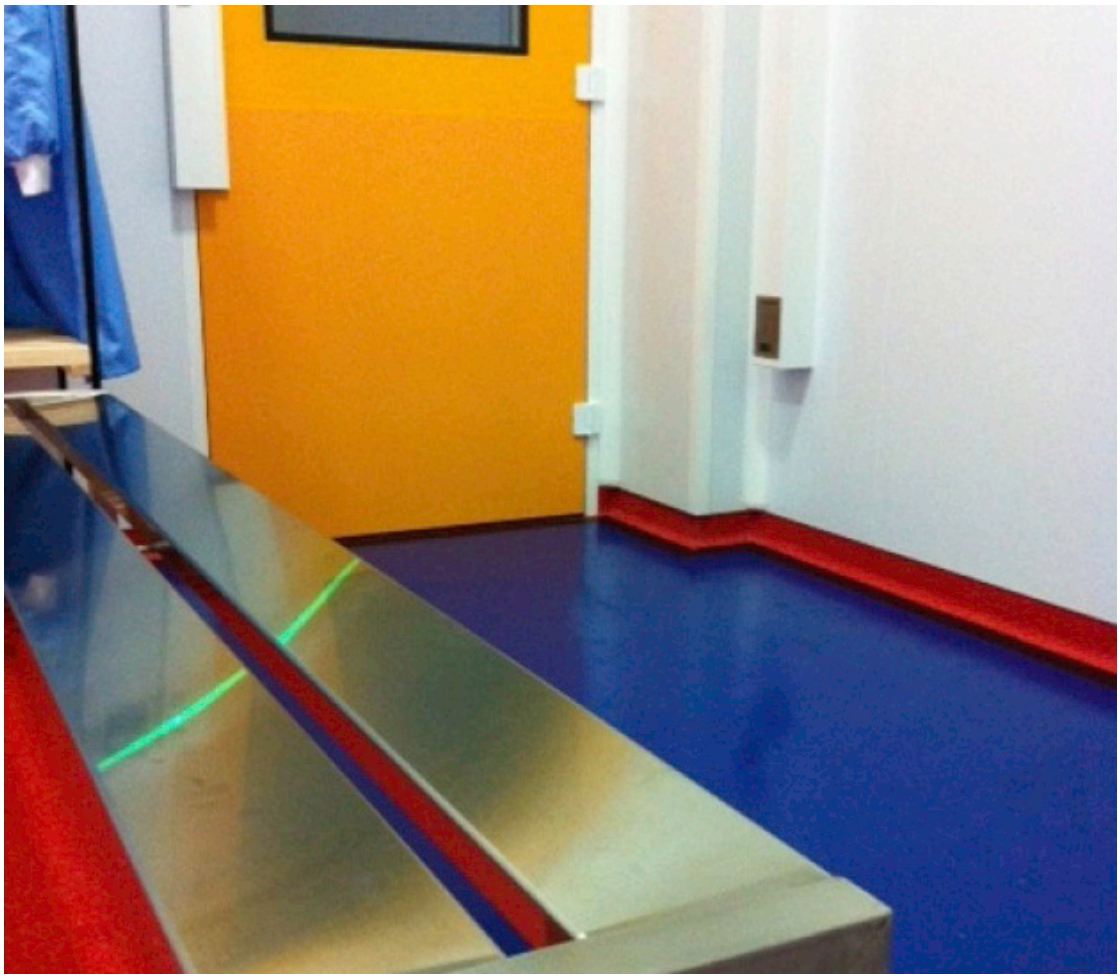
If left untreated, feet and wheels would be by far the biggest source of contamination in a cleanroom.

Permanent tacky mats and flooring, for efficient contamination control



This is why the access to all gowning areas and cleanrooms should include a contamination control system specifically designed to trap footborne and wheelborne particles. Two technologies are widely used by cleanroom managers to trap and retain this contamination : peel-off adhesive mats, and permanent tacky mats or flooring. Both systems show some distinct advantages, calling for a differentiated use according to the situation.

Comparative benefits of peel-off mats with permanent mats

Whereas peel-off adhesive mats are the best option for retaining the bigger particles, permanent tacky mats and flooring are proven to be the most effective option on particles smaller than 5 microns. This calls for preferably placing peel-off mats close to the general / dirtier areas, and to install the permanent mats closer to the cleanroom.

Peel-off mats require no investment, and can be replaced at very little cost if damaged. But over time, they will add up to be a rather costly solution. On the contrary, permanent mats and flooring represent a bigger initial investment but cost very little throughout their lifetime. Over a 3 to 5 years course, which is the typical lifetime of a permanent mat, peel-off mats can cost up to 4 times more than permanent solutions.

Both systems require a regular care to make sure they keep their optimal efficacy. The top layer of peel-off mats has to be removed when it is visibly dirty : cleanroom operators themselves are often entrusted

p. 2 : Permanent tacky mats and flooring, for efficient contamination control

with this easy task, avoiding extra labor cost, but with the risk of an irregular maintenance. An inconvenient of peel-off mats is that they generate a high volume of waste ; according to the local legislation, this can represent a non-negligible hidden cost. On the contrary, permanent mats and flooring require a wet cleaning to retrieve their tacky properties. This operation is usually done by the cleaning crew, and is fully integrated in the general cleaning process of the cleanroom or gowning area.

For reasons of transport and storage, peel-off mats have rather small dimensions. The biggest ones commonly found measure no more than 1,5m in length and 1m in width. This is sometimes too small to correctly cover a high-traffic area, and leads cleanroom operators to stride across the mat without respecting the famous 3-step rule (each foot has to touch the mat 3 times). Permanent mats and flooring allow for a bigger coverage, thus improving the contamination control.

How do peel-off mats and permanent mats work?

Peel-off mats are made of successive layers of polyethylene sheets, each covered with glue. It relies on the adhesive properties of the glue to trap and retain the particles. Even is the glue is evenly spread, on a microscopic level the surface of a layer is quite rough, with peaks and valleys. It explains why peel-off mats are particularly efficient on bigger particles, while smaller particles could stay on the sole of a shoe or on a wheel if they are not in direct contact with one of the peaks. When a layer is visibly dirty, it is peeled off to reveal a new and clean layer.

Permanent mats and flooring rely on a completely different technology. They are made of a proprietary polymer whose main characteristic is to naturally have a slightly tacky surface. This tack is not due to the presence of glue, but to the exceptional flatness of the surface. Such flatness allow for particular physics phenomenons to occur : short-range electromagnetic forces, called van der Walls forces, bind small particles to the surface. Van der Walls forces are strong enough to retain the particles on the surface, despite air movements and further foot traffic. But they are weak enough to be broken by a traditional cleaning with a wet mop. This way, a simple wet cleaning is enough to restore the efficiency of the permanent mat or flooring.

What are the advantages of the b'mat permanent mats and flooring?

The b'mat flooring is intended to cover large areas, and is very often used for wall-to-wall covering. It requires an installation, and the permanent bond to the subfloor means that it can get the best of its very good load resistance, making it compatible with heavy lift- or hand-trucks.

The b'mat permanent mats are intended to cover smaller areas, up to 1,2m x 4m. In order to minimize the investment, and to maximize exploitation of available space, b'mat permanent mats are manufactured to custom dimensions and adapt to each configuration. They feature beveled edges on all 4 sides, and have a very small thickness of only 2,5mm, reducing the risk of tripping and meaning that they usually can fit under door openings.

All b'mat permanent mats and flooring demonstrate high contamination control results, bacteriostatic properties, good chemical resistance, and ESD properties. With a 2-year warranty and a usual lifetime of 3 to 5 years, b'mat is a very cost-effective and long-term contamination control solution for all cleanrooms.

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The map shows where the readers of the cleanroom online newsletter are coming from: if you want to get in contact with these readers please contact us.

Dear readers, dear subscribers,

this is the last English issue of our cleanroom newsletter this year. We are looking forward to the next year – we started some month ago with the international issue and the response was phantastic.
The next months we will work at this communication-platform and optimize the internet, the newsletter and the printline.
If you are interested in adverts, banners, buyers-guide or articles – please contact me.

Yours sincerely

Reinhold Schuster

We wish you a relaxing and peaceful christmas

BEAR Scotland and Vaisala win Highways Magazine's Excellence Award for Highways Industry Product of the Year

BEAR Scotland and Vaisala, working in partnership have won the Excellence Award for Highways Industry Product of the Year, presented by Highways Magazine on October 10, 2013 at the Grosvenor Hotel in London.

BEAR Scotland and Vaisala received the award for the DSP310 Condition Patrol system, an innovative solution to obtain comprehensive, real-time road condition weather data from a mobile automated weather station.

BEAR is a service provider in the Scottish roads maintenance sector and is responsible for the Trunk and Motorway Networks across the North East, South East and North West regions. Vaisala is a global leader in environmental and industrial measurement. Using the latest weather technology designed for Intelligent Transportation Systems, Vaisala's leading weather observation products and decision support solutions help Road and Rail authorities worldwide optimize traffic safety, maintain mobility and improve operational efficiency.

Filling In the Gaps

Vaisala has an established road weather information system in Scotland consisting of weather stations and measurement equipment which are quality monitored in real-time by the company's Birmingham office 24 hours a day, seven days a week. BEAR has access to approximately 120 such weather stations reporting on road conditions and temperature via the Vaisala RoadDSS Navigator web application.

Historically data from the Road Weather Information System has been used to help manage winter salting actions. The data has been collected from static Road Weather stations strategically located across the road network. Following the severe winter of 2010 in Scotland, Vaisala and BEAR have been continuously working to improve the acquisition of more detailed weather data in order to better support decision making in winter weather road maintenance. Solutions were in place to collect temperature data however there were important gaps to fill. More detailed information on the actual road conditions (wet, dry, moist, ice, snow/frost and slush) as well as road slipperiness between the fixed weather stations was still missing.

