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## Be prepared for changes to pharmaceutical industry regulations



Ecolab Contamination Control Cleanroom

Ecolab Contamination Control, a worldwide provider of leading products and services for the control of microbial contamination in the cleanroom environment, has sounded a warning to the pharmaceutical industry as regulations with wide ranging compliance implications begin to come into force.

James Tucker, Marketing Director at Ecolab Contamination Control says: 'For an industry which is generally risk averse, the new regulation changes will challenge current protocols like never before, meaning companies need to be proactive to avoid the consequences of non-compliance.'

The Biocidal Products Regulation (BPR) which succeeded the Biocidal Products Directive (BPD), removing the ability for country interpretation, on 1 September 2013 is among the regulations which Ecolab Contamination Control has highlighted.

These changes are aimed at ensuring a high level of protection of human health and the environment. They also address the simplification and harmonization of the authorization procedures necessary to allow a company to market a biocide product for use across the EU.

To ensure compliance, the BPR's authorized list of active substances acceptable for use in biocides requires products to be registered with the European Chemicals Agency (ECHA).

Central to these new regulations is that biocidal

products should neither be made available on the market nor used unless authorized. This also applies to the purchase of raw materials with the intention of using them to biocidal effect, in-house.

The regulations apply to every manufacturer and mean that only products containing an approved active substance can be marketed legally. Failure to comply could incur fines and possible criminal proceedings for the manufacturer and end user.

Additionally, consideration should be given to market impact if the product can no longer be supplied. Ecolab Contamination Control is supporting its core range of biocides through the BPR with its regulatory department and is acting as a leader within consortia supporting the submission of actives.

Ecolab Contamination Control also has EPA Establishment Registration\* as part of the registration process under different authorities. The manufacturing facility is an EPA registered facility, ensuring quality and continuity of supply for its customers.

Meanwhile, Ecolab Contamination Control is advising manufacturers and importers of chemicals into the EU to review compliance with the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

REACH requires these companies to assess the health and environmental risks associated with the use of chemicals and take the appropriate steps to ma-

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nage these effectively.

Ecolab Contamination Control pre-registers every chemical it synthesizes or imports under the REACH directive, to protect customers and the environment from any potential hazards resulting from their use. Any active ingredient registered with the Biocidal Products Regulations (BPR) is part of the authorized list of active substances, acceptable for use in biocides from the BPR. The non-active ingredients used in biocides are registered under REACH.

'We continue to ensure compliance for all our substances and products and recommend other companies do the same.

'As part of this we are continually in contact with our suppliers, especially those who manufacture our raw materials to ensure the continued availability of the substances used in our existing products and future innovations.

'We also work with suppliers to make sure that the substances we use are covered by their REACH registration dossiers, chemical safety reports and Safety Data sheets,' adds Tucker.

Further regulation impacting on the pharmaceutical industry relates to the packaging and labelling of products, as part of the new European Legislation for Classifi-

cation, Labelling and Packaging of chemical substances and mixtures (CLP).

This is based on the UN's Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which aims to standardise the labelling of products worldwide and make their safe use more straightforward.

Although substances have needed to be classified and labelled according to CLP in the EU since late 2010, from 1 June 2015 formulations or mixtures will also need to be classified in the EU according to CLP regulations. Some classification of products will change, however Ecolab Contamination Control will not be changing any formulations because of CLP.

The update will include amended graphical representations (pictograms) of the type of hazard that a chemical product is classified as, the use of two signal words (Danger and Warning) and both hazard and precautionary statements.

'The cleanroom disinfectant manufacturers have been working towards the 2015 deadline for some time, with no penalty being imposed for lack of compliance,' says Mr Tucker. 'From this year that is all going to change and the industry needs to be ready. Put simply, if a customer purchases an un-

supported or non-compliant product, they may be forced to make a change, meaning the product in use would not be validated and could result in their production lines ceasing.'

In order to fully comply with all the latest industry regulations Ecolab Contamination Control has invested more than US\$1 million to date, with this expected to rise steadily over the coming years and employs a dedicated team of professionals.

Not only does that mean customers have complete peace of mind, but it keeps Ecolab Contamination Control at the forefront of delivering contamination without compromise, allowing its customers to focus on their own production.

\*The EPA Establishment Registration number is 001677-GBR-001.



