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Pharma in Nürnberg: efficiency meets excellence

Every 18 months thousands of process engineers from the pharmaceutical industry come to Nürnberg to update on the latest technology trends in production, filling, validation, packaging or anti-counterfeiting. TechnoPharm, which takes place in Nürnberg from 30 September to 2 October 2014 with some 250 exhibitors from more than 15 countries, has long been established as Europe's leading innovation forum for the manufacture of solid and liquid drugs and the related research. More pharmaceutical products are presented at POWTECH, the World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids, which is held in parallel: over half of the more than 700 POWTECH exhibitors show solutions relevant to pharmaceuticals.



**30th Sept. - 02nd Oct. 2014: TechnoPharm
and POWTECH 2014 Nuremberg (D)**

“Holding TechnoPharm and POWTECH at the same time is real added value, especially for visitors from the pharmaceutical sector,” says Willy Viethen, Director Exhibitions of both trade fairs at Nürnberg-Messe. “One in two of the altogether almost 1,000 exhibitors in Nürnberg offers products relevant to pharmaceuticals. In the six halls they show everything needed

for the efficient and GMP-compliant manufacture of solid, semi-solid and liquid drugs.”

TechnoPharm and POWTECH attracting attention

The great importance of the trade fairs for the pharmaceutical industry in Europe and the world is also shown by the international involvement at the events. Every fourth exhibitor at TechnoPharm comes from abroad and as many as every third exhibitor at POWTECH. The leading exhibiting nations at Techno-

Pharma in Nürnberg: efficiency meets excellence

Pharm are Switzerland, Italy, France, Austria and the Netherlands.

The exhibitors in Nürnberg show the latest plant and equipment for the manufacture of solid, semi-solid and liquid drugs, sterile plants, peripherals for sterile process technology, analytical and control systems, technologies for packaging and filling, and cleaning and hygiene products. The trade fair focuses on cleanroom technology for the third time at the "Focus Cleanroom" Forum.

Innovative solutions for a radically changing industry

The pressure of cost in the pharmaceutical industry is greater than ever. Productivity standards in comparison with other industries and operational excellence are advancing. Questions on online analysis and automated process optimization are permanent issues. The demand for single-use components is growing at the same time; not only hoses and valves are offered for single use, but even whole pumps too. Another challenge for the pharmaceutical industry is mandatory marking with effect from 2017.

The broad spectrum of burning questions demands the most innovative and efficient technological answers possible. These are

provided by the exhibitors at TechnoPharm and POWTECH 2014 in Nürnberg. Only in Nürnberg are the themes of sterile technology and powder and granule technology integrated so perfectly. One in two of the over 700 POWTECH exhibitors shows process solutions adapted to the high hygiene requirements of the pharmaceutical industry. Mills, mixers, screening machines, agglomerating and granulating processes, driers and the entire handling process from pneumatic conveying and dosing to containment: all these plants, apparatus and components shown at POWTECH are also available in sterile versions.

Highlights of supporting programme

The product spectrum is supplemented by a top-class supporting programme co-organized by the Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik (APV – International Association for Pharmaceutical Technology), the honorary sponsor of the event. In over 60 presentations, well-known knowledge experts from the industry provide information on the technological status quo – from sterile processes to packaging.

NürnbergMesse GmbH D 90471 Nürnberg

The Chillventa forums

Knowledge transfer at the highest level

The next Chillventa takes place from 14–16 October 2014. The International Trade Fair for Refrigeration, Air Conditioning, Ventilation and Heat Pumps starts on Tuesday and runs for three full days. After the extraordinary success of the last event, the event team is looking optimistically to Chillventa 2014 and is confident that the importance of this exhibition for the sector will continue to grow. Around 1,000 exhibitors are expected this year – a new record.

14th - 16th Oct. 2014: Chillventa 2014, Nuremberg (D)

Knowledge transfer is also top priority during the exhibition from 14–16 October, when more than 125 interesting presentations are lined up for visitors to the forums in halls 1, 4A and 7. Bernhard Rieger from Mitsubishi Electric Europe BV speaks on "Hotel air conditioning with maximum comfort – patented VRF R2 heat pump system for simultaneous cooling and heating". Hans Kaut GmbH is represented by Sascha Wittenstein, who delivers the paper on "A pleasant climate for your business". Dr. Nikolaus Meyer of Geo-En Energy Technologies GmbH deals with air conditioning of large buildings in his paper and shows efficient solutions with geothermics and photovoltaic systems. Another paper by Ulf Cartellier of Stulz GmbH provides ideas on "Why the discharge of large thermal loads can cause difficulties with air conditioning". These are just a few of the many presentations.

Applications & Training & Regulations

Hall 1 focuses on application, training and laws, standards and regulations. A key

role is played by the new F-Gas Regulation and associated new developments in refrigerants with low Global Warming Potential. The application of NH₃ in faraway countries is also on the agenda. At the forum on Tuesday morning, for example, refrigerant manufacturers Arkema, DuPont and Honeywell present global solutions for the use of low GWP refrigerants. The necessary oils for these refrigerants are dealt with in addition. A practical report by the Bundesfachschule Maintal (Federal College of Refrigeration and Air Conditioning Technology) shows the use of the refrigerant R-290 (propane) and discusses its possible commercial applications. Dave Godwin from the U.S. Environmental Protection Agency (EPA) will also speak on refrigerants at the forum on Wednesday morning.

Refrigeration

The products presented in hall 4A include components, refrigerants, electronic controls and the latest monitoring systems. Here the classic refrigeration for commercial and industrial purposes dominates. The initiative for more efficient refrigerants is just one focus of this forum. The presentation by Danfoss on "Optimized plant efficiency

through dynamic COP measurement" tackles a particularly interesting topic. The necessary parameters are detected by the specially developed module and reproduced as corresponding current COP, which is then compared with the ideal COP for the system. The comparison of these two figures enables the system to be optimized. The forum in hall 4A concentrates on refrigeration.

Air Conditioning – Ventilation – Heat Pumps

Hall 7 focuses on air conditioning, ventilation and heat pumps. The impact of the new F-Gas Regulation is also clearly noticeable in the presentations here. Other topics presented include heat transfer in buildings, the use of renewable energy sources, efficient air conditioning and ventilation systems, and ecodesign. The presentation on "Economic Energy and Climate Management by DA-IKIN Cloud Services" shows the possibility of obtaining precise statements on current operation, system reliability and energy consumption for already installed or new Daikin VRF systems with the existing bus topology and knowledge of the components used.

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Cherwell Secures UK Distribution Agreement with Mar Cor for Cleanroom Decontamination Products

New bio-decontamination range complements Cherwell's sterilisation process validation products

The importance of efficient, reliable decontamination of cleanrooms and other critical areas within the healthcare, pharmaceutical and biotech industries is undeniable. Having signed a UK distribution agreement with Mar Cor Purification, Cherwell Laboratories can now offer a range of dry fog technology and cold sterilant products to provide the ideal solution.

Cherwell Laboratories has built a reputation for providing high-quality products to meet the process validation and environmental monitoring requirements of the pharmaceutical and healthcare industries. The addition of Mar Cor Purification's decontamination products complements the existing product portfolio enabling Cherwell to offer a comprehensive solution to customers. The new decontamination range, suitable for use in pharmaceutical cleanrooms and other critical areas, incorporates the highly effective Minncare® Dry Fog and Mini Dry Fog systems plus Minncare and Acril Cold Sterilants.

Alongside the new decontamination range, Cherwell offers biological indicators for the validation of sterilisation processes, Redipor® prepared microbiological media and SAS microbial air samplers. The range



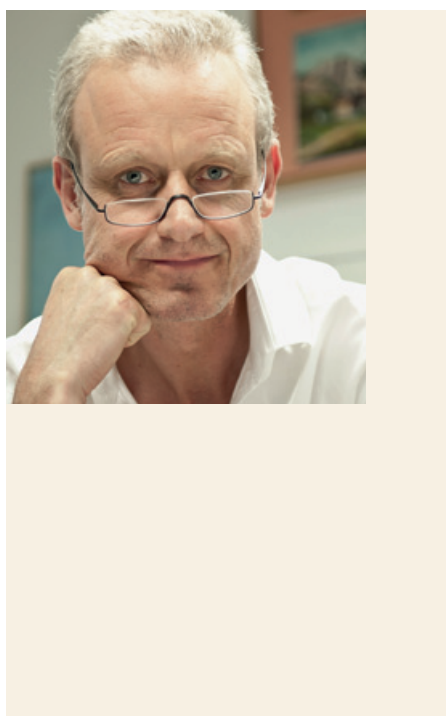
The Mar Cor Dry Fog system for cleanroom and critical area decontamination.

has been developed over time to meet the changing regulations within the pharmaceutical and related industries whilst maintaining Cherwell's commitment to offering the highest quality products, expert advice and customer service levels.

"We are very excited to enter a UK distribution agreement with Mar Cor Purification," said Andy Whittard, Managing Director, Cherwell Laboratories. "The Dry Fog

and cold sterilant decontamination products provide an ideal synergy with Cherwell's current product range, and meet our high expectations for product quality and customer service."

Cherwell Laboratories Ltd
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Vereinigtes Königreich Großbritannien und Nordirland



Dear readers, dear subscribers,

summer is almost over and we have a lot of interesting news and a lot of interesting events for your appointment calendar.

So the amount of the German and the international newsletter is growing constantly. We hope we can give you with this information a good help for your daily work and your planning tasks.

Yours sincerely
Reinhold Schuster
Reinhold Schuster



NEW

If you click at this sign in the pdf-document you will easily get more information in the internet

The new cleanroom printline 02-2014



The Drops of Life



Trelleborg Sealing Solutions supplies precisely molded silicone breast shields to Medela, the world leader in breast pumping and feeding solutions.

Breastfeeding research has been instrumental in the development of Medela's world-leading range of breast pumping and feeding solutions.

"Most health research focuses on just a few areas, such as cancer or Alzheimer's disease," says Martin Elbel, Head of Corporate Communications at Medela AG. "This is obviously vital but it means that hardly any money goes to fields like breastfeeding or lactation. Little attention is given to the beginning of life."

Medela, a manufacturer of breast pumps and breastfeeding products, has therefore funded research into breastfeeding and human milk for almost 20 years.

"Funding is into basic research not directly connected to our products," continues Elbel. "This may lead to applied research and, though rarely, eventually to product development and subsequent clinical research. Basic research influences the development of new solutions."

Medela has a long-standing relationship with the University of Western Australia (UWA) and also collaborates with other universities, hospitals and research institutions globally.

"Though human milk has been produced and breastfeeding has existed as long as the human race, it is amazing that we still discover something new," says Elbel. "For instance, recent research has identified stem cells in human milk that display a similar morphology with a similar gene expression to human embryonic stem cells."

These pluripotent human breast milk stem cells can differentiate into other types of cells, including brain, liver and pancreatic

cells. This stem cell research is very exciting and could potentially be lifesaving in the future."

There are more than five times as many components in breast milk as in formula and no formula can duplicate the properties of breast milk. The World Health Organization recommends that mothers breastfeed their babies for six months.

The benefits of breastfeeding are numerous. The baby receives nutrition exactly as required and breast milk prevents growth of certain harmful intestinal bacteria. This reduces infections and there are clear signs that it decreases the risk of allergies, cancer, diabetes and obesity later in life.

Despite the benefits, attitudes to breastfeeding vary in different cultures and countries. In China, for instance, breastfeeding was not encouraged for a long time. Medela, working in close cooperation with the Ministry of Health and specialists, helped to gradually change the attitudes of hospital professionals to breastfeeding and to make a positive impact on the mindset of millions of people.

Applied research in product design has led to development of solutions that maximize effectiveness of breast pumping and feeding systems for babies.

"Ultrasound proved the conventional representation of the anatomy of a lactating breast was incorrect," says Elbel. "Within the breast there is a complex network of ducts. These and glandular tissue branch closer to the nipple than used to be believed. The diagram of the lactating breast developed from research funded by us is now the standard used in text books and on the web."