DSP310 Condition Patrol

Initial work on a solution to acquire detailed surface condition data commenced in 2009 when BEAR began using the BETA version of new mobile technology being developed by Vaisala. Feedback from the initial trials by BEAR fed directly into the Vaisala development process.

Brian Davis, Vaisala Account Manager explains, „We welcomed the opportunity to work closely with BEAR to achieve their goal of obtaining real-time surface state data to support their winter treatment regime. Their feedback on the operational use of DSP310 Condition Patrol was invaluable in enhancing the effectiveness of the solution."

This led to the launch of Vaisala's DSP310 Condition Patrol solution in February 2012, a solution which mounts Vaisala sensors on the vehicle provide real-time monitoring of all road weather conditions. The in-cab display is realized using a smartphone running the Vaisala RoadDSS Navigator Mobile app. The DSP310 Condition Patrol is designed to provide a mobile solution to be deployed to collect critical road surface data at any given point on the network, at any time and viewed through the Vaisala RoadDSS Navigator software platform.

Brian Gordon, BEAR Scotland Managing Director, said: „DSP310 allows BEAR Scotland drivers, decision makers and Control Room staff to have access to data related to the state of the road in real-time across the entire network. This in turn enables faster, more accurately informed decisions and therefore more precise maintenance treatments to be applied during patrols, thus improving the safety of all road users in Scotland."

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Pilz opens a subsidiary in the Czech Republic

Pilz has opened a new subsidiary in the Czech Republic. From the autumn of 2013, the complete supplier for safe automation will be caring for customers in the Czech Republic and Slovakia directly from Prague.

„By establishing our own Czech subsidiary, Pilz is better able to meet the requirements of local customers and provide complete automation solutions with engineering and consulting", explains Renate Pilz, Chair of the Board of Pilz GmbH & Co. KG.

The new subsidiary is based in Prague and is responsible for sales activities in the Czech Republic and Slovakia. Customers include domestic machine builders and users as well as international companies from the automotive and mechanical engineering sectors. The subsidiary will be managed by Michal Nevěřil , who has many years' experience in the automation technology sector in the Czech Republic. A customer support and sales team is there to support him right from the start.

Pilz has been active in the Czech Republic for more than 20 years via a sales partner. With this new subsidiary, the technology leader in safe automation is expanding its commitment in the key Eastern European market.

Pilz GmbH & Co. KG D 73760 Ostfildern

Michal Nevěřil

Laborial wins 2013 Cleanroom Award

The interactive worktop for laboratories Blautouch developed by Laborial was the great winner of 2013 Cleanroom Award. This contest was organized by Reinraum Akademie GmbH, on the subject of the 2nd edition of the Cleanzone, which is an event of worldwide reference regarding controlled environments. The event took place between the 22nd and 23rd of October in Frankfurt.

Among several applications to the award, the product was initially chosen for a group of 5 nominees which were selected by a board of international specialists. The five nominees presented different products, the German Berner International GmbH have exposed "The next generation of laminar flow cabinets"; the German Albany Door Systems GmbH have shown "The first certified clean room door"; the German Curasan AG have shown an "Innovative clean room concept: maximizing energy efficiency and minimizing CO2 emissions by using combined cooling, heat and power for clean room air conditioning", the American CO2Nexus Inc. have presented "TersusTM liquid CO2 clean room laundry solution"; the Portuguese Laborial has shown Blautouch and seized the event to present their solutions in order the audience to vote. The viewers elected Blautouch as the Cleanroom Award 2013 Winner. This award consolidates the position and reputation of Blautouch in the European market, in addition to the innovation prize, on the subject of Contamin Expo 2013, awarded in March in Paris.

Blautouch is an interactive worktop for laboratories which is developed in partnership with Edigma and FEUP, in the course of "Intellab – Intelligent Labs" project, funded by QREN. Blautouch is manufactured with materials which are resistant to the most aggressive disinfectants and reactants. Blautouch is developed according to the most recent guidelines of „hygienic design" and allows the replacement of electronic devices such as computers, keyboards and mice, which represent a major source of contamination especially in highly sensitive areas such as hospitals, laboratories and clean rooms.

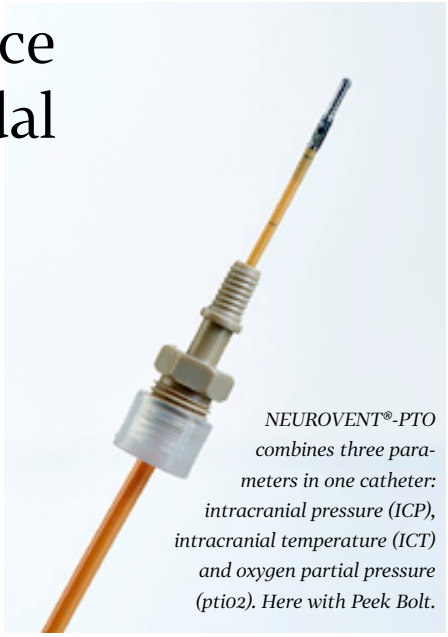
To José Branco, CEO at Laborial, this award „consolidates the international recognition of Laborial's work, which is particularly important in this period related to the recent foundation of the Swiss subsidiary and where increasing sales especially in the European market represents the main aspiration."

Blautouch is currently traded in Germany by Basan GmbH, the clean room company division of VWR group.

Reinraum Akademie GmbH is a German organization of reference in the field of clean rooms, whose main function is to support companies of this segment by optimizing their business processes, by training their managers and also by improving products quality. In this regard the company offers a large assortment of seminars, events and training courses related to clean rooms.

LABORIAL 4475-132 Maia, Portugal

Raumedic Announces FDA Clearance of NEUROVENT®-PTO; a Multimodal Catheter for Monitoring of Brain Tissue pti02, ICP and ICT.



NEUROVENT®-PTO combines three parameters in one catheter: intracranial pressure (ICP), intracranial temperature (ICT) and oxygen partial pressure (pti02). Here with Peek Bolt.

Raumedic, developer and manufacture of innovative neuromonitoring devices is pleased to announce the 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market NEUROVENT-PTO. NEUROVENT-PTO is the only marketed device that combines three parameters in one catheter to measure intracranial pressure (ICP), intracranial temperature (ICT) and oxygen partial pressure (pti02).

Measuring of oxygen partial pressure (pti02) shows the available oxygen in the brain tissue and allows for early detection of cerebral damage to help prevent secondary injury. Cerebral ischemia is the leading cause of preventable death in cases of major trauma with severe traumatic brain injury (TBI).

NEUROVENT-PTO uses the process of 'oxygen quenching' which does not consume oxygen when measuring available brain tissue oxygen and results in a rapid response to environment changes. The NEUROVENT-PTO catheter is pre-calibrated during manufacturing therefore does not require zeroing. NEUROVENT-PTO can be implanted via a low-profile Peek Bolt or using a Tunneling Sleeve. Furthermore it does not require refrigeration storage and has a sterility shelf life of 2 years.

"Our innovative neuromonitoring products have been sold in countries all around the world for over a decade to the benefit of patients and medical personnel. We are very pleased that we now have received 510(k) clearance from the FDA and can continue our market entry in the United States with the unique NEUROVENT-PTO", says Robert Reichenberger, Business Unit Director from Raumedic.

The addition of NEUROVENT-PTO puts the company in the forefront for offering advanced neuromonitoring devices for managing critical care patients. Raumedic's line of NEUROVENT products include microchip ventricular catheters which provide ICP and ICT monitoring with simultaneous CSF drainage and parenchyma catheters which provide ICP and ICT monitoring. All ICP and ICT monitoring catheters connect directly to the patient's bedside monitor eliminating an additional monitor which saves both time and money to medical centers.

Raumedic AG
D 95233 Helmbrechts

Integrated production from the ingot to the module

M+W Group receives order for a photovoltaic plant in Argentina

The global engineering and construction company M+W Group with headquarters in Stuttgart/Germany has won a large contract for design and construction of an integrated 70-megawatt photovoltaic production facility in Argentina. The Schmid Group (Freudenstadt/Germany) as general contractor and M+W Group bid jointly for the contract, and submitted the winning tender. M+W Group is responsible for engineering and construction, installation and project management as part of this important project.

The factory with a surface area of 13,000 square meters is being set up in the state capital of San Juan and will enable integrated production from monocrystalline silicon-ingot to the module from mid-2015. In a second stage of the development, the plan is to expand to include upstream polysilicon manufacture. The state energy supplier of the province of San Juan, Energia Provincial Sociedad del Estrado (EPSE) is awarding the contract.

„We are making an important contribution to increasing the proportion of the energy mix of EPSE generated by solar power. Annual solar radiation of over 2,300 kWh per square meter offers the best conditions for this," M+W Group CEO Jürgen Wild explained. „At the same time, M+W Group can expand its global presence to include one further, important country."

The glass-foil modules to be manufactured in the new factory as from 2015 should be used to supply energy to the gold and copper mines and the irrigation systems in San Juan province. At the same time, further Mercosur states are seen as potential sales markets. The project is among the most important initiatives in San Juan province and is also supported by the Argentine government, which was made clear by the personal visit of Argentina's President Cristina Fernández de Kirchner when the contract was signed.

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Chillventa Rossija takes place from 4–6 February 2014. Many top Russian and international companies have already firmly booked their stand space at the fourth edition of the exhibition. This shows the great acceptance of Chillventa Rossija as one of the sector's most important gatherings in the Russian market. Experts in the Crocus Expo International Exhibition Center in Moscow exchange views on the latest developments and trends in refrigeration, air conditioning and heat pump technology. Chillventa Rossija with its clear orientation to the Russian market is heading for success again in 2014.

Chillventa Rossija looking positively to 2014

- **Market leaders already on board**
- **Industry growing**

Chillventa Rossija is one of the most important gatherings for specialists from the refrigeration, air conditioning and heat pump industry. Innovative technical developments, best practice examples and the most modern equipment are helping to bring the Russian sector up to an international standard. Many answers are found at the exhibition or at the scientific conference, Chillventa Congressing, which the experts praise for its topicality and high quality every year.

