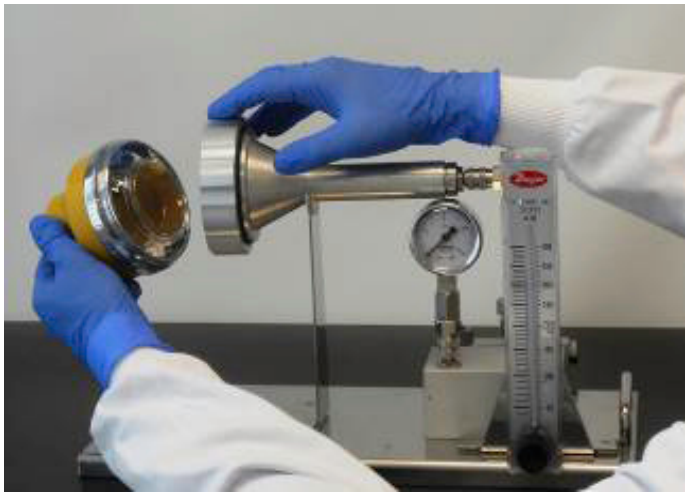
Standardising Cleanroom Production Line Monitoring for Microbial Contamination

Cherwell's SAS Pinocchio Compressed Air Sampler Supports Synergy Health



The SAS Pinocchio compressed air and bottled gas sampler

Synergy Health's Applied Sterilisation Technologies (AST) laboratory services are using Cherwell Laboratories' SAS Pinocchio compressed air and bottled gas sampler to deliver an enhanced service to its customers. Synergy's microbiological laboratories offer a wide range of services within the medical device and pharmaceutical manufacturing industries, including environmental monitoring, sterilisation validation and bioburden analysis. The introduction of Cherwell's SAS Pinocchio is enabling Synergy to help their customers meet regulatory requirements more effectively.

Cherwell have been supplying Redipor® prepared microbiological media, plus SAS air samplers for use within Synergy's fully accredited environmental monitoring service offering for a number of years. Having recently introduced the SAS Pinocchio to its monitoring programmes, Synergy can now enable their customers to demonstrate enhanced monitoring of product contact air on the production lines within their manufacturing cleanrooms.

Compressed air and bottled gas sampling has traditionally used sterile tubing to spray air across the surface of a media plate. However, this process is not quantitative as the volume of compressed air used is unknown and, since it is also highly pressurised, any microbes may be killed when hitting the plate. "Using the SAS Pinocchio not only lowers the flow rate to maintain viability of organisms, but also provides quantifiable results as it uses a known volume of air sample. This enables our customers to set microbial limits and meet the increasingly stringent requirements of regulatory auditors," explained Susan Finlay-Woods, Laboratory Manager, South Marston Labs, AST.

Susan Finlay-Woods continued, "We selected the SAS Pinocchio for compressed air sampling due to our positive long-term experience with Cherwell and its SAS Super hand held microbial samplers that we use routinely for air monitoring. Therefore, we were confident that SAS technology was the most effective and easy to use."

Importantly, Synergy technicians also find SAS Super and SAS Pinocchio microbial samplers highly portable, being very simple to assemble, use and dismantle into an individual carrying case - essential when visiting clients' manufacturing sites. "We have an excellent working relationship with Cherwell who are always very helpful, meet our specific needs and ensure reliability, just like their products. The SAS Pinocchio provides another example of this," concluded Susan.

Cherwell's SAS air sampling units use the multi-point impaction (single stage sieve) sampling technique and sample air at a fixed rate to give quantifiable results. Air borne particles are impacted onto the agar surface of a standard Contact plate, with Petri dish versions also available. The SAS Pinocchio is a non-powered air sampling unit, which provides a controlled method for bioburden monitoring of compressed air and other gases. Regulating air flow from the compressed supply before passing through a traditional head, it forms part of a compatible environmental monitoring programme when used alongside other air samplers within the SAS monitoring range, as demonstrated by Synergy AST.

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

A new range of Polyester wipes now available at Cleanroomshop.com

As a specialist supplier of cleanroom wipes and cleaning agents, Cleanroomshop.com understand that for many organisations the task of selecting the correct wipe can be daunting due to the wide range of options on the market.

Why use polyester wipes?

Polyester wipes are used because they are low abrasive and ultra-low in particle generation. Combined with the attributes of high absorbency, purity and cleanliness; the new polyester range is instrumental for mission critical environments.

Cleanroomshop.com partnering with Essentra

Working with Essentra Porous Technologies, a division of Essentra plc, Cleanroomshop.com now offers a range of polyester wipes that are of optimal strength and durability with low particle and fibre generation.

The range includes:

- 100% polyester interlocked wipes & 100% polyester Purity wipes with a knit construction for exceptional absorbency and cleanliness.
- Polyester Pinsonic 2 ply wipes 100% continuous filament polyester wipes deliver ultra-low particle generation - ideal for critical cleanroom environments.
- For a more general purpose wipe that can be used for cleaning and maintenance both inside and outside of a cleanroom environment, a Cellulose / Polyester blend wipe is now available at Cleanroomshop.com. Economical, the wipe is made up of 55% cellulose and 45% polyester fibres that are hydro-entangled to create maximum strength and durability.

"We are excited to be partnering with Connect 2 Cleanrooms Ltd and while we are changing our face to the customer with new products , marketing and innovations, our commitment to partnerships will continue to be our primary focus" Ninette van Lingen, Senior Sales Director, Americas, Essentra pl.

Offering unbeatable value, the new polyester wipe range offers further choice from the Cleanroomshop.com wiping range.

To find out more see the full product descriptions at Cleanroomshop.com where you can order online, or call its helpful team on +44(0)1524 813022.

Cleanroomshop.com has been providing specialist contamination control consumables, furniture and equipment to the cleanroom industry for over 10 years

Connect 2 Cleanrooms
Riverside House, Forge Lane LA2 6RH Halton, Lancashire
Vereinigtes Königreich Großbritannien und Nordirland
Telefon: +44(0)1524 813022 Telefax: +44(0)1524 811589
E-Mail: info@connect2cleanrooms.de
Internet: http://www.cleanroomshop.com

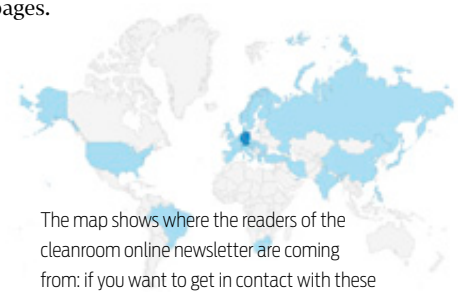
Dear readers, dear subscribers,

the system gets better and better : now the logos at the frontpage and the adverts are linked to the homepages.

Now again we will have a lot of new information, articles and contacts.

Yours sincerely

Reinhold Schuster



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.

The Korea National Quality Award is one of Korea's most prestigious business awards and one of the most important quality distinctions in the world. At the end of November ENGEL MACHINERY KOREA won this presidential quality award in the field of production innovation. Furthermore, Engel is the first foreign company ever receiving this award in the 39 years of its history. The award was handed over by the Korean Prime Minister Jung Hong-Won and the winners have been honored by the Korean President Park Geun-Hye.

Engel Machinery Korea receives Presidential National Quality Award

The Korea National Quality Award has been introduced by the Korean government to improve quality standards in Korea. It is based on the Malcom Baldrige National Award (USA), the European Quality Award and the Deming Prize (Japan) which underlines the international importance.

„This award is a great honour for us and also an important confirmation of the fact that we're on the right track with our global quality management system", says Robert Bodingbauer, Engel Machinery Korea's president. "Our plant in Pyeongtaek City abides by the same strict quality standards used at our main factory in Austria, and this award highlights the fact that this company motto is being adhered to consistently all over the world." The outstanding commitment of Engel Korea's management and employees to implement Engel's global systems has been the main factor to receive this prize.

Engel has been producing injection moulding machines in the small and medium clamping force segment in Korea since 2001. The decentralised production guarantees short delivery times for customers in Asia and also ensures that injection moulding machines and turnkey solutions are adapted to the specific requirements of the local markets. In spring 2013, the company doubled its capacities in Korea. Robert Bodingbauer states: „The demand for quality products and innovative technologies as well as short delivery times and extensive customer service will secure the company's success in Asia in the future."

ENGEL AUSTRIA GmbH
A 4311 Schwertberg

ISPE DACH Affiliate intensifies cooperation with colleges and universities with pharma technology-related courses and announces six Student Awards for 2014.

ISPE Dach announces six Student Awards for 2014 in pharma-technology-related courses

Pharmaceutical technology focused departments and disciplines are found at many colleges and universities in Germany, Austria and Switzerland. An understanding of the composition and effects of drugs, the chemical / physical analysis, manufacturing and packaging, validation and qualification, quality assurance and the legal framework in the preparation of medicines are taught in the different courses. Here are all the steps involved from the raw materials, via the intermediate products to finished products of a pharmaceutical formulation.

ISPE Dach wants to become this forming and research units known better, and networking for mutual benefit even more with the industry to integrate the technical colleges, colleges and universities in the ISPE network.

According to the ISPE target ‚Connecting a World of Pharmaceutical Knowledge'.

A key concern of the ISPE Dach is to support the students:
- it will give an industry orientation
- it will help to build students' first professional networks
- it will support the search for Bachelor-/ Master-Topics and internship places
- it will assist in the search for first career opportunities after graduation

Student Awards

For outstanding achievements and work in the field of pharmaceutical technology (pharmaceutical technology and production) ISPE DACH offers a reward. Study Prizes to undergraduate and graduate students. The ISPE Dach issues the award for outstanding practical, innovative thesis in the winter semester 2013/2014 or summer semester 2014. It will be awarded a total of six students of Bachelors/Masters or diploma disciplines in Pharmaceutical Technology, Chemical Engineering and Biotechnology at colleges and universities in Germany, Austria and Switzerland.

The prize includes a certificate, a free one-year ISPE Dach membership and an invitation to free participation in the ISPE Dach Annual Meeting 2015, including the social evening. The prize is for each award winner rewarded with 500€.

The application process is open to all high school teachers of the above disciplines. Interested students can get in touch with their teachers to be entered.

The criteria for the evaluation of the submitted works are 1) practical relevance, 2) practicability, 3) innovation and 4) clarity of presentation. Awarding of the ISPE Dach-Study Prizes will be decided by the Committee (Board) of the ISPE Dach .

Applications are available at http://ispe-dach.org/web/lehre-forschung/. Proposals may be submitted until 31 October 2014 by email at:

ISPE DACH
Rolf Sopp, Secretary ISPE DACH
Rolf.Sopp@ispe - dach.org

ISPE - DACH
D 37120 Bovenden

Eurozyto GmbH is a specialist in the provision of patient-specific infusion solutions. The pharmaceutical manufacturer from Königstein has invested in two separately constructed cleanroom labs for the manufacture of parenteral nutrition and cytostatic medicines. After a planning and construction phase spanning several months, the manufacture of medicines is now going into production.

Eurozyto GmbH investing in 200 square metres of cleanroom laboratories

Cleanroom laboratory for parenteral nutrition. CleanSteriCell® GMP A in B with laminar flow workbenches.

Cleanroom laboratory for cytostatics. CleanSteriCell® GMP A in B with safety workbenches.

Ready-to-use infusion solutions manufactured by Eurozyto GmbH are prepared in close cooperation with pharmacies, doctors and clinics. The service provider from Königstein has made it their goal to ensure the supply of patients individually, quickly and at top quality. The manufacturing process for the infusions is subject to a manufacturing permit pursuant to Section 13 of the German Pharmaceutical Law. Among other things, this mandates the use of GMP-compliant Class B cleanroom laboratories. In the production of toxic cytostatic solutions for cancer therapy, in addition to absolute sterility for patient safety, it is also necessary to guarantee absolutely gap-free workplace safety. Employees must be protected from any contamination while handling these toxic substances – even the transport of individual particles must be ruled out. The manufacturing process for parenteral infusion solutions thus represents a significant challenge in work process control and cleanliness of the rooms.

To ensure the best possible safety, Eurozyto GmbH installed two separate laboratories in cleanroom class GMP A in B. Pharmacist and managing director Uwe-Bernd Rose explains: „We want to achieve the best possible quality and safety standards, so we made no compromises when investing in the technical equipment for the laboratories. By separating manufacturing into toxic and non-toxic areas, we rule out any cross-contamination. We looked for an expert in construction of cleanroom technology who had experience in the manufacturing of cleanroom laboratories and could guarantee functional and especially consistently safe processes."

They decided on cleanroom specialists SCHILLING ENGINEERING. This company in Baden-Württemberg offers their own cleanroom system CleanSteriCell®, a cleanroom technology specifically developed for laboratories that meets all GMP requirements and ensures the best possible pharmaceutical safety.