Discoveries on the way that babies suckle have directly influenced Medela's products. Its breast pumps re create the two phases in which babies nurse. Initially babies suck fast and shallow to stimulate the milk ejection reflex, then switch to a slower and deeper suck.

"We worked with Professor Peter Hartmann, an internationally renowned specialist in the field of breastfeeding and milk synthesis and his Human Lactation Research Group at UWA. Since the mid-1990s, Medela has applied Hartmann's breakthrough research, which finally resulted in the development of an exclusive pumping pattern called 2-phase expression. It closely mimics a baby's natural nursing rhythm to maximize milk output when using a breast pump."

A new key focus area for Medela is the feeding of breast milk to premature babies. Though the benefits of breast milk are even more important to preterm infants, they are often not capable of feeding from the breast at birth, and even when they are, the mother's body may not be ready to give sufficient milk.

"Often a premature baby will need to be fed enterally and with a bottle," says Elbel. "However, feeding from a traditional feeder is nothing like feeding from the breast."

Through ultrasound imaging research it was discovered that milk flow is influenced by a vacuum produced by the baby through specific tongue movement.

"Analysis of the way babies suck and take milk from the breast led to the development of two similar feeding systems, one for term babies and one for use with premature babies," continues Elbel. "The teat of our Calma and our Calmita incorporates a vacuum-controlled valve that only triggers a flow of milk when the infant moves their tongue downward to create a sufficiently strong intraoral vacuum in the same way as the maternal breast opens the milk passageways under those conditions."

"Calmita teaches a premature baby how to suck properly, making it easier for the baby to transfer to the breast and encourage maximum milk flow from mum. This combined with effective breast pumping to stimulate milk production, even in mothers who are not quite ready, can mean the premature baby can benefit from their mother's milk as soon as possible and in as high a volume as possible."

Innovative manufacturing processes

Trelleborg Sealing Solutions molds silicone breast shields for Medela's world leading range of breast pumping and feeding solutions. The silicone component is accurately tooled to ensure the finest flash-free hole in the shield and is produced in a dedicated

The Drops of Life

cleanroom on a specially developed injection molding machine.

One hundred percent in-process quality checks combine with specialized pick-and-place manufacturing to transfer the product from machine to packaging without any manual contact that could impair the breast shields' super-clear finish and ensures high volume demands are met.

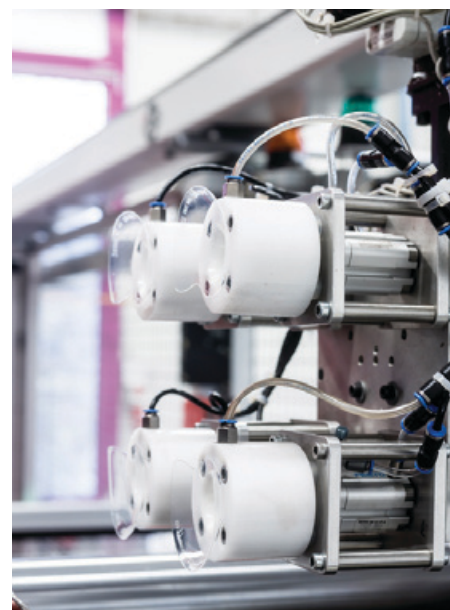
Silicone Solutions

Trelleborg Sealing Solutions in Stein am Rhein has been a supplier to Medela from the early 1990s and has contributed to the component design of over 40 engineered-molded silicone components for Medela's breastfeeding solutions, including numerous parts for its breast pumps and silicone breast shields.

"Both companies are connected by good an intensive cooperation in daily business, but also in the continuous improvement of products and in new projects," says Gotthard Suter, Streategic Producrement Manager at Medela. "We see Trelleborg as a professional liquid silicone rubber manufacturer with a full tool box of know-how in production. Collaboration is close on designs and Trelleborg will always come up wioth a variety of options in component design and manufacturing processes.

"Quality is vital in our breast pumping equipment, and from Trelleborg this is high and stable. The components we require are never simple but Trelleborg is able to effectively meet our requirements for complex solutions."

Trelleborg Sealing Solutions Silcotech AG
CH 8260 Stein am Rhein



Advanced manufacturing of Medela's silicone breast shields relies on accurate tooling to ensure the finest flash-free hole in the shield.

Schreiner MediPharm Presents New Security Concept for Original Containers

Flexi-Cap Protects against Counterfeit Drugs

Schreiner MediPharm will again be present at this year's InnoPack, as part of the CPhI trade fair in Paris from October 7th to 9th. One of the highlights is an innovative security solution that combines first-opening indication and labeling: Flexi-Cap irreversibly shows that a primary container has been opened, and thus prevents illegal reuse and filling of empty containers with counterfeit substances.

**7th - 9th Oct. 2014: CPhI trade fair,
Paris (F)**

Counterfeiters do not hesitate to take empty original containers from dumpsters, in order to refill them and illegally sell them as originals. Flexi-Cap, the new security concept from Schreiner MediPharm, based on an innovative combination of label and cap, prevents this misuse. The film cap is first put over the closed container, then the label is applied without covering the peel-open tab on the opening strip. Once the strip is opened, the bottom part of the cap, together with the label, remains attached to the container. Attempting to remove the rest of the cap destroys the label. This eliminates the possibility of illegal, unnoticed reuse.

The specialty solution is usable with different container types, forms and sizes. Unlike shrink-wrap solutions, the label construction can be applied without using heat, making it suitable for temperature-sensitive medicines. The top of Flexi-Cap allows space for bar code printing or NFC chip integration for electronic tracking. In addition, important user information can be commu-



nicated and patient compliance documented. The multilayer label provides enough space for information in several languages. Administration can be documented easily with the integration of detachable label parts. Robust hangers can also be included.

Adding extra security features such as holographs, color-shifting inks, guilloches



or hidden features such as a void effects or LaserSecure pigments gives suppliers, pharmacists, medical personnel and patients additional certainty that the product they are holding in their hands is genuine.

Schreiner MediPharm, a business unit of
D 85764 Oberschleissheim

Prevention of microbial contamination in pharmaceutical and biotech manufacturing areas: a holistic approach to establishing robust control measures.

A recent best seller¹ tackled the question of why an entire nation can be compelled to help one or a few people in life-threatening situations (e.g. Chilean miners), but will do little to help millions who are at equal or greater risk (e.g. Tsunami victims). This may be irrational, but is also an accurate characterization of how difficult it is for humans to work toward abstract goals based on concepts and proportions that are frankly, nearly impossible to grasp. Saving one person, who is right in front of you, is far easier to conceptualize than saving millions who are suffering in a distant land. In situations such as these, the tendency is to turn away, because we cannot understand how to effect change to that which we cannot understand or see. This phenomenon plays a role in environmental control of drug manufacturing areas, in that, we are asking individuals who work in these areas to exercise a great deal of caution and to follow rigid protocols designed to prevent contamination of the drug by entities that number in the millions, that they cannot see. To put it simply, those who work in critical manufacturing areas have an innate tendency to underestimate the impact that they as individuals may have on controlling a large complex system, or on even more abstract concepts such as impacting the public health, which can be the outcome of poor manufacturing control, as evidenced by recent influenza vaccine shortages² and product recalls³.

Effective management of drug manufacturing areas requires a holistic approach based on identifying and monitoring those components that play the most critical role in successful manufacturing outcomes. A holistic approach addresses behaviors of complex systems, based on a multi-disciplinary approach that relies heavily on metrics to understand the behavior of the system. The critical com-

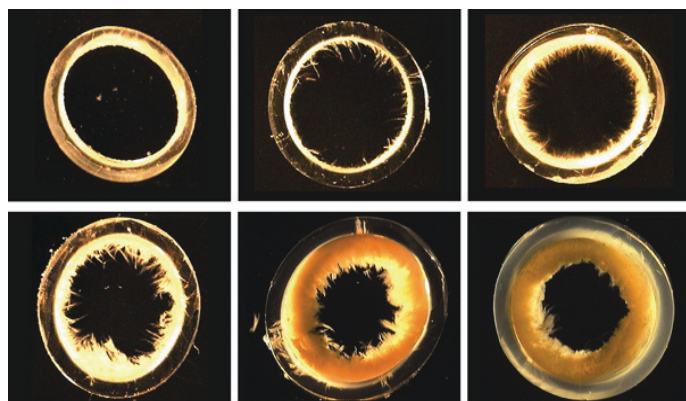
ponents that must be addressed and monitored in order to ensure drug production outcomes are: facility (design and condition), personnel (training and management) and microbial control programs (products and application). This article will address all three areas.

The best defense is a good offense, especially when there are millions of dollars and the public health at stake – which is not hyperbole when we are talking about vaccines and other biotechnology derived drugs. In this case, where terminal sterilization is typically not an option, a strong offensive position begins with a robust facility design that insulates the drug and packaging components from sources of contamination. This design includes adequate barriers (e.g. interlocking doors, clear zone demarcation), HVAC capacity (e.g. enough to handle seasonal fluctuations in temperature and humidity), water control (e.g. placement of drains and WFI drops), cleanable design features (e.g. smooth coving, limited obstructions) and selection of chemical and moisture resistant materials of construction (e.g. 316L stainless steel, epoxy or polymeric flooring), to name a few. In a situation with unlimited budget, time and expertise, design and construction of a drug manufacturing facility optimized to prevent product contamination can be easily achieved. However, in a less than optimized environment, the design and facility condition are often contributing factors to microbial excursions, and in some cases, to product contamination.

Even stainless steel may suffer the effects of chemical exposure, or over-exposure, resulting in rust. Rust and pitting, in particular, represent significant damage to the surface that present challenges to effective microbial control in two ways; one in providing shelter to microorganisms and residue, and two in inhibiting the cleaning and decontamination agents from reaching the microbes to achieve adequate contact time. Stainless steel is not the only surface that can be damaged; epoxy and polymeric floors can suffer significant damage from high foot traffic or the force of moving heavy equipment – and are not immune to the effects of significant chemical exposure. Both scenarios may lead to pooling water and the microbial control pro-



Image 1: Water damaged wall covered with mold. (photo by Jim Polarine)



© 1998 Center for Biofilm Engineering at MSU-Bozeman; Photos: Mark Groenenboom

Image 2: Biofilm formation in pipes. (photo courtesy MSU)

Prevention of microbial contamination in pharmaceutical and biotech manufacturing areas

blems associated with water, such as mold and *Bacillus* proliferation. Significant water damage to the structure, as a result of, for example leaking roofs or drainage problems, can establish endemic problems with molds (see image 1) and *Bacillus*. Drainage issues, can result in biofilm (see image 2) formation, which may lead to significant, recurring problems with *Bacillus* and other bacteria due to increased resistance to antimicrobial chemistries demonstrated by biofilms⁴. Another aspect of design is inclusion of sufficient barriers to isolate the drug manufacturing process. Older facilities or facilities that were not originally designed for this purpose may not have an ideal barrier design. For example, the warehouse or component staging areas may not be ideally located to prevent egress of undesirable particulate. In some cases, one-way traffic cannot be established due to structural limitations. Both situations make contamination control more problematic and consequently, the drug manufacturing process more difficult to control.

The most common approach to microbial control problems due to facility design flaws or damage is to increase the use of chemical antimicrobial products, by concentration, frequency of application or both. In some cases, extremely aggressive chemical agents, such as acidified bleach, may be used on a short-term basis. While these measures may result in immediate improvements in environmental monitoring data, in the long run, this approach may lead to even more damage and less ability to control the environment. The best solution to establish a high degree of control is to repair or retrofit the facility as required, a costly approach to be sure. However, it is less expensive than the alternatives of chasing root causes for microbial excursions or product contamination and rejection.