Large international involvement

The demand for refrigeration and air conditioning equipment in Russia is satisfied mainly by imports at present. Many leading international companies have already confirmed their presence, including Bitzer, Dorin, Güntner, Karyer, MTH, Promyshlennye Holodilnye Sistemy (PHS) and Thermofin. There are also well-known companies among the Russian exhibitors, such as Thermocool, Complect Ice, Prostor L, Farmina, NSK, Expokholod and Ariada.

The refrigeration industry in Russia

Experts assume that about 3,000 companies in Russia operate refrigeration systems with more than 500 kW refrigerating power. Specialists estimate that about 80 per cent of the systems are in need of modernization, maintenance and energy optimization. The change to refrigerants without ODP and with low GWP values is gaining more and more importance here. In the international market in particular, it is becoming clear that, for example, CO2 is increasingly discussed as a refrigerant in this context and is used in industrial and supermarket refrigeration systems; R717 (ammonia) is also used in industrial systems for direct cooling and for systems with brine cooling. The aim of the Russian government is to steer the whole sector onto a growth course.

Development factors in refrigeration

The development potential of the Russian refrigeration industry is very large. A guide to food security, agriculture and the food industry is helping to increase the focus on energy efficiency. Reducing the emissions of the climate-damaging greenhouse gas CO2 is right at the top of the Russian government's agenda. A state-controlled agricultural development programme has led to a forecast of growth in food production. This will necessitate improvements in refrigeration systems, the development of cold and refrigerated transport and the improvement of quality in cooling, freezing and storage of products in all segments.

A whole industry is growing

The demand for modern refrigeration systems is increasing steadily in Russia. The first steps towards modernization have already been initiated: The Murmansk region and other rural parts of Russia are currently being equipped with efficient and modern refrigerated and frozen food stores, and since then, for example, fish processing centres are also being planned. The foundation stone has already been laid for a network of modern logistic centres with refrigerated and frozen food stores.

The outlook for refrigeration applications is shown by sectors such as information technology. Here innovations in refrigeration and air conditioning are on the advance, triggered by the rising demand for cleanrooms in large IT companies – because they frequently need individual solutions that maintain accurate temperature and humidity. Other examples of the importance of refrigeration and air conditioning are found in the areas of home climate, optimum food supply and medical treatment. Refrigeration is essential for commercial applications in segments such as transport, electronics, building, medicine or sport.

Exchange between experts at the highest level – focus on energy efficiency

The organizers are looking positively to Chillventa Rossija 2014. Topics like energy efficiency, sustainability or the use of heat pumps will be discussed on a solution-orientated basis as in the previous years. The trade fair is one of the most important gatherings for specialists from the refrigeration, air conditioning and heat pump industry. This is where experts meet, update on the latest developments and find out everything about the current trends in refrigeration, air conditioning and heat pump technology. Specialists have the opportunity for discussion and exchanging views at the highest technical and scientific level.

NürnbergMesse GmbH
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Engel Austria is one of the 2013 winners of the Upper Austrian State Prize for Innovation. Thanks to its new all-electric and tie-bar-less injection moulding machine, the Engel e-motion 30 TL, the company secured second place in the large-scale enterprise category. This innovative machine again pushes Austria into the focus of the global electronics industry, thus safeguarding the future of local industry.

Engel Receives State Prize for Innovation

„Innovative force is the most important requirement for global success, not just for our own business, but also for our locations and the entire region," Dr. Stefan Engleder, CTO of Engel Holding emphasises. „This is why we are very excited about this award. Austria has been and always will be the source of our innovations." Stefan Engleder accepted the award, along with Werner Kappelmüller, Head of Mechanical Development for small to medium sized machines at Engel; it was handed over by Upper Austrian State Government Member Dr. Michael Strugl and Günter Rübig, the Chairman of the industrial section of the Upper Austrian Chamber of Commerce (WKOÖ).

KommR Günter Rübig, the Chairman of the industrial section of the Upper Austrian Chamber of Commerce (WKOÖ) (left) and Upper Austrian State Government Member Dr. Michael Strugl (right) handed over the award to Dr. Stefan Engleder, CTO of ENGEL Holding, (2nd from left) and Werner Kappelmüller, Head of Mechanical Development for small to medium sized machines at ENGEL AUSTRIA (2nd from right). (Photo: OÖ. Technologie- und Marketinggesellschaft (Upper Austrian Business Agency), Linz)

Pushing Austria into the focus of the electronics industry

Schwertberg in Upper Austria is the headquarters of the global Engel Group, and also the development and production location for injection moulding machines in the lower to middle clamping force segment. The Engel e-motion 30 TL is one of the latest products and was only introduced in autumn 2013.

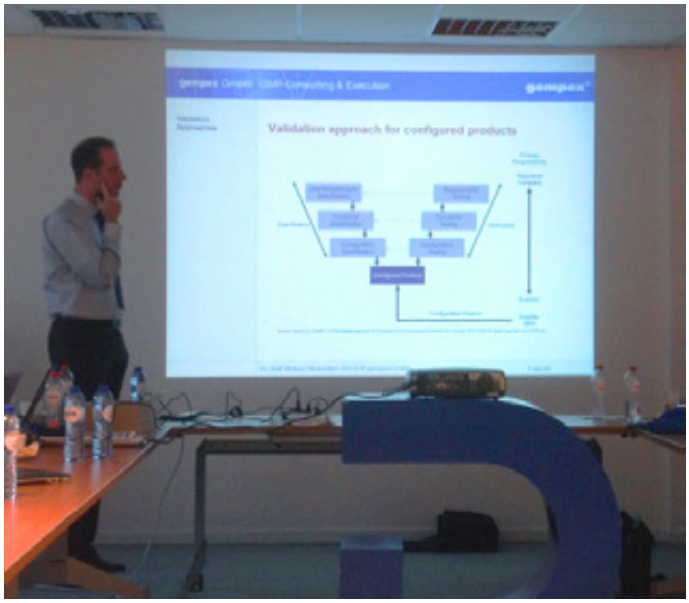
The new machine solution combines maximum manufacturing precision and productivity with maximum energy efficiency and an extremely compact machine design. One of the target groups for this unique combination of properties is the global consumer electronics industry, which frequently uses machines built in Asia to manufacture small, electronic precision components and premium optical components. With the new e-motion 30 TL, the company has now managed to win over a large, brand-name customer against Japanese competition. „All told, we see huge potential in this market sector." says Stefan Engleder.

ENGEL AUSTRIA GmbH A 4311 Schwertberg

GIRP provides expert GDP discussion platform to European wholesalers supported by gempex GmbH

During a workshop at the GIRP (European Association of Pharmaceutical Full-line Wholesalers) headquarters in Brussels, quality specialists from European wholesalers discussed the newly introduced regulatory GDP requirements with senior management of GMP consulting and execution company, gempex GmbH. Focusing on Quality Risk Management, Qualification of key equipment and Validation/Verification approach for quality-relevant IT-Systems, procedural knowledge from the GMP regulated industry was introduced and adapted to the GDP world of medicines wholesalers. Presentation of documents on Best Practice examples led to a comprehensive intellectual exchange between the experts coming from different countries and wholesale organizations in Europe.

gempex GmbH supports European wholesalers in the implementation of the new GDP guidelines.



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Construction at Arburg in the USA

- **Ground-breaking ceremony marks start of construction of new Arburg Inc. building in Rocky Hill, Connecticut**
- **First-class customer support on an area of 27,000 square feet (2,500 square metres)**
- **Machine warehouse for short delivery times**

In October 2013, the start of construction for the new Arburg building in Rocky Hill, Connecticut, was celebrated with a traditional ground-breaking ceremony. This investment in the US underscores the significance of the North American market, in which Arburg is extremely successful. In addition to the high-end technology, customers value the excellent pre and after-sales service. This will improve even more with the new building. With a useable floorspace of 27,000 square feet (2,500 square metres), the new premises will offer sufficient space to include a showroom, machine and spare parts warehouses and will cater to the growing turnkey solutions area.

Arburg Inc. President Friedrich Kanz invited a high-level delegation, including Rocky Hill Town Manager Barbara Gilbert and Mayor Timothy Moriarty, the architects Jeff Wyszynski and James Becker from Tecton Architects, as well as Vice President Don Swanson and Project Manager Eric Morse from AZ Corp / Construction Management, to the ground-breaking ceremony, which officially marked the start of construction for the new building.

During the occasion, Friedrich Kanz emphasised that, "The new building to house Arburg's US headquarters represents a further important milestone for our activities here in the USA." The company has been present with its own organisation in the country since 1991. In addition to the current Arburg Inc. headquarters in Newington, two further locations have also been established: The Arburg Technology Center in Irvine, California opened in 1993 and later moved into a new building in 2007, while the Arburg Technology Center Midwest in Elgin, Illinois, opened in 2007. The company is consequently very well represented in the US and its success there demonstrates that the long-term investments have paid off. Currently, 65 employees work at the three locations, of which 25 are involved in Sales and 32 in after-sales service and application technology consulting. This underscores the high value that Arburg places upon intensive customer support beyond the machine sales per se.

Groundbreaking ceremony for the new Arburg building in Rocky Hill: Friedrich Kanz (2nd from right), President Arburg Inc., with his colleagues Robert Arace (2nd from left), Vice-President & CFO, and John Adamowicz (left), Service, with the responsible architect James Becker (centre), Tecton Architects, and Donald Swanson (right), Vice President AZ Corp / Construction Management. (Photo: DFphotography (Daniel Ferrari))

New building in Rocky Hill for even better and more intensive customer support

Arburg's future US headquarters is conveniently situated only six miles from its previous Newington location. The new, 27,000 square feet (2,500 square metre) building offers all the facilities for further intensifying cooperation with the customers, which is becoming increasingly important in light of the ever more challenging technical requirements. Consequently, everything will be housed under one roof at Rocky Hill: numerous Arburg experts with many years' experience and comprehensive know-how, as well as a modern machine fleet. The central area will be the showroom offering space for up to seven Allrounders, which will be available both for customer-mould testing and training purposes. Adjacent to this there will be rooms for training and technical seminars, for example.