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# Pfeiffer Vacuum presents its vacuum solutions as a new online experience

- Discover and experience Pfeiffer Vacuum's extensive range of vacuum products
- Focus placed on practical vacuum examples and applications
- Films and 3D animations enhance the existing web experience



The new vacuum solutions website presents the Pfeiffer Vacuum range of products as an innovative experience. (Picture: Pfeiffer Vacuum GmbH)

Just in time for the new year, Pfeiffer Vacuum presents its new vacuum solutions website. Users can discover the wide spectrum of products and their functions in a real-life and practical setting.

The focus is to provide a virtual experience of vacuum solutions. The complete

range of Pfeiffer Vacuum products is demonstrated in films, application reports, 3D animations and cross-sections showing products from an inside perspective.

The website presents the world of Pfeiffer Vacuum in seven categories. Futuristic-looking rooms graphically highlight the

forward-thinking approach of the company. Aspects shown comprise the company's history, solutions, markets, applications, efficiency, products, and service.

With its vacuum solutions website, Pfeiffer Vacuum presents a platform that is unique to the market. Sophisticated 3D effects reveal insights into the inner workings of pumps and, at the same time, demonstrate the benefits and uses of the products. Films provide a behind-the-scenes look at pump installations, service repairs and maintenance. Viewers can virtually attend a training session, or have the features of pumps explained by the product manager.

The vacuum solutions webpage is a customer-oriented, innovative enhancement to Pfeiffer Vacuum's Internet presence and provides additional practical vacuum information. It is available on the company website.

Pfeiffer Vacuum GmbH D 35614 Asslar

An indispensable filter technology reference resource

# Hot off the press: the new Viledon® Product catalogue 2015/2016

The Viledon® Product catalogue of Freudenberg Filtration Technologies provides a comprehensive overview of the company's pioneering industrial air and liquid filtration solutions – in a highly informative and extremely user-friendly format. The 2015/2016 edition of this popular reference work will be released in January. It will initially be available in German and English versions, both printed and online via the company's website. French, Italian, Spanish, Russian and Chinese versions will follow later.



The provision of clean air and pure liquids is one of the great challenges of the 21st century. In this context, Viledon® filtration solutions from Freudenberg Filtration Technologies make an important contribution. The brand is known worldwide for the highest efficiency standards in industrial air and liquid filtration. For over 60 years, Viledon® filtration solutions have been proven to help optimize industrial processes and make them more economical. At the same time, they also save valuable energy, conserve vital resources and the environment, and

protect people.

The new edition of the Viledon® Product catalogue runs to 136 pages and presents the company's unique filter program for air and liquid filtration in the fields of industry and production. Clearly presented and well structured, it provides information about the entire portfolio and all filter classes, including the technical specifications, applications, properties and characteristics of each filter. Readers will also find useful information about delivery details.

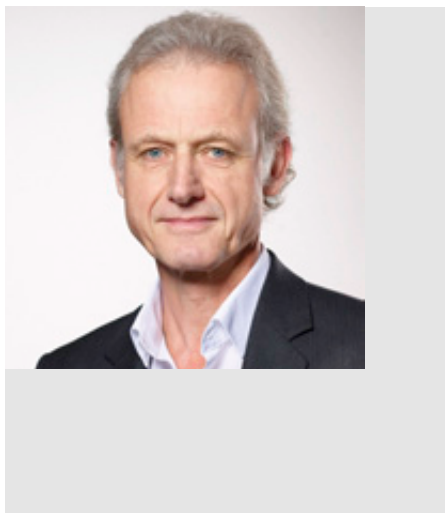
The catalogue demonstrates how Freu-

denberg Filtration Technologies is able to offer optimized packaged solutions for each application, all of which are based on the company's top-quality and highly reliable branded products. Using these products, Freudenberg can tailor complete air-purification solutions to precise customer requirements. The company's services range from plant design, construction and the installation of the complete filter system, right through to comprehensive technical application consulting and services for long-term quality assurance during operation.

A recent example of this holistic service approach is the Viledon® ChemWatch Online Monitoring System. Thanks to this innovative system, customers can continuously monitor corrosiveness in sensitive areas, at anytime and any-where via LAN, WLAN or Bluetooth, and can thus protect their electrical and electronic equipment from corrosion in a timely manner.

