMED and MEDI-CA provides a fixed time and place for dialogues which bring forth creative ideas for the entire medical technology value chain. This is unique worldwide. The main focal points of COMPAMED are: Components for medical technology (electronics, components, hoses, filters, pumps, and valves, among other items), materials/ substances, micro- and nanotechnology, made-to-order manufacturing, electronic manufacturing services (EMS), complex manufacturing and equipment partnerships (e.g. OEM - Original Equipment Manufacturers) as well as packaging and services.

Attractive programme highlights on trends in the supplier sector

Two forums also pick up relevant trends for medical technology suppliers in close cooperation with exhibitor presentations.

At the COMPAMED SUPPLIERS FORUM held by the specialist magazine, DeviceMed (Hall 8b), specialists from leading international companies and organisations will be talking about current developments throughout the entire process chain which concern medical technology. Mechanical and electronic components will also be a topic dealt with during the expert lectures, such as innovative materials and all sorts of made-to-order production. This year, particular focus is on: Additive Manufacturing (November 12), Cyber Security (November 13), Regulatory Affairs (November 14) and Wearables (November 15).

The COMPAMED HIGH-TECH FORUM (Hall 8a) presented by the IVAM Association for Microtechnology places key focus on microsystem technology, nanotechnology and production technology and process control.

As the floor space has been expanded this year, the product market "HighTech for Medical Devices" serviced by the IVAM Association for Microtechnology now offers space for even more exhibitors to present their innovations in micro- and nanotechnology, photonics and new materials. 45 international companies and research institutions have already confirmed their participation.

Another program element of COMPAMED 2018 is the ‘3D fab-print Additive Manufacturing Conference’ (held in English), in which renowned organizations and companies such as Evonik and Trumpf are participating with speakers. They show application options of the so-called generative or additive manufacturing processes for the fast and economic production of prototypes, components or tools, for example.

COMPAMED takes place in Halls 8a and 8b at Messe Düsseldorf and, due to its specific focus, primarily addresses technical buyers, specialists in research and development as well as packaging, production managers, construction engineers as well as process engineers. The event’s international significance is supported by the fact that out of the almost 200,000 previous trade visitors, 60 percent came from countries outside Germany.

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

Messe Düsseldorf GmbH
D 40001 Düsseldorf
Innovative packaging concept for medical and pharmaceutical products

MULTIVAC at FachPack 2018 in Nuremberg

At FachPack 2018 MULTIVAC will be presenting an innovative concept for packing medical and pharmaceutical products, where the main feature is the easy removal of the product thanks to a novel opening aid. In addition to this, a packaging line with automatic syringe infeed will be exhibited, as well as a new labelling solution, which enables folded products such as package inserts to be sealed closed automatically.

With Snapsil® MULTIVAC is showing a novel packaging concept for medical and pharmaceutical products, which is ideally suited to packing products such as syringes, tablets, plasters, injectors, catheters etc. With their integrated „snap-opening“ function, Snapsil packs offer an innovative opening aid, which enables the packs to be used more easily, even by elderly or disabled persons. When it comes to the hectic activity of everyday life in hospitals and care homes, it is simple and quick to open the packs and remove the product easily in a controlled way. Depending on the type of product, the pack can be equipped with a „click-to-close“ function, so that it can be opened again for multiple use and then closed securely. In addition to this, tamper-proof protection offers the maximum product safety. Snapsil packs can be produced on MULTIVAC thermoforming packaging machines and traysealers. The solution was developed in conjunction with the Snapsil Corporation.

MULTIVAC will also be presenting an automated packaging line for packing sterile medical products. The line consists of a R 245 thermoforming packaging machine with a syringe infeed system, a thermal transfer printer for printing variable production data on the packs, and a vision system for inspecting the print image. The R 245 can be freely configured and offers a high level of flexibility as regards packaging materials and pack formats. At FachPack it is equipped with an automatic infeed system for loading pre-filled glass or plastic syringes, and the system inspects the products before inserting them securely into the pack cavities. The infeed system consists of a shaft infeed system, a separating wheel, a transport conveyor and a pick & place robot. All the components of the infeed system are synchronised with the thermoforming packaging machine, and they can be operated via its control terminal in a convenient and reliable way.

The C 300 TC chamber machine will be on show from MULTIVAC’s wide range of chamber machines. It enables sterile medical products to be packed securely in film pouches, and packs can be produced either as vacuum packs or with modified atmosphere and reduced residual oxygen content. A temperature-controlled and permanently heated sealing bar, which can be both validated and calibrated, ensures that this clean-room-compatible machine achieves reproducible sealing quality.