Large storage area to ensure fast machine availability

Furthermore, there will be an extensive warehouse area for Allrounders which will merely require customer-specific adaptation prior to their rapid delivery. With a 38 tonne gantry crane, the necessary logistics will be provided for all machine sizes and large unit numbers. Moreover, there will be a large centralised spare parts warehouse for all Allrounders on the US market in order to ensure even faster deliveries.

Expansion of the project business

A further important area which is gaining significance in the US are turnkey systems, which Arburg supplies as a general contractor: from design and implementation through to commissioning and after-sales service. Sufficient space will also be available in the new building for the assembly and acceptance testing of customer-specific production cells of this type.

Ready for occupancy in around one year's time

Like all Arburg buildings world-wide, Arburg Inc.'s new home will also reflect the company's corporate identity, the most evident feature of which are the large glass facades. The facility management technology will be state-of-the-art to ensure that customers and employees feel completely at ease in the new building. "The new building will provide us with everything we need to offer our customers comprehensive, first-class support in a pleasant environment," says a delighted Friedrich Kanz, looking forward to the move from Newington to Rocky Hill following the construction period, which will extend to around 12 months.

ARBURG GmbH + Co KG
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Connect 2 Cleanrooms Exhibiting at Precision Fair 2013 – Stand 96

Connect 2 Cleanrooms and Cleanroomshop.com is exhibiting at Precision Fair 2013 on 3-4th December, alongside its Benelux distributor, Procleanroom. Veldhoven, NL will once again host the main European event on precision technology.

Precision Fair 2013
3rd to 4th December 2013
Veldhoven/Eindhoven (NL)

On stand 96 they will display a fully functional class 6 modular cleanroom, manned by cleanroom professionals. The company's staff will be on hand to advise on contamination control for the production of medical devices and components - giving people the benefit of their experience and industry knowledge. During the trade fair, some 260 specialised companies and knowledge institutions from the Netherlands, Belgium, Germany and other countries will be exhibiting in a wide array of fields, covering all areas of precision technology.

The fair taking place from 3rd to 4th December 2013 in the NH Conference Centre, Koningshof, Veldhoven/Eindhoven (NL), includes:

- New technologies, solutions and products
- Exhibition of 260 specialized companies and knowledge institutions
- More than 50 inspiring lectures

Connect 2 Cleanrooms is an industry leader in creating modular cleanroom solutions for critical environments, both in the UK and internationally. The company designs and manufactures 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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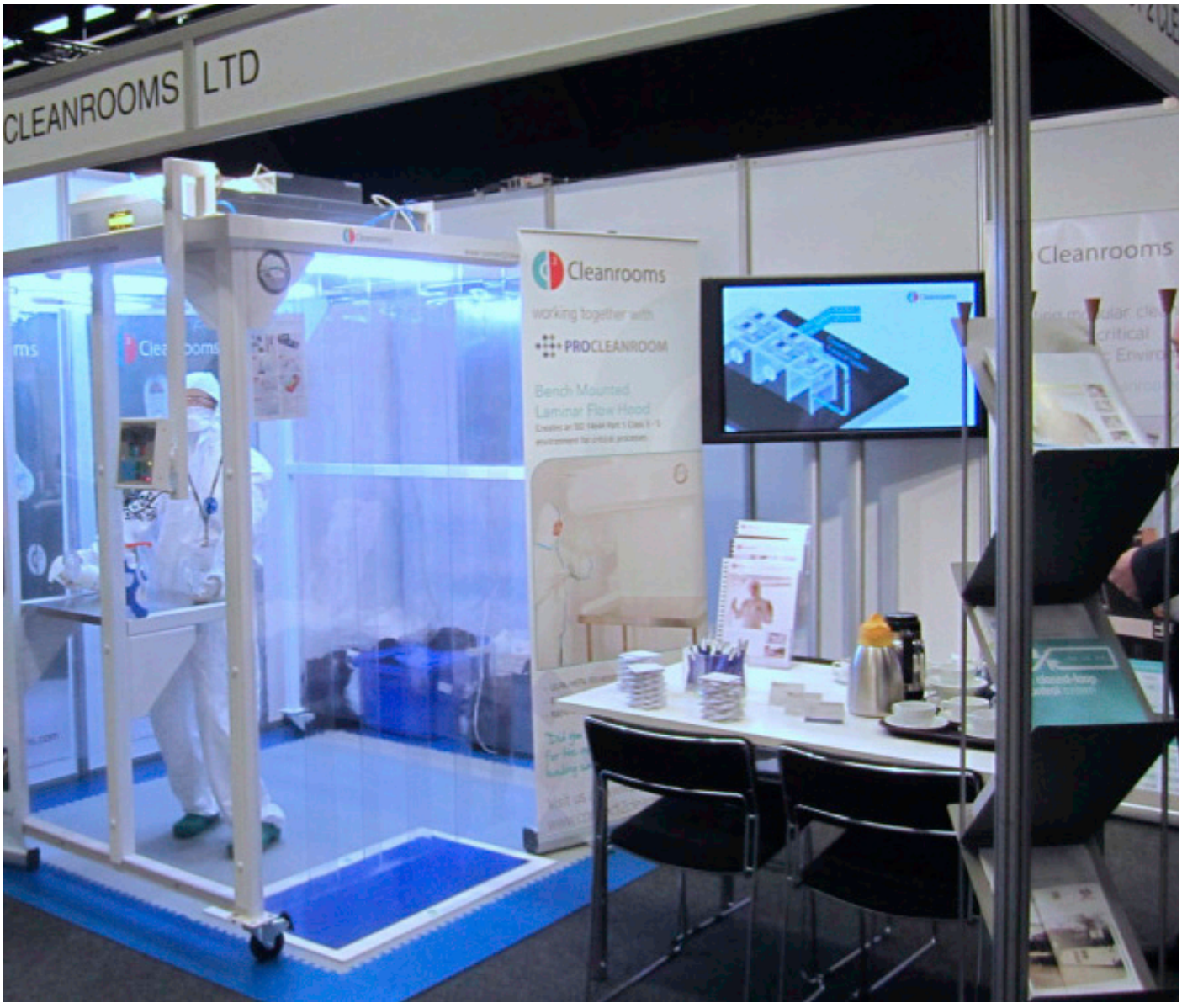

Vaisala GMW90 Carbon Dioxide, Temperature, and Humidity Instruments with Microglow Technology Released

The GMW90 is the ultimate tool for HVAC professionals looking for an easy to use, hassle-free solution to carbon dioxide measurements. Customer feedback played a vital role in developing the GMW90, a high quality measurement sensor which offers ease of use, compliance with standards, extended lifetime and minimal maintenance, all of which provide peace of mind.

Microglow technology

GMW90 is the first sensor to feature the new generation of CARBOCAP® sensors with microglow technology. Microglow is a Vaisala-patented silicon MEMS emitter infrared source. This unique low-power, silicon-based infrared source is built in-house at Vaisala. Using this technology, the performance of CARBOCAP® sensors has been even further improved. It represents next generation infrared technology that solves many of the challenges that impact traditional infrared sources. Low power consumption enables correct RH+T measurements in CO2 instruments. Replacing the incandescent light bulb sensor stability has significantly improved. Moreover, the sensors operational life has extended by 50%. Through simplified design and intelligent optical design fewer components are required, which help to increase overall reliability of the sensor. The GMW90 includes a sliding cover, which allows for faster calibration/service. Most importantly, the compliance and traceability of the measurements are never compromised.

Vaisala's reliable technology and state-of-the-art design offers the most efficient and robust carbon dioxide measurement device on the market. The GMW90 can be ordered from the Vaisala Online Store open 24/7. Alternatively, with personal customer service is available locally.

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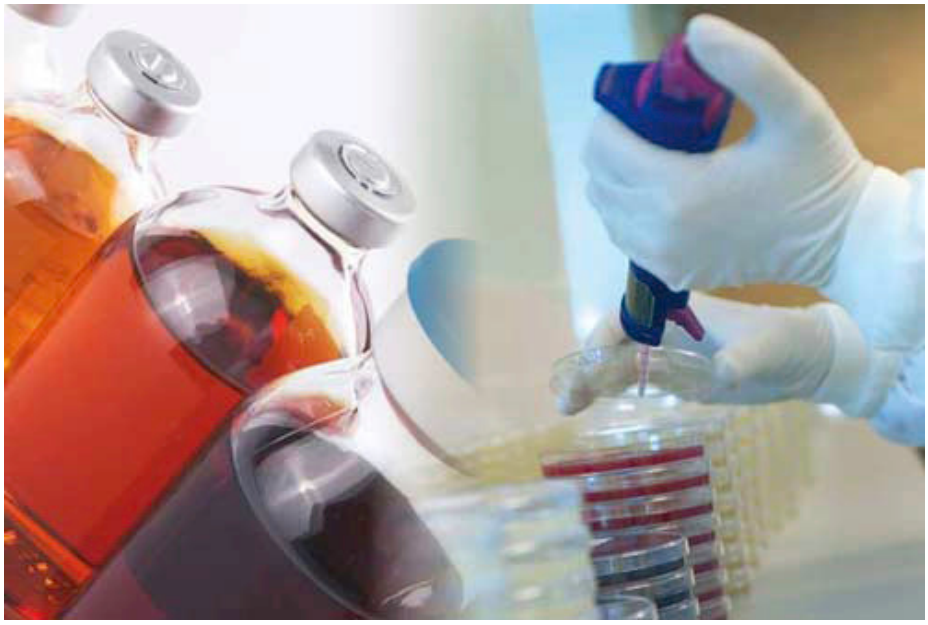
Pharmig Annual Microbiology Conference covers pharmaceuticals and medical devices

Key Microbiology Conference Supported by Cherwell Laboratories



Cherwell Laboratories, specialist suppliers of environmental monitoring and process validation solutions, will once again be supporting Pharmig's Annual Microbiology Conference at The Oxford Belfry Hotel, Thame. The annual conference, to be held on 20th & 21st November, provides the opportunity for individuals to keep up-to-date with the latest hot topics in microbiology.