The personnel who work in aseptic manufacturing areas continue to represent the greatest threat to drug production. This is certainly not a reflection of the lack of dedication, because most people take great pride in doing a good job, but rather the inherent nature of humankind. Human beings are prodigious bioreactors; by some accounts⁵ 90 percent of the cells on the human body are microbiological in nature. Further, even with robust training programs, the people who work in cleanrooms do not always adhere to good aseptic practices. The most common lapses in behavior have more to do with thoughtlessness, rather than willful disregard for aseptic practices. For example, one might thoughtlessly scratch an itch or mop a sweaty brow, or sneeze. Willful deviations from standard operating procedures may, in some cases, be meant to mitigate the risk of failing environmental monitoring data. For example, spraying sterile isopropyl alcohol on gloved hands or Tyvek suits immediately prior to plating, may reduce the risk of failing results, but is never condoned. Sometimes willful disregard for standard operating procedures and aseptic practices is more difficult to categorize. For example, during a training event years ago, an operator said that the reason she added an unapproved household dish detergent to the validated disinfectant solution to be used in the classified cleanroom was that she believed that the validated product did not produce enough foam, which she believed was essential to good cleaning (a fallacy that can be dispelled through training). In this situation, her intentions were noble, but her behavior was still non-compliant to cGMP practices. At the very least this placed her management in a poor regulatory situation, and in the worst case, her actions may have compromised the performance of the disinfectants, putting the drug at risk.

There are hundreds of ways that an aseptic environment can be compromised through the well-meaning efforts of insufficiently trained and monitored personnel. The key to reducing operating risk from the personnel who work in these areas is to include a solid cGMP platform in the training program. This platform should draw on the evolving history of drug production, incorporating real-world examples of the damage that adulterated drugs represent to human

health. Everyone knows someone who uses pharmaceuticals at least periodically (e.g. vaccines, chemotherapy); understanding what the risk of poor production control represents to a friend, loved one or to oneself, helps to personalize the message and drives more thoughtful behavior. Further, basic training in microbiology, antimicrobial chemistry and cleaning techniques, can ensure greater compliance by establishing a solid rationale for why certain products and conditions are used. In other words, through education, you are taking a large, complex system, which requires control of millions of non-visible objects, and scaling it to a level that the cleanroom operator can understand and embrace. Once this education is delivered, it must be reinforced through frequent management interaction. It is a sad fact of life that as operations management is asked to spend more time away from the manufacturing floor, there is less opportunity to observe behavior, which means there is less opportunity to reinforce the good and correct that which needs improvement. Further, as operations management becomes more involved in matters outside of their most basic function, personnel training and management, oversight problems may occur. "Specifically, no oversight to ensure that Shift Managers/Supervisors confirm employee completion of course requirements...Two current temporary employees were hired on..., but did not receive required training, SOP... "introduction to GMP", as required by the firm's training procedures." GMP Trends, Inc. December 1, 2010.

Cleaning is a cGMP requirement. The environment must be controlled in order to prevent particulate and microbial contamination of the drug, packaging components, and product contact surfaces. The manner (e.g. products, application methods and frequency) in which cleaning and microbial control takes place varies from site to site, in part because of differences in facility design and production needs. However, there are guidance documents^{6,7} and best practices that should be incorporated into the cleaning and microbial control strategy. There are also practices that are not universally applied or sometimes well-understood. One such practice is disinfectant/sporicide rotation. The term itself has undergone change over the last decade or so. At one time, rotation implied alternating use of two broad-spectrum disinfectants of similar chemistry (e.g. two phenols, or two quaternary ammonium chloride (quats) compounds). By rotating two different formulations, with similar active ingredients and different chemical or physical properties (e.g. pH, alkalinity), one might address a broader spectrum of microorganisms (bacteria, fungi, viruses), while minimizing the development of problematic residues that may occur from the interaction of two different, and potentially incompatible chemical species (e.g. phenols and quats). At this time, the above type of rotation is still prevalent as evidenced by recent 483 observations, "The firm failed to follow written procedures for cleaning and disinfection of Class 10,000 rooms, in that, production personnel do not alternate cleaning and disinfection agents for sinks and flat surfaces, as dictated in SOP..." GMP Trends 8/15/07. However, as the need to control more resistant organisms, such as fungal spores and bacterial endospores, becomes greater, rotation programs are often refined to include the use of a sporicide. This model of alternating routine disinfectants, or one routine disinfectant, with a sporicidal agent, is fast becoming a regulatory preference, and is noted in various regulatory and advisory documents, including USP Disinfectants and Antiseptics, USP 32-NF27: "It is prudent to augment the daily use of a bactericidal disinfectant with weekly (or monthly) use of a sporicidal agent. The daily application of sporicidal agents is not generally favored because of their tendency to corrode equipment and because of the potential safety issues with chronic operator exposure. Other disinfection rotation schemes may be supported on the basis of a review of the historical environmental monitoring data."

Selection of disinfectants and sporicides should be made based

Prevention of microbial contamination in pharmaceutical and biotech manufacturing areas

upon scientific evidence of efficacy against the target spectrum of organisms, as well as upon other important considerations such as substrate compatibility and operator safety. The references⁸ available to provide information on the mechanisms by which different chemical entities work against the structures of various microorganisms are too numerous to count. These tools can aid in the selection of disinfectants and sporicides. However, use of scientifically-based references and the conventional wisdom to select these products does not alleviate drug manufacturers of the requirement to validate their disinfectants and sporicides, and even isopropyl alcohol, for use in their facilities, against their environmental isolates, under actual use conditions. "Disinfectant agents used to sanitize surfaces in the aseptic processing areas (APA) have not been adequately qualified to assure that they provide the intended microbial decontamination when used in the manner as specified in the standard operating procedures as follows: a. The qualification study only evaluated stainless steel and not other surfaces in the APA such as glass, plastic and epoxy painted surfaces. b. The qualification study used a longer exposure time to the sanitizing agent than that time specified in the cleaning SOPs. c. The qualification study immersed the test surface in the disinfectant for Instead of wiping the surface as specified in the SOPs." GMP Trends May 1, 2003.

In addition to microbial efficacy, the question of the role that disinfectant and cleaning agent residues play in environmental control has become a more urgent concern. Most disinfectants and cleaning agents contain ingredients that are non-volatile, i.e. remain on the surface once the volatile components evaporate. In many cases, these are inert substances; however, they can lead to visual and functional impact on surfaces (see image 3), and the impact of these residues should be evaluated with regard to subsequent cleaning and environmental monitoring activities. "No evaluation has been performed

to ensure that cleaning solution residues do not negatively impact environmental sampling or testing." Warning Letter, July 2, 2008. Therefore it is prudent to incorporate a rinsing strategy into your cleanroom contamination control procedures. This strategy should identify the rinsing agent, frequency of rinsing and specific application procedures. Further, if a rinsing agent other than purified water or isopropyl alcohol (i.e. products that leave no residues) is to be used then consideration must be made to the nature of the residues being introduced from the rinsing agent. Frequency of application needs to be considered on the basis of risk versus reward. Introduction of water or other rinsing agents too frequently, especially immediately following disinfection, may lead to even more microbial control challenges through dilution of the disinfectant before sufficient contact time is achieved for optimum performance or through the presence of too much water, a growth nutrient. Drug manufacturers face a variety of challenges. They must ensure that environmental monitoring data demonstrate a state of sufficient control to prevent adulteration of their product in an environment where the facility design, the personnel who work there, and the contamination control practices employed may contribute to the control challenges. A holistic approach, emphasizing the contribution of each part to the function of the entire complex system, is the best approach to attain the control that drug manufacturers require and that consumers deserve.



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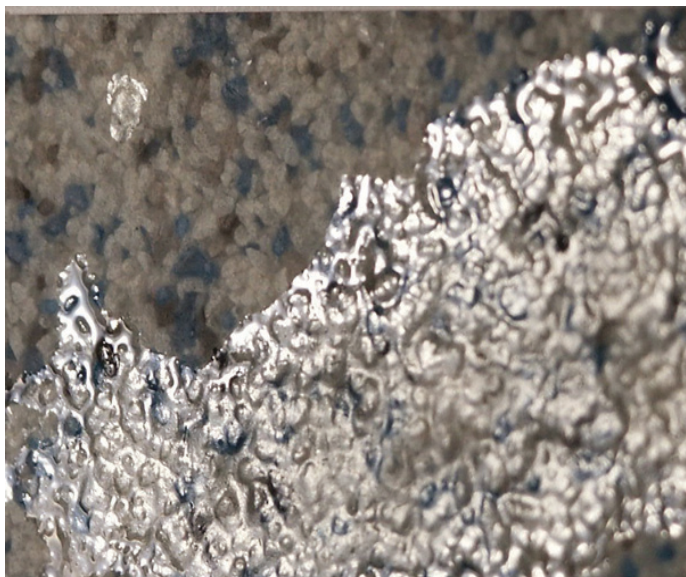


Image 3 (disinfectant residue on epoxy flooring)



Image 4 (disinfectant residue on vinyl flooring)

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Connect 2 Cleanrooms Celebrate Coveted Win at the BIBA Awards 2014 - E Business Award Winner

For the second year running Connect 2 Cleanrooms has won a BIBA Award 2014. Connect 2 Cleanrooms was shortlisted for 4 awards, Entrepreneur of the Year, Employer of the Year, Small Business of the Year, E Business of the Year. Despite very high competition from their fellow finalists they have been awarded with their 2nd BIBA win – E Business of the year 2014.

This prestigious award is a high accolade for elite Lancashire businesses and winning the E Business category is one of the highlights of the year for this company.

Hailed as the ‘the one they all want to win’, BIBA stands for Be Inspired Business Awards and the event is organised by the North West Chamber of Commerce. The awards recognise and honour the breadth of business achievement in Lancashire in all its variety.

Winning the E Business Award for 2014 is a true reflection of just where this company is heading.

Connect 2 Cleanrooms is proud to supply clean air solutions for mission critical environments across all sectors around the world and E commerce is a fundamental part of the business strategy. They continually strive to develop their product range and innovate to

remain the company that customers trust. Their company values do not just tick a box, they are lived and breathed by the whole company – from, inspire, educate & innovate to focus on solution, the company values are there to support the employees and to help customers make decisions that will improve their businesses. The company is certainly on an exciting journey.

“This award is a fantastic win for our company; I am really pleased for the whole team, both those who attended and the rest at home who followed on Twitter. E business is at the heart of Connect 2 Cleanrooms and we continually plan to innovate and develop this important function to offer impeccable customer choice and information within the cleanroom industry.” Says Joe Govier, MD.

With an increasing number of processes getting smaller and cleaner, as this innovative era brings new and emerging technologies, the cleanroom market is forecasted growth. Connect 2 Cleanrooms’ solutions have huge market potential due to their flexibility and quality and the company is positioning themselves to actualise the opportunity presented in this growing market.

The awards ceremony was a glittering event held at the Blackpool Tower and

hosted by Kevin Roberts Global CEO at Saatchi & Saatchi. Highlights of the evening also included a performance by Peter Andre.

Connect 2 Cleanrooms is an industry leader, creating modular cleanroom solutions for critical environments, both in the UK and internationally. The company designs and manufactures bespoke hard and soft wall cleanrooms in-house and delivers quality cleanroom solutions to meet the ISO 14644-1 standard required.

Its consumables division, Cleanroomshop.com, supplies a full range of consumables, equipment and furniture to the cleanroom industry worldwide.



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Endress+Hauser inaugurates a new 80,000 square feet state-of-the-art Customer Center in Greenwood, Indiana.

Endress+Hauser adds value for its North American customer base through continuous investments in US infrastructure

Endress+Hauser inaugurates new Customer Center

Endress+Hauser inaugurates a new 80,000 square feet state-of-the-art Customer Center in Greenwood, Indiana. This 16 million dollar investment in infrastructure helps to optimize customer support and further underscores Endress+Hauser's commitment to the US market and its loyal customers in the Americas.

Over the past few years, Endress+Hauser has continued to grow its market share in the United States and around the world. This growth is due to the high degree of trust customers have in Endress+Hauser to make their processes reliable, safe, efficient and environmentally friendly. Endress+Hauser answers to this development with sustained investments into US infrastructure which allows the continual strengthening of its market presence. "We want to be close to our customers providing the best possible support," underlines Matthias Altendorf, CEO of the Endress+Hauser Group, adding: "Our investments reflect both our commitment to customers in the process industry and our promise to sustainably generate outstanding value for them."

