The international group Vishay, one of the world’s largest manufacturers of electronic components, is expanding its headquarters in Selb and investing in state-of-the-art cleanroom facilities.

VISHAY Intertechnology expands cleanroom production in Selb

With 22,000 employees worldwide, Vishay is one of the largest manufacturers of discrete semiconductor elements and passive electronic components. The headquarters for Europe is located in Upper Franconia town of Selb. With the investment in almost 500 square meters of new cleanroom facilities for the production of high stability resistors, the global player was able to strengthen the German production site.

Highly sensitive components

There is a steady increase in the international demand for electronic components. The continued miniaturization and complexity of electronics allows for new developments and sales markets. Vishay Intertechnology provides high-end components for electronic products and is a technological leader in this market segment. The quality and long-term stability of the components is of decisive importance for the operation of the end products. Production and assembly of the high stability resistors requires a virtually particle-free environment. Since the highly sensitive components are impaired in their operation by the smallest of impurities, the production process takes place under controlled cleanroom conditions.

In order to be able to implement the increasing order volume flexibly and with usual high standard, the production capacity for passive resistances in Selb was expanded by a 500m² cleanroom facility of the ISO class 7.

The management of the Selb site explains the investment: „The Selb production site is a vital pillar of Vishay. With over 800 employees, we are the largest employer in the region. We invest a lot in our training and technical equipment. It is only thanks to innovation and technological advances that we can stay ahead. It is of the utmost importance to our customers to be able to obtain electrical components which perform their function perfectly without exception. Only a virtually particle-free production under clean conditions can guarantee perfect functioning of our products“.

Individual planning with cleanroom experts

The SCHILLING ENGINEERING Company from Baden-Württemberg, which specializes in cleanroom technology, was commissioned with the realization of the technically demanding facility. The new cleanroom was planned in close coordination and customised to the production conditions and space requirements.

The CleanCell 4.0® cleanroom system with a total area of 500 m² ensures a constant cleanroom air quality of the cleanroom class ISO 7. In the cleanroom, machines and workstations are accommodated for the production of the smallest electronic resistors. Three rooms divide different work areas. The areas are connected to each other by means of mutually interlocked electric sliding doors or swing doors. A 30-square-me-
VISHAY Intertechnology expands cleanroom production in Selb

ter staff lock provides enough space for the changing rooms of the staff. The changing room is actively flushed with pure air and ensures a change of the zone and safe processes in a confined space. Material pass-troughs ensure the safe input and output of the sensitive components.

After a few weeks of production the results of the production in Selb are quite positive: „The engineers at Schilling Engineering installed a customised cleanroom for us. We were always in close contact and were able to implement our wishes well. We attach great importance to quality and have also adhered to this principle in the installed cleanroom technology. The cleanroom facility is already in operation and meets our high standards. So far, we are very satisfied; our production has once again increased its quality and reliability."

Modular, energy-efficient system

The CleanCell 4.0® cleanroom system is equipped with ULPA-class U15 high-performance filters. Directed air flows remove the smallest airborne particles from the work environment. An innovative air recirculating and air return system within the cleanroom walls ensures a precise cleanroom flushing and provides high energy efficiency, since the already filtered and cooled air is again fed into the circulation of the air exchange. The cleanroom-adapted LED lighting also helps to reduce operating costs.

The CR Control® control system, which is accessible via a central touchscreen, ensures safe control and monitoring of the cleanroom. All important functions of the cleanroom, including the air conditioning technology, are monitored and recorded and can be individually controlled and regulated. In addition, remote maintenance is possible via the system.

The cleanroom system is modular and is connected with a silicone-free sealing clip system. This guarantees an extremely high tightness of the cleanrooms, a low particle emission and offers the advantage of flexible expansion possibilities.

The cleanrooms were qualified and delivered ready for operation and could be put into operation without start-up difficulties.

The Vishay Group is consolidating its importance in the electronics industry by investing in the state-of-the-art and flexible cleanroom systems and confirms the positive development of the German high-tech site in Selb.

Exterior view of the CleanCell 4.0® cleanroom system.

Schilling Engineering GmbH
Industriestrasse 26
D 79793 Wutöschingen
Telefon: +49 7746 9278971
E-Mail: i.doerffeld@schillingengineering.de
Internet: http://www.schillingengineering.de

Dear subscribers,

the rule of thumb has had its day, rough estimations are considered to be negligent and distances are becoming increasingly unimportant. The motto is instead: even more precise, even smaller, even higher, these words simultaneously formulating recent challenges that our industry has to cope with.

Even more precise: Increasingly, robotic arms carry out work that used to be done by human hands and are even more accurate.

Even smaller: In quantum physics research is done in areas that are far beyond human visibility and where one tiny particle seems to be huge as a mountain.

Even higher: Purity in outer space is one of the topics where Fraunhofer IPA with its cleanest cleanroom in the world plays a leading role. This topic will gather attention during Cleanzone 2017 in Frankfurt as well.

In this newsletter you will find news and relevant information on each of these thrilling topics. Cleanroom online is pleased to face the challenge of providing you every month with information on recent developments and the latest trends. What is new in your business? We will love to report on it.

Yours sincerely
Reinhold Schuster
Rotational Cleaning – What is it and what are the benefits?

Author: Rebecca Smith

Abstract

A cleanroom needs to be kept clean to minimise the retention of particles inside the room, as stated in the ISO standard 14644-1. Rotational cleaning is the use of more than one disinfectant in rotation to control the bioburden in your cleanroom.

EU-GMP guidelines recommend that you clean thoroughly, have a written cleaning programme and, if using disinfectants, use more than one. The reason you need to consider this is due to innate resistance. This means naturally occurring resistance, where microbes are just not affected by a particular disinfectant.

We use different types of disinfectant with different active chemicals because they have different modes of action. This means that they are effective against different types of microbe, and using more than 1 allows you to maximise your kill spectrum. There are many factors which will affect the type and frequency of disinfectant you choose to use including your process and cleanroom class, residues, what format it is available in, how easy it is to use and the environmental impact, amongst others. So, as a guide it seems sensible to rotate 3 agents - an alcohol, another general biocidal disinfectant and a sporicide.

Cleaning your Cleanroom

To answer the first question, yes of course you need to clean your cleanroom. Although it probably looks clean, most of the particles that need removing are not visible to the naked eye. Over time particles of dirt, cell debris, residues and such, will build up on the surfaces of the cleanroom and must be removed. The ISO standard 14644-1 defines a cleanroom as:

"a room within which the number concentration of airborne particles is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room"[10].

In cleaning your cleanroom, you are minimising the retention of particles inside the room. It is thought that the best technique to clean a surface in your clean room is a wet clean, which usually involves an impregnated wipe and a disinfectant or detergent solution. The mechanical act of wiping a surface will remove a number of particles from that surface. If the wipe and surface are wet, this will break more of the bonds that hold particles to the surface and allow you to pick up many more particles.

Microbial control and EU GMP Grade Cleanrooms

What is rotational cleaning then? Rotational cleaning makes reference to the bioburden, which is the number of bacteria and other microbes living on an un-sterilised surface. With this type of cleaning, we are not just trying to remove particles of dirt, fluff, cell debris and such; we are also trying to remove and kill the living element of contamination, which are the micro-organisms that may be present. In cleaning your cleanroom, you will undoubtedly remove...
a portion of the microbial population. However, it is unlikely that you will remove it all, which is why we must take steps to kill any microbes which are not removed.

To control the bioburden in your cleanroom you will need to use disinfectants; these are chemicals that have properties that can kill micro-organisms. You will probably need to use two or more disinfectants in rotation, and this is why the process of killing micro-organisms in your cleanroom is called rotational cleaning.

Annex 1 – Manufacture of sterile medicinal products - Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary use, point 61, states the following:

"The sanitation of clean areas is particularly important. They should be cleaned thoroughly in accordance with a written programme. Where disinfectants are used, more than one type should be employed. Monitoring should be undertaken regularly in order to detect the development of resistant strains." [6]

Why do we need to use more than 1 disinfectant? The simple answer is to stop resistance. There are 2 main types of resistance - naturally occurring resistance and selection for resistant strains.

Resistence - Selection for Resistant Strains

We have seen how developed genetic resistance has occurred in organisms such as MRSA. A bacterium that was once controlled by methicillin has developed a genetic resistance over time, and can no longer be controlled by that antibiotic. There is a theory that there is potential for this to happen with microbes in the cleanroom, to disinfectants.

Over time, bacteria that were once controlled by alcohols for example would develop a genetic resistance to that disinfectant, meaning it would no longer be an effective agent. For this reason it has seemed advisable to use different disinfectants to try and prevent this from happening. Although there does not seem to be any evidence to show this happening or even show the potential for this to happen, we still need to take precautions.

There are differences between the environment where MRSA developed and a cleanroom environment. In simple terms, for resistance to develop, a few bacteria will just about survive a dose of whatever agent has been employed to kill that type of bacteria. These bacteria then have the chance to multiply, and whatever advantage they had over other strains that allowed them to survive will be passed on, and you are left with a surviving strain which grows and thrives.