This year the Pharmig conference has presentations and discussions on regulation, investigation, best practice and risk management for microbiology, covering sterile and non-sterile pharmaceuticals and medical devices. There will also be an entertaining presentation from Professor Anthony Hilton on microbiology risk in more domestic environments, and a workshop entitled 'Questions you always wanted to ask an inspector but felt you couldn't'.

With over 40 years' experience, Cherwell Laboratories has developed a reputation for providing high quality products to meet the environmental monitoring and process validation requirements of the pharmaceutical, healthcare and other related industries. The range includes Redipor prepared media, such as agar plates and bottled media, plus SAS microbial air samplers and biological indicators, all available for a variety of applications. Redipor's flexible manufacturing process also ensures Cherwell is able to respond efficiently to changing requirements either within the industry or for individual customers.

"By keeping informed with the latest developments within the industry we can continue to develop our product range, which is designed to meet the specific microbiological requirements of our customers," commented Andrew Barrow, Sales Manager, Cherwell Laboratories. He added, "Pharmig offers an ideal forum for members to keep up-to-date with microbiology and Cherwell are pleased to continue supporting this event."

Cherwell Laboratories Ltd OX26 4XB BICESTER
Vereinigtes Königreich Großbritannien
und Nordirland

In Pharmaceutical, Biotechnology and Medical productions, keeping the particle and microbiological contaminations to minimal levels is of paramount importance. To achieve the targets defined by the ISO 14664 norm and/or the Good Manufacturing Practices, a cleanroom manager shall pay attention to all the incoming and outgoing flows of personnel and consumables, but also to the quality of the equipment and furniture that stay permanently in the cleanroom.

For all the reasons mentioned below, basan, your cleanroom specialist since 30 years and now division of VWR, has selected for you the worldwide reference for electropolished stainless steel furniture, Palbam Class.

Electropolished stainless steel, for high-end cleanroom furniture

Stainless steel is the preferred choice for all cleanroom furniture and equipment, because of its mechanical resistance, low particle shedding, resistance to chemicals, and ease of cleaning. However, significant differences in performance can be observed according to the type of surface finish used : not all stainless steels are equivalent, and the most qualitative finish is by far electropolishing.

What is electropolishing ?

Electropolishing is an electrochemical process by which surface material is removed by anodic dissolution. Electropolishing removes surface material, beginning with the high points within the microscopic surface texture. By removing these points, the electropolishing process will improve the surface finish, leaving a smoother and more reflective surface.

As electropolishing is not a surface coating, there is no risk of peeling or surface distortion over time. And because the process involves putting the piece of furniture in a bath of electrolyte, the whole surface is treated, even the most intricate areas that would be inaccessible to mechanical polishing.

Benefits of electropolishing

Electropolishing gives stainless steel several benefits for a use in cleanrooms :

1. Dramatically enhances **passivation** (corrosion resistance), by preferentially removing free iron, embedded particles and inclusions introduced during manufacturing (welding, ...). Electropolishing is recognized by ASTM B912-02 as the most superior form of stainless steel passivation.

2. Improves surface **smoothness** by leveling microscopic peaks and valleys. With Ra values down to a few nanometers, surface smoothness is typically improved by 50% or more, compared with the best mechanical polishing techniques.

3. Improves surface **reflectivity and brightness**. Electropolishing gives a very attractive and qualitative lustrous finish and, unlike mechanical polishing, doesn't leave directional lines, smearing or occlusions.

4. **Facilitates disinfection** and hygienic cleaning of the surface. In a study by the Israel Institute of Technology comparing several types of stainless steel finish, electroplished surfaces were found to be the most efficient against bacterial colonization. They reduce the initial attachment of bacteria, slow down the formation of biofilm, and drastically improve the efficiency of chemical disinfection.

In simple terms, electropolished stainless steel furniture is cleaner, more corrosive resistant, brighter and more aesthetic, smoother and easier to wipe down than standard mechanically polished furniture.

It is important however to note that the furniture and equipment must be designed specifically for electropolishing, to make sure that all the surfaces will be evenly processed, and that no traps could retain chemicals or residue to later contaminate the cleanroom.

The Palbam Class range includes modern, aesthetic and ergonomic furniture for all types of cleanrooms and gowning areas (work stations, cabinets, dispensers, gown racks, sit-over benches), as well as equipment (desiccators, carts, step-ladders).

With Palbam Class, basan not only provides you the highest quality products, but also a personalized service : custom products to fit your specific needs, CAD drawing to be inserted in your layouts, 3D modeling of the layout, etc.

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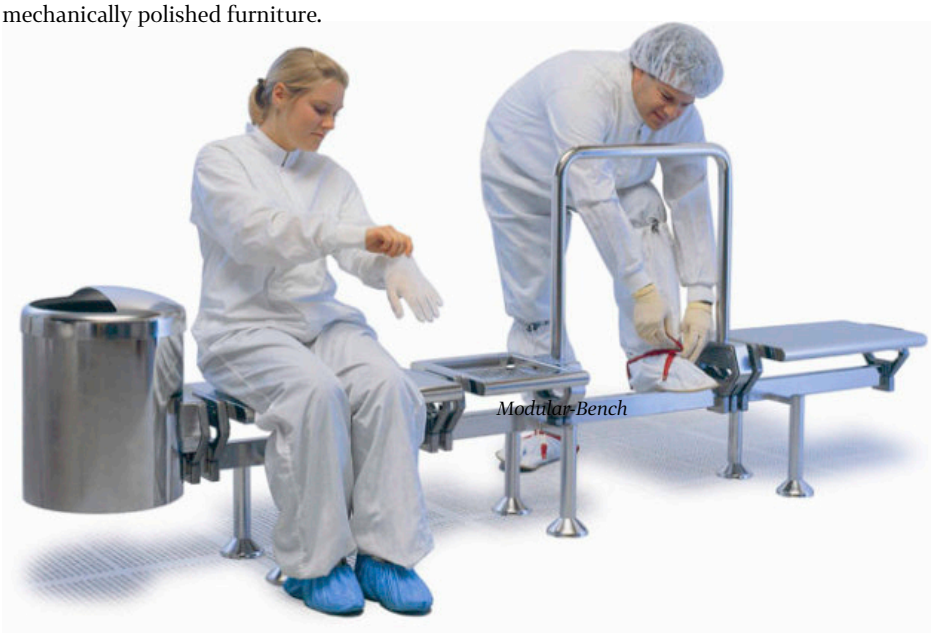


Modular-Bench

Maximum precision and reliability levels combined with a tiny footprint: At the Swiss Plastics trade fair that takes place in Lucerne from 21st to 23rd January 2014, Engel will be demonstrating how even very sophisticated applications can be realised efficiently and economically using innovative injection moulding technology.

Engel at Swiss Plastics 2014

Three-component hollow bodies with inlays in one step

Engel is setting a new trend in the manufacture of three-component hollow bodies with inlays. At its stand the company will be producing drip chambers for blood transfusions with an integrated filter in just one work step. An Engel e-victory 160 combi three-component injection moulding machine with an integrated Engel easix multi-axis robot will be used to make the chambers in a 4-cavity mould manufactured by Hack Formenbau. The chambers will consist of a PS and a PP component, which will be injection moulded simultaneously. The filter will then be mounted straight away in the same mould and joined by means of overmoulding with another PP. The cycle time will be 14 seconds.

Engel Medical e-victory 160 combi

Swiss Plastics trade fair 2014
21st to 23rd Januray 2014
Lucerne (Switzerland)

One key prerequisite for realising the integrated process is servo-electric drive technology for all movements of the index plate mould. This enables mutually independent movements to be controlled synchronously. The high-precision platen parallelism setting on the tie-bar-less hybrid machine provides a high level of mould protection.

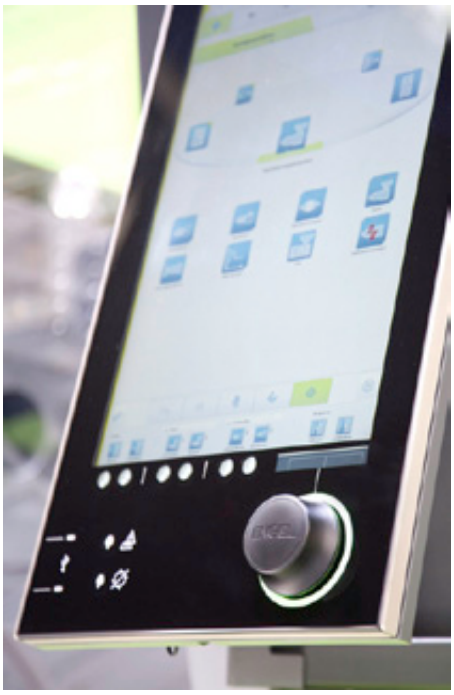
All-electric, highly precise and tie-bar-less

By combining the benefits of the company's tie-bar-less technology and all-electric drive technology, the new Engel e-motion 30 TL injection moulding machine brilliantly meets the needs of the electronics industry in the low clamping force segment. Outstanding precision, extremely low energy consumption levels and maximum flexibility are all essential here. The company will also be producing 60-pin board-to-board connectors in a 16-cavity mould on its new smallest injection moulding machine at Swiss Plastics 2014. This is an application that requires very high precision levels, as the distance between the pins is just 0.5 mm.