In the last 5 years, Endress+Hauser will have invested approximately 150 million dollars into its US operations alone in order to expand its flow, level, pressure, analytical and temperature manufacturing capabilities as well as investments in support structures, projects, services and training organizations. This figure does not include expenses related to the recent acquisitions of SpectraSensors, Inc. and Kaiser Optical Systems, Inc., both specialized in advanced analyzer technology.

Added value for customers

Endress+Hauser's dedication to its custo-

mers extends far beyond manufacturing and R&D. Demands on customers for higher productivity in the process control industry isn't changing. Today, customers are faced with an experienced workforce of operators and technicians retiring in coming years which means they will need to train their next generation of employees. Endress+Hauser's customer training program recognizes this trend and has built multiple PTUs (Process Training Units) nationwide to address this complex problem.

To help customers keep up with today's challenges, Endress+Hauser's new, state-of-the-art Customer Center is suited to greet visitors with a top-notch certified training facility with multiple classrooms and its largest yet PTU controlled by Rockwell Automation's PlantPAx system for real-world process simulation with over 120 measuring points.

Todd Lucey, Managing Director of Endress+Hauser Sales Center USA, believes that one of the keys to market success in the US is owed to heavy investments made in customer training - the new Customer Center being one of them. "Customers can send operators, maintenance personnel, engineers and other process people to our new Customer Center to get hands-on, real-world application expertise in a state-of-the-art customer training facility," he said, adding: "Customers are increasingly faced with process

and business issues and they can't get this type of unique training anywhere else."

Investments made in building the new facilities were to help stay ahead of increasing customer expectations. "5 to 10 years ago we had a handful of products at a typical customer plant site and the customer expected us to deliver high quality instruments," said Lucey. "But today, the whole plant is full of Endress+Hauser instruments so expectations are considerably higher on us in terms of our capability to support them and help solve complex customer problems. Frankly, the more complex problems we solve, the more complex problems we get from our customers which is really the position we want to be in - and we look forward to that challenge."

The Customer Center allows Endress+Hauser to provide additional, tailored service and support to its customers, for example with factory acceptance testing. Training, repair, and calibration are now stationed under one roof for faster, more accurate and efficient customer service and turnaround - with additional space for increased customer technical support with technicians available around-the-clock to answer customer questions, needs and concerns.

Endress+Hauser AG
CH 4153 Reinach BL 1

Guidelines raise standards for contamination control

Recent guidelines aimed at raising standards of contamination control in the pharmaceutical industry mean organisations need to assess their current practices, that's according to Ecolab Contamination Control, a worldwide provider of market leading products and services for the control of microbial contamination in the cleanroom environment.

A number of the recent guidelines such as the PI 007-6 PIC/S (Pharmaceutical Inspection Co-operation Scheme) 'Recommendation on the Validation of Aseptic Processes', the draft revision to Chapter 5 "Production" of the EU Guide to GMP and the MHRA'S Questions and Answers for Specials Manufacturers, all represent a shift in regulatory expectations against which organisations should assess their current practices.

For example, PI 007-6 highlights the need to use sporicidal agents wherever possible, but particularly for 'spraying in' components and equipment to aseptic areas.

This change means that users should consider a sporicide for transfer disinfection, rather than the alcohol which is traditionally used, but is not sporicidal.

Ecolab Contamination Control already offers an appropriate sporicide through a choice of Premier Klercide-CR Sterile Biocides C and E.

Furthermore PI 007-6 PIC/S and the FDA Aseptic Processing Guide also state that the effectiveness of disinfectants and how they react on different surfaces should be validated.

However, the validation of disinfectant efficacy and time taken to achieve a satisfactory log reduction of the specific in-house organisms on the surfaces used in the manufacturing area places additional demand on internal resources and will require significant technical support.

It is a complex process, but the technical expertise of Ecolab Contamination Control's Global Validation team makes it uniquely placed to support their customers and ensure it is carried out as stipulated.

Additionally, the draft revision to Chapter 5 "Production" of the EU Guide to GMP says the requirement to avoid contamination for all products through the appropriate design and operation of manufacturing facilities, implementation of operational and technical measures commensurate with the risks assessed and controlled through the principles of Quality Risk Management must be adopted.

One way to reduce the risk of contamination in critical product contact areas is with low residue disinfectants and especially with the use of endotoxin tested products.

Ecolab Contamination Control already offers a product range to minimise the impact of residues.

As part of its three step DDE cleanroom cleaning system, which when used correctly will Disinfect, Detect and Eliminate, the firm also provides a full programme to address this risk for the entire environment and reduce the likelihood of product contamination.

In the specific case of product contact areas, both the high grade wipes material and the solution used in them and applied to your surface are endotoxin tested, making them a highly efficient and powerful way to eliminate the risk of contamination in high risk areas.

Meanwhile, MHRA guidance on dispensing systems for disinfectants in cleanrooms states that they should prevent 'suck back', ensuring the integrity of the product is completely protected throughout its entire use and not simply at the manufacturing stage. In addition, PI 007-6 also highlights the requirement for disinfectants and detergents used in Grade A and B areas to be sterile at the time of use and not simply prior to use, as has previously been the case.

Both these requirements support Ecolab Contamination Control's unique SteriShield Delivery System (SDS), the only validated trigger spray system on the market which creates a fully closed system, preventing air entering the bottle.

Research has proved that conventional trigger sprays used with cleanroom disinfectants do suck back air, meaning the contents of the bottle can be contaminated from the first moment of use, leading to a spread of contamination around the cleanroom.

The fully validated protected trigger spray operates as a closed system due to the vacuum created in use, with the dip tube providing the only point of exit from the bag of sterile liquid, which protects the sterility of the contents indefinitely, with a recommended best practice in-use shelf life of three months.

As well as these latest guidelines, Ecolab Contamination Control acknowledges that the risk is not restricted to the point of manufacture and can be further spread to any and all component parts of the process.

The draft revision to Chapter 5 "Produc-

tion" of the EU Guide to GMP states that the quality requirements established by the manufacturer should be discussed and agreed with the suppliers. Appropriate aspects of the production and control, including handling, labelling, packaging and distribution requirements, complaints, recalls and rejection procedures should be documented in a quality agreement or specification.

For the first time, suppliers of starting materials must have fully audited processes in place which match those of their customers and that the level of supervision should be proportionate to the risks posed by the individual materials. This takes into account their source, the supply chain complexity, the final use to which the material is put in the medicinal product, as well as the manufacturing process.

Put simply, the quality of supplier and the manufacturing process is more critical than ever and customers need to ensure that suppliers are audited and validated, to provide the necessary level of assurance.

Ecolab Contamination Control is so confident that its own manufacturing processes match those of its customers, it has recently introduced the Process Match assurance mark, something which is unique in the market place.

James Tucker, Marketing Director at Ecolab Contamination Control says: 'Our fully validated sterile product range for use in the cleanroom environment is manufactured in our own purpose built cleanroom, under conditions which match those of our customers, a fact highlighted by Process Match.

'We also provide high levels of technical support, including product technical files, support for efficacy studies, as well as training and seminars.

'As a business we understand the advantages and constraints of working to GMP and as such are the ideal partners for the supply of cleaning and disinfection products and the related equipment, to help both new and existing customers deliver contamination control without compromise.'

For more information email: infoc@ecolab.com or call +44 (0)2920 854 395.



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Au terme de trois journées marquées par les innovations technologiques et de nombreuses opportunités de réseautage, le plus grand salon suisse de la technologie a fermé ses portes ce soir à Berne. En à peine deux ans, le salon SINDEX est devenu la vitrine du secteur technologique suisse, attirant pas moins de 13 500 visiteurs. Le prochain salon SINDEX se tiendra du 6 au 8 septembre 2016.

SINDEX 2014: un nombre record de visiteurs et des avant-premières très courues

**6 - 8 septembre 2016: SINDEX 2016,
Bern (CH)**

Depuis mardi, Berne a été le rendez-vous de la branche technologique suisse. A l'occasion du SINDEX, le plus grand salon technologique de Suisse, 430 exposants des secteurs de l'automatisation, la robotique et la commande, la technique des fluides, l'électronique, l'électrotechnique, la technique de production, mais également de la formation, de la recherche et du développement ont présenté leurs innovations technologiques et démontré la capacité d'innovation de l'industrie helvétique.

Un programme-cadre bien reçu

Cette 2e édition du SINDEX a débuté mardi avec le Symposium d'ouverture, placé sous le thème «La place industrielle suisse: les facteurs de réussite dans la concurrence internationale». Les intervenants ont plaidé en faveur d'une politique d'innovation de la Suisse. Il faut continuer de s'appuyer sur les points forts du système de formation dual et ainsi renforcer de l'intérieur la place industrielle suisse. Des exposants phares du salon SINDEX tels qu'Annette Heimlicher, CEO de Contrinex, ont réclamé une feuille de route claire en regard de l'application de l'initiative contre l'immigration de masse.

Cette année, le SINDEX a fait œuvre de pionnier en présentant deux nouvelles expositions spéciales, «Vivre la technologie» et «Cleanroom Robotics». Avec l'exposition spéciale «Innovation et formation», celles-ci ont permis de présenter aux visiteurs un programme-cadre exceptionnel qui a rencontré un grand succès. La technologie Beacon a quant à elle été utilisée pour la première fois sur un site d'exposition en Suisse, livrant aux visiteurs des informations complémentaires en temps réel, sur leur smartphone, grâce à l'application @BERNEXPO. Mercredi a vu le couronnement du meilleur professionnel de l'automatisation, distingué dans le cadre du «Grand Prix des automaticiens 2014». C'est Adrian Trachsel, de l'entreprise Deleproject AG, qui a remporté le chèque du vainqueur face à ses concurrents.



Bilan positif des exposants et des organisateurs

Le responsable du salon, Patrick Sägeser, tire un bilan positif au terme des trois journées du SINDEX: «Par rapport à 2012, nous avons eu plus de 100 exposants de plus pour un total de 430 exposants, ce qui a permis de remplir six halles. Côté visiteurs, les chiffres sont aussi en hausse et dépassent même légèrement nos objectifs, avec 13 500 personnes qui ont fait le déplacement.» Selon les exposants, les visiteurs étaient de grande qualité. Rolf Freiburghaus, General Manager de Parker Hannifin Suisse: «Cette édition du SINDEX a permis d'entretenir les contacts existants, mais aussi d'en nouer de nouveaux. De plus, le SINDEX 2014 a manifestement vaincu la barrière de rösti: nous avons en effet eu le plaisir d'accueillir de nombreux visiteurs de Suisse romande à

notre stand, ce dont nous nous réjouissons.»

Autre grand satisfait du salon SINDEX 2014: le partenaire de patronage swissT.net. René Brrugger, président de swissT.net, a souligné les éléments fédérateurs du salon: «Le SINDEX offre la possibilité d'avoir des échanges sur la technologie à tous les degrés de la hiérarchie. De par sa proximité géographique, le salon est accessible tant aux apprenants qu'à leur CTO, ce qui permet de renforcer les connaissances technologiques d'une entreprise dans son ensemble. C'est ce qui distingue le salon SINDEX des autres foires et qui en fait une plate-forme d'échanges inestimable pour la place industrielle suisse.»

Le prochain salon SINDEX se tiendra du 6 au 8 septembre 2016.

BERNEXPO AG
CH 3000 Bern 22

Focus on Braunform MED mold® standards

Braunform as an exhibitor at this year's FAKUMA

**14th - 18th Oct. 2014: FAKUMA 2014
Friedrichshafen (D)**

At this year's FAKUMA, the international trade fair for plastic processing from 14th to 18th October 2014 in Friedrichshafen, Braunform presents itself with the slogan "Welcome to our living room" and welcomes interested visitors on a 50m² booth in a friendly atmosphere.

One focus at the booth number 5207 in Hall A5 is, besides all other Braunform techniques and branches, the specific designed Braunform MED mold® standard for clean room represented by modular inserts of a 96-cav. injection mold for a Pen Hub (needle holder). During the exhibition period, the corresponding high cavity injection mold with a cycle time of 3,9 seconds will be exhibited at the booth of HEKUMA, Hall A7, booth 7305.