Printed copies can be requested by sending an email to [viledon@freudenberg-filter.com](mailto:viledon@freudenberg-filter.com). Online versions of the 2015/2016 Viledon® Product catalogue are available for download via the Download Center on [www.freudenberg-filter.com](http://www.freudenberg-filter.com).

Freudenberg Filtration Technologies SE & Co. KG  
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Dear readers, dear subscribers,

now it's February 2015 and we have a lot of interesting news and a lot of interesting events for your appointment calendar.

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Yours sincerely,

Reinhold Schuster



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Röchling acquires HPT Hochwertige Pharmatechnik GmbH & Co. KG. This expands the range of sophisticated high-performance plastics from the Röchling Group for use in Life Science Industry and offers positive prospects for the location Neuhaus am Rennweg.

## Strategic expansion in the field of Life Science Industry continues

# Röchling acquires HPT Hochwertige Pharmatechnik GmbH & Co. KG

The Röchling Group takes over HPT Hochwertige Pharmatechnik GmbH & Co. KG in Neuhaus am Rennweg with effect of January 1, 2015. This takeover is the continuation of Röchling's strategic expansion in the field of Life Science Industry.

The HPT Hochwertige Pharmatechnik GmbH & Co. KG specialises in the production of primary packaging for the pharmaceutical and diagnostic industry. Their product range comprises bottles, canisters, jars, closures and caps as well as assembly parts made of plastics such as PE-HD, PE-LD and PP for direct contact with liquid and solid medications. HPT produces made-to-order packaging according to their customers' specifications and offers a wide range of high-quality products from stock.

The packaging is produced through single- or multi-layer extrusion blow moulding, injection stretch blow moulding, injection blow moulding and injection moulding. Complete packages used in pharmaceuticals, diagnostics and medical technology world-wide are then created in downstream processes such as sterilisation, surface decoration and assembly in class 7 clean rooms. The management system is certified according to ISO 15378, which defines the high requirements for the production of pharmaceutical packaging, as well as ISO 13485, which determines

the high requirements for the production of medical products. For this reason, HPT products offer the highest possible standard of pharmaceutical hygiene, reliability and application safety.

### A consistently pursued strategy

This takeover is the logical next step in Röchling's previously announced strategy of expanding the use of plastic products for the field of Life Science Industry. Röchling already offers an extensive range of materials and production for this field through its medical grade semi-finished product program by Röchling Sustaplast and Röchling Engineering Plastics as well as its injection moulding products of Röchling Oertl Kunststofftechnik and the American subsidiary Röchling Advent Tool & Mold.

Ludger Bartels, COO of the Röchling Group, Mannheim, is positive about this takeover: „Through this acquisition we will expand our range of high-quality medical technology products made from high-perfor-

mance plastics and we expect synergy effects with our other locations dealing with the topic of medical technology. HPT and their customer base around the world will profit from the close cooperation in our global company network.“

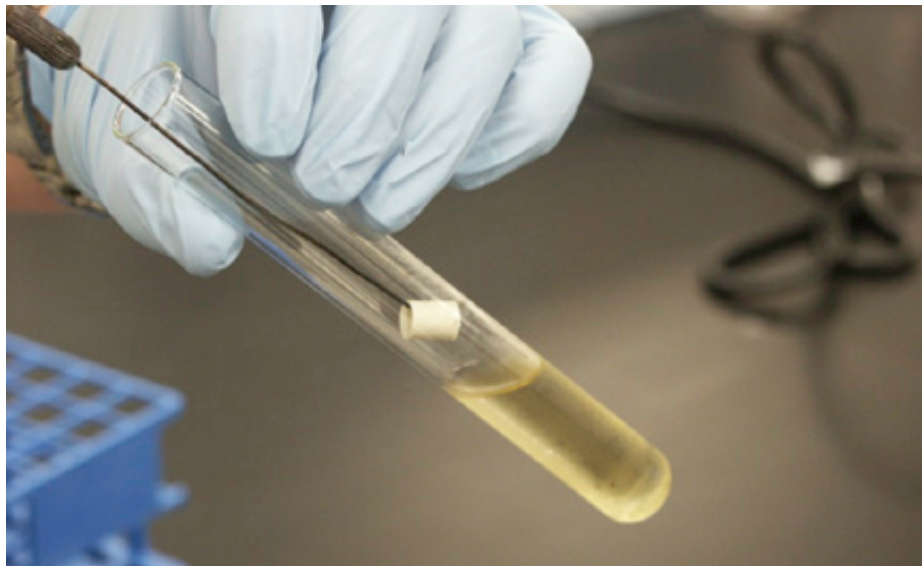
HPT will continue to be managed by the well-established management team led by Karl-Heinz Sladek. He views becoming part of the Röchling Group primarily as a new opportunity for his company, which generates a turnover of 33 million euros with 250 employees. „HPT will become part of a group of companies with a leading position world-wide. This presents us with excellent prospects for further growth and protecting the jobs in Neuhaus.“