Even complex processes can be kept safely under control

Another Engel highlight being showcased at Swiss Plastics 2014 is its new CC 300 generation of control units. Smartphones served as the example when the interface for these was being developed. In addition to allowing a machine to be operated, the central control element, e-move, gives a feel for the machine back to the operator. This unique combination means the new Engel control unit is able to ensure that even complex processes are controlled easily, efficiently and reliably.

The company doesn't just supply injection moulding machines and robots all over the world; instead it concentrates on providing highly integrated and automated turnkey solutions from a single source. It is only when all the components in a manufacturing cell are perfectly coordinated from the outset that efficiency potential can be fully exploited and new applications with extremely low unit costs can be realised.



Engel CC 300

ENGEL AUSTRIA GmbH
A 4311 Schwertberg

Sigmasoft® shows how to achieve first shot success for automotive applications with narrow tolerances at Swiss Plastics 2014

Automotive Molding: First Shot Success with Virtual Molding

Usually the search for an optimal process window for parts with narrow tolerances is very time consuming. With the help of Sigmasoft® Virtual Molding, the mold and process can be optimized without wasting valuable resources. Kalypso Ultra Technologies helped their customer achieve first shot success for a high precision automotive product using this Virtual Molding technology.

At Swiss Plastics 2014 Sigma Engineering GmbH presents how Sigmasoft® Virtual Molding helps optimize the mold and process, before the mold is built.

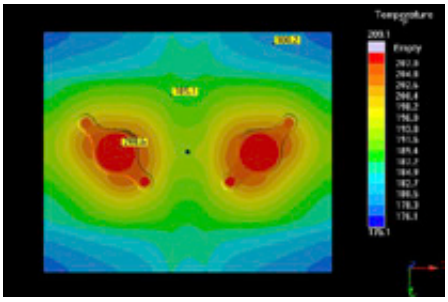
Swiss Plastics trade fair 2014
21st to 23rd Januray 2014
Lucerne (Switzerland)

Charged with the development of a structural mount (Picture 1) out of PA 6.6 with 30% glass fibers, a diameter of 10 cm and tolerances of +0,07 mm /-0,0 mm for every cross section, several challenges existed for Kalypso. The material behavior is very complex due to crystallization and fiber orientation and is difficult to predict so common design rules do not apply. The part geometry is unusually complex with large differences in wall thickness and narrow tolerances where only little experience could be gathered from past learning. Optimal gating and reliable tempering are a prerequisite for success on these kinds of products. Contrary to the usual trial-and-error approach, which is very time consuming and expensive, Kalypso consequently decided to develop the mold and process virtually with Sigmasoft® before building the mold.

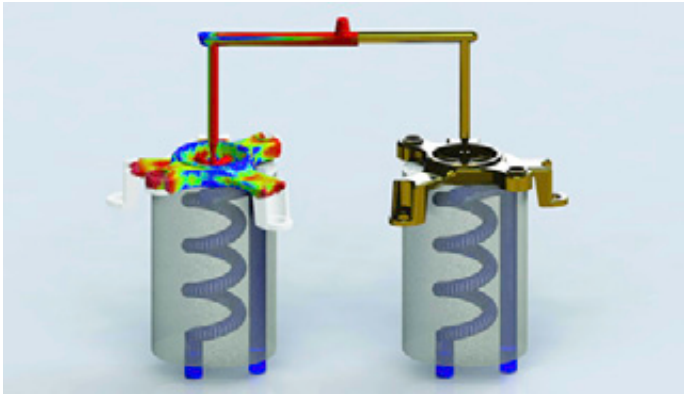
A multi-cycle analysis consisting of 20 consecutive virtual production cycles using actual process parameters and conventional cooling revealed hot spots on the mold cores (Picture 2a) during the steady production state of the mold. Hot spots are difficult to manage in a production mold and they influence part distortion because they create variations in crystallization, resulting in non-uniform shrinkage and distortion. Reducing water temperature typically only makes the cold areas colder and increasing cooling time is expensive so these common strategies don't always work. As an alternative, a potential solution using conformal cooling in the mold cores was discussed and then evaluated, virtually. In this case, the consideration of all mold components and process parameters over several cycles showed a more regular temperature distribution inside the mold (Picture 2b) as well as a reduction in cycle time.

Based on this new information, the mold was built and the process parameters were predetermined. The production staff was specifically prepared for the required process in advance to avoid wasting time during the physical trials at the molding machine. The new mold and process produced the required part quality from the start. Kalypso was able to deliver the mold and process to their customer on schedule and still achieve success during the first molding trial. Sigmasoft® Virtual Molding helped them achieve a first shot success without time consuming mold and process iterations.

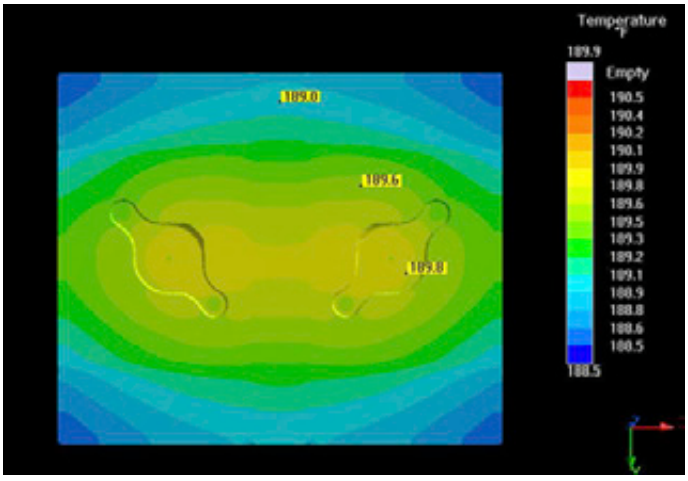
SIGMA Engineering GmbH D 52072 Aachen



Picture 2a: Hot spots on the mold cores with conventional tempering (Picture: Kalypso Ultra Technologies)



Picture 1: High precision structural mount with thick walls and narrow tolerances (Picture: Kalypso Ultra Technologies)



Picture 2b: More uniform temperature distribution with conformal cooling of the mold (Picture: Kalypso Ultra Technologies)

Maximum Reliability through Mesh Technology as well as Easy Installation and Expandability

New at CiK Solutions: Central Wireless Monitoring System

E-Senza - The Central Wireless Monitoring System

E-Senza is a centralised wireless monitoring system for data monitoring in nearly all industries and sectors. Monitor temperature, humidity, pressure, light, motion, CO2, AC/DC and much more - simply and reliably.

The E-Senza wireless monitoring system is ideal for networking sensors, transmitters, gauges, instruments and actuators with each other so data can be centrally monitored and managed.

This system is designed for extremely high reliability and allows wireless communication in even the harshest of industrial environments. The wireless network is self-healing and looks for alternative transmission routing paths, using the latest „mesh networking technology“, if one of the nodes malfunctions.

The cost of installation and maintenance of a monitoring system can therefore be dramatically reduced, and expanding the system will be a breeze, even when covering long distances. Monitor virtually any parameter on a single computer or via the network. Enter alarm thresholds and receive warnings on your PC, via SMS, email, alarm light or sounder.

CiK Solutions GmbH
D 76131 Karlsruhe

During the K 2013 fair in Düsseldorf, motan-colortronic added a new subsidiary to the family – motan colortronic do Brasil LTDA in Piracicaba (São Paulo region). Contracts were signed by Beat Amrein and Jefferson F. S. Macedo (for motan-colortronic do Brasil), as well as Ulrich Eberhardt and Frank Medgyesy (for motan-colortronic AG). The new sales and service subsidiary is equipped with the most modern equipment and systems for direct support of the plastics market in the region.

motan-colortronic establishes a subsidiary in Brazil

(from left to right): Beat Amrein, Jefferson F. S. Macedo, Ulrich Eberhardt, Frank Medgyesy

motan-colortronic enters the Brazilian plastics market with increased commitment

After good growth in the Brazilian market over the past several years, motan-colortronic customers can count on continued support in future by a strong sales and service team. The contract was signed on October 18th at the K 2013 on Stand B 24 in Hall 9, finalizing the formalities for establishing the motan-colortronic subsidiary in Brazil. Beat Amrein, Jefferson F. S. Macedo, Ulrich Eberhardt and Frank Medgyesy all agree, “high importance must be attached to this market in view of the strong growth potential. With this step, customers in the South American market will be reached quickly and directly. This fits in with the service strategy of the motan group”.

motan-colortronic LTDA subsidiary in Piracicaba

With its new office, the ancillary equipment supplier motan-colortronic can offer its Brazilian customers application-oriented consultancy, faster project development and comprehensive customer service. “Up to now, our customers in Brazil and elsewhere in South America have been supported through sales partners and our other subsidiaries in Europe. With the new office in Piracicaba, our customers now have the advantages of a local subsidiary within an international network” says Managing Director Beat Amrein.

Most modern ancillary equipment technology for Brazil

The company offers innovative modular system solutions for storage, drying & crystallisation, conveying, dosing and mixing of raw materials for the plastics producing and processing industry. This system complies with continually rising quality demands of the South American market. “motan-colortronic ensures that tailor-made solutions are made available for the respective process conditions which have a sustainable influence on final product quality, productivity and efficiency”, stresses Carl Litherland, Vice President Marketing at motan holding gmbh in Constance, Germany.

motan-colortronic gmbh
D 61381 Friedrichsdorf

Microbial contamination is recognized as a source of risk to the consumer. The presence of objectionable microorganisms in non-sterile products, or any type of microorganism in sterile products, denotes inadequate process controls. The control of microbial contaminants requires the interaction of a multidisciplinary group to identify root causes and to implement corrective actions.

This article assembles information to assist in this investigational process and offers a holistic approach to remediate microbial contamination in process equipment.