The high cavitation injection mold processes the article in a highly automated manufacturing cell under constant visual monitoring. With cores with a diameter of only 0.3mm and 0.5mm the mold is designed according to the latest state of the art. Special attention in the development of the mold was placed on the modular design i.e. the modules are individually centered and (de)mounted externally accessible. Furthermore, the mold cooling is developed to achieve



The booth concept resembles a living room and welcomes interested visitors.

the shortest cycle times, amongst others with vacuum brazing. For the implementation of the complete project the automation specialist Hekuma has developed the high-speed extraction with an acceleration of up to 17G and a camera surveillance system for automatically sorting out rejected articles in case of breaking cores in the mold. Also involved in the realization of the injection mold are the mold shop partners Meusburger, HEITEC and Listemann.

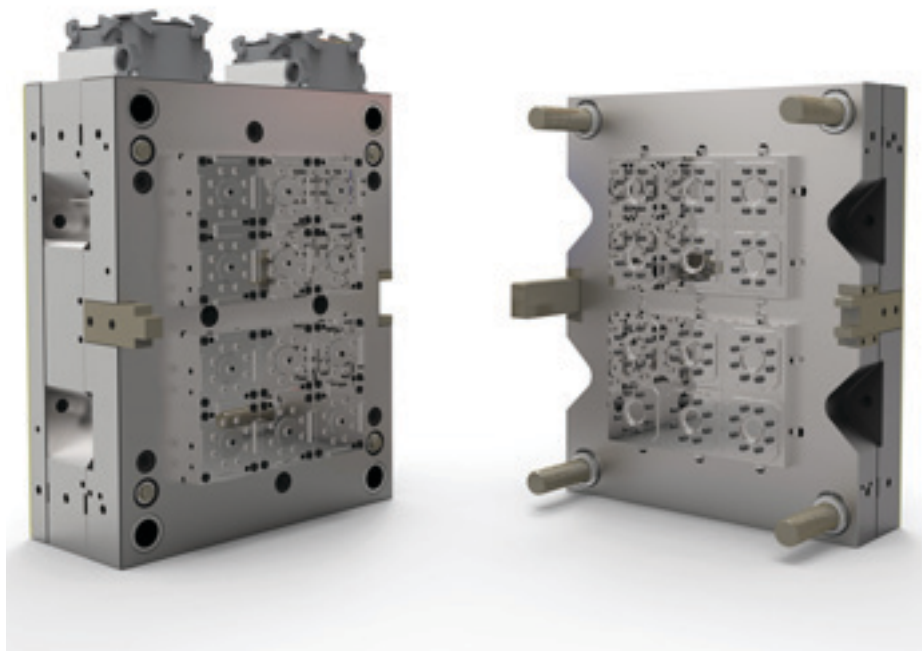
Double award for Bahlinger mold maker "Innovative by research" and "Top Job 2014"

As one of Germany's biggest private academic patron, the „Stifterverband" appreciates Braunform with the seal "Innovative by research". On the basis of an annual elevation, which is regularly carried out on behalf of the Federal Ministry of Research and Education, selected researching companies are awarded regarding their research and development activities and also their invested amount.

As a family managed company the employees are a central pillar in the vision of the company. Therefore it is a great honor for Braunform, to be one of the best employers of the German medium-sized companies (SME), and for that it has been awarded with the „Top Job" Award. „Top Job" mentor Wolfgang Clement honored the company in the German SME Summit in Essen on June 27. This was preceded by an employee survey in regard to employee satisfaction and leadership quality, which was conducted by the Institute for Leadership and Human Resource Management at the University Of St. Gallen Switzerland.

Sustainability has many faces - certification of the Energy Management System according to DIN EN ISO 50001:2011

Braunform pursues ambitious goals of environmental policy and resource conservation for some time, which are strongly anchored in corporate policy. The next logical step took place in December 2013 in form of the certification ISO 50001:2011 by TÜV Süd.



Braunform MED mold® combines process-safe pharmaceutical technology with a 96-fold high-speed injection mold

Braunform GmbH
D 79353 Bahlingen

Gerresheimer will be presenting glass and plastic syringe systems to an expert public on Stand 512 at "PDA The Universe of Prefilled Syringes and Injection Devices" (Hyatt Regency, Huntington Beach, California) on October 6 and 7, 2014.

Gerresheimer - glass and plastic syringe systems at "PDA Universe of Pre-filled Syringes"



© Gerresheimer AG

**06th - 7th Oct. 2014:
PDA The Universe of Prefilled Syringes and Injection Devices
Huntington Beach, California (USA)**

Increasingly complex and varied demands made by the healthcare market - especially physicians and patients - on the pharmaceutical and healthcare industries has driven up demand for different syringe systems. The Gerresheimer Group offers a comprehensive and innovative portfolio of pharmaceutical primary packaging products and is one of the leading experts in the development and manufacture of syringes made from glass and cyclic olefins.

Baked-on Gx RTF 1ml long and Gx TELC - the ideal combination for ophthalmic applications

The inside of ready-to-fill glass syringes is treated with silicone oil to ensure smooth plunger movement and even discharge of syringe content. However, this is associated with the disadvantage that the silicone oil forms fine droplets in the syringe's content. Although these droplets are entirely harmless to the patient when injected, they do in rare cases interact with the medical preparation.

Gerresheimer's baked-on Gx RTF syringe is a pre-fillable syringe with significantly less silicone oil than other syringes. In a patented process, a silicone oil emulsion is applied to the inside surface of the syringe and then baked on to the syringe wall. It provides excellent glide properties and considerably reduces the quantity of silicone oil particles, which makes this syringe ideal for ophthalmic

mic applications.

In conjunction with the Gx TELC (Tamper Evident Luerlock Closure), which is securely mounted on the syringe, this ready-to-fill syringe is perfectly suited to ophthalmic surgery applications. Luer lock adapters allow the user to screw finer needles into the syringe if necessary. The closure has another safety feature in addition to its extremely tight fit: an indicator which cannot be returned to its original position once the syringe has been opened, so that the medical personnel immediately knows whether it has been used or not.

The ophthalmic syringe also has a back stop to ensure that the plunger head cannot be pulled out of the syringe, keeping the medication safe inside. The back stop gives the syringe additional ergonomic handling properties which are an advantage in high precision ophthalmic surgery.

ClearJect 1 ml long version available

Ready-to-fill syringes are manufactured in both glass and COP. The Gerresheimer product portfolio of ready-to-fill syringes for the pharmaceutical sector now also includes the proven ClearJect COP syringes by Taisei Kako Co. Ltd. Gerresheimer is responsible for technical customer services and the marketing of ClearJect TasPack syringe systems in Europe and America.

The ClearJect syringe with needle is available in 0.5 ml, 1 ml, 2.25 ml and 5 ml Luer cone and Luer lock versions, as well as a 1 ml long version. It has a rigid needle shield

protecting a 27 gauge, ½ inch needle.

The ClearJect syringes are injection molded. The 1 ml long syringe with needle differs from a glass syringe in that it doesn't have a glued-in needle. The plastic is actually molded around the needle in the injection molding process, so ClearJect needle tips are adhesive free. Another difference between glass syringe and COP syringe production processes is that the COP syringe has no tungsten pin. As a result, the 1 ml WN (With Needle) syringes by Taisei are particularly suitable for sensitive drug formulations that interact with tungsten.

The ClearJect syringes also satisfy Japanese quality requirements. They are available in ready-to-use format under the TasPack (Taisei Kako Advanced Sterile Packaging) brand name. Customer-specific formats can also be manufactured if required.

COP is highly shock-resistant and break-proof. It also has glass-like transparency with high barrier properties against water vapor and oxygen. Syringes made of COP are therefore perfect as a primary packaging for the sensitive pharmaceutical drugs used in oncology, ophthalmology and other fields of medicine.

Like glass syringes, ClearJect TasPack syringes are packaged and marketed as ready-to-use systems. The rubber components in the ClearJect system (plunger heads and tip caps) conform to current requirements of modern pharmaceutical elastomers and are made of latex-free chlorobutyl.

Gerresheimer AG D 40468 Düsseldorf



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Closing report – International FoodTec Brasil

Successful premiere: International FoodTec Brasil provides strong impetus in the region

The premiere of International FoodTec Brasil, international supplier trade fair for the food industry, which took place in Curitiba, Brazil, closed its doors on Thursday, 7 August 2014 following an excellent event. 81 suppliers from nine countries took advantage of the full 6,595 gross square metre Expo Unimed trade fair grounds to present an information and business platform that was unique for the region. The exhibition covered manufacturing, processing and packaging food with a focus on meat, poultry, fish and cheese. The event, which was jointly organised by Koelnmesse GmbH and Hannover Fairs Sulamérica (HFSA), drew the interest of professionals and high-ranking representatives from politics and business in Paraná. Attracting approximately 3,000 regional and international visitors the trade fair gave a strong business impetus. „International FoodTec Brasil is fully focused on the growing demand for both products and technology in the Brazilian food processing sector,“ says Gerald Böse, Managing Director of Koelnmesse GmbH. „Close consultation with the industry during development yielded a concept that is 100 % suited to the branch requirements. This claim was firmly underlined by the success of the event. We can build on this positive resonance and strategically develop the trade fair further alongside our Brazilian partners.“

**02nd - 04th Aug. 2016:
International FoodTec Brasil 2016
Curitiba (Brazil)**

Valerio Regente, Director of Hannover Fairs Sulamérica shares his partner's enthusiasm: „With its premiere event, International FoodTec Brasil impressively cemented its claim to being the leading business platform for the industry in Southern Brazil. Subjects such as automation, packaging, hygiene and food safety show that technologists in Brazil are really committed to promoting safety, quality and sustainable production in the food industry.“

The trade fair covered the entire spectrum of food technology. Visitors were presented with innovative technologies and latest solutions for processing procedures at all stages in the production of meat and cheese goods. The suppliers on show included top companies such as Bettcher, Ishida, Linco Food, Marel, Middleby, Multivac, Ulma and Vemag.

A number of European companies also made the most of the opportunity to get a foothold in the promising food-technology market in Brazil by participating in the premiere of the International FoodTec Brasil event. Companies such as Cabinplant, CSB-System, Seydelmann, Unitherm and Verinox represent process technologies that are ‚Made in EU‘. The Danish pavilion also piqued the interest of the visitors. This is where firms such as Animalcare, Dybvad Stal Industri, DACS, Engsko, In-Mix Flow Technology, Hans Jensen Engineering and Vikan were showcasing their new solutions. Overall, the proportion of foreign suppliers was unusually high for a trade fair in Brazil, with more than 40 % coming from overseas. This provided buyers from across the whole region with an outstanding order platform.

Visitor services pay dividends

Both exhibitors and visitors at International FoodTec Brasil benefited from the Koelnmesse specialist competence as an international trade fair organiser. It was always certain that the calibre of visitors at the fair was going to be high following a visitor advertising concept that used business rounds to encourage on-going communication between exhibitors and visitors. The Internet-backed ‚match-making‘ service also made it possible for visitors to the fair to arrange their trade fair visit in advance and at the same time, formulate queries surrounding appointments and offers in a dialogue with the exhibitors. These services were very well received and led to exciting new business contacts being established.

Specialist supporting programme

The demanding specialist seminar programme, organised in cooperation with the Instituto de Tecnologia de Alimentos (ITAL – Institute for Food Technology) and Serviço Nacional de Aprendizagem Industrial (SENAI – National Service for Industrial Training) rounded off the spectrum of International FoodTec Brasil and also provided both visitors and exhibitors with further relevant information and a number of synergies. There was a focus on subjects surrounding the influences and trends of the meat and packaging markets, with a look ahead to 2020.