MULTIVAC will be demonstrating its comprehensive expertise in labelling solutions with the new series of L 352 labellers. This series is designed for automatically sealing folding products closed, such as for example package inserts. The L 352 model will be presented at FachPack with a label dispenser, which enables the package inserts to be sealed closed with either a label on the back of the package insert, or alternatively with a label on the front edge of the product and a further label on the rear facing edge.

The L 352 can be installed on folding machines from various manufacturers. The labeller accepts the paper products directly at the folding machine. Thanks to a central height adjustment feature on the frame, the labeller can be adjusted quickly to different working heights, while separate servo drives for the top and bottom transport belts ensure that it can be adjusted to different paper thicknesses and formats. The machine is changed over to other label widths and labelling positions by means of dispensing edges, which can be exchanged very easily, in conjunction with special format plates for the press-on system.
Humidity Measurement Module for OEM Applications

The EE1900 humidity measurement module is optimised for climate and test chambers. The sensor copes well with pollution and chemical contamination.

The EE1900 humidity module from E+E Elektronik is optimised for the measurement of relative humidity (RH) or dew point temperature (Td) in climate and test chambers. With outstanding temperature compensation across the working range from -70 °C to 180 °C (-94 °F to 356 °F) and the choice of stainless steel and plastic probes, the module is suitable for a wide range of applications.

High Accuracy in Harsh Environment

The excellent measuring accuracy of the EE1900 rests on the innovative E+E humidity and temperature sensing element HMC/zero.OSF. The proprietary E+E coating protects the sensor from dust, dirt and corrosive agents. Therefore, the EE1900 module features excellent long-term stability even in harsh environment.

Chemical Purge

Thanks to the Automatic Sensor Recovery (ARC) function, the sensor copes well with chemical contamination. By controlled, strong heating, the chemicals gaze out from the sensing element. After the ARC cycle, the sensor quickly returns to normal measurement conditions. The ARC mode can be triggered either via a push button on the board or an electrical signal.

Comfortable Configuration and Adjustment

The EE1900 module features an analogue output, which can be set to current or voltage with a slide switch. The service interface allows for output scaling and adjustment of the humidity measurement. The product configuration software EE-PCS is available free of charge on the E+E website. The operating mode of the module is indicated by status LEDs as well as by the output and status signals.

Stainless Steel or Plastic Probe

The EE1900 is available with either stainless steel or plastic (PPS) probe. The high quality, flexible probe cable up to 3m length facilitates the probe installation.

With two sizes of the electronics board (55 x 46.5 mm / 2.17 x 1.83” or 90 x 70 mm / 3.54 x 2.76”), the humidity measurement module can be easily integrated into existing climate chambers.
Veranstaltungen im September 2018
Details zu den Veranstaltungen und Anmeldung auf www.reinraum.de

Seminar
Webinar: GMP Update II, Q&A zu PDE, ICH Q11 & Co.
Termin: 12.09.2018 - 12.09.2018
Veranstaltungsort: Ihrem Arbeitsbereich
Veranstalter: PTS Training Service

Seminar
Anforderungen an Isolatoren
Termin: 13.09.2018
Veranstaltungsort: Allschwil (CH)
Veranstalter: Swiss Cleanroom Concept GmbH

Seminar
Der Qualifizierungs-Workshop - Wie kann eine schlanke Qualifizierung aussehen? (QV 10)
Veranstaltungsort: Berlin
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
GMP-Aufbauschulung (B 2)
Veranstaltungsort: Mannheim
Veranstalter: CONCEPT HEIDELBERG GmbH

Workshop
19. Jenaer Reinraum-Stammtisch
Termin: 13.09.2018
Veranstaltungsort: Kahla
Veranstalter: COLANDIS GmbH

Seminar
Basis: GMP
Veranstaltungsort: CH-Olten
Veranstalter: PTS Training Service

Seminar
Experte für GMP Modul 1
Veranstaltungsort: Niederkassel
Veranstalter: PTS Training Service

Seminar
Die Leitung der Herstellung
Veranstaltungsort: Frankfurt/Main
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Der Computervalidierungs-Beauftragte Block I (CV 7)
Veranstaltungsort: Heidelberg
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Umgang mit Abweichungen in der Sterilproduktion (S 9)
Veranstaltungsort: Karlsruhe
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Isolator- und Barriere-Technik (PT 33)
Veranstaltungsort: Mannheim
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Beschaffung trifft GMP - Anforderungen und Umsetzung von GMP-Compliance bei Beschaffung und Einkauf
Veranstaltungsort: Mannheim
Veranstalter: CONCEPT HEIDELBERG GmbH

Tagung
ZVO-Oberflächentage - Kongress für Galvano- und Oberflächentechnik
Veranstaltungsort: Leipzig
Veranstalter: Zentralverband Oberflächentechnik e.V.