Addressing Microbial Contamination in Process Equipment

Author: Paul Lopolito, Elizabeth Rivera, STERIS Corporation, Life Science Division

Part I: Pre-inspection work:

The pre-inspection review should include: identification of the microorganism (genus and species); the history of microorganism onsite; process, personnel and waste flow diagrams; equipment drawings; and equipment cleaning procedures and sanitization practices. Understanding this information allows an auditor to investigate intrinsic or extrinsic sources. Intrinsic sources are those integral to the manufacturing process or equipment. Extrinsic sources are those associated with a transfer into the product via air, liquid or surface contact. Historical information regarding prior microbial contamination can be helpful in understanding whether the contamination is from a single incident, or from insufficient practices or controls.

Microbial contamination can be introduced from a number of sources (figure 1) including Gram-negative and Gram-positive bacteria, mycobacteria, mycoplasma, viruses and fungi (mold and yeast). Bacterial spores are a concern due to their high resistance to destruction. Gram-negative bacteria are often associated with biofilm in process systems or utilities. The presence of biofilm often involves a modification of the cleaning procedure to effectively remove the residue.

Part II: Inspection:

The inspection process should consider potential causes of microbial contamination and focus on areas of high risk.

Raw materials, processing aids and packaging

A microbial risk assessment of each raw material from each supplier should be performed. Microbial reduction of the raw material through pasteurization, filtration or sterilization can be performed before use if warranted. All recent changes in raw materials or product formulations should be investigated. Storage, sampling and dispensing of raw materials should be reviewed for possible ingress of microorganism. Any processing aids or packaging components used during the manufacturing process should also be assessed for microbial risk.

Personnel and room environment controls

Personnel are the largest contributor of viable and non-viable particles. The way to control viable and non viable particulate contamination via personnel is to control access and attire, and to provide rigorous training in gowning procedures and appropriate clean room behavior. Other environmental controls include process equipment selection, and cleaning and disinfection practices (Bartnett, 2007 and USP 1072).

Utilities (water, steam, compressed air and gases)

Any utilities used in direct contact with the product should be inspected, and routine monitoring test results and contamination control practices reviewed. This might include routine microbial, total organic carbon (TOC) and endotoxin testing. Filters and ultraviolet (UV) bulbs should be changed per manufacturer recommendations. Common bioburden reduction steps for water systems include distillation, filtration and/or UV treatment. Compressed air and gases should

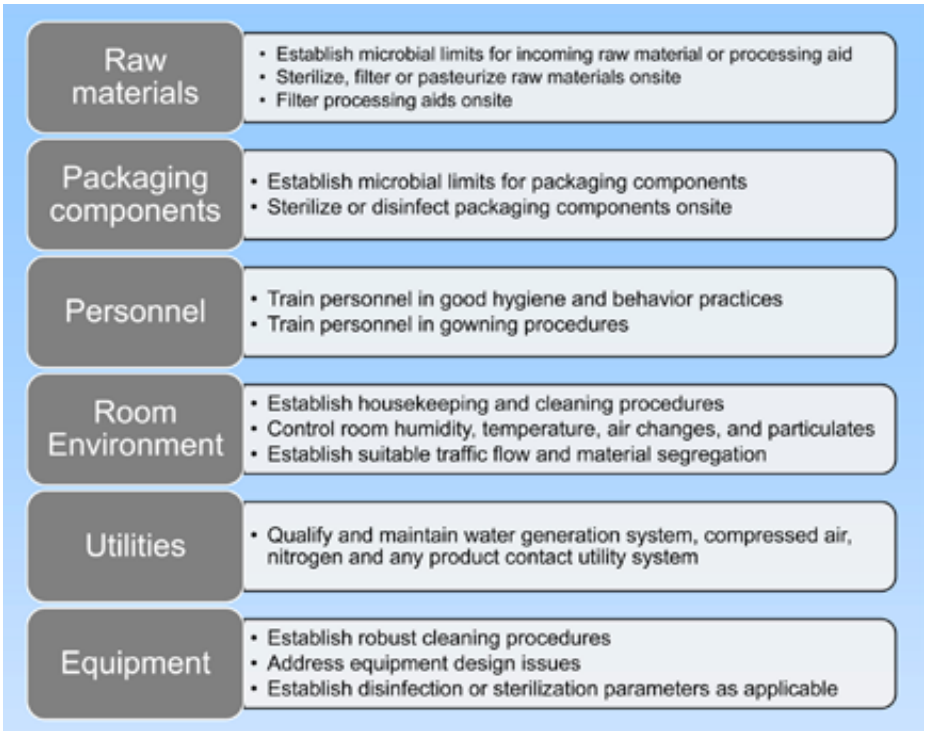


Figure 1

p. 2 : Addressing Microbial Contamination in Process Equipment

be filtered before use to prevent viable and non-viable particles, oil, and condensation from entering the process system. Non product contact utilities, such as cooling or heating systems, should be inspected for possible cross-contamination with product or product contact surfaces.

Walk-through of process, personnel and waste flow

It is important to walk through the manufacturing process and observe how each raw material, utility, and processing aid is introduced or exposed to the product. The auditor can assess possible intrinsic and extrinsic risk and verify controls. Personnel from quality, engineering and operations should accompany the auditor to address questions. Photographs and additional sampling data outside of routine environmental and product samples are helpful when seeking support for changes to contamination control practices.

Processing equipment and microbial decontamination

The major elements that must be considered when addressing microbial contamination in processing equipment are the surfaces and equipment design, residue type and cleaning parameters, and sterilization / disinfection. Deficiencies found in one element may have a significant impact on the others, and vice versa. (see figure 2)

Residue type and cleaning parameters

A successful cleaning process is necessary for microbial control. Indeed, many biocidal agents require a clean, soil-free surface before application or their microbial efficacy is reduced.

Process changes in manufacturing steps, batch composition, dirty hold time, raw material sources, environmental factors and other elements may affect the soil condition at the time of cleaning. If changes have occurred, then lab evaluations are recommended to confirm the adequacy of the current cleaning process. This is done by testing the four key parameters that govern cleaning effectiveness. These parameters are the contact time of the cleaning solution with the dirty surface; the action or force acting on the surface; the concentration of the cleaning agent; and the temperature of cleaning solution [Verghese, 2009]. In addition, if the residue was dried, baked, autoclaved, denatured, or polymerized onto the surface, it is important to mimic the actual conditions at time of cleaning, including the amount of soil present on the surface, the tenacity of the soil adhesion, and the extent of dispersion of the soil in the cleaning solution during the cleaning process.

Laboratory evaluations should also be used during a microbial contamination investigation. A lab study helps to identify any difficulties with the efficacy of soil removal and to access the impact of residual soil on microbial contamination risk in the system. (see figure 3)

Surface and process equipment design

Surface characteristics and equipment design can affect successful cleaning and microbial efficacy. Surface characteristics such as rouge and scale may be removed chemically, however scratches, crevices and corrosion will need more aggressive maintenance. Process residues and microbes might adhere more tenaciously to the irregular surface and become more difficult to remove. Equipment design elements such as coverage, flow rate, component selection, size and orientation of dead legs, valve selection, drainability and pitched piping are also important factors for successful cleaning and sanitization (Rivera, 2012 and Verghese, 2009). (see figure 4)

Sterilization or disinfection parameters

Several technologies are available for disinfection or sterilization of equipment. High temperature sterilization techniques would be steam-in-place and dry heat. Gas/Vapor technologies include vaporized hydrogen peroxide, chlorine dioxide, and ozone technologies. Chemical sterilization can also be performed using commercially available sporicidal/sterilant agents.

In the case of non-sterile pharmaceuticals, it is neither required nor expected to sterilize processing equipment. Generally, a low and controlled bioburden is acceptable. An effective cleaning procedure followed by a disinfection or sanitization step may be sufficient, provided these can kill objectionable microorganisms. References such as the USP "Microbiological Attributes of Non-sterile Products" provide assistance in defining and setting microbial limits for finished products. Nonetheless, the significance of other microorganisms must be established on a case-by-case basis. These are microbial contaminants that, depending upon species, cell number, dosage form and intended use of the drug, may adversely affect patient safety [USP 1111]. The aforementioned methods should be validated to ensure that they will consistently meet pre-established criteria. Change in the soil level, microbial load or species, and surface attributes can impact the disinfection or sterilization method being used. Critical parameters governing the effectiveness of any of these methods must be periodically monitored to verify the validated state. (see figure 5)

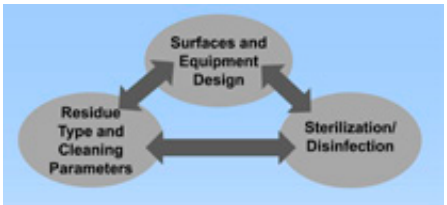


Figure 2

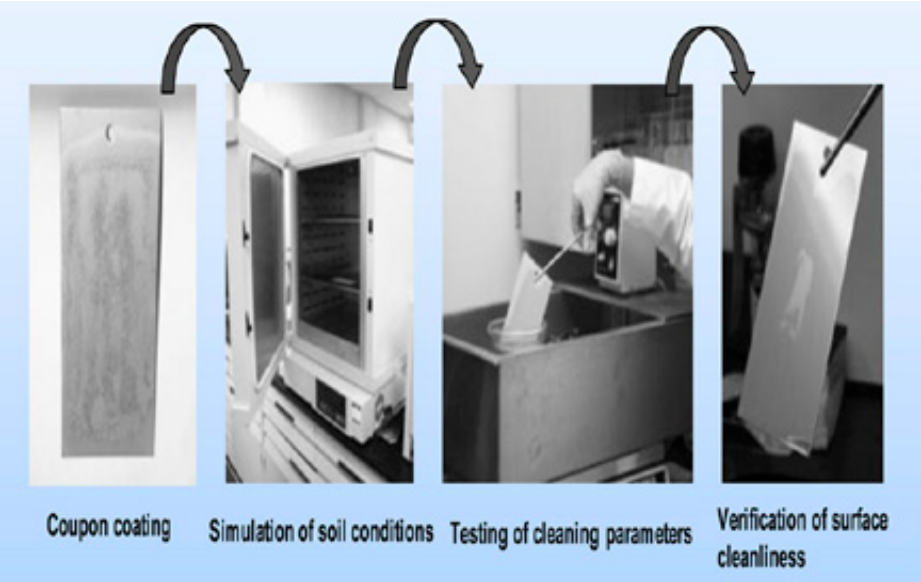


Figure 3

p. 3 : Addressing Microbial Contamination in Process Equipment

Conclusions:

Contamination of a product with an objectionable microorganism is a costly and time consuming problem that needs to be addressed quickly and efficiently by a cross-functional team. It is critical to identify the microorganisms early in the investigation and determine whether they are from an intrinsic (of the manufacturing process) or extrinsic (outside of the manufacturing process) source. A careful walk-through of the process can be used to flag areas of microbial risk; identify the presence or lack of controls; understand when the product is at highest risk; and provide solutions to reduce the risk. A holistic approach is commonly used to address contamination issues. As part of a holistic approach, assess the cleanability of the system and make engineering changes to address issues such as coverage, drainability, etc. as needed. Perform a robust high temperature, alkaline cleaning to remove process and microbial residue. If rouge or water scale is present, perform a high temperature acid cleaning to remove the inorganic residue. When possible, use a disinfection/ sterilization procedure that is routinely performed onsite, and ensure critical parameters are achieved during the process. Once the manufacturing process is back up and running, schedule regular meetings to review current microbial control measures and internal plans to quickly and effectively address the next microbial contamination event.