Again, a few of these bacteria will just about survive a dose of agent, multiply, and the advantage that allowed them to survive is passed on again and gets stronger. This happens over and over with continued use of that same agent. The advantage grows and grows, until you are left with a strain that it totally resistant to that agent. Plasmid acquisition can also create this type of resistance. In the cleanroom environment, because we tend to overdo the quantity and frequency of disinfectant use, very few microbes actually do survive. This means that it is unlikely that selection for resistant strains will occur. Also, antibiotics have a very specific and targeted action which makes selection more likely. Disinfectants have a very broad action which means it will be less likely that selection can take place.

The process of selection for resistant strains is developed and is gradual. The resistance is not inherent in that organism. This is the main difference between this type of resistance and the naturally occurring resistance.

Resistance - Naturally Occurring Resistance

Naturally occurring resistance is due to the fact that as disinfectants work in different ways, they have different modes of action. This means that they are not all equally as effective at killing all microbes. Some may be very effective against bacteria but not fungi, whereas some may be effective against viruses but not endospores.

Due to the way that disinfectants kill, some micro-organisms will naturally be better able to resist their actions. This is not learned, selected for, or genetically passed on, it is down to the nature of the micro-organism itself and the properties it already had. In the same way that tall humans may naturally be better at basketball; they didn't learn to be good, or have any better understanding of the game which was passed on by their parents; they just happen to be closer to the hoop!

Disinfectant Mode of Action

Alcohol based disinfectants tend to be effective against most micro-organisms, but not endospores. Their mode of action is to destroy proteins in the cell which can cause them to clump together and lose their function. When this happens to the cell wall it can lose structure and collapse.

Quaternary Ammonium Compounds (QACs or Quats) work by causing disorganisation of the cell membrane and the cell's insides leak out and degrade. They are effective against bacteria, enveloped viruses and fungi, but have little activity on non-enveloped viruses or endospores.

Biguanides alter the permeability of the cell membrane. They can damage the outer layers and attack the inner layers and this will also cause leakage. They have similar effects to the Quats.

Chlorine is a highly active oxidising agent. It oxidises DNA and cell proteins destroying their activity. Disinfectants containing chlorine kill most things including endospores at higher concentrations.

Hydrogen Peroxide is highly reactive and acts as an oxidant, producing free hydroxyl radicals. These free radicals can then attack the essential cell components. Hydrogen Peroxide based disinfectants tend to kill everything including endospores, but this kind of disinfectant is very harsh on the surfaces it cleans.

So because a biguanide kills by affecting the cell wall and cell membrane, it may not be very effective against a micro-organism with a very strong cell wall. That kind of micro-organism will be naturally resistant to the effects of a biguanide.

Endospores

Endospores are extremely difficult to kill. The endospore is a state that bacteria can enter into when conditions are unfavourable,
Rotational Cleaning – What is it and what are the benefits?

Choosing a Disinfectant?

What disinfectants should you use? It is clear that using a sporicide is highly important, but agents that have sporicidal activity tend to be harsh and unacceptable for everyday use. For this reason it is recommended that a sporicide is used in rotation with another effective disinfectant that is more suitable for regular use. It would also be advisable to use an alcohol as well, as they have good efficacy against most microbes and can also remove any residues that may build up from using other disinfectants.

Summary

In conclusion, you need to keep your cleanroom clean to minimise the retention of particles inside the room, as stated in the ISO standard 14644-1. Rotational cleaning is the use of more than one disinfectant in rotation to control the bioburden in your cleanroom.

EU-GMP guidelines recommend that you clean thoroughly, have a written cleaning programme and, if using disinfectants, use more than one. The reason you need to go that far is to prevent resistance. This means naturally occurring resistance, where microbes are just not affected by a particular disinfectant and also selection for resistant strains where microbes that were once controlled by a disinfectant, have developed resistant strains that are no longer controlled by the same disinfectant.

We use different types of disinfectant with different active chemicals because they have different modes of action. This means that they are effective against different types of microbe, and using more than 1 allows you to maximise your kill spectrum. There are many factors which will affect the type and frequency of disinfectant you choose to use including your process and cleanroom class, residues, what format it is available in, how easy it is to use and the environmental impact, amongst others. So, as a guide it seems sensible to rotate 3 agents - an alcohol, another general disinfectant and a sporicide.

Kill Spectrum

Using different disinfectants will increase your kill spectrum. This is the total portion of the microbial population that you are able to kill. It can be helpful to think of the kill spectrum in a similar way to the light spectrum. If you only ever consider visible light, you are missing out a huge portion of the light spectrum, what about X-rays and UV rays? In the same way, if you only ever use disinfectants that kill bacteria, you are not doing anything to combat endospores and other types of micro-organisms. We need to try and select disinfectants that when used in rotation cover as much of the spectrum as possible, therefore increasing your kill spectrum as much as possible.

We also must consider that if we only use a disinfectant that kills bacteria but not viruses, we are creating the conditions for viruses to thrive. We are creating an environment where viruses will flourish, and the disinfectant we have chosen to try and prevent this from happening will be unable to make an impact.

for example lack of food, lack of water or nutrients, temperature or ph. changes. They build an ultra-strong coat around the cell’s nucleus and essential parts to protect it. They can remain in this dormant state until conditions improve, when the coat will break down and the cell returns to normal.

Endospores have been found to survive in alcohol for over 70 years and can still be viable when removed and nurtured.

This strong coat means that in this state the endospore can be very difficult to kill, as it will resist the effects of gamma irradiation and many disinfectants. Chlorines and Hydrogen Peroxide are two disinfectants that do have an effect on endospores, and are often referred to as sporicidal. Chlorines can increase the permeability of the endospore coat and Hydrogen Peroxide can remove proteins from the coat.

References:

Interested companies and research institutes can join the Innovation Center

Technology for the smart labs of the future

Today, laboratories often resemble a traditional manufactory structure. Devices and processes are not connected and valuable samples are often processed manually by employees. For a long time, this system has been sufficient to maximize the innovative strength of laboratories. However, they now generate much more data and the familiar model cannot keep up with this increased complexity. At the Innovation Center for Laboratory Automation Stuttgart, nICLAS for short, Fraunhofer IPA and industry partners are developing new technologies for the smart laboratory of the future. The team introduced itself for the first time at the nICLAS forum in Stuttgart on March 23, 2017.

Currently, automation solutions have only been introduced in a fraction of laboratories worldwide. One reason for this is the strict regulation as well as the sheer variety of everyday lab processes which are non-standardized. nICLAS Project Leader Mario Bott at Fraunhofer IPA: “Samples and products which are processed in laboratories are subject to strict quality requirements. Establishing new technologies is therefore expensive and time-consuming for companies.” Additionally, the manual working environment of laboratories was advantageous for many years, as processes could supposedly be adapted more flexibly and quickly than would be the case with automated devices and platforms.

Laboratories are becoming data factories

Gradually, companies are starting to rethink this, as Bott explains: “Laboratories are increasingly turning into networked data factories which are an integral part of the company interface, be it diagnostic laboratories, the lead discovery for new drugs or quality control and product approval. They generate information which is extremely valuable for corporate management.” Moreover, laboratories are facing new challenges from the growing personalization of products and processes via personalized diagnoses and therapies. In order to get to grips with emerging complexity, sustainable, modular solutions must be developed for hardware and software systems. This is where nICLAS comes in.

The Innovation Center at the Fraunhofer Campus in Stuttgart offers companies and research institutes a platform for networking and developing innovative technologies and automated solutions together. Among the project members, there are representatives from industrial end users and developers as well as partners who bring research and academic education into the mix. The project leader adds: “The interdisciplinary scope of duties means that a multidisciplinary team is necessary in order to successfully compete at an international level. This is why we are delighted to have found strong partners in Precise Automation, TECAN, LI-CONIC, Thermo Fisher Scientific, Promega and Festo, who provide us, for instance, with the latest devices and innovative technologies for collaborative development.” This means that the team can always rely on the latest equipment and the necessary expertise to create the foundations for the laboratory of tomorrow.

Virtual laboratory and networked research

The nICLAS FutureLab has already provided some initial stimuli and food for thought. For example, there are applications in the field of intralogistics for tracking materials. The project leader Bott explains: “This means the position of valuable samples or patient material is always known. The digital record can be a great help for laboratory staff when it comes to planning, process monitoring and documentation.” A second area of focus is human-machine interaction in regulated environments. For example, Teacht substantially simplifies the teaching process for robotic solutions. The project team is also investigating how augmented reality could be introduced to support regulated processes. Bott gives an example of this: “In many laboratories, the central information and documentation interface is still a handwritten lab journal. With augmented reality, employees could in future be shown any necessary information when it is required and on a personalized basis.” Furthermore, experts are tackling the question of how laboratory processes can be virtualized through service-oriented platforms. For example, ordering cell systems via a lab store is being tested within the Cell-Share project. The result is quick, economical and uncomplicated for customers.