Luis Madi, Director of ITAL, pointed out: „Brazil plays an important role as a producer and exporter of meat, poultry and dairy products and is on a level playing field with the very best on the international market. International FoodTec Brasil provides the market with the right platform for us to benefit from.“

Impressions from the trade fair

The outstanding impression made by the organisers and the positive turnout reflect the excellent mood of the suppliers, who were more than happy with the way the trade fair played out. A large number of companies reported on high-quality business contacts that they had established and direct conclusion of contracts by new costumers.

Ulma, a packaging machines manufacturer of loading and unloading robots, present in this first edition of the International FoodTec Brasil is very optimistic. „The level of visitation is similar to fairs already consolidated,“ said José Segovia, director of the multinational company Ulma based with its headquarter in Spain. He says that the market was in need of an event like this where customers could visit them with comfort. „During the show we established new partnerships and met customers in order to follow up on existing projects and verify new technologies. We support this event and its organizers in order to become the largest one in the industry,“ he concludes.

At the booth of Bettcher do Brasil, CEO Edson Bittencourt celebrates the good results that the company had during the fair due to the quality of the attendees. „Being it the first edition of International FoodTec Brasil, we didn't expect that qualified visitors beforehand, but we were surprised,“ he says. According to him, since the first day, the Bettcher booth had very good visits both in quantity and quality. „I can say that this fair is already at the level of visitors similar to fairs already established in the market.“ He believes that the high potential of anchor companies that are exhibiting is one of the factors responsible for this high rate of visitors. „The result that we are having surpasses the expected. Our customers are happy to visit the event“ he celebrates. Bittencourt also

Successful premiere: International FoodTec Brasil provides strong impetus in the region

talked about market trends on his field. „I have noticed that in recent years companies have sought to perfect the deboning process and utilization of meat increasing productivity and generating products with added value,“ he says.

World leader in processing beef, mutton and poultry, and a strong competitor in the production of pork, JBS attended the business rounds at International FoodTec Brasil. „In the pre-scheduled meetings we've looked for partner companies that would like to grow with JBS, to offer advanced equipment and first-line products primarily related to industrial products,“ comments Alessandro José Baldissera, responsible for the Mercosur supplying area. „In the business rounds we have a chance to explore new opportunities, something that is not possible on a

daily basis,“ he says. In Brazil, JBS has twelve distribution centers for the operation of beef. Besides the new structure in São Paulo, the company has distribution centers strategically located in Porto Alegre, Itajaí, Rio de Janeiro, Belo Horizonte, Salvador, Recife, Fortaleza, Brasília and two units in Curitiba.

Cristián Ciancio, Managing Partner of Baci, an Argentinian company representing brands like Tecmaes to Argentina, Chile and Uruguay: „I usually visit several trade shows and the choice of Curitiba for holding International FoodTec Brasil was the right one, because the region has an excellent location, infrastructure access and it is suitable for business development. The quality of the brands exhibiting here, even though the show is making its debut only, makes its potential already clear.“

International FoodTec Brasil in figures

81 companies from nine different countries participated in International FoodTec Brasil 2014, which took place on trade fair grounds that measured 6,595 gross square metres. This included 44 exhibitors and 4 additionally represented companies from Brazil as well as 33 from abroad (including 23 suppliers from Europe). Estimations including the last day of the trade fair suggest that approximately 3,000 professional visitors took part in International FoodTec Brasil.

The next International FoodTec Brasil takes place from 02.08 to 04.08.2016 in Curitiba, Brazil.

Koelnmesse GmbH D 50532 Köln

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- Special theme for the first time: Energy-efficient data centres – sustainable solutions for air-conditioning
- Energy inspections of air-conditioning and room ventilation systems

Chillventa is continuing its success story in 2014 and entering a new era of growth when it comes to exhibitors and exhibition space. In just a few weeks, the world's largest international trade fair for refrigeration, air-conditioning, ventilation and heat pumps, with around 1,000 exhibitors, will be starting. The event actually starts on Monday, 13 October 2014 with Chillventa Congressing, the know-how highlight. On Tuesday, 14 October, the trade fair will then open its gates for three days. In addition to top innovations in the halls there will also be plenty of exciting special presentations, as in previous years.

**14th - 16th Oct. 2014:
Chillventa 2014, Nuremberg (D)**

Special presentation: Energy-efficient data centres

Growing volumes of data, increased demand for energy, volatile energy sources and the resultant rise in energy costs plus planning uncertainties are presenting major challenges for the operators of data centres worldwide. The special presentation „Energy-efficient data centres – sustainable solutions for air-conditioning“ will be taking place in a specially designated area in hall 7, with a focus on sustainable solutions. Here companies from the air-conditioning, ventilation and heat pumps industries will be presenting themselves and their products. Areas covered will include precision air-conditioning for data centres and server rooms, planning companies for designing new data centres and modernising existing ones, efficiency and GreenIT plus the topic of heat recovery.

Special presentation: Heat pumps in commercial and industrial use

The special presentation on heat pumps focuses on the hybrid generation of heat and cold as a future energy use for commercial and industrial applications. The possibilities and solutions for saving energy through the use of heat pumps will be presented on a special area. The focus is on presenting the advantages of heat pumps in comparison with other methods of heat generation, using the hot and cold side at the same time. This special presentation will be shown in hall 7 within the Heat Pump Area. Nearby, companies from the air-conditioning, ventilation and heat pumps sectors will be presenting themselves and their products. The participating firms can exhibit on the special area with their solutions under the relevant headings. The special presentation will be supported by Chillventa's technical partners: European Heat Pump Association (EHPA) and Bundesverband Wärmepumpe (BWP) e.V.

Energy inspection of air-conditioning and room ventilation systems

In practice, the energy inspection of air-conditioning and room ventilation systems according to Art.12 EnEV [Energy Saving Ordinance] is barely known, at least in terms of its practical implementation. The revision of EnEV will make the inspection a general obligation, in combination with DIN SPEC 15240, which is now also in effect. The transitional periods for existing systems have already expired or are about to expire. Within a special area, a training line will be available where visitors can learn about the practical skills that are necessary for the inspection. Temperatures, volume flows, room air qualities and power take-ups will be measured and the mechanical energy state of the system will be evaluated on an actual system.

NürnbergMesse GmbH
D 90471 Nürnberg

Statement by Joachim Schäfer, Managing Director of Messe Düsseldorf GmbH on MEDICA 2014 in Düsseldorf

**12th - 15th Nov. 2014: MEDICA 2014
Duesseldorf (D)**

Medical technology is and shall remain an export hit. The German medical technology industry makes more than two-thirds of its revenue through the business with buyers in other countries. Above all, the medical advancement, the growth of the middle class in emerging countries, an increase in diseases of affluence, which are also present and unchanged in the industrial nations, as well as a total rise of the older population represent constants for the lucrative health business. Furthermore, with regard to medical technology and medical product demand, it results in a positive effect that certain countries undertake great efforts to establish themselves as a destination for health tourists. For example, this applies to destinations such as Saudi Arabia, the United Arab Emirates (UAE), Thailand, Turkey, or also Tunisia.

Independent from positive growth forecasts considered over the long term, the market climate has not been marked by such much euphoria as was the case just a few years ago. The majority of business volume is still determined by state health expenditures and is marked by forced budgetary cutbacks. This is because, with regard to this issues, markets in other countries are not significantly different to the German market. In addition, exchange rate risks are also involved, whereby currently, the European suppliers are primarily fighting the strong value of the euro.

All in all, the innovation orientation is at least on the rise. Even in emerging countries, the demand volume is growing and there is less based on a rise on increased volumes of supply, but driven by targeted investment in modern systems and processes. With regard to this issue, necessary instruments for minimally invasive surgery or also other equipment for medical imaging have to be mentioned.

Therefore, the medical technology manufacturers are particularly at an advantage. Those that do not neglect their own research and product development and can clearly highlight the additional benefit of new generations of equipment and processes have the best cards on the market.



Joachim Schäfer, Managing Director of Messe Düsseldorf

MEDICA: Success generates inventiveness

For the trade show and event business, the innovations and continual “product care” also represent crucial factors for success. Even very successful events are regularly subjected to a “checkup”.

In this way, the MEDICA in Düsseldorf has already claimed to be the world’s largest medical trade show. Most recently, with more than 4,500 exhibitors and over 130,000 professional visitors, it is undisputedly the leading market and information platform at an international level. More than half of the visitors and three-quarters of the exhibitors come from abroad, whereby the quality of the visitors is very high. 95 percent have decision-making authority. This high value with regard to visitors explains why 96% of MEDICA exhibitors are extremely satisfied with regard to their business success due to their trade fair participation and the contacts that have been generated.

The “vital signs” are just right and so that it stays that way, product ranges in the trade show and the accompanying congresses are continually revised and adapted to changed requirements of the visitors.

Seeing that in previous years the new forms integrated into the trade show had been initiated successfully and the internationalization of the points in the program

with many English-speaking presentations had been promoted – these include the MEDICA TECH FORUM or also the relaunch of the MEDICA HEALTH IT FORUM – it was also important to subject the MEDICA congress program to a far-reaching “live-cell therapy”.

The MEDICA Congress was changed into the MEDICA EDUCATION CONFERENCE. The focus on key topics was intensified while building up the international part of the program, offering seminars in the English language.

“Live-cell therapy” continues – DGIM a new conference partner

As of this year, another “step” of the indicated “live-cell therapy” is on the move. A new addition was made with the German Society for Internal Medicine (DGIM), as a renowned partner for the further development of the MEDICA EDUCATION CONFERENCE program. With its network of 23,000 members, DGIM is closely networked in the fields of science, medicine and health services on a European-wide basis. Since its founding in 1882, it unites all scientists and physician that are active in the field of internal medicine under a single organizational umbrella.

Under the motto, “Science Meets Medicine”, the content orientation of this year’s MEDICA EDUCATION CONFERENCE is providing a thematic integration between the conference program and what the trade show offers, represented by the medical technological innovations of the MEDICA exhibitors. Thereby, it has to do with asking the central question of which concrete values result to doctors and patients from using the latest procedures in clinical routine.

The broad field of medical imaging provides the best examples of this. The latest generation of equipment, such as ultrasound systems primarily leads to valid diagnosis assessment when the forms of interpretation of the doctor using the equipment are in tune with the advancements in technical development.

The other days with special themes of this year’s MEDICA EDUCATION CONFERENCE on “telemedicine and robotics” or also “interventional medicine”, among other things will also shed light on the opportuni-

Statement by Joachim Schäfer, Managing Director of Messe Düsseldorf GmbH on MEDICA 2014 in Düsseldorf

ties of using technical innovations.

With reference to the conference program, being oriented toward those interested belonging to important target groups, MEDICA is also ensuring that what is being offered is also linked with the topics presented at the trade show. An example of this includes the 37th German Hospital Day, a leading event for the directors and management of German hospitals that, in addition to current political topics, sheds light on the topic of "tangible issues", e.g. aspects of human resources and hospital IT.

There are two more conferences that also represent this. Each of them had their highly respected debuts last year and shall be continued this year: The conference for disaster and military medicine, DiMiMED, as well as the MEDICA MEDICINE + SPORTS CONFERENCE, all on the issues of prevention and sports medicine treatment concepts. It has to do with conferences held in the English language that are geared for an international audience.

This year, the MEDICA PHYSIO CONFERENCE, organized by Thieme, is new in the program this year with treatment-oriented talks for the professional scene of physiotherapists emphasizing the treatment of pain and sports physiotherapy.

Forums and trade show

In close connection with the MEDICA presentations of the exhibitors and the MEDICA conference program, significant trends also convey the numerous forums that are integrated in the trade show. These include MEDICA HEALTH IT FORUM (IT trends, telemedicine/hall 15) and MEDICA TECH FORUM (political, economic and legal framework conditions in the field of high-tech medicine) with English-language presentations respectively, MEDICA PHYSIO FORUM (on professional and treatment-related questions for physiotherapists/hall 4) as well as Messe Düsseldorf and the „Techniker Krankenkasse“ (TK, a German health insurance company) along with MEDICA ECON FORUM jointly initiated by both (hall 15) on issues of benefit assessment and funding innovation, primarily from the perspective of patients and cost bearers.