The new cleanroom laboratories at Eurozyto GmbH, together with their lock and work preparation chambers, are about 100 square metres of cleanroom space. Each laboratory is reached through a multi-level personnel and material lock system that ensures structured work processes and additional safety. Three personnel locks arranged one after the other with connected work preparation rooms increases the cleanroom class to GMP B using falling pressure differentials and increased rates of air exchange. Cytostatic workbenches ensure absolute germ-free conditions and unlimited personnel safety during the process of manufacturing cancer drugs. The second cleanroom laboratory, for parenteral nutrition, is equipped with laminar flow workbenches. Flush-mounted laminar flow units with high-performance ULPA filters supply the clean areas and working areas with ultra-clean air using a low-turbulence laminar flow system. The circulation and air return is integrated into the walls of the cleanrooms. An air circulation process developed by SCHILLING ENGINEERING for use with air-conditioned air allows the system to be operated more energy-efficiently than comparable systems. A GMP-compliant monitoring system ensures continuous control and precise calibration of the required cleanroom parameters. One special feature of the innovative cleanroom system is the wall connectors, which are mounted using a silicone-free GMP sealing clip system. The connections are not subject to any wear and can be dismounted for possible expansions or reconfiguration.

The CleanSteriCell® cleanroom laboratories were designed, built and ready for use within 16 weeks. Uwe-Bernd Rose was impressed by the construction of the cleanroom systems: „The cleanroom technology was built in record time. The work of the service technicians from SCHILLING ENGINEERING was truly impressive. They're fast, communicative and know what they're doing. We are looking forward to future tasks and are sure that our cleanroom laboratories will make a significant contribution to the safe care of patients in our community."

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

Precision tooling for big results in the life sciences industry.

Tiny precision tooling can produce big results in the life sciences industry. When a membrane in the cap of a medicine bottle weighs just three one-thousandths of a gram, extremely demanding accuracy is crucial through the production of millions of items.

Life science matters to us all – after all, it could be our life that's at stake. And we want to be sure that, if we have to depend on it, we get only the best. The industry, which includes medicine, pharmaceuticals, biotechnology and patient care, is one with which we may have a very intimate relationship, often at a time when we need all the protection we can get.

So it's no surprise that the standards for products in the life sciences industry are extremely demanding. It may take years to bring something to market, as validation, approval and adjustment follow discovery and development. And a company like Trelleborg, whose solutions are used extensively in life sciences, has to meet those high demands.

Ursula Nollenberger, Product Line Director for Liquid Silicone Rubber (LSR) Components at Trelleborg Sealing Solutions, says there are three main areas in which Trelleborg can offer its expertise on a global basis. "We have design competence, we have manufacturing competence, and we have material competence," she says.

Trelleborg helps companies design the products they need and the process by which they will be manufactured. "Sometimes a customer comes to us with a black box idea," says Nollenberger. "They know what they want done, but they only have a few ideas about how to do it. We work with the customer to find a solution."

At Trelleborg's LSR Competence Center in Stein am Rhein, Switzerland, Trelleborg engineers help to determine the correct material and design solution, developing the tools and process for the realization of that solution. The aim is a high-quality, cost-effective product and reliable process, using Class 7 and 8 cleanrooms as needed. Cleanliness, product purity and biocompatibility are key criteria.

One issue the center tackled was a problematic valve in a sterilization unit for hospital instruments. The valve was made of a thermoplastic body sealed with an O-Ring, and the assembly created space where bacteria could build up.

"The company came to us for a solution, and we worked with them on a suitable design," Nollenberger says. "In the design phase we supported the customer with our non-linear finite element analysis tool, which is one of the most advanced in our industry, to optimize the new design."

The decision was made to use a two-shot Liquid Injection Molding (LIM) process, where, in a single tool, first the thermoplastic and then the LSR is injected in a closed-loop, automated system to produce the composite. A single sealing component was created that closed the gap in the assembly. "The two-component process demands the highest levels of tool precision, but avoids the need for a second assembly step and the risks and cost associated with that for the customer," Nollenberger explains.

That product is now undergoing validation, and production of several million parts a year will start in 2014.

Many of the parts that Trelleborg makes for the life sciences market are very small, and micromolding presents its own challenges. The smallest piece Trelleborg manufactures is a septum, the membrane in the cap of a medicine bottle through which one can insert and withdraw a syringe. This weighs just 0.003 grams and at that size you can hardly pick the part up with standard molding burrs being bigger than the object itself.

Manufacturing a micro-component such as this requires extreme accuracy in tool construction, control of shot weight and the molding process. Automatic handling of the product after molding is done by a unique, specially developed robot gripper arm. The process ensures levels of accuracy are maintained reliably for millions of shots.

"We are always pushing the envelope in tool and process design," Nollenberger says. "The global team thrives on developing the tiniest precision tooling, finding ever-newer solutions for the dosage of ever smaller weights and devising new process automation tools to handle and control such small parts. Perhaps as Stein am Rhein is in Switzerland, where there's always been a watchmaking industry, we have a special tradition of dealing with tiny and complex components."

A breast shield for nursing mothers with sensitive nipples may look straightforward, but it's a product of high-precision LSR technology and it's the component's spherical surfaces that provide a challenge to toolmakers. The four holes in the dome-shaped tip of the nipple are produced directly by the mold. The asymmetric shape makes it particularly difficult to split the mold, but with extremely accurate dosing of the shot size, it's completely flash-free. There's no need for any finishing treatment and the unit is completed in one stage.

High precision in-house tooling

Trelleborg's main Liquid Silicone Rubber (LSR) plant in Stein am Rhein, Switzerland, has its own tooling center, where all tools at the facility are designed and finished. Critical success factors are high precision, flashless and wasteless design, high quality and robustness. In addition, Trelleborg's special expertise is to design tools and processes to remove products from their molds automatically, without the need for finishing operations. If required, the parts can be tested to customer requirements within the same process and then immediately packaged in a cleanroom – from the machine to the box.

Tight sealing O-ring

Trelleborg provides an engineered O-Ring for a new kind of inhaler made by Boehringer Ingelheim that improves uptake of medication. It requires precision technology with very low manufacturing tolerances. Trelleborg's O-Ring, which seals the dosing chamber, has to be manufactured to a tolerance of ±1 cubic millimeter and the flash at the mold split must be less than 0.05 millimeter.

Trelleborg Sealing Solutions Silcotech AG
CH 8260 Stein am Rhein

Simulation supports part quality control and avoids expensive tooling rework

Sigmasoft® Delivers First-Shot Success in Powder Injection Micro-Molding Application

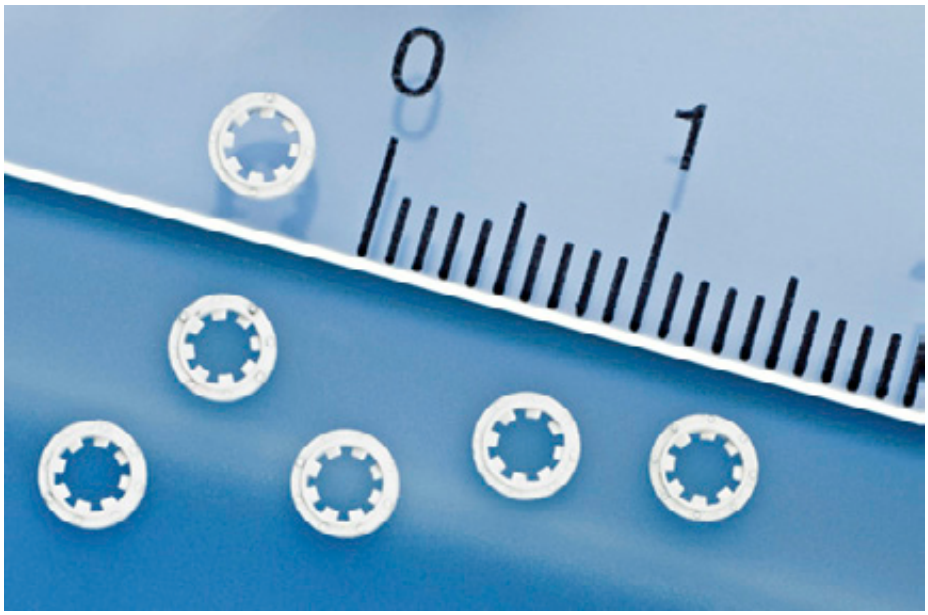
A micro wheel developed for a turbine guide shows how simulation with Sigmasoft® in PIM applications can significantly reduce the manufacturing costs and reliably predict in-molded defects early and at low cost in the design stage.

Miniaturization is one of the key demands in industries like electronic, medical or automotive, but when part dimensions decline drastically, the geometrical complexity increases proportionally and functional integration comes as an additional demand. The manufacturing of such complex-shaped micro-applications becomes challenging and hence a perfect target for powder injection molding (PIM) technology.

Micro-molding of MIM and CIM applications is not new to the industry. However industrial applications are rarely found outside the academic environments. One reason for this hesitation might be based on the uncertainties and challenges in quality control posed by the extremely small dimensions.

Even in macroscopic PIM applications, the quality inspection of green parts is often skipped to the sintered stage, with costly consequences. Micro-PIM brings this question to a next level: how can molded-in defects be determined reliably but with acceptable cost and time effort, for part with edge lengths of 1 to 2 mm and functional dimension of just some tenth of a mm? "The answer is in a well-structured part and mold design phase, with sufficient time for thorough design iterations based on simulation results. This time spent in the beginning is saved later multiplicatively", explain Dr. Marco Thornagel, from Sigma Engineering GmbH, and Jochen Heneka and Tobias Müller, from the Karlsruhe Institute of Technology (KIT) in their paper Micro-Molded CIM-Components: Simulation based Mold- and Process Development, presented at the EuroPM 2013 Conference in Gothenburg, Sweden.

The paper describes the successful design process of a turbine guide wheel made of ZrO2. During mold design significant effort was spent to simulate the thermo-rheological behavior of the complete mold and to predict the later green part properties. Based on the recommendations derived from simulation results, the runner layout was optimized, the feasibility of the mold design proved, the mold built and successful micro CIM parts produced, with the impressive result that the mold stably delivered flawless parts with over 99% of theoretical density right from the first shot, without requiring tooling rework.



The use of Sigmasoft® allowed producing flawless PIM-micro parts right on from the first shot.

Thinking powder, thinking micro

Since 2009 the injection molding simulation software SIGMASOFT® has been available specifically for CIM applications. The integration of a rheological model which accounts for the viscosity increase at low shear rates increases the reliability of the predicted flow front. Also the state-of-the-art flow solver technology, able to accurately predict kinetic flow effects such as jetting, reveals the driving forces behind such phenomena and thus makes it possible to control their appearance and the part quality defects associated.

Micro dimensions create specific challenges, as they influence properties such as surface tension, heat transfer or surface-to-volume ratio. These variations require specifically developed material models to be integrated into the simulation. SIGMASOFT® has been adapted specifically for the simulation of micro-applications through material models validated over the years in several research projects.

Molds used in micro injection molding, and particularly in micro-powder injection molding, need to fulfill special requirements in terms of quality and precision. For example, a variothermal process control needs to be conducted, and vacuum must be generated in the cavities, to provide for the best preconditions to get complete mold filling and to avoid defects in the final product, such as shrink marks or diesel-effect marks. Especially the runner system and the mold inserts are crucial: the insert manufacture is expensive and time consuming, mainly due to the requested tolerances, which are often close to the limits of conventional machining methods. Consequently it is worth to approach the design and manufacture of micro applications using injection molding simulation tools.

Case study: a turbine wheel molded right from the first shot

The research project SFB 499, conducted at the Karlsruhe Institute of Technology (KIT) in Germany, dealt with the process chain for the development of highly stressed micro-parts made of ceramic and metal alloy.

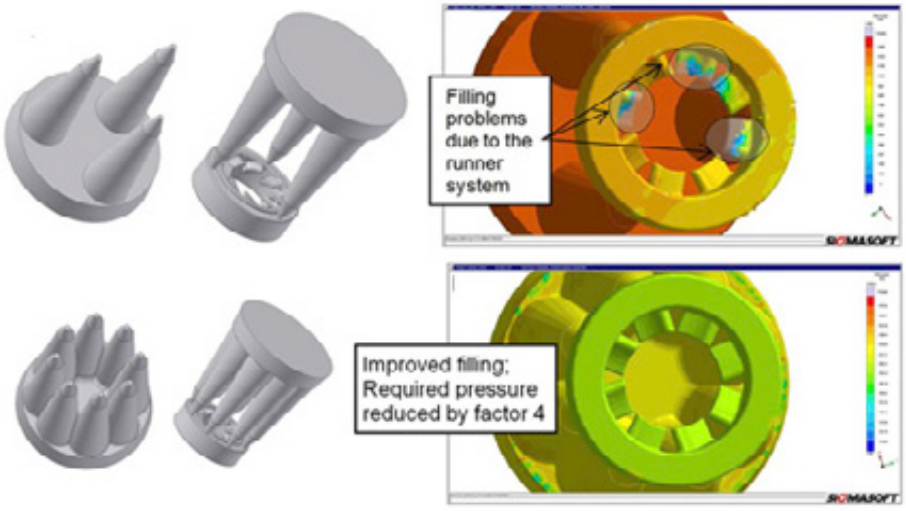
Page 2: Sigmasoft® Delivers First-Shot Success in Powder Injection Micro-Molding Application

The core of the micro turbine demonstrator was a guide wheel, made of ZrO2. In a first layout, the runner system of the guide wheel was designed with three distribution channels, which delivered an incomplete mold filling, required high molding pressure and produced weld lines in the turbine blades, which could lead to a poor performance. Acquiring this knowledge early in the design stage allowed reacting extremely fast, creating a new optimized design of the runner at very low costs without incurring in reworks on expensive machines.