In the acquisition of HPT, Röchling was advised by the M&A and strategy consultancy firm Contrada Partners.

Röchling Engineering Plastics SE & Co. KG  
D 49733 Haren

A roadmap for regulatory compliance.

# Disinfectant Validation



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The U.S. FDA (United States Food and Drug Administration), MHRA (Medicines and Healthcare products Regulatory Agency), HPRA (Health Products Regulatory Authority) and CFDA (China Food and Drug Administration), amongst others, routinely make observations about disinfectant validation studies and disinfectant practices. The U.S. FDA Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing (Aseptic Processing Guide September 2004) states “Each manufacturer must have a formal program governing the qualification, use and disposal of disinfectants.” The current United States Pharmacopeia, USP 37 chapter gives some guidance on selection, use and qualification of disinfectants. There is no question that drug manufacturers should provide evidence that room decontamination programs achieve and maintain desired contamination control levels. This paper will provide considerations and discuss best practices for validating disinfectants used in drug manufacturing areas.

It is important to understand that disinfectant validation is a process that includes three distinct components. These components are: disinfectant qualification testing or in vitro studies, in situ evaluations, and environmental monitoring with trending during routine operation. In vitro (Latin for “in glass”) studies are those that are conducted in a laboratory or artificial environment. Because there are a number of variables that can impact disinfectant performance under

actual use conditions, it is important to conduct in vitro studies to demonstrate that a particular product is inherently effective against a particular organism under well-defined conditions, such as concentration and contact time. Most countries require in vitro testing in order to register and market a disinfectant or sporicidal product. The product labeling reflects the particular organisms (e.g. American Type and Culture Collection or ATCC strains) that were included in these studies, and the specific conditions under which testing was conducted (e.g. temperature, concentration, contact time, etc.). However, the testing required for product registration typically does not meet the needs of pharmaceutical manufacturers who must comply with regulatory expectations.

Regulatory expectations include: demonstrating effectiveness on materials of construction that are representative of actual manufacturing surfaces (e.g. epoxy flooring, Lexan™ polycarbonate curtains, etc.), demonstrating effectiveness against environmental isolates, and demonstrating effectiveness when applied following the organization's Standard Operating Procedures (SOPs) e.g. dilution water quality, wet contact time, expiration dating of use-solution, soil loading, application techniques, etc.

The condition and composition of the surface can have an adverse impact on the performance of the disinfectant for a number of reasons, e.g. reactivity to disinfectant, porosity, etc. Warning Letter January 29, 2013:

“The coupons used in the “Disinfectant Efficacy Verification for Hard Surfaces...” were not representative of the surfaces found in the tissue processing laboratories (TPL) and BioAdhesive laboratories. For example, \_\_\_\_ was used in the study to represent biological safety cabinets, laminar flow hoods, and tables in the processing and manufacturing areas. However, the equipment is comprised of \_\_\_\_” “All surfaces that are used in critical processing and manufacturing areas were not evaluated...”

Environmental isolates are of particular interest simply because they were isolated from the manufacturing environment, which clearly indicates that they are being introduced into the facility with some degree of regularity and therefore, may pose a risk to the product. As far back as the early 1990's, there has been an expectation that pharmaceutical manufacturers include environmental isolates in validation studies. GMP TRENDS, November 15, 1993, “The Firm's sanitizing agents have not been validated with environmental microorganisms which have been observed to be part of the firm's environmental bioburden.”