In the middle of November, more than 4,500 exhibitors from around 65 nations will in turn use MEDICA 2014 in order to present the entire spectrum of new products, services and procedures to raise efficiency and quality in outpatient and in-patient care on almost 116,000 square meters of booked floor space.

Clearly structured according to hall, focuses of the MEDICA trade show include:

Electromedicine/medical technology (more than 2,500 exhibitors), laboratory technology/diagnostics, physiotherapy/orthopedic technology, commodities and consumables, information and communication technology, medical furniture and specialist furnishings, and building technology for hospitals and doctors' offices.

MEDICA reveals trends – innovations for the entire workflow

A central strength of the MEDICA is that it not only deals with solutions for individual medical specialist disciplines at a single place and a single time, but for the complete "workflow" of patient treatment.

In reference to product developments, the advancements made, for example, in imaging technologies are impressive. In the meantime, ultrasound devices of the best class offer a resolution and, at the same time, contrast with a penetration depth that would have seemed unimaginable just a few years ago. First systems even had built-in "anatomic intelligence" consisting of an integrated database with anatomic structural models. In this way, better balance can be achieved if the transducer does not sit entirely right. Advantages also result in the creation of tomographies. As a result, an image quality is achieved that is suitable for the high requirements of cardiology.

As a further crucial trend in light of the innovations of the MEDICA exhibitors, the advancement of digitalization and automation in the operating room can be accounted for. Altogether, information and medical technology continue merging with each other more and more. In high-tech operating rooms equipped with the state of the art and so-called hybrid operating rooms (with equipment for medical imaging "on the spot"), surgeons can fall back on a continuously growing number of systems that can facilitate intervention and patient monitoring and even be able to assist in the process. Here, the circle is complete with regard to presentations on "telemedicine and robotics" as well as "interventional medicine" at the MEDICA EDUCATION CONFERENCE.

However, the last few years a few years back may have been seen as failures when robots – in the case of hip operations for example – had guided the incision with the scalpel entirely on their own. In the process, the error rate was simply too high. Nevertheless, robotics have paved their way into the field of medicine. Systems that are established include those that are computer-based on the basis of data of medical imaging and a defined planning and marking of the "target area" before intervention that navigate

surgeons very precisely, controlling incision. There is already a special 3-D x-ray system for clinical use that had been presented at MEDICA in 2012 as a research project entitled ORBIT. It made intraoperative imaging during operation possible (e.g. control scans). For this, the intervention did not have to be interrupted for a long period of time. This is because the x-ray detector and source are independent from each other on the operating table and secured in such a way that access to the patient remains constant. The scan takes place in a fully automatic fashion. It is sufficient enough beforehand for the operator to guide the x-ray head over the area where an image should be taken later.

Medical technological equipment in the operating room is increasingly networked with one another and can exchange required information among each other or between the hospital operating system for intervention or for creating documentation. The various equipment can be centrally controlled by (touchscreen) panels that are easy to operate.

Marching on: "Wearables"

Furthermore there is already a conceptual approach on how data glasses ("Google Glass") could optimally support surgeons in connecting to patient monitoring systems on the heads-up display, showing the most important vital signs.

By the way, wearables: Advancements in the field of sensor systems, material development, energy storage, and chip technology are motors for growth of this diagnosis and communication "all-rounder" used close to the body. The spectrum of current technology developments ranges from a chip-sensor band-aid to determining specific body parameters by connecting to a smartphone app, all the way to contact lenses that analyze blood sugar content, transferring this information using radio technology.

The Wearable Technologies Show being held in hall 15 communicates to MEDICA visitors a fine selection of wearables that possess a lot of market potential from a medical perspective. Apart from that, light will be shed on interesting aspects in even more detail at the MEDICA MEDICINE + SPORTS CONFERENCE (in the Congress Center Düsseldorf/ CCD South). For example, many athletes use so-called "Activity Trackers" that generate a plethora of data. Which data is relevant in terms of preventive or therapeutic measures from a medical standpoint? And: Which standards do the data have to comply with in order to be able to be used by doctors at all? The conference presentations and discussions are going to clarify such questions.

Statement by Joachim Schäfer, Managing Director of Messe Düsseldorf GmbH on MEDICA 2014 in Düsseldorf

Suppliers as important pacesetters for innovations

Those that would like to stay up-to-date on what is currently trending in the professional scene and above all, to what extent the suppliers in cooperation with the medical technical industry drive on medical advancement. This is also a reason that a visit to COMPAMED 2014 is worthwhile. Within the scope of the international leading platform for suppliers, around 700 exhibitors are presenting their technological and service solutions for use within the medical technological industry – from new materials, components, primary products, packaging and services, all the way to complex custom manufacturing.

Here, microsystem technology solutions for mobile diagnosis, monitoring, and therapy systems are particularly trendy. With reference to the “wearables” mentioned earlier, specialist suppliers deal, for example, with how the required technology can be best integrated into clothing. Thereby, there are numerous challenges to tackle: In this connection, wearable textiles must furthermore be stretchable without losing contact and should also be sufficiently robust for care.

In the meantime, the technical requirements for this are fulfilled by tiny sensors, flexible and stretchable substrates made of silicon, polyurethane, polyimide, or textiles that can accommodate electronic assemblies over a wide area, as well as miniature connection technologies, energy efficient

communication electronics and high-performance energy storage that can be wirelessly charged, among other things.

This unique combination allows MEDICA and COMPAMED to represent the entire process chain and the full range of medical products, devices and instruments. Together, they fill the whole Düsseldorf trade show complex (19 halls).

In 2013, the two fairs welcomed a total of 132,000 trade visitors, almost 17,000 of whom were particularly interested in the topics covered by COMPAMED.

As in previous years, it is possible to visit both events with a single ticket.

Messe Düsseldorf GmbH
D 40001 Düsseldorf

POWTECH from 30 September to 2 October 2014 in Nürnberg is a must event for anyone wanting to find out how to really handle powder and bulk solids. At the World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids, over 700 exhibitors from more than 25 countries show cutting-edge technology for mixers, mills & co. The large international involvement and the many new products make the trade fair the undisputed number one bulk solids event for process engineers from many industries all over the world. A visit to the parallel TechnoPharm, the Trade Fair for Life Science Process Technologies, is also worthwhile, especially for engineers from pharmacy and the food industry.

POWTECH 2014: powder and bulk solids technology en masse

**30th Sept. - 02nd Oct. 2014:
POWTECH 2014, Nuremberg (D)**

“We’re looking forward to three productive days at the exhibition in Nürnberg,” says Willy Viethen, Director Exhibitions for POWTECH and TechnoPharm at Nürnberg-Messe. “The hustle and bustle in the halls will be highly international again. Many exhibitors also bring innovations. These are exactly the ingredients that have made POWTECH the world’s biggest and most exciting shop window for processing and handling powder and bulk solids for years.”

This year too, POWTECH offers a 360-degree view of current worldwide processing, analysis and handling of powder and bulk solids. Nowhere else can process engineers from the fields of chemicals, pharmaceuticals, food and feed manufacture and processing of mineral source materials obtain such a comprehensive overview of new products for milling, mixing, screening, dosing, conveying and weighing. Every third exhibitor at the trade fair is an international firm. The POWTECH exhibitors travel from a total of more than 25 countries and from four continents. Over 200 other exhibitors at the parallel TechnoPharm supplement the range of products with the latest process technolo-

gies for production in a sterile environment.

An industry between CO2 footprint and automation

We constantly hear that the powder and bulk solids industry is not characterized by particularly large innovation changes. But the exhibitors at POWTECH present many new products every one and a half years. More than a third of the exhibitors in 2013 said they presented an innovation. Over 100 new products have also already been announced for autumn 2014. Nürnberg shows that processing technology is not available off the peg. Every powder and every bulk solid imposes different challenges on the technology.

“What makes POWTECH so unique is that here you find engineers with very specific solutions,” says Viethen. “The exhibitors are prepared to tailor their solutions exactly to the customers’ requirements. Here in Nürnberg specialists talk to specialists in order to solve apparently insoluble problems.”

Nevertheless, some general trends can be recognized. Popular topics at the moment are energy efficiency, CO2 footprint and system retrofitting. Analysis and automation are also penetrating increasingly deeper into processing technology processes. Today hardly any system can manage without reci-

pe management, batch control and transparent tracking and tracing. It is therefore not surprising that the world-leading providers of field instrumentation or process control systems too have presented their products at POWTECH for years.

Also very interesting: almost a quarter of the POWTECH exhibitors offer analysis. This large number of exhibitors reflects the outstanding role of analysis in powder and bulk solids processing. Optimized process control and, of course, the pressure of quality and cost are the main drivers of particle analysis in or at least close to the process. Some 150 exhibitors at POWTECH provide probably the world’s most comprehensive overview of various analysis systems for powder, granule and bulk solids technology.

Highlights of supporting programme

This year’s product spectrum is supplemented by a broad-based supporting programme at POWTECH and TechnoPharm. Well-known experts from the industry provide information on the latest trends in processing powder and bulk solids in over 60 presentations.

NürnbergMesse GmbH
D 90471 Nürnberg

Innovative packaging solutions in plastic and glass

Gerresheimer at CPhI 2014

Gerresheimer will be showcasing innovative glass and plastic packaging solutions for the pharmaceutical industry in the Innopack exhibition area at CPhI Paris from October 7 to 9, 2014. The comprehensive product range extends from simple pharmaceutical vials to complex drug delivery systems. Two Gerresheimer experts will also be giving presentations on ready-to-fill sterile syringes on October 7.

**7th - 9th Oct. 2014: CPhI trade fair,
Paris (F)**

This year's CPhI venue is the Paris Nord Villepinte Exhibition Centre. Gerresheimer's booth is number G55 in Hall 2.

Syringe systems

Increasingly complex and varied requirements of the healthcare market - especially physicians and patients - on the pharmaceutical and healthcare industry have driven up demand for different syringe systems. The Gerresheimer Group offers a comprehensive and innovative portfolio of pharmaceutical primary packaging products and is one of the leading experts in the development and manufacture of syringes made from glass and COP. One of its flagship product lines is the Gx RTF sterile syringe systems.

The qualities of these syringe systems will be highlighted by Bernd Zeiss, Technical Presales Support Manager at Gerresheimer Syringe Systems, in his presentation at 3 p.m. on October 7. He will also be explaining why the syringe systems are ideal for biotech and ophthalmology applications, and for home use.

Customized plastic systems

As a full-service provider, Gerresheimer Medical Plastic Systems has a portfolio covering all stages of the development and production process. It develops complex, customer-specific plastic systems for pharmaceutical and medical technology applications. Drug delivery systems enable simple and fast medication administration. Inhalers, pens and syringes are examples of plastic drug delivery systems. Gerresheimer also manufactures and assembles components for a range of laboratory analysis systems and tests performed at medical practices and in hospitals, as well as skin-prick aids and lancets for diabetics.

Plastic containers and closures for solid and liquid pharmaceuticals

Gerresheimer Plastic Packaging specializes in plastic packaging products for the



pharma industry. Its multifaceted product portfolio extends from plastic packaging products for solid pharmaceuticals such as drugs and powders to containers for liquid drugs, including ophthalmic and rhinological applications.

It also manufactures a special product for parenteral drugs called the MultiShell vial, which is made of COP (Cyclic Olefin Polymer). Although the vials have glass-like transparency, they also have a far higher break-resistance than glass, which makes them very safe to use. They are suitable for parenteral medications with a wide pH range and ideal for pharmaceutical drugs and formulations which attack the surface of the glass, causing particles to form.



Glass primary packaging

Gerresheimer plays a leading role in the glass sector as specialist for primary glass packaging made from molded and tubular glass. The Gerresheimer Group manufactures glass tubes and shape them into pharmaceutical vials, ampoules and cartridges in numerous filling sizes and designs for many pharmaceutical applications.

Gerresheimer Moulded Glass manufactures high-quality injection and infusion bottles as well as dropper and tablet bottles of various types, shapes and sizes in glass categories I, II and III.