In the next iteration step, the amount of channels of the runner system was increased to eight and all edges were rounded to improve the flow conditions of the melted material. To avoid weld lines in functional areas of the final part, each runner system was connected to the turbine guide wheel in the middle of each blade. As a result, the mold was filled with a pressure four times lower, without any defects. Furthermore, the weld lines were relocated between the turbine blades, in non-functional regions.

The molded micro wheel showed a nicely shaped outer contour, without any visible defects. The mold with the optimized mold inserts and runner system provided a stable replication process, suitable for mass production, without additional iteration. The sintered parts had over 99% of theoretical density, without any shrink holes, burrs or chip-offs, and presented a linear shrinkage of about 21%. "This first-shot success was achieved due to the consequent use of injection molding simulation at the mold design stage, based on well characterized feedstock data", conclude the authors in their paper. "Molding simulation has to be understood as a valuable tool and has to be well-established into the part- and mold design process. Only then can the described success potential for micro PIM be actually achieved", they add.

SIGMA Engineering GmbH
D 52072 Aachen



Simulation can reliably predict part defects and processing problems in PIM micro applications. Above: the initial runner configuration produced high molding pressure, partially unfilled regions and weld lines in functional sections of the part. Below: a re-design in the runner avoided part defects and reduced the molding pressure.

M+W U.S., a subsidiary of the global engineering and construction company M+W Group, Gehrlicher Solar America and EDF Renewable Energy (EDF) have announced the commencement of construction of their second, 6 MW project in the State of Massachusetts. M+W U.S. will perform the engineering, procurement and construction activities while EDF will own and operate the project. The Commercial Operations Date is scheduled for the second quarter of 2014.

M+W U.S. and EDF Renewable Energy commence construction on their second 6 MW project in Massachusetts

This ground-mounted fixed tilt solar photovoltaic project is located on approximately 26 acres of privately owned land at the former Shirley Airport, 50 miles northwest of Boston. The power generated will be delivered to the town of Billerica, MA under a long-term Power Purchase Agreement, pursuant to the State's Virtual Net Metering Credits Program.

"We extend our gratitude to the town officials of Lancaster, Shirley and Billerica for their strong support for the project and we look forward to continue to work closely to deliver clean solar power at a time when communities are seeking cost-effective energy solutions that reduce greenhouse gases," said Nader Jandaghi, Director of Commercial Solar for EDF. "The Lancaster solar project adds to the company's 300+MWp development portfolio of both distributed generation and utility-scale solar projects across North America and will deliver cost-competitive renewable energy and economic benefits to the host communities."

Through an integrated approach, M+W U.S. will contract with Gehrlicher Solar America Corp. (GSAC) to execute the implementation of the project. M+W acquired GSAC in August of last year. Similar to the initial 6 MW project between M+W and EDF, called Lepomis, this project will use the same project team in the deployment. "M+W is excited to have a partner like EDF in the development, and deployment of these two exciting projects," said Robert Wanless, Director of Business Development at M+W U.S.

Rick Whitney, President and CEO of M+W U.S., Inc. stated, "The combination of M+W's experience in engineering and construction of PV manufacturing facilities, utility infrastructure and large scale power plants, and Gehrlicher's competency as a photovoltaic system integrator provides this project with industry leading capability from a single source. We are extremely pleased that our major customer, EDF, has selected us for this second project in Massachusetts."

M+W Process Industries GmbH
Lotterbergstr. 30 D 70499 Stuttgart
Telefon: 0711 8804 1822
Telefax: 0711 8804 1888
E-Mail: ilga.palfner@mwgroup.net
Internet: http://www.pi.mwgroup.net

Technical cleanliness: Determining particulate cleanliness in fields ranging from the automotive industry to medical device technology

Autor: Y. Holzapfel and G. Kreck, Fraunhofer Institute for Manufacturing Engineering and Automation IPA, Stuttgart, Germany

1. Requirements of particulate cleanliness

The need for high levels of particulate cleanliness is obvious for some products such as integrated circuits (with structural widths currently as low as 22 nm) that are manufactured in the semiconductor industry. However, particulate cleanliness, i.e. the absence of micrometer-sized critical particles, is an important quality feature for numerous products in many other industries spanning the automotive industry, through aerospace and right up to life science, such as medical device technology. The reasons for this are as diverse as the products themselves, ranging from improved performance, miniaturization, reliability and durability up to legal requirements and even personal and environmental safety [1].

Although the sizes ranges of critical particles vary from one product to the next and therefore require regulation, some questions overlap, such as:

- How much particulate contamination of which size is on the product?
- What type of contamination is it?
- Can a particle source be identified?
- To what extent can a state of cleanliness be improved by using cleaning technologies?

To answer these questions, different cleanliness analysis methods can be used which are universally applicable.

2. Technical cleanliness: cleanliness analysis in the automotive industry

About 15 years ago, subject to the development of more powerful components such as common rail injection systems, the automotive industry started to become affected by particulate contamination. Hard metallic particles cause the most problems (Figure 1).

In the automotive industry, the state which describes the absence of functionally-critical contamination on relevant functional surfaces is known as »technical cleanliness«. To ascertain a component's technical cleanliness, a cleanliness analysis has to be performed. However, due to the range and complexity of automotive components (Figure 2), it is not easy to apply the obvious method of direct inspection to search for potential »killer particles«.

Figure 1: Particles on a filter membrane extracted in tests on an automotive component (left), and single critical particles (right)

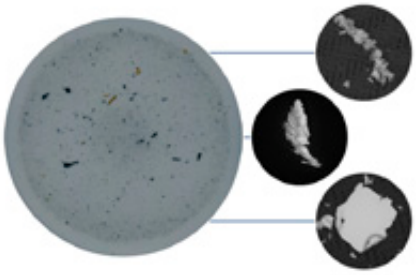


Figure 2: Wide range of automotive components

Consequently, a testing method was required that is capable of reliably detecting critical contamination. Under the direction of Fraunhofer IPA, a solution to this problem was jointly developed with participating industrial companies in the industrial alliance »Technical cleanliness (TecSa) «. The fruit of the development was the publication of the guideline »VDA Volume 19 Inspection of Technical Cleanliness - Particulate Contamination of Functionally Relevant Automotive Components«, in which detailed descriptions of procedures and variations of cleanliness analyses for determining particulate cleanliness are given [2]. In this context, a cleanliness analysis can be divided into two steps (Figure 3):

1. Extraction: a liquid process to remove particles from relevant component surfaces with the aid of different techniques (pressure rinsing, ultrasound, rinsing, agitation) (Figure 4) and

Figure 4: Example of an extraction by means of pressure-rinsing

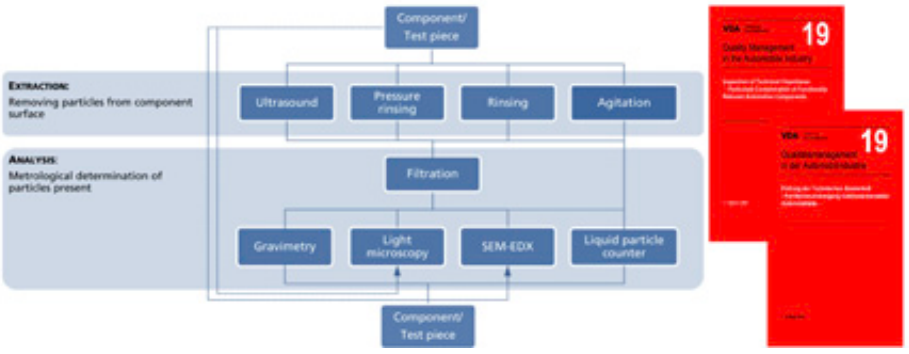


Figure 3: Elements making up a cleanliness analysis (left) according to VDA 19 (right)

Seite 2: Technical cleanliness

Figure 5: Information obtained from different analysis techniques

2. The actual analysis, which usually starts with filtration to transfer the particles extracted from the component to an analysis filter. Several different methods can also be used for the analysis, such as gravimetry (determination of residue weight) and automated microscopic techniques (light microscopy or scanning electron microscopy combined with energy dispersive x-ray spectroscopy EDX, Figure 5).

As well as the blank value, which also has to be ascertained for numerous other analytical determinations, it is especially important to assess the suitability of the extraction parameters chosen. Because no »normed contaminated components« (= components with a known uniform initial state of contamination) exist which would allow cleanliness analysis results with different parameters to be compared with one another, a so-called qualification test or declining test is carried out. Here, the same component is repeatedly subjected to an extraction process. The aim is to remove 90 % of all particles present within a maximum of six successive extraction steps (Figure 6):

- If this is already the case after the first declining tests, the chosen parameters can be kept.
- If values only decline after further extraction steps, parameters are adjusted for the routine inspections to be carried out later on, e.g. by lengthening the duration of the extraction process.
- If no declining values are obtained, another declining test is performed using more appropriate parameters or a different technique.

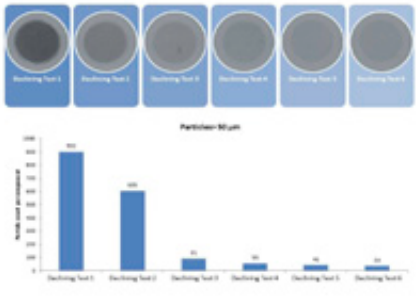


Figure 6: Analysis filters (top) and analysis of a qualification test (bottom)

3. Problem of recontamination due to assembly

The observation that technically clean single components do not guarantee a clean overall system underlines the need to ascertain which factors influence product cleanliness in assembly.

These factors were determined in the industrial alliance »MontSa« and documented in the guideline »VDA Volume 19.2 Technical Cleanliness in Assembly - Environment, Logistics, Staff and Assembly Equipment« [3]. The guideline describes influencing factors, such as the environment, staff, logistics and assembly equipment, from the point of view of cleanliness in assembly with the aim of identifying potentials for optimizing cleanliness in a production facility, or of designing it in a cleanliness-orientated way right from the beginning (Figure 7).

Figure 7: Factors influencing cleanliness in assembly (left) according to VDA 19.2 (right)

The main basic principles are:

- »from inside to the outside«, i.e. when taking optimization measures, the initial focus should be on processes taking place close to the product, and
- »as clean as necessary, not as clean as possible«, i.e. transferring production to a cleanroom often does not achieve the desired result of clean products because the sometimes millimeter-sized assembly chippings are too heavy to be airborne and therefore cannot be removed by the airflow in the cleanroom.

Consequently, an important starting point for optimizations is the identification of particle sources in the assembly environment. This is achieved using methods such as Tape Lift to ascertain the cleanliness of surfaces, or particle traps to capture particles sedimenting on an adhesive pad in order to monitor the environment in various areas of the production facility. Particle traps can also be utilized to ascertain the contamination potential of processes (Figure 8).

The same analysis techniques are used as for analyzing component cleanliness (automated microscopic analysis with light and scanning electron microscopy). In certain cases, by identifying particle sources it may be possible to avoid contamination (e.g. by designing assembly equipment appropriately) or to remove it effectively (e.g. by integrating a cleaning process into assembly).

In order to minimize particle generation and contamination transfer, a further focus is placed on supplementary suitable logistic concepts, such as cleanliness-orientated packaging or suitable lock concepts.

Staff members are also considered because they can decisively influence the state of cleanliness of a product. The workers concerned may be responsible for generating the contamination or for removing it.

4. Applying methods to life science products

Despite the fact that the cleanliness issue is deeply rooted in the life science sector, especially in pharmaceutics, and that national and international standards and legal requirements have been in existence for some years now, problems due to insufficiently clean products still occur.

Medical technology products are one example of this. Over the last ten years, approx. 250 medical technology products have been recalled by the Food and Drug Administration (FDA), with approx. 30 % of these being due to contamination [4].

One explanation for this is the currently inadequate verification of the level of particulate cleanliness. At the moment, the main emphasis of cleanliness analyses performed on these products is on assuring sterility, which is often wrongly equated with the absence of particles. Particulate contamination entering the human body is also associated with a risk potential because it may have a toxic or pyrogenic effect. A logical consequence would be to continuously monitor and reliably verify the state of particulate cleanliness. However, at the moment there are a number of deficits in this respect. One of them is limiting values for particulate

Figure 8: Principle of the Tape Lift method (left) and collecting particles with sedimentation traps (right)

Seite 3: Technical cleanliness

contamination; these were originally conceived for injection and infusion fluids but have since been transferred in part to a whole range of medical products. Another deficit concerns determining cleanliness levels because specific test methods exist only for a handful of medical technology products.

To determine particulate contamination, various norms e.g. [5], [6], [7], [8] describe the following procedures:

1. Testing by means of liquid particle counters
2. Filtration and manual analysis with a microscope

A critical aspect here is the extraction step: in order to collect contamination from a product, a rinsing method is described for infusion devices, for example, and a swilling method using a test fluid for elastomer components in parenterals [6]. These product-specific methods cannot be generally applied to the broad spectrum of medical products (Figure 9) without first assessing their suitability. Only after procedures have been validated can their application be appropriately modified for other products. Methods can be validated by means of a declining test, such as that described in VDA 19 for inspecting automotive components.

Figure 9: Broad spectrum of medical products

To support the identification of contamination sources, automated systems as well as analysis techniques could be utilized to characterize particles in more detail (e.g. SEM-EDX to determine elementary composition).