SOPs should include specific details for preparation of the disinfectant (e.g. use-dilution concentration, water quality, water temperature, etc.), required wet contact time for the surface, application devices and instructions (e.g. mopping direction and room grid) and expiry dating of both the use-dilution and the opened source container of disinfectant or sporicide. FDA Warning Letter October 31, 2008, “However your response to our FDA-483 is inadequate because the following were not addressed: Effectiveness of \_\_\_\_\_ solution at the dilution used, and 2) effectiveness of \_\_\_\_\_ throughout the shelf life (up to the expiry date).”

## In vitro testing

When considering several potential disinfectants or sporicidal agents, it may be prudent to begin in vitro testing with suspension studies. A suspension study in its most simple form involves exposing a known inoculum of a specific organism to a known concentration of disinfectant or sporicide, for example, for a specified period of time. This type of assessment offers a relatively quick read on whether or not a particular product and/or set of use conditions (e.g. water quality, temperature) is effective against

## Disinfectant Validation

a particular organism or group of organisms. Once the suspension studies are complete, a comparison of effectiveness of various products should allow selection of a limited number of highly effective products that can then be included in more rigorous testing, including coupon studies representing the materials of construction (MOC) of areas or equipment to be treated.

A number of recent FDA Warning Letters have been focused on coupon studies. In particular, the regulators have expressed concern about the selection and condition of MOC failing to represent both the actual MOC and the condition of such materials in manufacturing areas. A recent FDA warning letter stated: "All surfaces that are used in critical processing and manufacturing areas were not evaluated." (FDA Warning Letter January 29, 2013). "There is no evaluation of the effectiveness of cleaning and chemical agents used to control microbial populations on approximately 15 different hard surfaces (e.g. Aluminum) found in classified areas used to manufacture sterile products." (GMP Trends November 1, 2013). When developing a testing matrix, it is important to consider MOC that fairly represent the manufacturing surfaces and that represent the condition of the surfaces. In an ideal world, damaged surfaces would be immediately repaired or replaced. However, this is not always possible, and if damaged surfaces are to be kept in use for an extended period of time (e.g. until the next scheduled maintenance event), then damaged surfaces must be represented in coupon studies. "The materials that were tested in the Disinfectant Efficacy study were not representative of all the surfaces present in the Aseptic Processing Area." "The stainless steel coupons tested did not represent these damaged surfaces." (Warning Letter May 25, 2011)

In addition to the MOC and condition of coupons, selection of environmental isolates to include in testing is a key consideration. Selection should include organisms most commonly isolated from manufacturing surfaces and personnel (e.g. gram positive and gram negative bacteria), organisms that are known to demonstrate resistance to decontamination or otherwise harsh conditions (e.g. spore-formers, mold), and organisms that are introduced into the area via known vectors, such as raw materials. In the event that a facility is newly operational and a substantial body of isolates has not yet been established, inclusion of a broad spectrum of organisms sourced from ATCC, for example, may be considered.

In addition to MOC and isolate selection, regulators will also scrutinize other aspects of the in vitro work including, log

reduction goals and results, recovery and neutralization studies, and controls. A recent FDA Warning Letter stated: "Your disinfectant qualification for (b)(4) and (b)(4) bi-spore disinfectants documented that the log reduction criteria (Bacteria  $\geq 4$ , Fungi  $\geq 3$ ) was not met when challenged with multiple organisms in a variety of surfaces." (FDA Warning Letter, October 7, 2011). "There is no assurance that the disinfectant \_\_\_\_\_ is effective against mold, since it did not meet your established recovery rate acceptance criterion in the December 2001 "Disinfectant Validation and Efficacy Study of \_\_\_\_\_ by the Surface Test Method" study." (FDA Warning letter, May 24, 2007)

The study design and method used for in vitro testing of disinfectants by a pharmaceutical manufacturer must be carefully planned and be scientifically justifiable to the regulatory authorities. USP provides very little guidance on how these studies should be performed. While USP does refer to AOAC (Association of Official Analytical Chemists) methods, these are not necessarily appropriate when qualifying a disinfectant for use in a pharmaceutical facility and moreover, some AOAC tests, such as Use-Dilution Method require exceptional expertise as they are very technique dependent and often difficult to perform consistently. Unfortunately, there is not one perfect testing method. However, there are several published methods that do provide good general information for performing these studies and that can be modified and adapted for use in disinfectant qualification testing. Such examples include, the ASTM E2197-02 (American Society for Testing and Materials) Quantitative Carrier Test (QCT) and the European Norm EN13697. These methods utilize stainless steel disks (other surfaces can be adapted) inoculated with the challenge microorganism that are treated with the disinfectant followed by neutralization and quantitation of survivors in order to establish the activity of the product.