The Fraunhofer-Gesellschaft is providing startup funding of over EUR 600,000 for nICLAS. Interested companies and research institutes are able to join the community so that together we can create the laboratory environment of tomorrow. The launch event on March 23, 2017 provided the first insight into nICLAS and enabled participants to get to know the project partners on a personal level.
ImpactAir® high performance air sampler range joins Cherwell’s portfolio of cleanroom microbiology products

Cherwell makes an Impact with new continuous monitoring microbial air samplers

Cherwell Laboratories, specialists in cleanroom microbiology solutions, have signed a distribution agreement with Pinpoint Scientific for the ImpactAir® range of microbial air samplers. The new ImpactAir range of high performance microbial air samplers has been designed to meet the demanding environmental monitoring requirements of aseptic processing in the pharmaceutical and healthcare industries.

ImpactAir is a state-of-the-art range of slit-to-agar microbial air samplers that fully complements Cherwell's existing portfolio of environmental monitoring products, including SAS microbial air samplers and Redipor® prepared microbiological media range. Whereas SAS samplers are ideal for rapid and frequent routine sampling regimes, ImpactAir is designed for continuous monitoring in high-grade areas where in-process sampling of viable particles is critical. Due to its unique design, ImpactAir does not shed particles, so it can be used alongside particle counting devices, and as it runs with extremely low levels of vibration, it can also be operated near balances.

By using larger 140mm petri dishes, such as those in the Redipor range, the ImpactAir can continuously sample to a single dish over longer periods. This sampling time can be easily programmed on the touch screen user interface, from minutes up to several hours, depending on the process to be monitored. The petri dish rotates slowly under the inlet slit to present fresh agar throughout—dramatically reducing the probability of 'twin impingement' (where two microbes impact on an agar plate at the same point to incubate as a single colony) for enhanced accuracy and enabling an estimate of any event times during key processes.

ImpactAir is the first sampler of its kind to employ precision sensing and control to automatically adjust and maintain the distance between air inlet and agar surface, further enhancing sampling efficiency. Critically, this ensures a consistent d50 value of <0.5µm is maintained throughout an entire sampling run, as independently verified by Public Health England (PHE) following physical and biological validation.

Andy Whittard, Cherwell's Managing Director, commented, “The new ImpactAir microbial air sampler is an exciting addition to our ‘cleanroom microbiology solutions’ offering. It fully supports our existing portfolio of quality environmental monitoring products for our pharma customers. Effective viable monitoring within high-grade areas is vitally important and ImpactAir allows users to perform high efficiency, continuous environmental monitoring. We look forward to working with the manufacturer, Pinpoint Scientific, in developing the UK and Irish markets.”

smartGAS is expanding its EVO series of NDIR gas sensors for the measurement of carbon monoxide (CO). The FLOWEVO CO (100 vol. %) complements the new series, which already includes the FLOWEVO CO (2000 ppm).

New: NDIR gas sensor for CO measurement in the vol. % range

The great importance of industrial CO measurement is addressed by smartGAS with the expansion of its EVO series. It plays a central role in many sectors, including gas analysis or emission measurement for flue gas monitoring and process control.

Additionally to the FLOWEVO CO (2000 ppm) sensor, the product portfolio has been complemented with the NDIR-based FLOWEVO CO gas sensor with a measuring range of 100 vol. %. In the coming months, further CO sensors of the first generation will be replaced successively by the EVO technology. The NDIR gas sensors in the FLOWEVO product line are characterised by their optimised optical components, their adjusted software and their flexible power supply, while maintaining the proven smartGAS technology of their predecessors. The principle of infrared measuring technology ensures that a high level of long-term stability and performance are achieved, while the plug&play interfacing of the gas sensors simplifies the connection to your hardware. As with all NDIR gas sensors in the EVO line, the new FLOWEVO CO sensor (100 vol. %) has an ASCII modbus and RTU interface with automatic recognition of the communication settings. The communication speed is up to 38,400 baud. An on-board LED also visually displays the status of the gas sensor.

Besides lower maintenance effort, the benefits of the new technology to smartGAS customers are primarily an even more precise gas analysis and process control, as well as a significantly easier integration into the customer’s own units. The result is more efficient operation of the customer's systems as well as significant cost savings.

The new EVO gas sensors are almost completely compatible with the NDIR sensors of the first FLOW and PREMIUM generation.
Achieving competitive advantage by investing in a new ultra-high purity water system

The investment of AP&S International GmbH (AP&S) in a ultra-high purity water system (UHPW) pays off. The system, with a state-of-the art concept brings not only pure water and cost savings, but primarily technological progress, considerable benefits for the customers and consequently competitive advantage for AP&S in the international equipment market.

Since the beginning of 2017 the new UHPW system is in operation at the AP&S manufacturing facility in Donaueschingen. The system reduces the impurities of city residues up to the ultratrace level of <1ppb per cationic element. The system was installed by Haage & Elsässer (H&E) from Stuttgart, Germany. H&E provides industrial water treatment systems for more than 40 years and is one of the technological leaders in this field of UHPW concepts.

The main reason for the investment decision lies in the strong requirements on stability and purity of wet process applications in the semiconductor industry. Before a new wet process application can be used in production, it has to fulfill and demonstrate the required purity specifications. In practice, it means that before commissioning long-term rinsing and cleaning process at customer’s fab is necessary, which is associated with time, resources and material consumption.

The AP&S process engineer team recognized that an optimization of this process set up would bring considerable advantages for the customers. Thus the basic idea for the project was born. In 2016, the investment and installation of the new UHPW system followed.

Prior to delivery to customers the AP&S tools are rinsed with the ultra-high purity water and qualified with optical particle counters (OLCs @ > 0.1 µm resolution). Samples for trace impurity measurements are checked for cation concentrations typically to levels <1ppb each. An ICP-MS or GF-AAS is used in an external laboratory close by.

The value add for each customer is, that tools can be much faster qualified, less effort is needed on site and defect density requirements for production output can be achieved much faster.

“The new water system enables AP&S to provide customer wet process applications, which meet the highest SC-technology standards”, says Robert Preisser, Adjunct Professor at AP&S, who has initiated, specified and supported the project.

„With the implementation of this advanced water treatment technology, AP&S has put itself at the forefront of the medium-sized equipment providers for wet process solutions, which support the semiconductor and nanotechnology industries around the globe“, adds CEO of AP&S Alexandra Laufer-Müller.
Increased production will meet growing demand for sustainable antibiotics

**DSM Sinochem Pharmaceuticals to boost manufacturing capacity at Dutch plant**

Building on its commitment to producing antibiotics sustainably in the fight against antimicrobial resistance (AMR), DSM Sinochem Pharmaceuticals (DSP) has announced the expansion of its manufacturing facility in Delft, the Netherlands. The company’s aim with this investment is to meet the growing demand for sustainably produced 7-ADCA, the key intermediate for cephalosporin active pharmaceutical ingredients. A new fermenter will be added to the DSP site in Delft, the Netherlands, which will make use of leading-edge technology that is energy efficient and environmentally friendly. DSP expects the new extension to the plant to be fully operational in the last quarter of 2017.

The Delft site produces 7-ADCA, the key intermediate for making the company’s sustainable cephalosporin APIs including cephalxin, cefadroxil and cefradine. DSP is the only remaining producer of this intermediate in the Western hemisphere. In the early 2000s, the company revolutionized the industry by introducing a new breakthrough process for the sustainable production of high-quality 7-ADCA. So far this process, based on proprietary technology, is the only one of its kind for manufacturing 7-ADCA worldwide.

Irresponsible manufacturing has been recognized as one of the key causes of AMR due to the uncontrolled release of antibiotics into the environment. In particular, waterways downstream of production facilities may contain significant concentrations of antimicrobial activity, and risk becoming breeding grounds for resistance.

As a leader in the sustainable production of β-lactam antibiotics, DSP has implemented the cleanest production technology available and installed dedicated wastewater treatment plants. These operate all year round as an integral part of DSP’s manufacturing process at Delft and all other sites, in combination with the testing of effluents for antimicrobial activity. In response to the threat of antimicrobial resistance (AMR), the company is committed to minimizing the release of antimicrobial active ingredients into the environment.

In addition to improving its own production processes, DSP actively collaborates with industry partners, public and private stakeholders, associations, health professionals and regulators – such as the United Nations, World Health Organization, Access to Medicines Foundation and PSCI - to clean up the supply chains. The company has been one of the driving forces in establishing the United Nations Industry Roadmap for Progress on Combating AMR, signed by 13 leading pharmaceutical companies in September 2016, and particularly underwrites the commitment to reduce the impact that the production of antibiotics has on the environment.

In the same year, DSP celebrated the significant milestone of 15 years of green production of 7-ADCA at its Delft site, which has resulted in more than 2.5 billion cephalosporin patient treatments while significantly reducing CO2 emissions, as well as preventing the release of antimicrobial active ingredients into the environment.