Figure 10: Particle analysis under cleanroom conditions

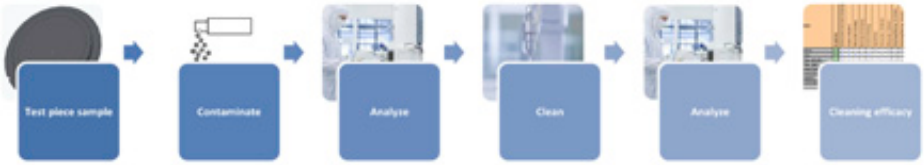


Figure 11: Determining the efficacy of cleaning methods for the purpose of comparison

5. Cleaning processes as a control strategy

Cleaning steps are often necessary to control contamination. Depending on the product and manufacturing process concerned, it may make sense to carry out a cleaning step at various stages of the production process, e.g.

- At individual component level because they should/must be clean for a specific reason,
- Integrated into assembly in order to directly remove contamination generated by assembly processes or
- At the end of production when the system is complete.

The efficacy of the cleaning technique used can be verified by means of a cleanliness analysis.

In cases where a comparison between different cleaning methods is required, an assessment matrix can be used which takes, among others, the following points into account:

- Investment and operating costs
- Compatibility with the product to be cleaned
- Environmental aspects
- Cleaning efficacy

Especially when ascertaining the efficacy of different cleaning methods, it makes sense to work with test pieces that allow contamination to be determined directly without extraction losses. After contaminating test pieces with a tracer in a defined way and then analyzing them, they are cleaned using one of the various techniques. Cleaning efficacy is calculated quantitatively by carrying out a second analysis of the test piece after cleaning to ascertain the residual amount of tracer present (Figure 11).

6. Summary and further activities

The life science industry, in particular the sectors of pharmaceutics and medical technology, is required to validate all its procedures. Especially in the area of particulate cleanliness analysis, there is often a lack of suitable detection procedures, with the consequence that strongly-deviating non-comparable results tend to be obtained.

It was possible to demonstrate the application of the VDA 19 procedure to cleanliness-sensitive medical technology products in several tests [10], [1]. To discuss these aspects as well as other cleanliness-related problems in a dialog, Fraunhofer IPA is now inviting people to participate in an event with a podium discussion that is scheduled on 25th February 2014 in order to identify – together with industry - the focus of future research and standardization work (http://www.ipa.fraunhofer.de/Braucht_die_Medizintechnik_neue_Ansaetze_fuer_die_Reinheitsvalidierung.2581.0.html). Also a survey on the topic of validating cleanliness in medical technology: www.ipa.fraunhofer.de/medizintechnik.

This approach has already proved its effectiveness in the automotive industry: through continuous discussions with relevant partners, VDA 19 is currently being revised subject to the formation of an industrial alliance with 40 industrial member companies. This enables the needs and requirements of industry to be mapped according to the state of the art, taking the knowledge gained from the VDA 19 project into account. The book is being revised by several different work groups divided into subject groups (extraction, analysis, limiting values, escalation, Figure 12).

Figure 12: Main topics of the revision of VDA 19

Seite 4: Technical cleanliness

7. Training courses

A further very important point is the motivation of workers carrying out cleanliness-related tasks. Targeted training courses can make employees more aware of the various issues related to cleanliness. In collaboration with VDA QMC, the following training courses are available:

Bibliography

[1] L. Gail, U. Gommel, H.-P. Hortig: Reinraumtechnik, 3rd Edition, Springer, Berlin, Heidelberg, 2012.

[2] Verband der Automobilindustrie e. V. (VDA): Volume 19 Inspection of Technical Cleanliness – Particulate Contamination of Functionally Relevant Automotive Components, 1st Edition, 2004.

[3] Verband der Automobilindustrie e. V. (VDA): Volume 19.2 Technical Cleanliness in Assembly – Environment, Logistics, Staff and Assembly Equipment, 1st Edition, 2010.

[4] U.S. Food and Drug Administration: Recall of Medical Devices. URL: http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm, invoked on 27th June 2013.

[5] European Pharmacopoeia (Ph. Eur.): Methoden der pharmazeutischen Technologie, Kapitel 2.9.19: Nicht sichtbare Partikel, 7th Edition, 4th Amendment, 2013.

[6] ISO 8536-4: Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed, 2013.

[7] ISO 1135-4: Infusion equipment for medical use - Part 4: Infusion sets for single use, 2012.

[8] ISO 16671: Ophthalmic implants – irrigating solutions for ophthalmic surgery, 2004.

[9] DIN EN ISO 8871-3: Elastomeric parts for parenterals and for devices for pharmaceutical use – Part 3: Determination of released-particle count, 2004.

[10] EUMINAfab: Your gateway to micro nano fabrication. URL: http://www.euminafab.eu/, invoked on 27th June 2013.

[11] G. Kreck und Y. Holzapfel: Sauberkeitsanalyse und Präzisionsreinigung von reinheitskritischen Life Science Produkten. In:15. VDI-Fachtagung „Reinraumtechnik", 13th June 2013.

7.1 Training course to become a »Technical Cleanliness Inspector« (VDA 19)

Topics:
The technical cleanliness of components and aggregates is an important functional quality feature in the manufacture of modern vehicles. The first comprehensive standardization work of its kind, the book »VDA Volume 19 Inspection of Technical Cleanliness - Particulate Contamination of Functionally Relevant Automotive Components« addresses methods and procedures for characterizing the cleanliness of products in the automotive quality chain.

Aim of the course:
In a unique training course given by Fraunhofer IPA in collaboration with VDA QMC, people are trained to carry out technical cleanliness inspections. Participants learn not only to independently configure cleanliness analyses in accordance with VDA 19 but also to carry them out with the aid of state-of-the-art equipment and document results compliant with the relevant regulations.

Target group:
The course is aimed at people who are involved with construction, quality assurance, technical purchasing and sales in the automotive and supplier industries, in aerospace, hydraulics and precision engineering, or are responsible for carrying out cleanliness inspections or confronted with the quality characteristic of »technical cleanliness«.

Next course (course language German): 4th to 5th February 2014

7.2 Training course to become a »Technical Cleanliness Planner« (VDA 19.2)

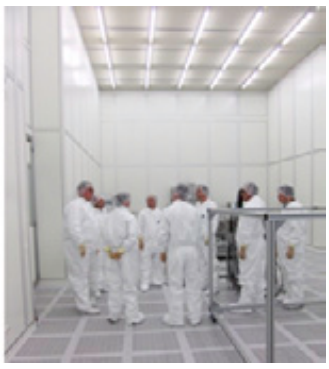
Aim of the course:
The course teaches participants how to derive and assess measures to prevent re-contamination that are based on component or system cleanliness specifications. The structure of the guideline and the training program allows the comprehensive cleanliness planning or optimization process to be divided into separate compact, manageable packages. By dealing with the influencing factors of environment, logistics, staff and assembly equipment as well as individual and general methods for measuring cleanliness influences, participants learn how to approach technical cleanliness in assembly in an independent and systematic way. This helps them recognize inappropriate or excessive cleanliness measures and avoid misinvestments.

Target group:
The course qualifies people working in the automotive and supplier industry to plan and optimize production with regard to technical cleanliness. It is especially aimed at assembly planners as well as process owners of existing assembly and logistics technologies and building services. The course is also intended for design engineers and developers, quality controllers and people responsible for technical cleanliness in customer-supplier relationships. Because they are confronted with similar cleanliness issues, it is also suitable for people active in the fields of aerospace, hydraulics and precision engineering.

Next course (course language German): 11th to 12th March 2014

Fraunhofer-Institut für Produktionstechnik und Automatisierung IPA
Nobelstraße 12 D 70569 Stuttgart Telefon: +49 711 970 1863
E-Mail: nicole.goeldner@ipa.fraunhofer.de Internet: http://www.ipa.fraunhofer.de

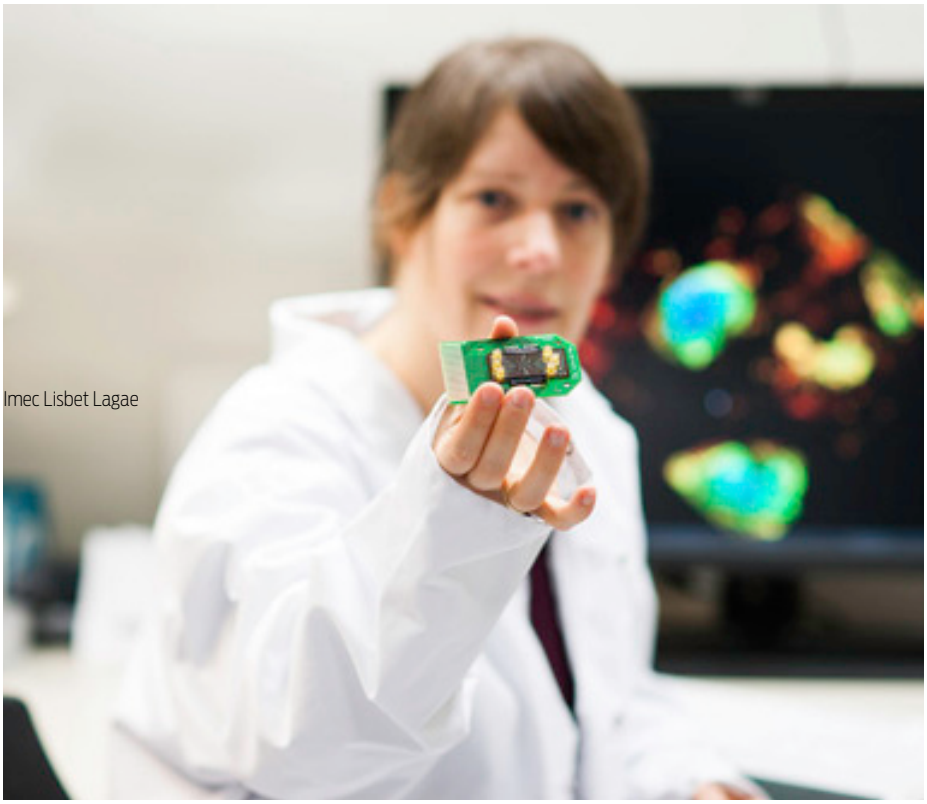
Figure 13: Training courses to become a technical cleanliness inspector or planner



SCALPEL Project to Develop Scalable Microfluidic Platform that Analyzes and Sorts Single Cells to greatly simplify Cancer Research and Treatment follow up.

Imec's Liesbet Lagae Awarded Prestigious European Research Council Grant

Imec, a world leading nanoelectronics research center, proudly announces that Prof. Dr. Liesbet Lagae, R&D Manager Life Science Technologies at imec and professor in Nanobio Physics at KU Leuven, has been awarded a Consolidator Grant for her research project SCALPEL* by the European Research Council (ERC). The ERC grant is the most prestigious grant for top researchers in the European Union. The grant funding, with a budget of 2 MEuro and for the duration of 5 years, will lead to the development of a high-content, high-throughput cell imaging and sorting device, that is more compact and easier to use than any existing single cell analyzer. The new device should support the work of pathologists, surgeons, and nurses and aims to improve the individualized follow-up and survival rate of cancer patients.


Imec Lisbet Lagae

The single cell analyzer that Prof. Dr. Lagae and her team will develop for the SCALPEL project is based on lens free digital imaging to analyze the physical morphology of single cells flowing at high speeds through a microfluidic network with gentle cell sorting switches to route the cells towards different outlets. It thus combines the virtues of microscopic 'high content' imaging with the virtues of automated 'high throughput' single cell analysis and sorting at a fraction of the cost. Because all optomechanical components, such as lenses, detectors, and nozzles, are replaced by nanoelectronics and advanced signal processing technology, the devices will be cheap and compact.

Currently, single cell analysis remains tedious with many different instruments and protocols, typically taking a few days of intense, hands-on work. The process not only slows down research, but also hinders the translation to application in clinical practice.

Billions of dollars have been spent trying to cure primary tumors, but very little was spent in trying to detect or kill circulating tumor cells causing metastasis. Metastasis is responsible for more than 90 percent of cancer-related deaths, and originates from single circulating tumor cells, spreading via the blood stream to seed new tumors. Detection of those highly aggressive circulating tumor cells at an early stage would greatly improve the chance of survival. This is an example of an application that could greatly benefit from the 'SCALPEL' cell sorter. Prof. Lagae will collaborate with Prof. Deniz Wirtz from John's Hopkins INBT and Prof. Johan Swinnen from KU Leuven's dept. of oncology for showing the potential of the device in metastasis detection.

ERC is a flagship component of the 'Ideas Programme' of the European Union's Seventh Research Framework Program (FP7). Through open competition it awards grants to projects led by top researchers in Europe. With scientific excellence being the sole criterion for selection, the ERC's aim is to recognize the best ideas, and retain and confer status and visibility to the best brains in Europe, while also attracting talent from abroad. By challenging Europe's brightest minds, the ERC expects that its grants will help to bring about new and unpredictable scientific and technological discoveries—the kind that can form the basis of new industries, markets, and broader social innovations of the future.