### In situ testing

In situ testing demonstrates that the disinfectant or sporicidal agent in conjunction with preparation procedures and application procedures used by the facility and employees are effective at maintaining the environmental microbial levels deemed necessary for production of the target product. Efficacy of the disinfection program is demonstrated through evaluation of environmental monitoring data both over time and during "worst-case" remediation events. For example, many firms will compare environmental data pre and post decontamination

after a preventative maintenance shut-down, when the room is more likely to show relatively high levels of environmental contamination. It is critically important that the procedures used to decontaminate the area during the in situ evaluation reflect the written SOPs, as evidenced by regulatory feedback, "There is a lack of written procedures assigning responsibility, providing cleaning schedules, and describing in sufficient detail the method, equipment and materials to be used for sanitation. Specifically, your firm does not maintain written and approved procedures for the cleaning/disinfection of equipment and materials." (FDA 483, June 11, 2013). Clearly, the personnel who are assigned to perform these functions, must have sufficient training and oversight. Failure to have and/or to follow written procedures, problems with cleaning, sanitization, and maintenance, and failure to provide sufficient training are amongst the most frequently occurring FDA 483 observations.

USP 1072 provides some general guidance for in situ testing, "To demonstrate the efficacy of a disinfectant within a pharmaceutical manufacturing environment, it may be necessary to conduct the following tests...a statistical comparison of the frequency of isolation and the numbers of microorganisms isolated prior to and after the implementation of a new disinfectant." Further, the FDA Aseptic Processing Guide from 2004 states, "the effectiveness of these sanitization procedures should be measured by their ability to ensure that potential contaminants are adequately removed from surfaces (i.e., via obtaining samples before and after sanitization)." It is clear that evaluation of surfaces in order to compare contamination levels before and after sanitization or disinfectant treatment is an expectation in substantiating disinfectant performance.

### Environmental monitoring and trending

Environmental monitoring practices, including frequency, location, and number of samples per sampling interval, should be based upon best available guidance documents and a valid scientific rationale suited to the type of product being manufactured. That being said, a single day of environmental monitoring data is but a snapshot in time, and cannot, alone, convey much useful intelligence about the state of control of a manufacturing area. Ongoing environmental monitoring, with data trending, is further validation that a holistic contamination control program is effective. It is recommended that any organisms detected be identified to the species level, and that they be stored for inclusion in future in vitro studies. Data

## Disinfectant Validation

should be reviewed periodically for negative trends; once a month is a common frequency. Additionally, criteria must be established for identifying a negative trend. "Procedures do not define how data must be presented in the (b) (4) trend reports generated by... The investigations include environmental data for the aseptic area that is reviewed for trends. However, there is no procedure that defines the search criteria for trending. No evaluation of environmental monitoring data for the support areas within the aseptic core were conducted during the investigations." FDA 483 March 01 2013.

### Summary

Disinfectant validation is a process that includes *in vitro* studies, where the disinfectant or sporicidal agent can be evaluated under highly controlled conditions; *in situ* evaluations which demonstrate how effective the disinfectant or sporicidal agent is under actual use conditions (typically conducted in a worst-case environment); and routine environmental monitoring with trending and assessment of negative trends. While there is no single regulatory or advisory document available that offers a blueprint for development of a disinfectant validation study, there are several documents and references, including FDA 483 observations and Warning Letters, which both highlight pitfalls and offer solid input on study design.

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- Intelligent connection of machine and software
- Reliable serialization and application of safety seals

Bosch Packaging Technology, a leading supplier of process and packaging technology, has expanded its portfolio for the serialization of pharmaceutical packaging. In the fight against counterfeit drugs, many countries are about to implement legislation changes for a stricter labelling of pharmaceuticals. Consequently, drug manufacturers require safer and more flexible solutions. "With our serialization concept, we offer customers more than just a machine," explains Daniel Sanwald, product manager at Bosch Packaging Technology. "Bosch offers the complete package, which also includes the corresponding IT."