Frans Vlaar, Business Unit Director Europe America at DSP said: “Our sustainable and environmentally friendly manufacturing process not only results in a higher 7-ADCA product quality and significant reduction of the product carbon footprint, but also prevents unnecessary active antimicrobial discharge. It is highly encouraging to see that our customers increasingly recognize these benefits linked to our 7-ADCA product and manufacturing process. Thanks to the state-of-the-art techniques and processes that we apply and continuously develop further, we are able to maintain our strong position in this highly competitive industry.”

**Diba Industries Offers Cleanroom Assembly and Packaging for High Purity Applications**

Fluid handling expert Diba Industries’ manufacturing facilities feature an ISO certified Class 7 / Fed Std Class 10,000 cleanroom to meet the needs of customers with high purity and particle-free assembly requirements. The flexible 600 square foot space can be configured to accommodate a team of workers for high volume production of tubing assemblies, kits and integrated manifolds complete with valves, flow regulators and other controls.

“Diba’s OEM customers are global leaders in diagnostics, life sciences and medical devices,” explained John Auer, Quality, Health, Safety & Environmental Manager. “Increasingly, they are looking to us for a seamless one-stop solution. From helping a customer develop the initial specification, through design, manufacture and assembly to packaging, Diba can provide a complete and customized solution. Our cleanroom helps complete that seamless one-stop solution they seek,” says Auer.

Diba employees are trained in cleanroom protocol to ensure consistent quality standards. Diba’s cleanroom procedures are integrated into the Diba Quality Management System.

Sample cleanroom projects include assembly and testing of a diffusion bonded manifold complete with flow restrictors, rocker valves and tubing assemblies with temperature controls. For another original equipment manufacturer, Diba assembled and packaged kits with tubing assemblies, filters and other consumable accessories.
Gerresheimer’s new Indian plant manufacturing vials and ampoules in line with global standards.

CPhI South East Asia

With seven plants, Gerresheimer enjoys a strong position in the South East Asian market for the highly specialist manufacture of glass and plastic products for the pharmaceutical sector. A new factory making vials and ampoules recently went on stream in Kosamba.

“We are the specialist when it comes to vials, ampoules, and cartridges,” says Jens Heymann, Senior Vice President Europe & Asia Tubular Glass. “With our new plant in India and its counterparts in China, we will be able to fully meet demand from the Asian pharma industry for high-quality primary packaging made from tubular glass.” Having a uniform global standard for its state-of-the-art machinery and employees who are trained in the production process ensures that all the workflows in all the plants meet the same standards. “Our zero-defect strategy is based on a „product-by-process“ approach. We want our customers to get the same high-quality products from us wherever they are in the world. Which factory they were made in cannot be allowed to have an influence.”

Vials, or injection vials as they are also known, have played a key role in Gerresheimer’s presence at this year’s CPhI trade show. They are amongst the world’s most popular pharmaceutical packaging solutions and Gerresheimer’s can hold between 1 and 50 ml. As well as its vials, the company has also showcased other core products including ampoules, cartridges, flasks, and more specialty products made from clear and amber borosilicate glass types I, II, and III.

Gerresheimer manufactures its primary packaging for the Asian market in Shuangfeng in China and at its new plant in the Indian city of Kosamba. The Chinese factory has 30 years’ experience in making vials and has been awarded a range of certificates that no other competitor in the region can match. The company supplies over 300 pharmaceutical customers in Asia, the U.S., and Eastern Europe and enjoys a leading position on the Chinese market.

Appointment will allow for active involvement within the Fraunhofer Institute for Manufacturing Engineering and Automation IPA

Vetter’s Dr. Claudia Roth is appointed to the Fraunhofer Advisory Board

Dr. Claudia Roth, Vice President for Vetter’s department of Innovation Management, has been appointed to the Advisory Board of the Fraunhofer Institute for Manufacturing Engineering and Automation IPA in Stuttgart. Over the next two years, Dr. Roth will be active in the Process Industry business unit.

Cooperation among scientific research organizations, such as Germany’s preeminent Fraunhofer-Gesellschaft, is an integral part of Vetter's innovation management. “Sharing information with the sciences offers significant stimuli, particularly in the field of manufacturing,” said Dr. Roth. “This appointment is particularly exciting since it allows me to contribute knowledge I gained as a member of the Advisory Board of the Fraunhofer Institute for Manufacturing Engineering and Automation IPA.” The IPA’s Process Industry business unit researches how programs such as Industry 4.0 can be applied to processes in the pharmaceutical sector.

The fact that Vetter’s innovation manager is discussing such issues with members of the IPA Advisory Board is valuable for both Vetter and the Fraunhofer-Gesellschaft. Commenting on the appointment, Dr. Michael Hilt, deputy head of Fraunhofer IPA in Stuttgart said: “Dr. Roth’s years of experience will help us better focus our development and solutions on the corporate needs of the process industry.”

Vetter is currently working on securing its future due to a 360-degree process involving internal and external impulses to find new incitements. The ideas are integrated in a multi-stage innovation process which starts with a potential appraisal and ends with the possible market launch. The focus is on new manufacturing processes and technologies, additional services and innovative application systems to increase customer value.

Dr. Claudia Roth, who holds a diploma in Process engineering, has been with Vetter since many years. As a specialist in development she has played a major role in setting up the Vetter Development Service. She also headed up Vetter Development Service Chicago, USA, from 2009 to 2014.
Towards an EU Digital Industrial Platform for Robotics through Open-Source Software

The ROSIN project

Open-Source Software for robots is a de-facto practice in academia, and its advantages can also benefit industrial applications. The worldwide ROS-Industrial initiative has been using ROS, the Robot Operating System, to this end. To consolidate Europe’s dominance in advanced manufacturing, ROSIN with Fraunhofer IPA as one of the partners will push the role of the EU within ROS-Industrial to a leading position. It will achieve this through three main actions: ensuring industrial-grade software quality, promoting new business-relevant applications by providing 50% of the project’s budget for European users and developers, supporting educational activities for students and industry professionals. Interested entities are welcome to apply for participation.

Several training sessions within Europe will be held to make ROS-Industrial more accessible and well-known. (Source: Fraunhofer IPA)

Targeted investments for interested entities

In parallel to the developments bringing quality improvements, more ROS-Industrial tools and components will be created and existing ones will be improved. This will be performed by making 50% of the ROSIN budget available to collaborating European users and developers for so-called Focused Technical Projects (FTPs). ROSIN maximizes budget efficacy by alleviating yet another deadlock: experience shows that industry will fund ROS-Industrial developments, but only after successful delivery. ROSIN provides pre-financing for FTP developers to each the first milestone (up to 30% of the total costs), when such developers commit to subsequently fund the remaining expenses. Entities (with a legal seat in the EU and collaborating countries) interested in this financially supported collaboration are welcome to apply via www.rosin-project.eu.

Support for educational activities and commercial exploitation

Broad EU-wide educational activities, led by FH Aachen, and community-building activities, led by Fraunhofer IPA, will make ROS-Industrial a well-known, accessible tool for factory automation. To ease commercial exploitation of ROS-Industrial applications, Tecnalia will coordinate the creation of a commercial release template with guidelines addressing technical and non-technical (e.g., licensing) matters. The critical mass of trained students and professionals, together with a clear path to commercial exploitation, will result in a widely adopted, high quality, open-source industrial platform.

The ROSIN project will fund ROS-supported industrial applications like for example pick-and-place applications as they were presented at the 2016 Amazon Picking Challenge. (Source: TU Delft)

The second question focuses on the level of industrial interest in Europe towards OSS and the opportunity to further invest in it. On the one hand, there are already examples of operating installations running on ROS. On the other, this question is closely related to code quality, with the two factors holding each other in deadlock: further quality improvement requires industrial investment, and vice versa. ROSIN will resolve this deadlock.

The ROSIN project consortium, which can thus benefit from the existing ROS-I network and collaboration activities with industrial partners.

Bringing ROS to the factory floor by improving software quality

To achieve the project’s aims, the partners – besides Fraunhofer IPA it is TU Delft as coordinator, the IT University of Copenhagen, the FH Aachen University of Applied Sciences, Fundacion Tecnalia Research & Innovation and ABB AB – need to answer two questions on the suitability of open-source software (OSS) for manufacturing. The first one is about software quality, which has to conform to industrial requirements. To ensure this, ROSIN introduces a breakthrough innovation in automated code quality testing in an effort led by the IT University of Copenhagen. This is complemented with a full palette of quality assurance measures including novel model-in-the-loop continuous integration testing with ABB robots.

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Several training sessions within Europe will be held to make ROS-industrial more accessible and well-known. (Source: Fraunhofer IPA)
Messe Frankfurt has established a strategy commission for Cleanzone, to which the following individuals have been appointed: Dr. Jürgen Blattner, BSR Ingenieurbüro, Frank Duvernell, profi-con, Joachim Ludwig, Colandis, Michael Müller, vali.sys, Josef Ortner, Ortner Reinraumtechnik, Thorsten Schmitt, Siemens and Markus Thamm, Cleanroom.de.