IMEC Belgium
BE 3001 Leuven

Engel will be demonstrating how maximum output, consistent quality and permanent availability can be combined with excellent efficiency levels through perfect cooperation between an injection moulding machine, a mould, automa-tion, application technology and support at the Saudi Plastics and Petrochem exhibition taking place from 17th to 20th February 2014 in Riyadh, Saudi Arabia.

Engel at Saudi PPPP 2014

17th - 20th February 2014: Saudi Plastics/Petrochem exhibition Riyadh (Saudi Arabia)

Perfectly tailored to specific requirements

The company will be focusing on the packaging and building industries over the four days and will be presenting four examples of application:

Caps: The all-electric Engel e-cap injection moulding machine is designed to produce extremely high performance levels and achieves cycle times of under three seconds. The Engel e-cap can be used to manufacture both standard drink caps and special caps for the cosmetics, cleaning and food industries. Andreas Leitner, Engel's Middle East sales director says: „29/25 caps are definitely becoming more and more popular for water. We've already completed a number of projects for this new, lighter cap type in co-operation with a well-known Swiss mould manufacturer and have had some very good experience with the Engel e-cap along the way."

Thin-walled containers: The all-electric Engel e-motion injection moulding machine turns thin-walled containers that meet high-tech requirements into low-cost products. Engel packaging turnkey solutions help processing companies to conserve energy and raw materials, and to integrate various process steps by incorporating techniques such as in-mould labelling. ENGEL works with system partners who are also leaders in their respective fields here, and some of these partners will be exhibiting in cooperation with Engel in Riyadh. Those joining Engel at the trade fair include Swiss IML expert Beck automation and Otto Hofstetter, which is also Swiss and a leading producer of moulds for thin-wall applications.

Pallets: The company helps plastics processing companies to follow the trend of switching to plastic pallets early with flexible system concepts based on its large yet compact Engel duo machine. In doing so, the company creates systems from a wide technology spectrum, in order to reduce pallet weight and optimise part handling. The system partners Engel works with in this area will also be at the Saudi PPPP in Riyadh, which means even very sophisticated turnkey solutions will be able to be worked out during the exhibition.

Fittings: When large moulds with lots of core pulls and sliders are used, as the production of fittings requires, for example, the tie-bar-less Engel victory machine keeps both the investment and the operating costs low. In addition, the barrier-free clamping unit facilitates automation and enables moulds to be changed more quickly. Irrespective of whether it's the increasingly popular PPR that's being used or PVC and CPVC, which are difficult to process, the company will adapt the plasticising unit to the individual requirements of the materials being processed, and therefore enhance the efficiency of the whole system as well.

Efficient turnkey solutions from one source

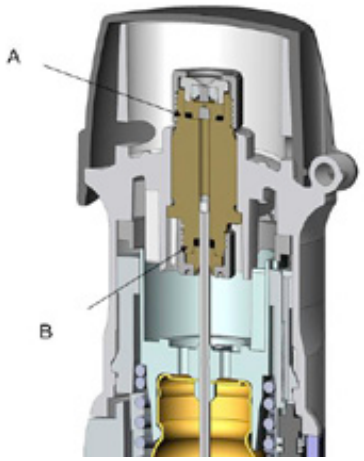
When selling a system to a customer, the company supplies the injection moulding machine, the automation, the mould project engineering, the process technologies and its services from a single source, which enables efficiency potential to be exploited in the best possible manner. The Austrian-based machine builder's dense network of subsidiaries, offices and service locations ensures that it is always close to its customers – regardless of where they are in the world. At the same time, Engel's cost- and time-efficient support is aided by intelligent Internet-based software solutions.

ENGEL AUSTRIA GmbH
A 4311 Schwertberg

The all-electric Engel e-cap 420 has a clamping force of 420 tonnes and is the largest machine in the high-performance series. It achieves cycle times of less than three seconds.

With metered-dose inhalers, precision is paramount, in terms of both medication delivery and the technology involved in creating the product. A device from Boehringer Ingelheim is a leap forward on both scores.

New silicone O-Ring - a leap forward for inhaler users



A. Large O-Ring - upper section. B. Smaller O-Ring - lower section

Anyone who's ever taken medication with a conventional metered-dose inhaler will know how hard it is to inhale firmly and precisely enough to get the sudden spray down into the lungs. Many users take an extra dose or two, as they're unsure if they took it quite right the first time.

And they probably didn't. A lot of the medication simply gets swallowed. The drops are too big and the propulsion speed is too high for the process to work well, even if the user breathes properly.

But what if you could simply take a deep, relaxed breath, and the medication would glide down into the lungs?

The pharmaceutical company Boehringer Ingelheim has developed an inhaler, the Respimat®, that produces a gentle cloud, leaving plenty of time to breathe in and get the medication where it needs to be. The Respimat® directs two powerful jets of liquid that merge at a controlled angle, dissipating into what the company calls a soft mist that lasts well over a second.

The inhaler is made at Boehringer Ingelheim's microParts subsidiary and is proving a success. "Several studies have shown that Respimat® is preferred by patients over other inhalers," says Frank Dieckheuer, Production Manager at Boehringer Ingelheim.

Currently the Respimat® Soft Mist™ Inhaler is being used with three medications, one for asthma and two for chronic obstructive pulmonary disease, or COPD. "It allows a lower dose than the conventional inhaler, because the droplets in the mist are very consistent in size and smaller," explains Dieckheuer. "More gets inhaled and less gets swallowed."

The heart of the inhaler is the uniblock nozzle system. Fine grooves are etched into a wafer of silicon using the same technology as in the semiconductor industry, and when the liquid is forced through, two fine jets are produced that dissolve into mist when they meet.

By turning the base of the inhaler, liquid is drawn from the cartridge through a capillary tube into a dosing chamber. Turning the base also primes a spring, which is trigger-released to force the liquid through the nozzle.

This is a precision instrument. If everything is to work exactly, manufacturing tolerances have to be very tight. For example, says Stefan Böhmer, Technical Supplier Manager at Boehringer Ingelheim, "the pump system has to deliver precisely 15 cubic millimeters, with a tolerance of just 15 percent."

The biggest challenge for this precision is the silicone O-Ring at the bottom of the assembly, which prevents the medication in the dosing chamber from running back down the capillary. It requires a standard volume of 7.464 cubic millimeters, to minimize evaporation and to remain tight against the high pump pressure. And for this seal, as well as three others in the Respimat®, Boehringer Ingelheim microParts turned to a part of Trelleborg that specializes in liquid silicone seals for the life sciences industry.

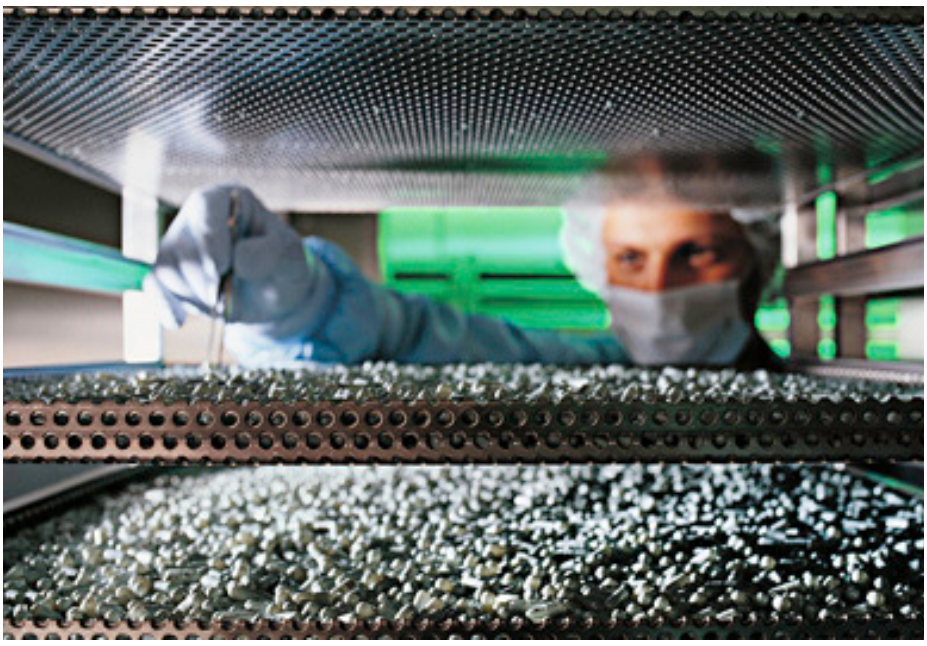
"We're used to defining dimensions by size," says General Manager of the Trelleborg silicone manufacturing facility, Matthias Jakob. "We had to develop a new volume-measuring method for this product." Surfaces have to be perfect without any trimming, and the burr where the two halves of the mold join has to be under 0.05 millimeters. "That has placed high demands on our tooling and process performance," Jakob says.

In fact, there are limits to perfection. Liquid silicone is a difficult material, and Boehringer Ingelheim microParts has to allow a tolerance in the O-Ring of ±1 cubic millimeter. This has to be compensated for by variations in the volume of the plastic central tube. Böhmer explains, "We have three different versions of the central tube so that we can match it with the O-Ring and reach the correct total volume."

The two companies are now working on improving the tolerance in the manufacture of the O-Ring to just ±0.3 cubic millimeter, which will make this matching process unnecessary.

The Respimat® is an innovative tool for the treatment of asthma and COPD, and its development has pushed manufacturing technology a little further, all so that patients just have to "take a deep breath" and the medication is delivered where it needs to be.

Trelleborg Sealing Solutions Silcotech AG
CH 8260 Stein am Rhein



Trelleborg has invested in cleanroom manufacturing of silicone components and in the production of silicone multi-component products for the pharmaceutical and medical industries.

Ultra-modern clean room manufacturing cell for elastomer and plastic components is specifically designed for meeting the demands of the medical and pharmaceutical industries

Parker-Prädifa plant in Czechia now with clean room cell

Following the launch of an ultra-modern clean room cell at its Czech location in Sadská Parker-Prädifa now has extended capabilities specifically designed to meet the exacting demands of the medical and pharmaceutical industries. The central focus of the operation is on manufacturing custom solutions made up of elastomer and plastic components developed at the German locations Pleidelsheim and Bietigheim.

The 130-square metre GMP-conformant clean room cell currently consists of several ISO 7 to ISO 9 clean rooms and has been designed to allow for a quick and easy extension of the facility as needed. A connection of manufacturing cells exclusively dedicated to custom products is possible as well.

State-of-the-art injection moulding technology

State-of-the-art injection moulding technology to process a wide range of materials such as silicones (LSR and HCR), TPE and other elastomers is the centrepiece of the cell. 2-component solutions (such as silicone/plastic or TPE/plastic) in clean room class 8 are possible as well. A new micro-injection moulding machine in clean room class 7 is available for manufacturing high-precision, particle-free moulded parts and seals as well as processing high-transparency liquid silicones.

Over-moulding for single-use systems

Specifically for single-use systems advanced over-moulding technology is available as an alternative to conventional cable ties. This technology primarily serves to combine silicone and TPE tubes with other plastic components, such as aseptic connectors, filters or transport containers, or various tubes with each other. Due to the lower risk of leakage compared to cable ties over-moulding is particularly well-suited for assembling products intended for use in critical process areas.

Clean room assembly of plastic components

As well as conventional bonding or gluing, ultrasonic welding work is performed in clean room class 7. The significant advantages of this method are high reproducibility and the elimination of the need to use additives, which benefits the purity of the product. PTFE or PES diaphragms can be securely and reliable affixed to plastic components. Ultrasonic welding is mainly used in the assembly of products for clinical use in the area of infusion therapies.

Fast support for system solutions

With the new clean room manufacturing cell in Sadská the growing quality requirements can now be met through faster and better support of relevant system solutions as well. For quality assurance Parker-Prädifa uses state-of-the-art inspection and testing technology that meets the exacting safety requirements of the medical and pharmaceutical industry as well as the needs of cost efficiency and economy. For packaging the products manufactured in the clean room cell various options are available, from simple PE bags and PETG single blisters with Tyvek covers through to moulded pallets.

The Sadská location is currently certified according to ISO/TS 16949. Certification according to ISO 13485:2012 is planned for the beginning of 2014.

Parker Hannifin GmbH
D 33659 Bielefeld

A case study about the use of Sigmasoft® in rubber processing

Virtual Molding Saves Costs in Rubber Injection Molding

In a 48-cavity rubber application, Virtual Molding Technology, available through Sigmasoft®, reduced in 47% the runner volume and in 30s the cycle time.