## Connection of machine and software

The CPS (Carton Printing System) forms the basis of all serialization solutions from Bosch. It has been continuously developed regarding flexibility and user-friendliness. Depending on customer requirements, the system prints 1D or 2D data matrix codes on up to 400 folding cartons per minute. Thanks to an upgrade of the camera system, both codes can now be checked on different carton qualities even more reliably. If the contrast and readability of the data matrix codes do not conform with the required level of quality, the products are automatically sorted out. The machine is easy to operate from the front, so that mechanical components are easily and quickly accessible in case of format changes. An optimized threading of the labelling tape reduces downtime of the CPS 1900 to a minimum.

The CPS systems can be connected to both machine software and company IT in a multi-level process, ensuring that serial numbers are attributed reliably. Therefore, Bosch Packaging Technology has adapted the proven automation technology from Bosch's automotive sector to the specific requirements of the pharmaceutical industry. "This experience enables us to offer our customers IT solutions that not only process the entire order management; they also control both import and export of the serial numbers," Daniel Sanwald explains. Depending on country and guideline, the numbers are either allocated centrally or generated by the

company. Contract manufacturers in turn receive the numbers from their clients. According to Sanwald, "our IT system is equipped for all three cases. The Bosch machines can also be flexibly combined with systems from other IT providers." The IT concept has further advantages for production companies: production parameters and data of all packaging lines are clearly visible at all times. "For instance, in the case of unforeseen events like downtime or modification, capacities are automatically re-planned," Sanwald says. "The connection of our machines with the corresponding IT offers companies a new production foresight."

## Modular design for additional safety

Thanks to its modular design, the CPS system can be extended by further modules. For example, a weighing module inspects the weight of each folding carton individually. Existing machines can also be equipped with a Tamper Evident module. The labeller applies additional safety seals across the side flap of the folding carton, thus offering optimum protection against manipulation. Sensor systems carry out safe and reproducible checks of seal presence and correct application. The machine and all applications, such as the camera, are operated via a single HMI (Human Machine Interface). "The operator has a uniform look and feel, and does not need to switch between different HMIs. Moreover, this makes the central audit trail a lot easier," Sanwald underlines.

## Growing global need for serialization

According to the Bosch experts, the need for serialization technology will continue to grow over the coming years. Amongst others, 2015 will see the implementation of new guidelines in Saudi Arabia, where drug packaging must be equipped with a data matrix code step by step, followed by serial numbers in 2016. In Brazil, individual batches must be serialized as of 2015, before it becomes obligatory the following year. The U.S. Food and Drug Administration (FDA) aspires to implement a standardized identification for all prescription drugs in form of a 2D data



Consequent expansion of serialization portfolio: The CPS (Carton Printing System) forms the basis of all serialization solutions from Bosch. The printer can be flexibly adjusted, either to print the data matrix codes on top or on the side of the folded cartons.



Reliable protection against counterfeit pharmaceuticals: The CPS systems from Bosch ensure that pharmaceutical packaging is reliably serialized. For an optimum protection against manipulation, the labeller applies additional safety seals across the side flap of the folding carton.

matrix code in a step-by-step approach until the end of 2023. The European Union's Falsified Medicines Directive 2011/62/EU stipulates coded packaging with a 2D data matrix code and a unique serial number for nearly all prescription drugs, presumably from the first quarter of 2018. With the flexible serialization solutions from Bosch, pharmaceutical manufacturers are well-equipped for all regulatory requirements worldwide.



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Gerresheimer is a recognized partner to the pharmaceutical industry supplying standard packaging solutions and patient-friendly drug delivery systems from cough medicine bottles to asthma inhalers.

# Gerresheimer focuses on pharmaceutical customers at Pharmapack 2015



**11 th - 12 th February 2015:  
Pharmapack Europe, Paris (FR)**

“We’re fully focused on our customers in the pharmaceutical industry and committed to offering them custom solutions in excellent quality,” said Andreas Schütte, member of the Management Board of Gerresheimer AG with responsibility for the Medical Systems Division. He also referred to

the company’s most recent projects, which include the expansion of syringe production operations in Bünde (Germany) through the installation of a new, ultra-modern production line, the opening of a new Technical Competence Center in Dongguan City (China) and the extension of its production plant in Peachtree City (USA).