Johannes Schmid-Wiedersheim, Head of Brand Management for Cleanzone, explains the reasons behind this move: “For a trade fair to grow and prosper, it has to interact and work closely with the industry and maintain a dialogue. That is why we established this strategy commission, to ensure that we could rely on professional advice for determining the direction and topical focus of the trade fair.”

The commission met for the first time in March, and it emphasised the fact that Cleanzone, as an international, innovative and interdisciplinary event with a practical focus, is tremendously important to the industry. The commission considered the economic situation of manufacturers of cleanroom technology to be very positive overall, stating that the cleanroom market was one of the world’s fastest growing sectors, although it also identified a number of challenges. Josef Ortner, Ortner Reinraumtechnik, described these as follows: “In coming years, four core elements of cleanroom technology – security, flexibility, information and energy – will be undergoing change across various sectors, with each of these elements playing a major role in driving the development and deployment of services and technology. All processes and activities will be characterised by fundamentally new concepts employing seamlessly networked approaches.” Shorter construction phases, lower costs, faster reaction times and a more intelligent use of data within processes are among the concrete results that he identified for these rapid changes.

The commission’s deliberations also resulted in suggestions for the top themes for Cleanzone. In addition to space exploration as a driver of innovation in the field of cleanroom technology, Cleanzone 2017 will also be focusing on digital and smart solutions. These include automation and robot technology, as well as networking measurement equipment and the resulting data. Furthermore, the ability to flexibly adapt cleanrooms to new production will be increasingly important, including the rapid integration of new machinery and configuration of production facilities to suit the latest requirements. Digital solutions are also important when it comes to increasing energy efficiency, which is another key theme at Cleanzone 2017. The simulation of airflows is growing ever more important, as this makes it possible to achieve greater planning certainty. Visitors will be able to obtain more information on these pressing issues on the Cleanzone website under “Top themes”, as well as at the trade fair on 17 and 18 October 2017 from exhibitors and as part of the extensive supporting programme.
Staying ahead of the competition with state-of-the-art cleaning solutions

New cleaning challenges to be addressed at parts2clean 2017

It’s the same for the car industry, the component supply industry, medical technology, mechanical engineering, aviation, precision engineering and microengineering, optics, electronics and many other sectors of modern industry: The purpose of industrial parts cleaning is to ensure the necessary degree of cleanliness required for subsequent processing operations or for the long-term, trouble-free functioning of the given part or component. As such, properly cleaned parts bring added value to the industrial manufacturing process. Global trends such as electromobility, lightweight construction, Industry 4.0, sustainability, smaller production runs due to increasing customization, and the onward march of globalization are posing new challenges for businesses all over the world – including those specializing in industrial parts and surface cleaning. All these issues will feature prominently at the next parts2clean, which runs from 24 to 26 October in Stuttgart.

“The exhibitors at parts2clean will be presenting cleaning solutions that deliver consistent results economically and efficiently, enabling manufacturers to meet the requisite standards for the cleanliness of industrial parts – not only for now, but also for the long term,” says Olaf Daebler, Global Director for parts2clean at Deutsche Messe. The products and systems on display at the 15th Leading International Trade Fair for Industrial Parts and Surface Cleaning help users of industrial cleaning technology to maintain their competitive edge in the marketplace – as a brief glance at the lineup of exhibitors makes clear. Among the 150-plus companies that had already booked their space by mid-March 2017 are nearly all the major market players and technology leaders represented in each of show’s display categories. “We are very pleased about the industry’s enthusiastic response”, notes Daebler. “Moving the show back to its autumn timeslot was definitely the right decision.”

At the Stuttgart venue, trade visitors can learn all about the latest trends and innovations in industrial parts and surface cleaning for a high-tech world. This includes, for example, cleaning plants that have been designed from the outset to be adaptable - easily and without major investment - so as to stay in stride with changing needs. Possible scenarios here would be handling different kinds of parts, meeting various cleanliness standards or utilizing different processes.

Also on display are innovative cleaning technologies for use in fine and ultra-fine cleaning processes, which make it possible to quickly and economically achieve very high degrees of cleanliness. Responding to the growing industry demands for more highly automated cleaning processes and integration in smart-factory environments, exhibitors at parts2clean will be presenting intelligent automation concepts and solutions for adaptive cleaning processes. These include systems that allow continuous in-line monitoring of the cleaning baths, with fully automatic dosage of additional cleaning agent, continuous acquisition and documentation of all process parameters, and in-line inspection of the resulting cleanliness.

Know-how on every conceivable aspect of parts and surface cleaning

“Adding value to the exhibition lineup will be a three-day parts2clean Industry Forum, which is an invaluable source of information for visitors about the latest trends and innovations,” remarks Daebler. Distinguished guest speakers from industry and the worlds of R&D and scientific research will be highlighting new developments, talking about the best ways to optimize processes and costs and assure quality, and sharing examples of best practice with their audiences. All presentations will be simultaneously translated (German <-> English).

Guided Tours – the quickest way to the best-fit solutions

Guided Tours to selected exhibitor stands enable visitors to focus on specific areas of interest in industrial parts and surface cleaning, and to gather relevant information in a time-efficient and concise way. The tours will take place twice throughout the show, in two languages (English and German).
Portfolio for CCI technologies completed

Interpack 2017: Bosch launches new KLV series for leak detection of rigid containers

At Interpack 2017, Bosch Packaging Technology presents the new KLV series for Container Closure Integrity Testing (CCI). "In the pharmaceutical industry, non-destructive CCI technologies are becoming increasingly important," explains Dr Jérôme Freissmuth, product group head at Bosch Packaging Technology. “Even the smallest leaks can be highly hazardous for patients. The active ingredient could alter, administering the medication could lead to serious side effects as a result of non-sterility, or the medication could become ineffective. Furthermore, non-destructive integrity testing protects pharmaceutical manufacturers against the loss of valuable medication, since the container remains intact during testing.”

Bosch has continuously expanded its portfolio of CCI technologies in recent years. High voltage leak detection and laser-based headspace analysis are now complemented by the new KLV series for vacuum leak detection. At Interpack, Bosch unveils the first in the series – the KLV 1360, which has been specially developed for vials. Generally, the platform is suited for all rigid glass containers from the inspection chamber simultaneously in one chamber. This enables us to significantly increase the output,” Schindler explains.

Maximum protection even after inspection

The KLV ensures a consistently high inspection quality. It is the first machine of its kind where the integrated robotic system not only feeds the containers that require inspection into the process. It also adds reference samples for internal process control. In addition, automatic re-inspection makes sure that only containers, which have clearly been tested, leave the machine.

Even after inspection, the product and closure quality remain a top priority. The KLV does not grip the containers from above. Instead, the slightly slanted transport system makes it possible to remove the containers from the inspection chamber sideways in order to prevent leaks occurring due to closure gripping. Furthermore, a star-wheel system ensures gentle transportation through the system with minimal wear and tear. Thanks to its modular construction, the KLV 1360, which has a turntable fitted as standard, can be seamlessly integrated into existing lines.

New KLV series for leak detection of rigid glass containers.

At Interpack 2017, Bosch unveils the first member of the new KLV series – the KLV 1360 for vials. The platform is suited for inspection of up to 600 standing glass containers per minute. (Picture: Bosch)

Inspection of up to 600 glass containers per minute based on group testing. The KLV 1360 achieves its maximum performance thanks to special inspection chambers, where the containers can be tested either individually or in groups. (Picture: Bosch)

04th - 10th May 2017: Interpack 2017, Duesseldorf (D)

Everything from a single source

The new KLV 1360 completes Bosch’s inspection portfolio. Visitors to Interpack can learn about the entire range of technologies – from visual inspection and headspace analysis to vacuum testing, all of which will be showcased as benchtop models. “Our customers not only have a wide choice of technologies," Schindler underlines. "We also advise them on the best inspection solutions for their liquid or lyophilized medications and are their experienced partners when it comes to regulatory requirements and individual solutions.”

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Bosch Technik fürs Leben

Robert Bosch Packaging Technology GmbH
Stuttgarter Straße 130
D 71332 Waiblingen
Telefon: +49 711 811 0
Telefax: +49 711 81158509
E-Mail: packaging@bosch.com
Internet: http://www.boschpackaging.com
A pioneering event at Arburg

Spectacular Technology Days 2017 Event

– Inspired: Over 6,700 guests attend the Arburg Technology Days 2017
– Comprehensive: Over 50 exhibits demonstrate trends in injection moulding and additive manufacturing
– Practical applications: „Industry 4.0 in practice“, specialist presentations and factory tours

Over 6,700 guests from 53 different countries once again made the Arburg Technology Days, held from 15 to 18 March 2017, the biggest in-house event in the industry. There was much more to be seen at the company’s 171,000 square metre headquarters in Lossburg (Germany) than at most trade fairs. The presentation included more than 50 exhibits in action, the Efficiency Arena under the motto of „Industry 4.0 in practice“, turnkey injection moulding solutions, the new Arburg Prototyping Center for additive manufacturing with the Freeformer, as well as a special service area. Trade visitors also found further inspiration in specialist presentations and factory tours.