Seminar
Der Validierungsbeauftragte in der pharmazeutischen Industrie (QV 16)
Veranstaltungsort: Hamburg
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
ICCCS Symposium: “The world behind contamination control”
Veranstaltungsort: The Hague (Niederlande)
Veranstalter: ICCCS (International Confederation of Contamination Control Societies)

Seminar
Webinar: Wenn Nicht-Juristen Verträge entwerfen
Veranstaltungsort: Ihrer Arbeitsbereich
Veranstalter: PTS Training Service

Seminar
Computervalidierung Modul 1: Grundlagen, Regeln, GAMP 5
Veranstaltungsort: Wiesbaden
Veranstalter: PTS Training Service

Messe
Louges on Tour
Veranstaltungsort: Wien (A)
Veranstalter: Inspire GmbH - LOUNGES ON TOUR

Seminar
Intensiv: GMP-Auditor
Termin: 25.09.2018 - 27.09.2018
Veranstaltungsort: CH-Olten
Veranstalter: PTS Training Service

Seminar
Der QS-/GMP-Beauftragte in der pharm. Industrie (QS 5) - Block I
Veranstaltungsort: Mannheim
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Qualitätskontrolle Modul 2: Kalibrier- und Gerätemanagement
Termin: 27.09.2018 - 27.09.2018
Veranstaltungsort: Darmstadt
Veranstalter: PTS Training Service
### Veranstaltungen im Oktober 2018

Details zu den Veranstaltungen und Anmeldung auf [www.reinraum.de](http://www.reinraum.de)

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Seminar
**Experte für Validierung**
Veranstaltungsort: Baden-baden
Veranstalter: PTS Training Service

Seminar
**GMP-gerechte Reinräume (PT 19)**
Veranstaltungsort: Mannheim
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
**Validierung computergestützter Systeme (CV 1)**
Termin: 16.10.2018 - 17.10.2018
Veranstaltungsort: Heidelberg
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
**GMP-gerechte Dokumentation und Administration**
Termin: 17.10.2018 - 17.10.2018
Veranstaltungsort: Karlsruhe
Veranstalter: gmp-experts GmbH

Seminar
**GMP-Basis-Training TECHNIK (PT 28)**
Termin: 18.10.2018 - 19.10.2018
Veranstaltungsort: Heidelberg
Veranstalter: CONCEPT HEIDELBERG GmbH

Messe
**CLEANZONE 2018**
Termin: 23.10.2018 - 24.10.2018
Veranstaltungsort: Frankfurt am Main
Veranstalter: Messe Frankfurt

Messe
**parts2clean**
Termin: 23.10.2018 - 25.10.2018
Veranstaltungsort: Stuttgart
Veranstalter: Deutsche Messe AG

Seminar
**Medizinprodukte kompakt: Neue Anforderungen**
Termin: 23.10.2018 - 23.10.2018
Veranstaltungsort: Karlsruhe
Veranstalter: PTS Training Service

Seminar
**Sachkundige Person Leitung QK sowie Herstellung**
Termin: 23.10.2018 - 23.10.2018
Veranstaltungsort: Frankfurt am Main
Veranstalter: PTS Training Service

Seminar
**API: Experte für Wirkstoffe Modul 1**
Termin: 23.10.2018 - 24.10.2018
Veranstaltungsort: Unna bei Dortmund
Veranstalter: PTS Training Service

Seminar
**Containment: Single-use-Technologien, flexible Einwegsysteme**
Termin: 30.10.2018 - 30.10.2018
Veranstaltungsort: Karlsruhe
Veranstalter: PTS Training Service
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Qualifizierung zugekaufter Materialien in der pharmazeutischen Industrie
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QSRein Grundlagenseminar Qualitätssicherung in der Bauteilreinigung - Prozessoptimierung -
Termin: 15.11.2018 - 16.11.2018
Veranstaltungsort: Frankenthal
Veranstalter: fairXperts GmbH & Co. KG

Seminar
Datenmanagement und Datenintegrität
Termin: 15.11.2018 - 15.11.2018
Veranstaltungsort: Karlsruhe
Veranstalter: gmp-experts GmbH

Seminar
GMP Webinar: Schnell- und online Messung von Keimzahlen in Pharma-Wasser
Termin: 15.11.2018 - 15.11.2018
Veranstaltungsort: Heidelberg
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Praxisseminar Sicherheitstraining Zytostatika
Termin: 16.11.2018 - 17.11.2018
Veranstaltungsort: LEAC Hamburg
Veranstalter: Berner International GmbH