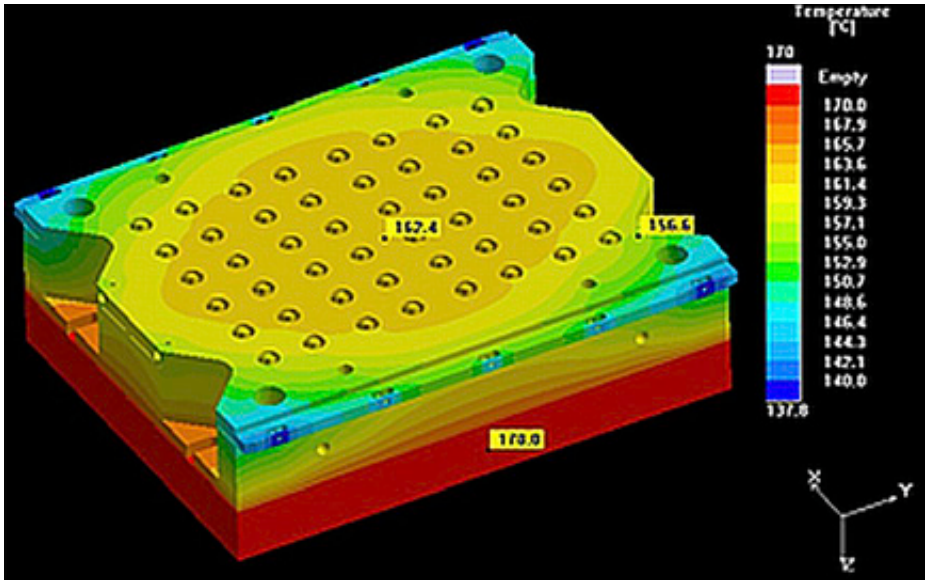


Figure 1: Virtual Molding Technology, available through Sigmasoft®, enables predicting the temperature distribution in a complete rubber mold.

The design of molds for rubber processing has always been linked to a great deal of trial-and-error. Features such as tempering and runner layout, as well as material selection are done based rather on guessing or experience than on knowledge, and the processing parameters are not set until the mold has been completely built. Often the mold has to be reworked and operates far from its optimum, wasting energy and raw material.

Sigmasoft®, through its Virtual Molding Technology, changes this fundamentally, as it allows simulating the complete mold over several molding cycles, with all detail about molded material and mold components. Virtual Molding has been conceived to support the part and mold design, as well as the processing set-up, in such a way that all iteration can be done virtually, without material or machine-time waste, while understanding the causals for process problems and identifying potential for improvement.

The company Aspem Ferramentaria, Brasil, used Virtual Molding to optimize a 48 cavity mold, with forming dimensions of 700 x 550 mm2. The objective was to analyze the tempering concept and to evaluate possibilities for raw material savings.

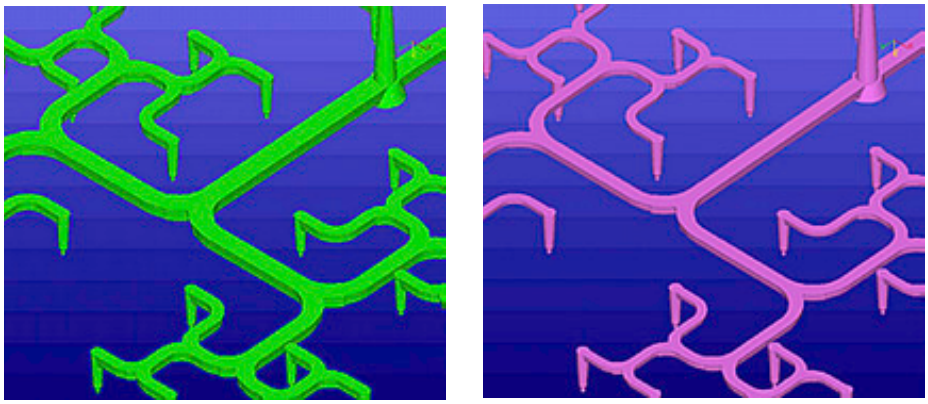


Figure 2: through the analysis of shearing rate, pressure demand and scorch, Sigmasoft® allows the optimization of the runner size in rubber molding. A reduction of 47% in the runner volume was achieved. Left: initial runner layout. Right: optimized runner layout.

At first, the thermal behavior of the mold was considered. The complete mold design, with all parts and tempering elements, was introduced in Sigmasoft® and run virtually, just as in the injection molding machine, for several cycles.

The effectiveness of the tempering layout can be seen in the temperature distribution of Figure 1. In this case, the temperature distribution is presented after 340s of cycle time. From the thermal analysis it was evident that the cavities of all four corners of the mold had a lower mean temperature than the rest of the parts. The pieces molded in the center of the cavity would achieve 90% average curing degree within 310s, while the parts located at the four corners had only 75% of average curing degree at the same time. They would need 30 longer to achieve 90% of average curing degree. Therefore, it was decided to eliminate those four cavities, to avoid material waste, and it was possible to reduce the cycle time from 340s to 310s.

A second objective was to reduce the amount of raw material. In this case a cold runner was used, and the possibility of reducing the runner diameter was evaluated. When considering a size reduction in the runner system, it is important to consider different factors: a very small cross section increases the shearing stress and may lead to material degradation in the cavity. Also the scorch in the runner must be considered, as a higher proportion of surface-to-volume reduces the required curing time in the runner. Additionally, the pressure demand must be considered.

Several simulations with Sigmasoft®, evaluating the parameters of critical shearing, scorch and pressure demand, leaded to a reduction of 47% in the runner volume, from 159 cm3 to 75 cm3, as seen in Figure 2. The raw material consumption was reduced in 89g per shot. With a total cycle of 360s over 24 h, and the cost of raw material based at 4,95 EUR per kg, the savings over a year added to 25,587 EUR.

"Experience demonstrates how the project and process can be analyzed beforehand. When combining technical experience and simulation, it is possible to attain a high profit margin", commented Luciana Stewe, the Sigmasoft® engineer in Brazil who supported the project. "The whole project, from the thermal analysis of the mold, the dimensioning of the runner, the selection of the cavity numbers and the reduction in the volume channel was completed in 4 days", she commented.

SIGMA Engineering GmbH
D 52072 Aachen

STRUBL PACKAGING – specialist for cleanroom packaging

Cleanroom packaging and cleanroom supply chain

Autor: Dr. Christoph Strubl, Geschäftsführer STRUBL KG Kunststoffverpackungen

Cleanroom bags and films produced by STRUBL are an effective solution to protect against contamination at all steps of the cleanroom supply chain. Does packaging cause contamination risks ? Sure – if the packaging material has been produced under low-level terms of hygiene- and cleanroom conditions. Packaging and Product need to be produced in similar quality conditions.

Typical application of bags in a cleanroom production at Gerresheimer AG.

STRUBL cleanroom production ISO 7 for manufacturing of cleanroom packaging

Qualification and training provide highest product quality.

Manufacturing and packing under cleanroom conditions became a standard process in the pharmaceutical and medical-device industry. That's the only way to achieve the extrem requirements concerning hygiene and cleanliness. This applies for pharmaceutical and chemical substances as well as for plastic components, implants, pumps, tubes, bottles, caps, plastic or glass primary packaging. Before leaving the cleanroom areas, the products need to be packed carefully to protect them against damage and contamination during transport and handling. For this operation plastic films, tubes and bags are the mainly used packaging materials all over the cleanroom supplychain.

Risk of packaging

Plastic packaging is used all over the cleanroom supply chain. All companies being part of this supply chain have to deal with potential packaging risks. This indicates, that on every supply chain's level packing materials need to reach a primary packaging quality status. (see figure 1)

<u>These plastic packaging materials are in direct contact with the product which implies significant risks, such as:</u>

1. raw material risks
- conformity of raw materials in reference to the application has to be checked
- migration between packaging material and product has to be eliminated absolutely, because this may change important product quality properties

2. process-risks
- to contaminate cleanroom production areas and
- to contaminate cleanroom products by low-quality packaging materials

3. logistic-risiks
- contamination during handling and transport
- locking in and out into controlled cleanroom areas

The only way to handle and eliminate these risks is to use GMP-qualified packaging materials. This implies a packaging manufacturer with cleanroom facilities and GMP-qualified production systems. But the most important key factor is an intense cooperation and networking between customer and packaging manufacturer.

Specification of cleanroom packaging

The basic principle for packaging specification: packaging materials used in cleanrooms need to achieve the same quality requirement as the final cleanroom product.

1. The final product's quality level specifies the quality level for the packaging materials all over the supply chain.
2. The customer's cleanroom level specifies the quality level for the packaging

page 7: Cleanroom packaging and cleanroom supply chain

supplier's manufacturing process.

3. The only way to handle and eliminate these risks is to use GMP-qualified packaging materials.
4. An absolut clean and controlled production area is the basic condition for cleanroom applicable packaging materials.
5. If these principles are implemented the customer is able to verify that the product contacting packaging supports the product quality.

STRUBL cleanroom packaging solutions

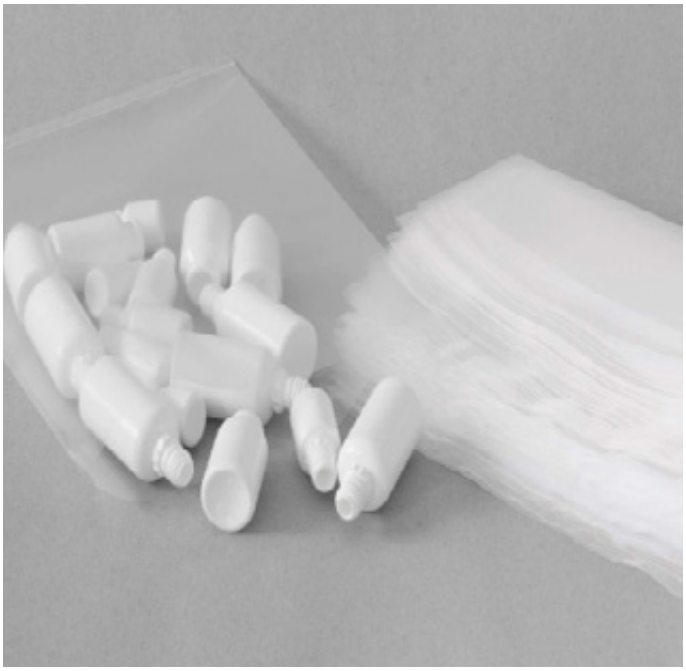
STRUBL Packaging is a German specialist for cleanroom packaging. The company develops and supplies blown film and flat film, bags, side gusseted bags, bag systems (double / triple) and sterilization bags for cleanroom products. These packaging products are produced in a cleanroom production with an integrated high professional GMP-system supported by ISO 9001 quality management systems based on DIN 15378 (primary packaging materials for medicinal products) and DIN 15593 (management of hygiene in the production of packaging for food-stuffs). These systems specify the main demands on product and process such as order fulfillment, operations and logistics. This implies: cleanroom production, hygiene management, bio-burden-monitoring, pest control, risk-analysis, traceability, documentation and specification, validation and qualification.

Cleanroom packaging materials by STRUBL are used by a lot of well named brands and companies in the pharmaceutical markets as well as in medical device, chemical, electronics, automotive or food industry. These companies use STRUBL cleanroom packaging as primary or secondary packaging on a high quality level.

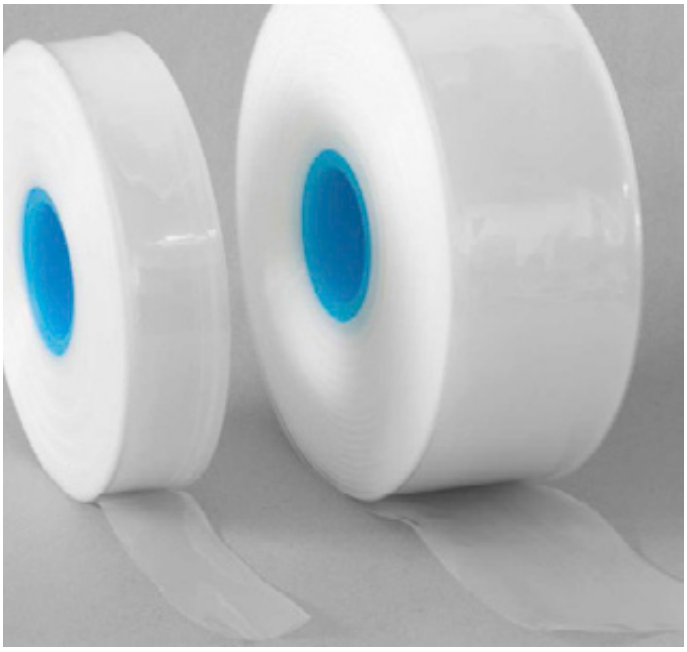
GMP-culture is a learning process

To install a GMP-organization is comparable with a company wide learning process. Finally, there exists no "one-best-way", every company has to design a specific GMP-system to harmonize own and customers product-, process- and quality requirements. Only a longterm teamwork between customer and supplier will be successful for both partners.

STRUBL KG Kunststoffverpackungen
Richtweg 62 D 90530 Wendelstein
Telefon: +49 9129 9035 0 Telefax: +49 9129 9035 49
E-Mail: christoph.strubl@strubl.de
Internet: http://www.strubl.de



Sample: Cleanroom bag for medical plastic parts.



Sample: Cleanroom film for instruments.