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	What to look for?
Surface Condition	Rouge, scratches, roughness, crevices, welding imperfections, porous substrates
Valves	Non-sanitary designs, worn gaskets, operating mechanism, orientation
Dead Legs	Orientation, size, quantity
Coverage (spray device)	Spray device mechanism, clogged holes, riboflavin coverage testing results
Piping	Rouge, welding imperfections, misalignments, poor drainability, non-sanitary fittings, worn seals and gasket
Vessels	Flat bottoms, non-sanitary nozzles, poor drainability, instrument or equipment inserts
Pumps	Non-sanitary design, worn seals and gaskets, bearing failure, shaft leakage, rouge
Sampling ports	Orientation, drainability, operation, cleaning and flushing procedure, non-sanitary fittings, environmental exposure concerns, worn seals and gaskets
Flexible hoses	Poor drainability and storage, non-sanitary fittings, worn sidewall, seals and gaskets

Figure 4

Type	Critical Parameters
Steam	Time, temperature and saturated steam
Dry Heat	Time and temperature
Hydrogen peroxide	Vapor concentration, time, humidity and saturation
Chlorine dioxide	Gas concentration, time, temperature, humidity and pressure
Ozone	Gas concentration, time, humidity and pressure
Liquid chemical	Concentration, wet contact time, temperature, water hardness

Figure 5

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Rotational Cleaning

– What is it and what are the benefits?

Autor: Rebecca Smith

Why do I need to clean my cleanroom, it is already clean? What is rotational cleaning and do I really need to go that far? Why are there so many chemicals and how do they all work? What chemicals should I use? As a Business Development Coordinator for a cleanroom consumables provider, I get asked questions like this every day.

To answer these questions I have asked for advice from experts, consulted the wealth of information there is available into micro-organism resistance and disinfectant mode of action, and read about the standards of cleanliness required to keep a cleanroom up to specification. The article that follows, are the conclusions I have come to.

Cleaning your Cleanroom

To answer the first question, yes of course you need to clean your cleanroom. Although it probably looks clean, most of the particles that need removing are not visible to the naked eye. Over time particles of dirt, cell debris, residues and such, will build up on the surfaces of the cleanroom and must be removed. The ISO standard 14644-1 defines a cleanroom as: "*a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimise the introduction, generation, and retention of particles inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary.*" [10]

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

Microbial control and EU GGMP Grade Cleanrooms

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

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

Annex 1 – Manufacture of sterile medicinal products - Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary use, point 61, states the following: "*The sanitation of clean areas is particularly important. They should be cleaned thoroughly in accordance with a written programme. Where disinfectants are used, more than one type should be employed. Monitoring should be undertaken regularly in order to detect the development of resistant strains.*" [6]

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

Resistance - Selection for Resistant Strains

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

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

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

Again, a few of these bacteria will just about survive a dose of agent, multiply, and the advantage that allowed them to survive is passed on again and gets stronger. This happens over and over with continued use of that same agent. The advantage grows

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and grows, until you are left with a strain that it totally resistant to that agent. In the cleanroom environment, because we tend to overdo the quantity and frequency of disinfectant use, very few microbes actually do survive. This means that it is unlikely that selection for resistant strains will occur. Also, antibiotics have a very specific and targeted action which makes selection more likely. Disinfectants have a very broad action which means it will be less likely that selection can take place.

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

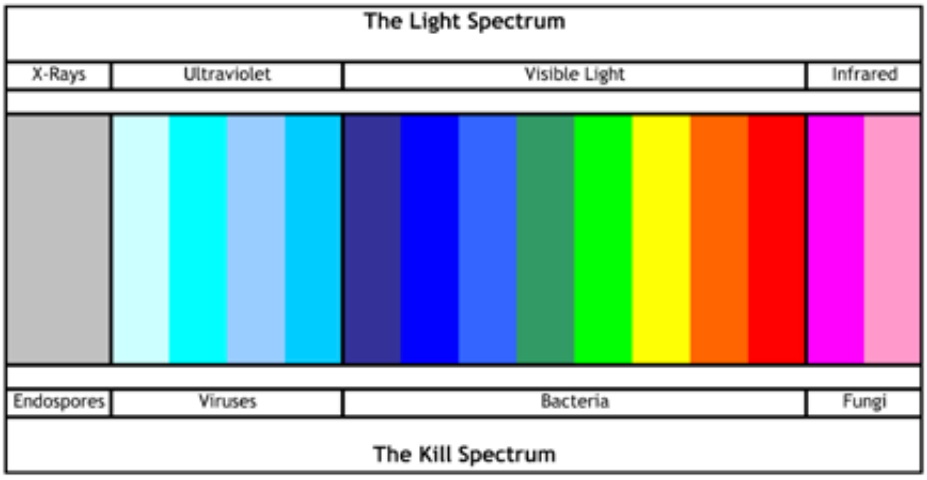

Table 2

Resistance - Naturally Occurring Resistance

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

Due to the way that disinfectants kill, some micro-organisms will naturally be better able to resist their actions. This is not learned, selected for, or genetically passed on, it is down to the nature of the micro-organism itself and the properties it already had. In the same way that tall humans may naturally be better at basketball; they didn't learn to be good, or have any better understanding of the game which was passed on by their parents; they just happen to be closer to the hoop! (see table 1)

Disinfectant Mode of Action

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

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

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

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

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

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

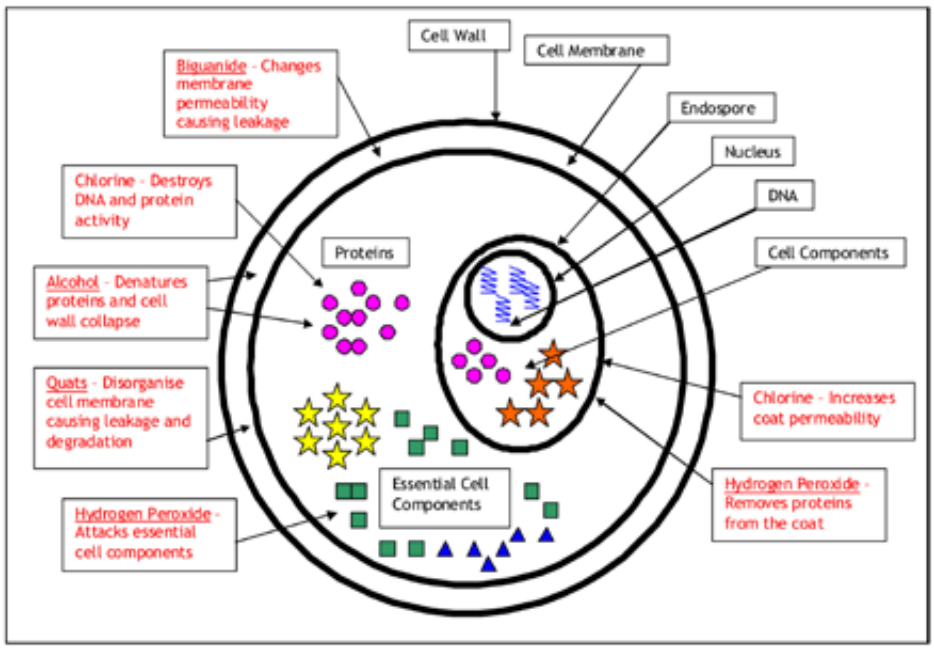

Table 1

Endospores

Endospores are extremely difficult to kill. The endospore is a state that a bacteria or virus can enter into when conditions are unfavourable, for example lack of food, lack of water or nutrients, temperature or ph. changes. They build an ultra-strong coat around the cell's nucleus and essential parts to protect it. They can remain in this dormant state until conditions improve, when the coat will break down and the cell returns to normal.

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

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often referred to as sporicidal. Chlorines can increase the permeability of the endospore coat and Hydrogen Peroxide can remove proteins from the coat.

Kill Spectrum

Using different disinfectants will increase your kill spectrum. This is the total portion of the microbial population that you are able to kill. It can be helpful to think of the kill spectrum in a similar way to the light spectrum. If you only ever consider visible light, you are missing out a huge portion of the light spectrum, what about X-rays and UV rays? In the same way, if you only ever use disinfectants that kill bacteria, you are not doing anything to combat endospores and other types of micro-organisms. We need to try and select disinfectants that when used in rotation cover as much of the spectrum as possible, therefore increasing your kill spectrum as much as possible. (see table 2)

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

Choosing a Disinfectant?

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

Summary

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

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

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

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