Gerresheimer AG D 40468 Düsseldorf

Starting 2016: “Pharma.Manufacturing.Excellence.” gets central location at POWTECH

From 30 September the POWTECH and TechnoPharm trade fairs attract process engineers to Nürnberg once again from all over the world. The date of the next event is already fixed: POWTECH, the World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids, and PARTEC, the International Congress on Particle Technology, will take place in the Exhibition Centre Nuremberg from 19–21 April 2016. With effect from 2016, TechnoPharm, which was previously held in parallel, will receive a central position at the heart of POWTECH activity as a focus on “Pharma.Manufacturing.Excellence”. This focus will continue to reflect the entire pharmaceutical process chain and show everything required for the manufacture of solid, semi-solid and liquid drugs. The Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik (APV – International Association for Pharmaceutical Technology) and the VDI-Gesellschaft Verfahrenstechnik und Chemieingenieurwesen (VDI-GVC – Association of German Engineers – Association of Process and Chemical Engineering) will support POWTECH 2016 as honorary sponsors.

**19th - 21st April 2016:
POWTECH 2016, Nuremberg (D)**

“We have intensively tackled the future-orientated organization of TechnoPharm,” says Willy Viethen, Director Exhibitions for POWTECH and TechnoPharm at Nürnberg-Messe. “We see the integration as the natural and logical consequence of developments over the past years. With this decision, we are meeting a longstanding desire of the exhibitors and visitors to integrate the pharmaceutical segment into POWTECH and appreciably increase the awareness among visitors. New halls will be available for POWTECH with effect from 2016. We will use this as an opportunity to establish the pharmaceutical segment at the heart of POWTECH and adapt the structure of the exhibition.”

Clear aim in mind: 1,000 POWTECH exhibitors

The aim of integration is already clear in Viethen's mind: “The trade fair duo has always had almost 1,000 exhibitors. We are now continuing to work on reaching and topping the 1,000 mark.” For this purpose the lists of products and exhibitors as well as the hall allocation have been revised. In the pharmaceutical segment the entire production process has been included. Besides the manufacture of solid drugs, which has always been part of the POWTECH product spectrum, the manufacture of semi-solid and liquid drugs has now been integrated into the product list of the trade fair.

VDI-GVC and APV as honorary sponsors of POWTECH 2016

“We welcome the new exhibition concept and will continue our support as honorary sponsor,” says Prof. Jörg Breitreutz, President of APV. “The pharmaceutical industry remains one of the two most important groups of visitors at POWTECH. I am convinced that the focus on “Pharma.Manufacturing.Excellence.”, the extended list of exhibitors and the valuable knowledge transfer



at the forum at the heart of the exhibition will enable us to establish a top-quality and attractive platform on which the pharmaceutical industry can update on all trends in the manufacture of solid and liquid drugs in a more concentrated and easier way than previously the case.”

“Exhibitors and visitors profit from the integration,” says Dr. Ljuba Woppowa, General Manager of VDI-GVC. “Nowhere else in the world can process engineers obtain such a breadth and depth of information on handling and processing powder and bulk solids in one place. The focus on pharma adds a totally new dimension to the 360-degree view that visitors get in Nürnberg.”

Pharma.Manufacturing.Excellence: what exhibitors and visitors can expect

The heart of the focus on “Pharma.Manufacturing.Excellence” is a high-quality forum – similar to a congress – in hall 4. The forum in cooperation with APV will offer a supporting programme that will bring renowned experts to Nürnberg from all over the world to meet the pharmaceutical industry's need to discuss trends and new developments. Starting in 2016, exhibitors with solutions for GMP-compliant production will

receive centrally located stand spaces at the heart of POWTECH activity. This offers the advantage that visitors must no longer find their way around two events as previously, but only one trade fair. Exhibitors can communicate their products relevant to pharmaceuticals to the broad international audience more easily. In addition, exhibitors who previously only presented their solutions to the pharmaceutical, food and cosmetics industry at TechnoPharm will also have the opportunity to approach other sectors from 2016 onwards.

About POWTECH

POWTECH, the World-Leading Trade Fair for Processing, Analysis and Handling of Powder and Bulk Solids, registered its best result ever in 2013. Nowhere else can process engineers find such a comprehensive overview of technologies for mixing, size reduction, screening, dosing, weighing, conveying and analysing powders, granules and bulk solids – for virtually all industries, including chemicals, pharmaceuticals, food and feed, and processing mineral source materials.

NürnbergMesse GmbH
D 90471 Nürnberg

Compact Moisture in Oil Transmitter

Accurate and Reliable Monitoring of Moisture in Industrial Oils

The EE364 in-line transmitter from E+E Elektronik measures moisture and temperature in transformer, lubricating, hydraulic or motor oils, and diesel fuel. This device can assist in planning condition-based maintenance operations to aid in avoiding equipment breakdown, leading to lowered costs.

Compact moisture in oil transmitter EE364
from E+E Elektronik.
(Photo: E+E Elektronik GmbH)



E+E
ELEKTRONIK

The EE364 can measure water activity (aw) and oil temperature (T), and calculate water content (x in ppm). The readings are available on two 4-20 mA analog outputs and a Modbus RTU interface. The analog outputs can be scaled and configured by the user with the optional converter cable and free configuration software.

The EE364 is pressure rated to 20 bar (290 psi) and features G 1/2" ISO or 1/2" NPT process connection threads. Its compact size and robust stainless steel IP65 enclosure allow for easy integration into demanding OEM applications and harsh environmental conditions.

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Made for mass applications

New Miniature Air Flow Transmitter for HVAC

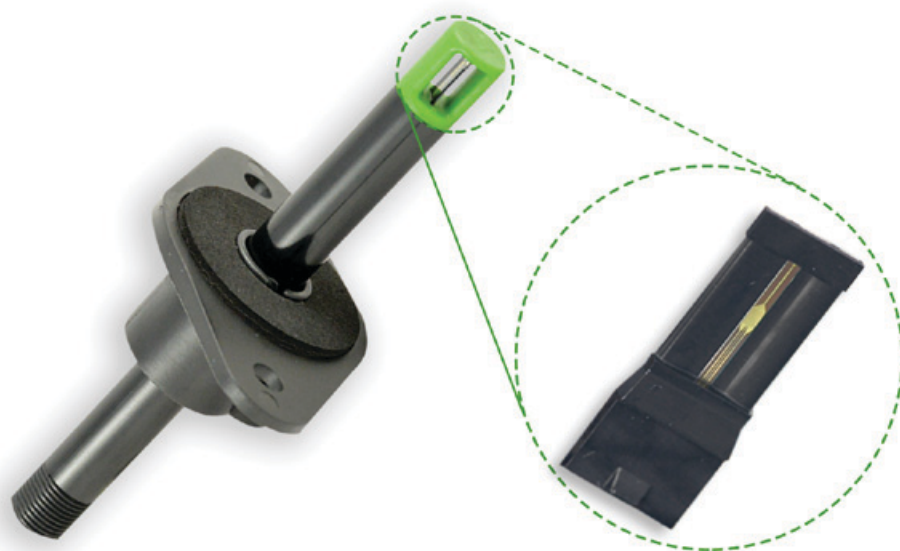
The new transmitter EE671 measures air velocity up to 20 m/s. Thanks to its compact design it is ideal for mass applications in HVAC. The flow sensing element sets new standards in terms of accuracy and resistance to pollutants.

The built-in VTQ flow sensing element based on thin-film technology works on the hot-film anemometer principle. Thanks to its innovative design - made possible by the use of the latest transfer molding technology - the sensor is particularly resistant to contamination. A high reproducibility of the sensor characteristics, fast response time, low angle dependence and excellent long-term stability are further advantages of the high-quality sensing element.

The EE671 is available with cable or plug connection. An alignment strip on the probe and matching mounting flange simplifies installation and ensures proper alignment of the sensor. The flange enables the immersion depth to be infinitely variable.

The measured air velocity is available as linear voltage output (optional 0-1V, 0-5V or 0-10V). The digital interface in combination with a configuration kit allows the customer to set the measurement range, to configure the output signal and to adjust the transmitter.

The EE671 is suitable for use in heating and ventilation systems, for flow monitoring and control or for inlet air monitoring in ovens.



EE671 air flow transmitter for mass applications. (Photo: E+E Elektronik GmbH)

E+E
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Connect 2 Cleanrooms introduce a modular pre-engineered version of the Puracore® cleanroom system to their modular cleanroom range

Connect 2 Cleanrooms Ltd has introduced a modular pre-engineered version of the FM Approved Puracore® Aluminium Honeycomb cleanroom wall and ceiling panel system as an additional structural option to their hard wall modular cleanroom range. The Puracore® cleanroom panel system will be customised by C2C as an off-site pre-engineered version that will bring increased customer choice when planning cleanroom solutions. The Puracore® flush finish enables Connect 2 Cleanrooms to offer a top specification Modular hardwall system that can be customised to include all cleanroom component features including transfer hatches and steel skinned doors.

Joe Govier, Managing Director of Connect 2 Cleanrooms Ltd said, "We are pleased to offer the Puracore® panel system as part of our Modular Range. As the highest FM Approved cleanroom panel manufactured in the UK, we were extremely aware of Puracore®'s high profile in the Cleanroom Market, the ISO 9001 stamp of quality and the capability to tailor the system for our needs makes it the obvious choice as we look to offer our clients a complete range of Modular Cleanrooms.

With its lightweight construction, walk on ceilings and range of pre formed accessories we can ensure that all of our Puracore® based modular cleanrooms will be extremely robust and quick to assemble on site, offering an enhanced cleanroom solution for mission critical environments. We see the introduction of the customised Puracore® cleanroom panel system as a winning option to our modular cleanroom range."

Kevin Gillham, CEO of Gilcrest Manufacturing Ltd (Puracore® System Manufacturer), said, "We are delighted that our FM Approved Puracore® Aluminium Honeycomb

cleanroom panel system has been selected and introduced to Connect 2 Cleanrooms's modular hardwall cleanroom range, becoming utilised by one of the most reputable and experienced modular cleanroom provider in the UK.

As an alternative to on-site traditional installation, Puracore® and all its benefits will now be available to those seeking to have off-site pre-engineered solutions. We see this as a separate market to our established supply chain and we look forward to an ongoing relationship with Connect 2 Cleanrooms."

Company and product information:

The Puracore® High Specification Cleanroom Systems are designed and manufactured by Gilcrest Manufacturing Ltd., specialist panel manufacturer since 1946 and experienced worldwide composite panel supplier based in Bristol (UK).

Puracore® offers a complete fully flush cleanroom system with windows, doors, wall and ceiling panels specifically developed to offer custom solutions for a variety of cleanroom applications and industries. The components of the Puracore® cleanroom panel systems are constantly updated by a specialist in-house engineering team and tailored to current industry needs. The latest innovative addition to the Puracore FM Approved Aluminium Honeycomb system is the 17.5mm Aluminium Honeycomb Lining Panel.

The Puracore® cleanroom systems meet the highest ISO and GMP quality standards required for Class 3-9 cleanrooms worldwide. The Puracore® Aluminium Honeycomb Panel System is FM Approved Class 4882, being the only cleanroom panel manufacturer in

the UK assured by FM Global for the highest level of fire resistance.

The Puracore® cleanroom panel system continues to be specified for major national and international pharmaceutical companies throughout the world.

Connect 2 Cleanrooms Ltd is an award winning industry leader in creating modular cleanroom solutions for critical environments, both in the UK and across the world. Connect 2 Cleanrooms Ltd has worked with many clients focusing on bespoke solutions for leading universities, aerospace and pharmaceutical companies, as well as the vapour market, medical device manufacturers, laboratories and many companies within the electronics and energy sectors.

Connect 2 Cleanrooms designs, manufactures and installs hard wall and soft wall cleanrooms in-house and delivers quality cleanroom solutions to meet the varying gradients of cleanliness (EU GGMP & ISO 14644-1) standards required. All cleanrooms are designed to fit the required environment and can be extended or relocated. Its consumables division, Cleanroomshop.com, supplies a full range of consumables, equipment and furniture to the cleanroom industry worldwide.



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