The Arburg Technology Days 2017 attracted over 43 percent of its visitors from abroad. The largest contingencies from overseas were North America with over 170 visitors and China with around 125. The largest numbers of European guests were brought along by the subsidiaries Switzerland (around 210), Czech Republic (around 180) and France (around 160).

„For our annual Technology Days, we do everything we can to ensure that our invited guests get a comprehensive insight into the Arburg product range, trends in plastics processing and innovative applications. The unique industry event involved a large number of employees and trainees. Our customers really appreciated the unique atmosphere, made great use if the opportunity to talk with our experts and, at the end of the day, took away some key ideas for their own production,” summarises Michael Hehl, Managing Partner and Spokesperson for the Arburg Management Team.

Highlight - the Allrounder 1120 H

There was a great deal of interest among the public in the new hybrid Allrounder 1120 H, which extends product and services into a clamping force range of up to 6,500 kN. Visitors to the Technology Days 2017 had the opportunity to take a closer look at the new large machine with its new design and visionary Gestica control system following its premiere at the K 2016 leading international trade fair. As part of an innovative turnkey solution, the exhibit produced ready-to-use folding step stools in an exclusive Arburg design. This involved producing eight individual parts using an eight tonne family mould in a cycle time of around 60 seconds and then assembling them ready to use in a combined set-up with a Multilift V 40, six-axis robot and assembly station.

„Industry 4.0 in practice“

The Efficiency Arena was also very well received. Here, Arburg and a number of selected partners showed practical and pragmatic examples of the implementation of Industry 4.0. Customers were offered a host of different perspectives on how to implement Industry 4.0 and make their own production more efficient. A pioneering practical example was the spatially distributed, digitally networked production of „smart“ luggage tags in single-unit batches. An Allrounder injection moulding machine and two Freeformers for additive manufacturing were combined for this purpose. The Arburg host computer system (ALS) ensures end-to-end traceability for each individual part. Two ALS add-on modules were also presented: „Energy Visualisation“ for order-based allocation of energy data and „Material Staging Interface“ for batch changes.

Other topics covered in the Efficiency Arena were the traceability from finished part to the original granulate, online monitoring for
quality assurance purposes, systematic energy consumption records and the integration of peripheral equipment in the Selogica machine control system.

Eight Freeformers in action

A total of eight exhibits relating to Arburg Plastic Freeforming (APF) were on view, five of them in the new Arburg Prototyping Center. The focus here was on the industrial additive manufacturing of functional parts, either individually or in small batches - including grippers made from PA and TPE, mobile phone covers with optimised surfaces and parts made from a PC approved for use in the aerospace industry. In addition, flame-proof electronic parts and implants from medical-grade PLA were also presented. Another Freeformer in the Customer Center produced mechanically optimised rope pulleys from organic polyamide. The two exhibits in the Efficiency Arena individualised the „smart“ luggage tags.

Diverse applications

The broad range of injection moulding machines included pioneering machine and mould technology, a wide range of products and applications, as well as innovative processes for the efficient production of plastic parts.

In the medical technology area, Arburg showed five applications and different clean room concepts, including a GMP-compliant stainless steel electric Allrounder 370 A as a high-end injection moulding solution which produced long-term PEEK implants in a clean room environment. The performance capabilities of the Hidrive series for the packaging industry were demonstrated by an Allrounder 570 H in a Packaging version specially configured for thin-walled parts. The production cell produced four IML tubs from PP in a cycle time of less than two seconds.

Arburg presented Fibre Direct Compounding (FDC) and Profoam physical foaming technology based on the example of two automotive applications. As well as reducing weight, these processes can also be used specifically to improve mechanical part characteristics and minimise distortion, as was demonstrated with a glass-fibre reinforced cable drive housing for power windows and a foamed base plate.

LSR/LSR wristwatches required complex manufacturing processes and set the standard for what can currently be achieved in the processing of liquid silicone. The associated turnkey system based on an electric two-component Allrounder 570 A that produced two-colour LSR wrist bands fully automatically. Assembly as a ready-to-use wristwatch took place within the injection moulding cycle.

A highlight in the area of powder injection moulding was the world’s first MIM frame for smartphones. A hydraulic Allrounder 470 C Golden Edition processed feedstock from BASF to produce a green compact in an Arburg design with a thickness of only 1 millimetre and a length of 136 millimetres.

Spacious turnkey area

The well-equipped turnkey area had everything, from simple pickers and linear Multilift robotic systems to six-axis robots featuring the Selogica user interface and customised turnkey systems. Highlights included the fully automated production of ready-to-use step stools and LSR/LSR wristwatches, the „playing field“ for robots in action and the new Multilift V 40 with a load-bearing capacity of 40 kilos. A number of current customer projects were also presented - from the hydraulic Allrounder 520 S with Multilift Select to the hydraulic two-component Allrounder 920 S with six-axis robot and downstream station with Agilus robot.

Comprehensive programme of side events

In the service area, visitors were able to find out about topics such as Industry 4.0, preventive maintenance and the current training offerings.

Over 2,000 participants attended the informative specialist presentations in German and English. Here, some of the company’s experts spoke about lightweight construction, Arburg Plastic Freeforming and turnkey solutions. External specialist presentations covered topics such as Industry 4.0 and the strong partnership that Arburg offers from the customer’s perspective.

Almost 1,500 visitors from Germany took the opportunity afforded by the factory tours to become familiar with machine production. Furthermore, the company was also presented to all international groups visiting the Technology Days with their Arburg subsidiaries and trading partners in their respective national languages.

The new large hybrid Allrounder 1120 H with a clamping force of 6,500 kN attracted a great deal of attention at the Technology Days 2017, producing folding step stools.
IMMUT met, le 4 et 5 octobre 2017 à Lausanne, à la disposition de la communauté chimie et sciences de la vie une nouvelle plateforme et comble une lacune sur le marché en Suisse francophone. La «recherche et développement», la «biotechnologie» ainsi que la «chimie de spécialités» sont considérés dans le secteur comme les grands potentiels du marché romand.

ILMAC LAUSANNE
première pour la Suisse francophone

L’industrie pharmaceutique est, avec près d’un tiers du volume total, le moteur des exportations de la Suisse. La région Espace Lémanique (cants BE, Fr, GE, NE et VD) est l’un des principaux pôles des sciences de la vie pour les secteurs à forte intensité de recherche que sont l’industrie pharmaceutique, la biotechnologie et l’agrochimie. Le canton voisin du Valais joue également un rôle très important en tant que pôle de production et de sous-traitance de produits de la chimie spéciale et des médicaments.


ILMAC LAUSANNE est la plateforme pour la chimie, la pharmacie et la biotechnologie et se déroule pour la première fois, le 4 et 5 octobre 2017, dans les halles de l’Expo Beaulieu Lausanne. Cette nouvelle manifestati-

12-13 September 2017, National Conference Centre, Birmingham

Cleanroom Technology Conference 2017

Keep up to date with cleanroom standards and ensure compliance

The Cleanroom Technology Conference 2017 is designed to highlight best practice and regulations affecting both cleanroom design and cleanroom operation across various sectors for those working in controlled environments and cleanrooms.

The conference will feature case studies, panel discussions and papers from leading industry experts across two days, covering topics including:
- Regulations & Standards
  - ISO 14644 & ISO 14698
- Microbiology
- Containment
- Operation and Validation
- Consumables
- Clothing & PPE
- Cleanroom Design
- Safe Utility Usage

Why attend?
- Hear from industry experts the most recent revisions and proposed standards that will affect cleanroom practices.
- Obtain practical guidance on important factors to consider when planning and specifying your new cleanroom or controlled environment.
- Learn how to maximise the effectiveness of existing contamination control procedures.
- Identify methods to enhance your cleaning regimes and how to effectively implement them.
- Look at the future of cleanroom design and technologies that will be key to cleanroom operation and design.
- Broaden your industry network by meeting key contacts within the industry.


ILMAC LAUSANNE est la plateforme pour la chimie, la pharmacie et la biotechnologie et se déroule pour la première fois, le 4 et 5 octobre 2017, dans les halles de l’Expo Beaulieu Lausanne. Cette nouvelle manifestati-

La zone de networking, le cœur de la manifestation

La manifestation associe transfert de connaissances actuelles et offres de produits de haute qualité, dans une atmosphère détendue et conviviale. La zone de networking ouverte est le cœur de la manifestation et met l’accent sur l’échange mutuel d’opinions et d’idées, les rencontres et le dialogue. Le déjeuner qui a lieu entre 12h00 et 14h00 est compris dans le ticket d’entrée (CHF 40.-).