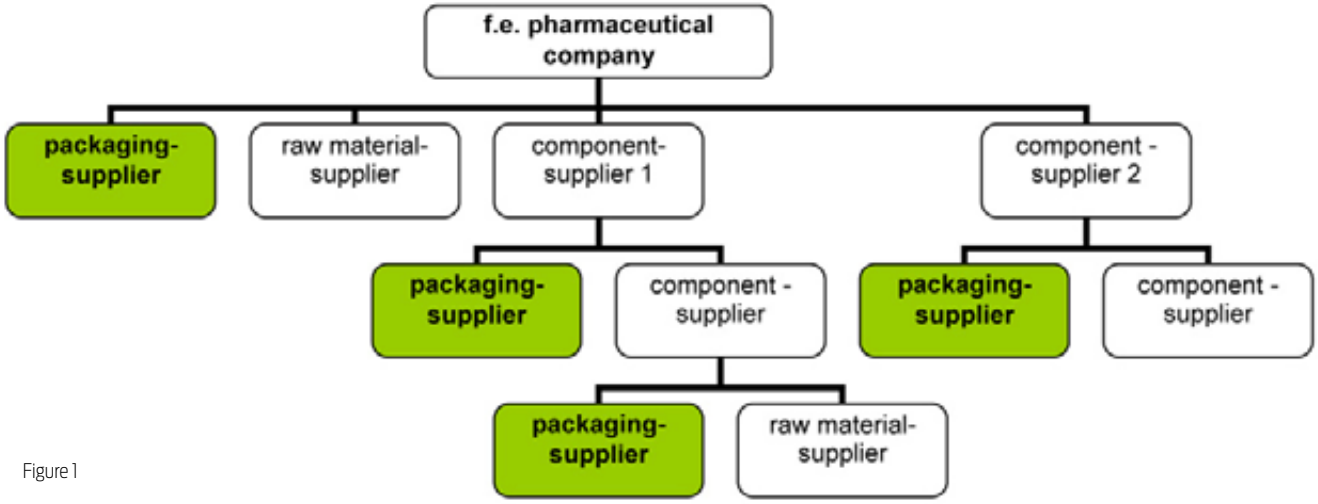


Figure 1

Injection moulders producing very small parts are faced with the unique challenge of being able to dry just the right amount of material for their process. Operating in extremely critical production conditions, these smaller throughputs can present considerable problems. Consequently, it is important to scale the drying to the size of the moulding machine. The new LUXOR CA S range of dryers fits perfectly into this concept. It is also suited for cleanroom applications.

LUXOR CA S from motan-colortronic – lightweight compact dryer for small and micro parts

LUXOR CA S – compact dryer for small and micro parts

The LUXOR CA S range with hopper volumes of 0.75 / 1.5 / 3 and 5 litres has been conceived especially for the production of small and micro parts. The range is comprised of a modular line of correctly sized drying equipment helping moulders to meet the small tolerances without waste or contamination. On account of their light and compact construction, the dryers can be simply mounted on all processing machines, also when space is highly restricted. The LUXOR CA S compressed air dryers take factory supplied compressed air which is expanded to atmospheric pressure. This produces dry process air – with a very low dew point – which is then heated to the required drying temperature. No desiccant is necessary making the dryer prefect for clean room conditions. All models are equipped with a thermostat and low air flow safety switch to prevent overheating of the material in the event of insufficient air throughput.

Due to the wide temperature range (30 - 180°C) the LUXOR CA S micro dryers can be used for many different materials. A prefilter cleans the compressed air. This feature prevents contamination of high-quality materials and provides optimum drying conditions. The complete drying bin body is made from a single piece of special glass – ideal for contamination critical process applications. An additional benefit of the all glass construction is its transparency. The operator can always see the actual status of material in the bin. Constant and stable conditions in the entire drying hopper are an essential prerequisite. Therefore, the complete drying hopper right down to the material discharge is heat insulated because of a double glass wall construction. This design is an important energy saving advantage. The expertly designed air diffuser provides uniform distribution of the dry air ensuring that the material – even at the material bin outlet – is kept at a constant temperature and in the required dry condition.

motan-colortronic gmbh D 61381 Friedrichsdorf

LUXOR CA S has been conceived especially for the production of small and micro parts.

The complete drying bin body of the LUXOR CA S is made from a single piece of special glass – ideal for contamination critical process applications.

Raumedic presents new polymer products for the pharmaceutical industry at Pharmapack in Paris on February 2014. The focus of the presentation on booth 407 is on products for injection, drug delivery and inhalation.

Raumedic presents customised polymer solutions at Pharmapack 2014

12th - 13th February 2014:
Pharmapack Europe
Paris (France)

Effective Protection against needle stick injuries – RauSafe™

Worldwide, there are an estimated 3.5 million needle stick injuries annually in doctors' offices, hospitals and in the home care field. Associated with this is a risk of infection with dangerous viral diseases such as HBV, HCV or HIV. The resulting health and financial consequences after an infection are risk factors that have to be taken seriously.

In May 2013, the new EU Directive 2010/32/EU for the prevention of needle stick injuries came into force in all Member States of the EU. It dictates that employers in the medical field should provide systems with an integrated safety mechanism.

For this reason Raumedic has developed a new safety device for injection systems. RauSafe can be adapted to a variety of existing injection systems on the market and provides reliable protection whilst being simple and intuitive to use.

The RauSafe safety device can be activated after an injection by simply pushing it forward. As soon as the needle is completely enclosed, you can hear and feel the system click into the end position.

Drug Delivery

Drugs can only develop full efficacy if they are correctly dosed. However, experience reveals that many patients use their drugs incorrectly. Therefore the market is increasingly demanding precise and user-friendly dosing aids. The company develops customised drug delivery systems which offer better handling, exact dosage, easier and safer application as well as better patient compliance.

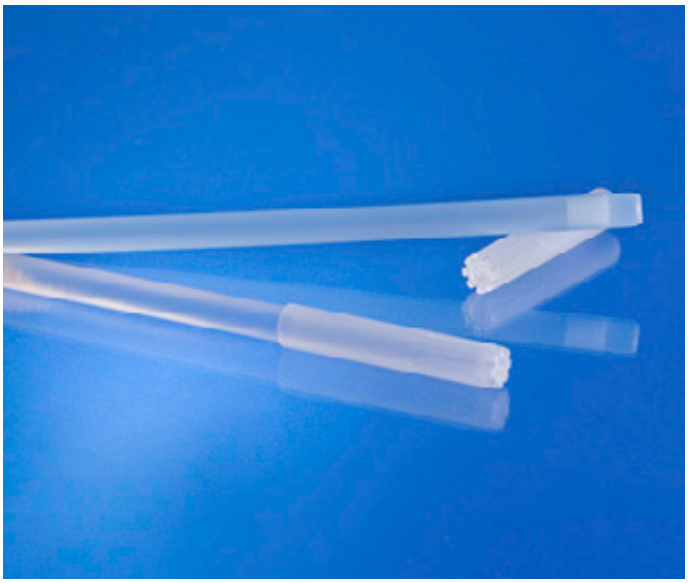
Therefore Raumedic and DS Technology offer a patented system which enables easy and safe dosing of drugs in the form of pellets.

Imprecise dosing is prevented through the exact predosing by the pharmacist. Therefore, this system is perfectly suited for the areas pediatrics and geriatrics.

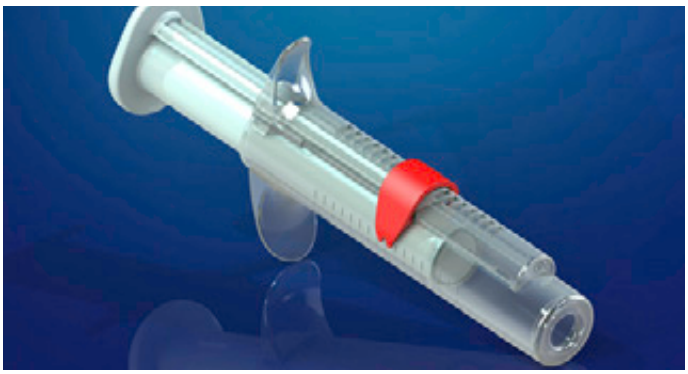
Raumedic is capable to produce and package the plastic components fully automatically. Filling and packaging of XStraw™ is handled by DS Technology at its fully automatic assembly line.

Another example, that has already been developed and patented by Raumedic, is a new dosing syringe with an external locking mechanism for the application of liquid drugs. The dosing is adjustable in increments of 0.5 ml which permits an individual and exact dosage.

Raumedic AG
D 95233 Helmbrechts



XStraw – for a simple, safe and exact dosage of drugs in the form of Pellets.



Dosing Syringe

RauSafe provides safe protection against needle stick injuries.

New plant inaugurated in India

The new 2,500 square metre building of the Indian subsidiary of Zahoransky AG has been formally inaugurated in mid November. At the new regional production site in Tamil Nadu, southern India, 60 employees manufacture assembly injection moulding machines for the Indian and Asian market. In the long term, complex automated moulds are expected to be offered and supplied from India.

The service personnel in India is already capable of handling the support and the maintenance of German moulds in India and other countries in Asia. Also, the plant in India is now the first contact for customers throughout the whole of Asia. Owing to the time difference, communication with Germany is now much easier.

The local design department is fully networked with the parent plant for mould construction in D-79108 Freiburg. The construction software is linked with a team centre solution in Freiburg, with the effect that all manufacturing data can be controlled from there.

Zahoransky is therefore superbly positioned for global projects. With locations in Germany, India and the USA, customers can now be supported and served around the clock.

The new corporate building in Tamil Nadu is the first of its kind in southern India and the seventh in the whole of India which has won the „IGBC Dream Factory Platinum Award“. A „green“ building boasts lower water consumption and makes optimised use of energy, and so generates less waste and saves natural resources. Unlike conventional buildings, they also create healthier places for the people working there.

Zahoransky Group is also known for its social commitment, with far over 500,000.00 Euros donated over the past ten years for various projects. One example: Zahoransky donated and installed a solar unit on the roof of the primary school in the village neighbouring the new plant in India. For the first time, the school with its around 25 pupils now has electric light and ventilators for a better room climate during the hot season. The company has so prepared the ground for giving the children a better future.

ZAHORANSKY AG Systemtechnik
D 79108 Freiburg

Managing Director Ulrich Zahoransky at inauguration

Primary school in Tamil Nadu

What to consider when you're monitoring clean rooms

Clean Room Monitoring

For GMP (Good Manufacturing Practice) and GAMP (Good Automated Manufacturing Practice) compliant products there are more and more strict rules and regulations. The compliance with these rules and regulations has to be observed as a part of the company's quality management system.

For this purpose a customized clean room monitoring system is a very helpful instrument. Ideally, the monitoring system documents the critical environmental and production parameters automatically, continuously and completely - without further effort.

The system allows the user to intervene if parameters differ from the desired value and records the actual parameters so that they are verifiable in the long-term.

To make the monitoring system a useful tool, the facility's life cycle must be taken in consideration from the beginning of the planning.

This is the only way to make sure that the system does not unnecessarily impede production procedures and instead supports the user in their day-to-day work and spares them the extra effort of complex documentation duties.

The planning should not start from a technical point of view because almost everything is feasible going from there. Much more important is that the system fulfills any product and user-specific requirements and conforms to the respective rules and regulations.

Therefore the following questions must be answered as part of the planning process:

- Which rules and regulations have to be observed? At this one has to consider the product-specific requirements and approval procedures as well as any statutory requirements regarding the monitoring system.
- Which tasks and possible problems might come up in the future? Key words: system extension, maintenance requirements, adjustable equipment, qualified status
- In which areas does it make sense to just monitor specific parameters and in which areas do we need a holistic monitoring system to monitor and record all relevant parameters continuously?
- How does the system have to be configured to optimally support the user?

Statutory provisions are an important factor from planning to production. To acquire the necessary manufacturing permit the requirements of GMP, GAMP and FDA must be met. The demands in regards to the monitoring system are a direct result of this.

At the beginning there's the URS

The first step is drawing up the URS (user requirements specification). Three factors should be considered to define the basic requirements:

- Production process for the respective product (clean room class, safety aspects, storage)
- Risk factors concerning the product (sensitivity to temperature / humidity changes)
- Requirements regarding the monitoring system

Customer-specific wishes and demands should also be taken into account, e.g.:

- Material: flush mounted, stainless steel measuring instruments (key word: hygienic design).
- Quality of measuring equipment: What's the permissible allowance for sensors? Do we have refrigerators or climate cabinets for which we need high-precision measuring instruments due to the very low permissible tolerance?
- Design: Where should the displays and alarm indicators be located in the clean room to effectively inform the personnel during the production process?

Employees who will be working with the system on a daily basis should definitely be included in the planning.

After defining the requirements the system supplier will issue the FSD (functional specification document) to specify how the user requirements will be put into practice.

The user should review the FSD and adjust it if necessary. Then the production in the supplier's facility can begin. The FAT (Factory Acceptance Test) should also take place there. For the FAT the complete system has to be assembled and tested to allow the customer to assure themselves of the system's functionality and quality before the components are installed in their own facility.

User training during operation

After the successful FAT the next step is the installation of the components at the customer's facility and after that the commissioning of the system including the IQ (installation qualification), OQ (operational qualification) and GMP compliant documentation on site. An important point is the user training which should take place after the commissioning when the system is fully functional to ensure that the users learn to work with their customized version of the system.

As soon as the commissioning and qualification is complete the system can be used in the production process. The life cycle according to GMP however continues. The monitoring system has to be maintained and the sensors must be re-calibrated in regular, predetermined intervals (usually every 12 months).

Therefore it is important to ensure from the beginning that the system can be maintained in built-in conditions. Especially the sensors have to be calibrated including the complete measuring chain and if necessary adjusted. The maintenance must be completed according to the maintenance plan and the process has to be documented accordingly.