Seminar
Kompakt: Datenintegrität und Audit Trail Review
Termin: 20.11.2018 - 20.11.2018
Veranstaltungsort: CH- Olten
Veranstalter: PTS Training Service

Seminar
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Termin: 20.11.2018 - 20.11.2018
Veranstaltungsort: Karlsruhe
Veranstalter: gmp-experts GmbH

Seminar
Dichtigkeitsprüfung von Parenteralia
Termin: 20.11.2018 - 20.11.2018
Veranstaltungsort: Heidelberg
Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Erfolgreiche Personalführung im Reinraum
Termin: 21.11.2018
Veranstaltungsort: Rheinfelden (CH)
Veranstalter: Swiss Cleanroom Concept GmbH

Seminar
Reine Räume „kompakt“
Veranstaltungsort: Karlsruhe
Veranstalter: gmp-experts GmbH

Seminar
Effizientes Projektmanagement bei Reinraum Um- und Neubau
Termin: 22.11.2018
Veranstaltungsort: Rheinfelden (CH)
Veranstalter: Swiss Cleanroom Concept GmbH

Seminar
Ausbildung zum GMP-Auditor
Termin: 22.11.2018 - 23.11.2018
Veranstaltungsort: Karlsruhe
Veranstalter: gmp-experts GmbH

Seminar
Anforderungen an die Raumlufttechnik
Termin: 27.11.2018
Veranstaltungsort: Niederlenz (CH)
Veranstalter: Swiss Cleanroom Concept GmbH

Seminar
Abweichungen und CAPA
Termin: 27.11.2018 - 27.11.2018
Veranstaltungsort: Freiburg
Veranstalter: gmp-experts GmbH

Seminar
GMP-gerechte Dokumentation und Administration
Termin: 27.11.2018 - 27.11.2018
Veranstaltungsort: Aarau / Schweiz
Veranstalter: gmp-experts GmbH

Seminar
Isolator Technology Workshop
Termin: 27.11.2018 - 28.11.2018
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Veranstalter: CONCEPT HEIDELBERG GmbH

Seminar
Basis: Von der Risikobewertung zum Managen der Risiken
Termin: 27.11.2018 - 27.11.2018
Veranstaltungsort: CH-Olten
Veranstalter: PTS Training Service

Seminar
Datenintegrität in der Praxis
Veranstaltungsort: CH-Olten
Veranstalter: PTS Training Service

Seminar
Change Control
Veranstaltungsort: Freiburg
Veranstalter: gmp-experts GmbH

Seminar
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Veranstaltungsort: Berlin
Veranstalter: CONCEPT HEIDELBERG GmbH

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Termin: 28.11.2018 - 30.11.2018
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Veranstalter: CONCEPT HEIDELBERG GmbH

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Veranstaltungsort: CH- Olten
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Sterilerstellung „aktuell“
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Veranstalter: gmp-experts GmbH

Seminar
Medizinprodukte
Termin: 29.11.2018 - 29.11.2018
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Veranstalter: gmp-experts GmbH

Seminar
Lieferantenqualifizierung
Termin: 29.11.2018 - 29.11.2018
Veranstaltungsort: LEAC Hamburg
Veranstalter: Berner International GmbH

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Seminar
Aseptische Zubereitungsprozesse von nicht toxischen Parenteralia
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Veranstaltungsort: LEAC Hamburg
Veranstalter: Berner International GmbH

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Computervalidierung Modul 4: Keep IT Validated
Veranstaltungsort: Baden-Baden
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Abweichung, CAPA und Änderung
Veranstaltungsort: CH-Olten
Veranstalter: gmp-experts GmbH

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Veranstalter: PTS Training Service

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Seminar
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Termin: 05.12.2018
Veranstaltungsort: Rheinfelden (CH)
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Tagung
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Veranstalter: PTS Training Service

Seminar
1. Fachtagung „Fluch der Mikrobiologie in Unternehmen“
Termin: 06.12.2018
Veranstaltungsort: Nürtingen
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Seminar
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Termin: 06.12.2018
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Veranstalter: Swiss Cleanroom Concept GmbH

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Seminar
GMP-Regularien: Übersicht und aktuelle Entwicklungen
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Veranstalter: gmp-experts GmbH

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Termin: 06.12.2018 - 06.12.2018
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Veranstaltungsort: IHK Mittlerer Niederrhein, Nordwall 39, 47798 Krefeld
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Veranstalter: PTS Training Service

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Veranstalter: gmp-experts GmbH

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