Transfert de connaissances actuelles

Le forum d’ILMAC LAUSANNE est réalisé et organisé en étroite collaboration avec les associations professionnelles. Les exposés ont lieu de 9h00 à 12h00 et complètent le nouveau format.

12-13 September 2017, National Conference Centre, Birmingham

Industry expertise

The 2017 Cleanroom Technology Conference is organised by the leading international publication for cleanroom operators and contamination control specialists in the healthcare, pharmaceutical, food and high tech industries.
Efficient alternative to distillation

interpack 2017: Bosch launches its new system for producing WFI using membrane processes

At interpack 2017, Bosch will present its new system for the production of water for injection (WFI). As the name implies, first and foremost WFI is used in solutions for injection and infusion, making it a key component in pharmaceutical manufacturing. To date, it was only possible to produce WFI for the European market using distillation. However, as of April 1, 2017, the revised European Medicine Agency (EMA) Pharmacopoeia allows, for the first time, WFI to be obtained using other comparable processes. “Our generation unit is specially designed to meet the EMA requirements,” explains Dr. John Medina, Sales Manager at the Bosch subsidiary Pharmatec, which developed the unit.

WFI production using membrane processes

The generation unit employs the “cold” membrane processing methods reverse osmosis and electrodeionization, together with an additional ultrafiltration step. Reverse osmosis is a physical filtration process that removes ions from the water, and the subsequent electrodeionization further reduces the remaining salt content through a combination of ion exchange and electrodialysis. The unit’s ultrafiltration module then separates out particles such as microbes and pyrogens on the basis of their weight and molecular size. Until now, in the European Union this method was only approved for the production of highly purified water (HPW), while in the USA and Japan it has already been approved for obtaining WFI. In the future, the process will also be permitted by European authorities – albeit with additional, specific requirements.

Offering both thermal and chemical sanitization

Essentially, the unit must produce water under conditions that prevent the growth of microorganisms and other impurities. For reverse osmosis systems, the EMA stipulates regular sanitization of the unit using hot water – primarily to prevent the formation of biofilms. Biofilms are caused by microbes, such as bacteria, and are difficult to remove from industrial systems. For additional protection, chemical sanitization must also be an option.

According to Medina, “The unit on display at interpack allows routine thermal sanitization. When it comes to hot water sanitization, temperatures of 85 degrees Celsius can be reached.” In addition, the EMA recommends chemical sanitization using ozone, to minimize the risk of microbial contamination. The unit offers this option as well. To prevent contamination as a result of insufficient barrier properties, the membranes’ integrity is checked on a regular basis.

Bosch has now reworked the WFI unit, including a more hygienic design and built-in measuring technology to monitor the system. The stainless steel used in the storage and distribution systems does not affect the water quality. Further, the system allows all the components to be thermally sanitized at any time.

Process monitoring is essential for water quality

“Monitoring all the processes in the production chain is essential to guaranteeing the microbial quality of the water,” says Medina, “which is why we fitted the unit with various sensors and measuring devices to monitor the water quality throughout the process and to check the individual steps.” Total organic carbon (TOC) is a key indicator of the water’s quality, and since it is also a parameter for the risk of microbial contamination in the overall system, it has to be continually monitored. Conductivity is another important parameter, and here the EMA stipulates inline process control. The unit is equipped with an online measuring system to monitor specific conductivity. In order to routinely test the water in real time, Bosch has also installed an online microbe counter, which continuously records and quantifies the level of microbes and inert particles using light-induced fluorescence measurements and algorithms. All parameters are centrally monitored and controlled by means of an intuitive interface.
Concrete Benefits for Industrial Value Chains

Industry 4.0 – From Vision to Reality

Author: Hans Peter Fritsche

The digital transformation towards networked production environments in terms of Industry 4.0 (I4.0) and/or the Internet of Things (IoT) is gaining momentum. Numerous applications from the areas of product and process monitoring, labelling technology, packaging, logistics as well as maintenance and repair show already today the optimisation potential that this transformation to the Internet of Things holds.

These “things” are sensors, RFID chips (Radio Frequency Identification), devices, machines and plants. In future, these “things” are not only expected to deliver information on all important process and system conditions independently and continuously but they are also expected to communicate with each other via the Internet and intervene in manufacturing processes to correct and optimise them without human intervention. The basis for this web-based communication is the Internet Protocol (IP) with its unique-identifier IP addresses. The old Internet Protocol IPv4, however, was only capable of delivering an address space of just under 4.3 billion IP-addresses – and these had already all been allocated as early as 2012 – to PCs, notebooks, tablet-PCs and mobile phones. This is why the new standard IPv6 was developed which has an address space of \(3.4 \times 10^{38}\) IP addresses. So a lack of addresses is no longer a worry. The changeover to IPv6 is still in full swing. So the challenges are not so much the things as such and their addresses but rather the flood of data they cause when one fine day billions of sensors will be transmitting thousands of data per second to host computers. This data then has to be evaluated for visualisations and simulations and to be saved for documentation purposes (traceability).

So the Internet of Things is primarily about data; about the information retrieved from this data – to be precise. And this is the domain of software and algorithms. What can be achieved with this alone should be reason enough to actively drive this transformation. The following examples show applications that pay off in the short term.

Paradigm Change in Maintenance

Damaged bearings, transmissions, pumps or filling and dosing systems do not occur out of the blue but “give notice” long before the damage actually occurs by unusual vibration and temperature deviations or by changed power consumption, a loss of pressure and the like. These deviations detected by sensors as part of condition monitoring can today be evaluated and visualised in real time thanks to highly complex analysis and simulation programmes and therefore be seen in the process engineering context. On the basis of this information machine and plant operators can intervene in the system by remote control in a targeted manner and above all location-independently with a view to always running systems in the optimum mode, to introducing programme changes or to installing new applications and control software. Furthermore, simulation results permit precise forecasts regarding the remaining service life of critical machine parts, which opens up completely new perspectives for maintenance.

This means we are moving away from the reactive as well as preventive maintenance with its cycle-based component replacement intervals and towards predictable, precisely planable maintenance measures – to so-called “predictive maintenance”. The benefits are a higher machine and plant availability, substantially reduced downtime risks, higher operational and production safety as well as considerably lower maintenance costs.

Beyond this, predictive maintenance is a key element in sustainability. It is true that operators always played it safe when replacing components at set intervals but they also wasted valuable remaining service life of expensive components because they lacked reliable part behaviour data. Today, the knowledge about material behaviour, continuous stress under alternating loads and the like is far more advanced than 10 or even 20 years ago. Another aspect is the significantly higher computing performance available today as well as smarter analysis, FEM (Finite Element Method) and simulation software. They allow the remaining service life to be determined and predicted with a high degree of precision – and this knowledge benefits predictive maintenance.
Industry 4.0 – From Vision to Reality

Chatting with Machines

The increasing performance, flexibility and intelligence of machines and plants results in ever more complex systems posing the greatest of challenges for the developers of concepts for operating human-machine interfaces (HMI). By HMI hardware we mean terminal devices with touch-screen functionalities that most people know from their smartphones or tablet PCs. This means they can build on existing knowledge for learning to handle these machines and plants – this motivates and definitely shortens familiarisation time.

One central aspect in the development of graphical user interfaces is to ensure that these machines can also be safely operated by people without specific vocational training and often also without sufficient language skills. To avoid operating errors the developers of GUIs rely on intuitive graphical elements instead of language. Also up and coming are photo-realistic 3D CAD displays of machines, plants and components. Furthermore, HMIs have to live up to the needs of various users – in line with their skills and authorities. Therefore, machine operators see different graphical user interfaces to shift managers, maintenance staff or production managers. This means, every user only sees the data that corresponds to their area of responsibility and is of relevance to their specific situation. Furthermore, the data is limited to the essentials; this ensures an easy-to-grasp display and an instant presentation of the key machine parameters and production data.

Other characteristics of modern HMIs are mobility and consistency. There is a trend towards mobile devices with which the user can control machines and equipment remotely depending on their authority level. This saves time and travel expenses especially in the field of service and maintenance.

Working in Virtual Worlds

When it comes to the Internet of Things, there is hardly a topic that currently causes as much a stir as virtual, or rather digital twins. The technical basis for virtual twins are high-performance 3D CAD, simulation and analysis software programmes as well as virtual 1:1 copies of real machine and equipment control software. Based on such software tools digital twins map the complete manufacturing process including components, machines, plants and their controls as a virtual model – complete with all the physical data required for the simulation. In addition to this, digital twins permit offline programming. All of this makes virtual twins universal tools for developers, operators and maintenance staff.

Thanks to these near-reality simulations design errors and/or weak spots can already be detected and eliminated in the development stage without having manufactured a single real part beforehand. This also applies to the programming and optimising of controls.

One of the most important applications, however, is virtual commissioning or start-up. This is not only a virtual trial run but also serves to familiarise the operator in charge of the machine with the properties and possibilities of the system in a targeted manner. In other words: the digital twin is the “flight simulator” for industrial processes, machinery and equipment. The virtual pre-start up before the real commissioning pays off in more ways than one. Should there still be any bugs in the system or control concept, they can be remedied without causing damage to real system components. Offline programming, in turn, allows production planners to virtually test various operating modes. The most important aspect, however, is that the virtual twin brings together the expertise of many specialists, which can later also be used for other projects.