Should the necessity for system extensions or amendments arise during operation these changes must be implemented in compliance with predetermined standards (change control) and must be docu-

Page 7: Clean Room Monitoring

mented accordingly. This may become necessary if the monitoring system has to be extended by adding incubators or climate cabinets or measuring instruments with different limit values. In these cases the amendments have to be planned, implemented and documented in compliance with GMP guidelines to ensure the continued qualified status of the system.

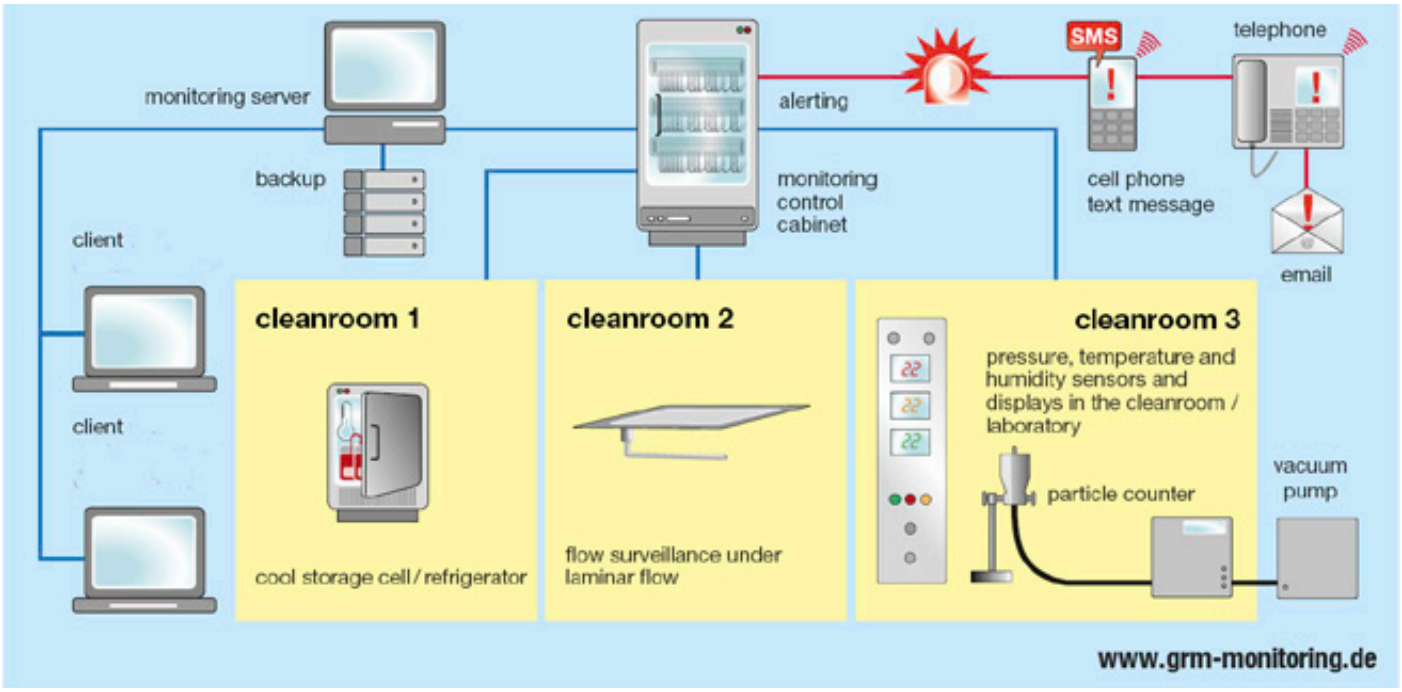
An ideal clean room monitoring system offers:

- holistic project management from planning to maintenance
- investment safety due to modular system structure with possible extensions and amendments (e.g. adding refrigerators)
- multistate alarm and warning concept with several escalation levels
- audit safety due to complete GMP documentation
- short training period due to an intuitive operating concept for devices and software
- optimized life-cycle-costing (LCC) consideration - including acquisition cost, availability, maintenance, support and possible extensions

BRIEM Steuerungstechnik GmbH
Lauterstraße 23
D 72622 Nürtingen
Telefon: +49 7022 6092-0
Telefax: +49 7022 6092-60
E-Mail: info@briem.de
Internet: http://www.briem.de

The basic structure of the holistic clean room monitoring system consists of the following modular components:

- probes to acquire different parameters
- visual indication in the clean rooms (digital displays, touch panels, signal lights)
- alarm forwarding (telephone, email, text message)
- data retention and analysis for long-term documentation
- user-friendly software allowing for easy intervention, analysis and documentation.



A first-rate and exciting program of events awaits visitors at the 24th analytica in Munich. From April 1–4, the International Trade Fair for Laboratory Technology, Analysis and Biotechnology will once again be a center for key players in science and industry. More than 1,100 exhibitors will present the latest products and developments for laboratory operations. For the first time ever, the fair will also feature a special show on occupational safety and health and safety in the workplace.

analytica 2014 to focus on food and plastics analysis, genetic analysis and bioanalysis

01st - 04th April 2014:
analytica 2014
Munich (D)

This year's analytica will revolve around three main themes - i.e. food analysis, plastics analysis and genetic and bioanalysis - whether in the exhibition, the Live Labs and the program of related events. "We are pleased that we have managed to put together a comprehensive and practice-oriented exhibition and conference program for our visitors that are in tune with this year's focal points," says Susanne Grödl, Exhibition Director of analytica 2014.

How does one identify pathogenic germs, analyze residues such as pesticides or heavy metals or verify the origin of raw materials? Visitors will get answers to these and other practice-oriented questions in the food-analysis sector and can familiarize themselves with the latest equipment and techniques on location. That also applies to the fair's other focal points: Everything in the sector for plastics analysis revolves around modern materials and their diverse applications. Ecological and economical aspects play a growing role in all branches of industry. Exhibitors will present the latest developments at analytica 2014. In the sector for genetic and bioanalysis, visitors can expect fascinating analysis techniques and customized solutions—from specific sampling, typical trace analysis and select coupling techniques to procedures for evaluating and archiving the tests.

Live Labs feature practice-oriented lectures

Anyone who wants to experience analysis live at the fair should be sure not to miss the three Live Lab events on the topics of food analysis, plastics analysis and genetic and bioanalysis: Some 3,000 participants attended the live demonstrations in 2012, and visitors will profit from these practice-oriented events again this year. That will allow them to exchange ideas and information directly with manufacturers and experts, have new products explained to them and discuss examples of specific applications.

analytica Conference with scientific highlights

Once again, the program of events at this year's analytica Conference follows the focal points of the fair. In the sector for food and water analysis, for example, there will be a lecture on "The new Challenge in Water Analysis: Metabolites, Transformation Products and Non-Target Analysis". On the topic of bioanalysis and genetic analysis, experts will discuss metallomics and clinical proteomics, among other things. As always, key scientific topics in analysis, the latest study results, innovations and new techniques from the most important application sectors will also be introduced. For the first time ever, the analytica Conference is being held at the ICM – Internationales Congress Center München, directly next to the exhibition halls.

New show: Occupational safety / Health and safety in the workplace

The topic of safety plays a major role in everyday laboratory work. That is why, for the first time ever, analytica will feature a special show on the topic of occupational safety and health and safety in the workplace. In Hall A3 there will be three lectures on "Fires and Explosions," "Handling Hazardous Materials Safely," and "Avoiding Health Risks for You and Your Employees" on each day of the fair. The special show will also give exhibitors an opportunity to present products that are necessary for safety such as safety cabinets, gas detectors and protective clothing.

analytica's program of events will be rounded out by lively discussions in the Laboratory & Analytics Forum and the Biotech Forum as well as interesting lectures as part of Finance Day and analytica Job Day.

Messe München GmbH
D 81823 München

The modular CO2 transmitter EE870 from E+E Elektronik is designed for maintenance-free use in demanding OEM applications. It offers various analogue outputs, Modbus interface, and a wide range of AC and DC supply voltage ranges.

Modular CO2 transmitter for demanding OEM applications

The compact, interchangeable probe measures CO2 concentrations up to 10,000 ppm and can be replaced within seconds without the need of calibration or adjustment. The user can change the measuring range of EE870 by simply plugging in another probe.

The probe is based on infrared technology (NDIR) and uses a dual wavelength autocalibration procedure. Thus, it is completely maintenance free and highly resistant to environmental influences.

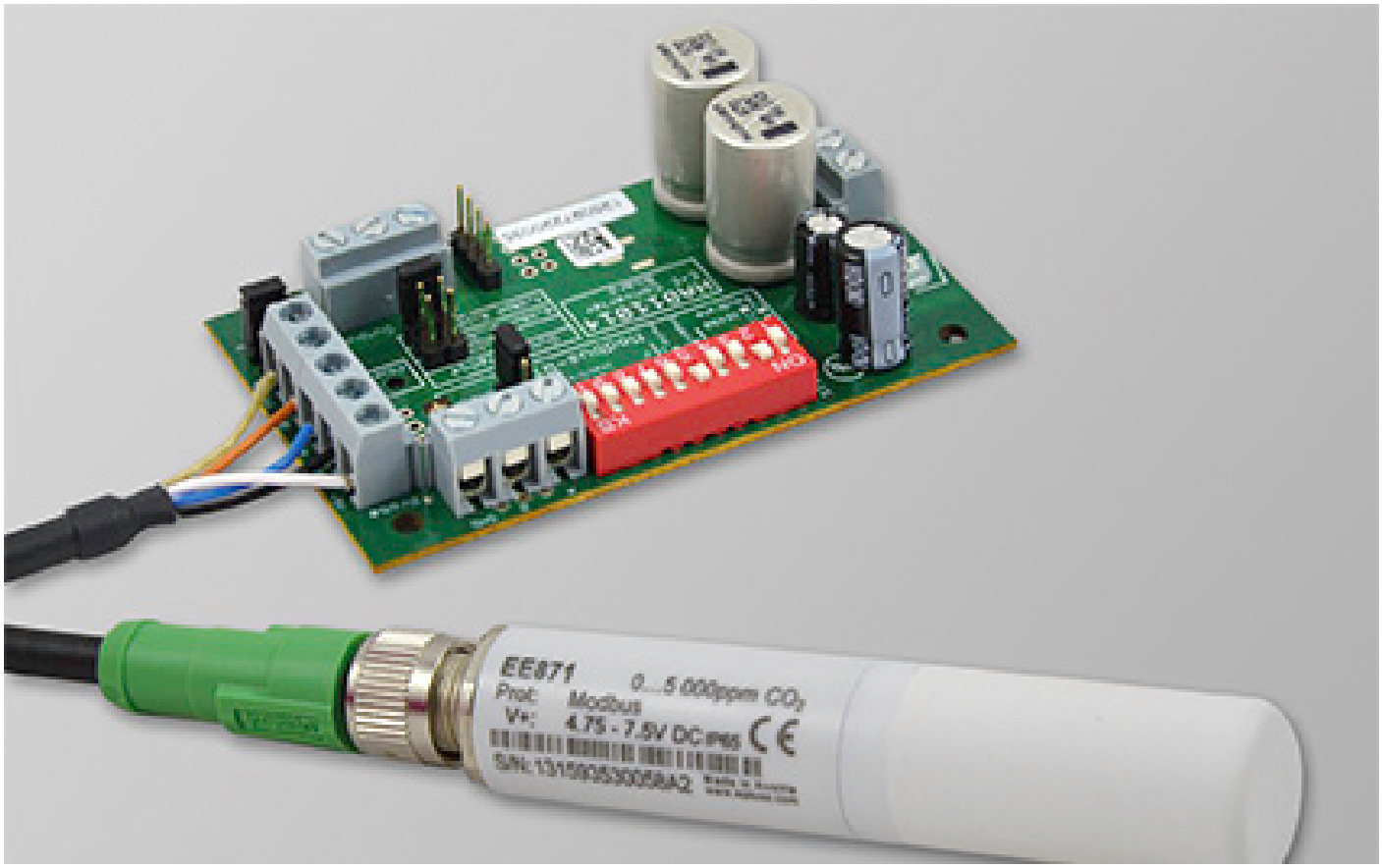
Thanks to the factory multipoint CO2 and temperature adjustment, temperature compensation ensures excellent measurement accuracy over the entire operating range of -40... 60°C.

Due to the probe's very high resistance to pollution, the EE870 is particularly suitable for use in harsh conditions, such as greenhouses, stables, fruit and vegetable storage facilities, hatchers and incubators.

Advantages at a glance:

- Excellent long-term stability via auto-calibration
- Highest measurement accuracy due to temperature compensation
- High resistance to pollution thanks to the IP65 housing and replaceable filter
- Easy installation and service due to modular design

E+E Elektronik GmbH
Langwiesen 7 A 4209 Engerwitzdorf
Telefon: +43 7235 605 0
Telefax: +43 7235 6058
E-Mail: info@epluse.at
Internet: http://www.epluse.com



EE870 Modular CO2 transmitter from E+E Elektronik.

Impressum:
cleanroom online / W.A. Schuster GmbH · Mozartstrasse 45 · D 70180 Stuttgart · Tel. +49 711 9 64 03 50 · Fax +49 711 9 64 03 66
info@reinraum.de · www.cleanroom-online.de · GF Dipl.-Designer Reinhold Schuster · Stgt, HRB 14111 · VAT DE 147811997