In a nutshell: thanks to the sophisticated simulations plant manufacturers and users can achieve significantly shorter project lead-times, faster start-ups and marked efficiencies for the development of similar plants and processes. This saves time but above all resources, energy and manpower.

Standardised Interfaces a Must

Standardisation continues to be a major challenge because most machinery producers still rely on their own interfaces. However, integration is the decisive feature in the Internet of Things. This integration requires especially consistent data and information exchange between machines – both vertically and horizontally. And this makes open standard protocols necessary. Therefore, there is a trend towards Open Source solutions since these offer high security of investment and independence being non-proprietary systems. One example is the OPC Unified Architecture (OPC UA), a package of specifications for linking machines of various manufacturers. OPC UA ensures security through authentication and authorisation, encryption and data integrity.

This means OPC UA is ideally suited for a safe, reliable and non-proprietary transport of raw data and pre-processed information from the manufacturing level to superior production planning or ERP systems.

Even Old Systems can Handle 4.0

Many older machines, lines, motors and compressors are not equipped with the sensors and communication technology for Industry 4.0 – sometimes not even for operation as part of networked systems. This does not mean that these systems are obsolete in view of digital transformation. Here – as an entry-level solution for Industry 4.0 – smart sensors can be retrofitted. They regularly measure important condition parameters of the machines and systems and transmit the data via built-in communication interfaces wirelessly to the HMIs and/or employees’ smartphones or tablet PCs for evaluation. With these and other simple methods companies can enter the world of Industry 4.0 inexpensively and still benefit from reduced downtimes, longer machine uptimes as well as lower power consumption and the like.

At interpack 2017, the VDMA Food Processing and Packaging Machinery Association is organizing a special exhibition on the topic of Industry 4.0. It will take the form of a Technology Lounge at the VDMA stand, featuring examples of solutions in packaging machinery and process engineering and opening up new opportunities for applications in security, traceability, copying and counterfeit protection as well as in customised packaging.

04th - 10th May 2017: interpack 2017, Duesseldorf (D)
The EE360 moisture in oil transmitter measures accurately the moisture content in hydraulic, lubrication and insulation oils as well as diesel fuel.

**Transmitter for Moisture in Oil Monitoring**

The EE360 moisture in oil transmitter from E+E Elektronik is dedicated for reliable monitoring of lubrication, hydraulic and insulation oils as well as diesel fuel. The device measures water activity and temperature, and calculates the absolute water content of the oil. The probe can be employed up to 180 °C (356 °F) and 20 bar (290 psi). The colour display shows actual as well as logged measured data.

The well proven E+E sensing technology ensure highly accurate measurement of water activity (aw) and temperature (T). Based on the measured values and on oil-specific parameters, the EE360 calculates the absolute water content (x) in ppm.

On the 3,5 inch colour display all three physical quantities can be read simultaneously. The integrated data logger stores 20,000 values per measurand, which can be shown as graph on the display. This means that, beside current data, the user can keep an eye on the oil condition trend.

The stainless steel probe can be installed into the process with an ISO or NPT slide fitting, which facilitates the accurate control of the immersion depth. Using the optional ball valve, the probe can be mounted or removed even without process interruption. The plug-gable probe version allows for easy installation and replacement.

The measured data is available on two analogue outputs or on the digital Modbus RTU interface. The configuration of the outputs as well as the humidity and temperature adjustment can be easily performed via display and push buttons. Extensive error information and diagnosis are available on the display as well as via status LEDs and acoustic warnings. Two optional relay outputs can be used for alarm or control purposes.

Comfyable setup and adjustment of the EE360 is also possible with a computer and the free EE-PCS configuration software. The USB service interface is used as well to download logged data and perform firmware updates.

The modular IP65 enclosure facilitates mounting and maintenance of the transmitter. The evaluation unit, which accommodates the electronics and the probe, can be replaced within seconds, while the wiring remains untouched. The material of the enclosure is approved according to UL94-V0.

The EE046 condensation monitor indicates condensation danger before condensation actually occurs. It is ideal for monitoring chilled beams and other surfaces operated close to the dew point.

**Early Warning of Condensation Danger**

The compact EE046 from E+E Elektronik monitors reliably the condensation danger on chilled beams and other critical cold spots, in air conditioning systems or switching cabinets. It can be installed on plane surfaces and on pipes up to 50 mm (2") diameter. For preventing condensation, the switch output can trigger actuators like valves or heaters.

The EE046 measures accurately the relative humidity at the surface temperature. Thanks to the special E+E proprietary coating, the humidity sensor is optimally protected against contamination. This improves the lifetime and long-term stability of the EE046 in dirty, dusty environments. Another advantage of the condensation monitor is the fast response time to humidity or surface temperature change.

The potential-free relay (max. 24 V AC/DC, 1 A) switches when the relative humidity at the surface reaches 90% RH, or in case of a supply failure such as a broken cable. A LED indicates the status of the EE046: normal operation, risk of condensation or fault/failure.

Due to the compact design, the condensation monitor requires little space and the installation is remarkably simple. On plane surfaces, the EE046 is fixed with two screws, for mounting on pipes up to 50 mm in diameter a mounting strap is included in the scope of supply.
The CONTROL and CONTROL FLUSH-MOUNTED (FM) HMI systems are suitable for integration into cleanroom walls or switch cabinets in areas demanding high standards of cleaning and hygiene.

Fitted systems especially for cleanrooms - flush-mounted or with stainless steel frame

Its polished stainless steel front panel distinguishes the CONTROL from the CONTROL FM. Mounting of the fitted system can be performed either by way of threaded bolts or a hole on the front. The device is then fully recessed in the wall, with just the thickness of the front panel on the surface of the wall.

The CONTROL FM is designed for completely flush integration into the wall. The back of the fitted system can be inserted into a perfectly fitting recess made in the cleanroom wall. With this solution, there is no frame and so no projecting edges whatsoever.

The CONTROL and the CONTROL FM are available in various sizes (display from 17.3" to 32") and customized configurations – from a monitor to an industrial PC with Intel® Core™ i7 processor. Both HMI systems have a shallow installation depth of 44 - 55 mm.

The two systems also feature an IPS display, offering high color accuracy, distinct color presentation and the added advantage that the viewing angle makes hardly any difference. The display is optically bonded to the touch panel. The multi-touchscreen offers multi-finger gesture control and supports all standard operating systems.

Systec & Solutions GmbH
Emmy-Noether-Straße 17
D 76131 Karlsruhe
Telefon: +49 721 6634 400
Telefax: +49 721 6634 444
E-Mail: talk@systec-solutions.com
Internet: http://www.systec-solutions.com
Always dry: New maintenance-free stainless steel chains for cleanroom applications

iwis introduces b.dry maintenance-free stainless-steel chains. The corrosion-free chains run completely dry, are extremely wear-resistant and withstand high dynamic loads. They are also maintenance-free and don’t need any form of lubrication. These characteristics make them predestined for use in aggressive environments, for applications in which water or steam are applied or where strict cleaning regulations apply, such as the food and pharmaceuticals industries, in cleanrooms and in painting lines.

The new b.dry precision chains are the ideal choice wherever relubrication is undesirable or not possible. They are hygienic and run completely dry: Thanks to the high-performance plastic friction bearings in their links, they need no lubrication of any kind, which also eliminates the need for relubrication. Made from a high-performance polymer, the sleeves are heavy-duty, low-friction and FDA-compliant. Contact with foodstuffs or hygiene products is safe. The stainless-steel bushes are thin-walled, seamless and ball-drifted. The CF base chain is made from austenitic stainless steel, making it highly resistant to aggressive media. The wear life of the b.dry chains is significantly longer than that of comparable chains: in test runs at iwis, it proved twice better in dry condition and as much as four times better with initial lubrication. In a dry state, the chains are free from paint wetting impairment substances (PWIS), which is important, for example, in painting lines in automobile manufacture. b.dry chains are made in length tolerances compliant with ISO 606. They can be used in a temperature range from -100 to +200 °C. They are also available as roller chains with attachments or extended pins. Custom-developed chains and ANSI chains are also available on request.

Munich chain specialist iwis supplies a comprehensive product range for all drives and conveying applications. The full product range comprises precision and high-performance roller chains, conveyor chains, maintenance-free and corrosion-resistant chains, accumulation chains, special-purpose conveyor chains, flywheel chains, flat-top chains and modular belts for industrial applications, chains and accessories for agricultural machinery, and timing drives for the automotive industry.

iwis antriebssysteme GmbH & Co KG
D 81369 München

The high-performance polymer sleeves of the new b.dry chains from iwis withstand high loads and are low-friction and FDA-compliant. The ball-drifted stainless-steel bushes ensure high strength and wear-resistance.