Gerresheimer will be exhibiting a comprehensive range of glass and plastic packaging products and systems for the pharma-

ceutical industry and healthcare sector at Pharmapack in Paris on February 11 and 12.

The product highlights at Pharmapack are the MultiShell vials and the Clearject syringes made of COP, which are ideal for parenteral medications, biopharmaceuticals and oncological drugs due to their special high-performance polymer structures.

Gerresheimer AG  
D 40468 Düsseldorf

**Phillips-Medisize – Pharmapack, Paris, 11 to 12 February 2015, Stand 719**



# Pharmaceutical primary packaging with high-priority quality assurance

**11 th - 12 th February 2015:  
Pharmapack Europe, Paris (FR)**

Countless people take them, and to many of them, they are indispensable: medication, pharmaceuticals are supposed to provide patients of all ages with the best possible help. Primary packaging plays a very important role in that respect: it is intended to protect medical products as well as possible, irrespective of their physical form, while at the same time remaining user-friendly. The main objective is to put design and production expertise into practice. Phillips-Medisize will show specialised visitors its expertise in developing and manufacturing pharmaceutical primary packaging made of plastics at stand 719 in the Pharmapack exposition, which will be held in Paris on 11-12 February 2015. A wide variety of products will be displayed, ranging from special drug delivery devices, dosage systems, disposable insulin pens, inhalers, mixing injectors, bottles and caps, on to sterile multi-chamber bags. Phillips-Medisize offers customers complete end-to-end service, from the idea to the finished solution, from designing to the product in sterile packing. Its strong points on the market are especially drug delivery and dosage systems which undergo cross-process inspection through high-priority quality assurance in

accordance with ISO 13485 and FDA standards as well as GMP (Good Manufacturing Practice). One of the items displayed from the rich repertoire – a special spray applicator – is a paragon of high-quality pharmaceutical primary packaging.

## Spray applicator:

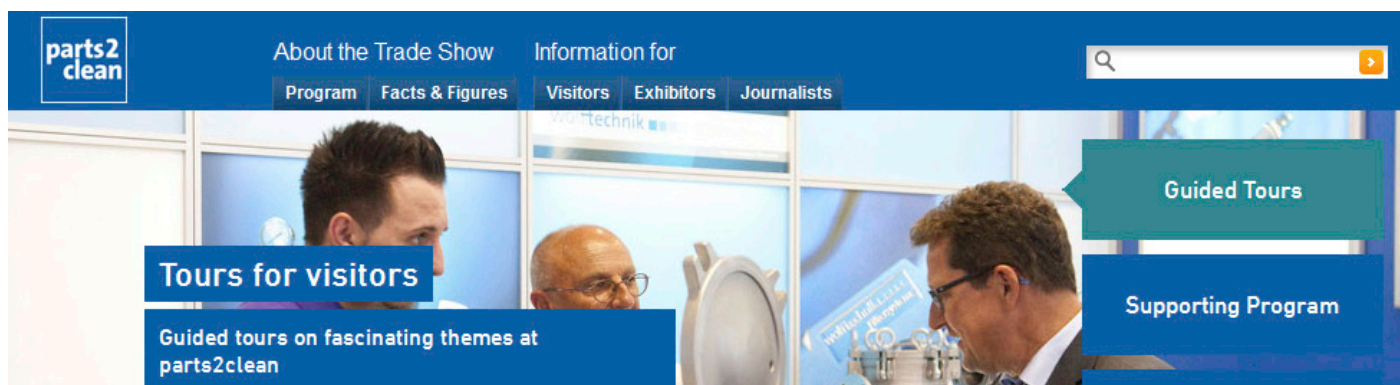
The customer’s design requirements demand that the product was child-proof, an important factor for the product launch – particularly on the US market – and a container made of PET, considered to be a harmless type of plastic. All of its components are produced and assembled under the necessary conditions of hygiene in the plant in Nürensdorf, Switzerland. Small metal springs for the spray mechanism and the pumps are purchased. The chosen manufacturing process consists of injection moulding and injection stretch blow techniques. With the latter, the nozzle section of the bottle is formed in the first step, and then the lower part is blow-moulded separately. This ensures proper sealing. Precise processing and proper sealing of the sprayer are also very important to ensure that the product is child-proof. The customer awarded the contract to Phillips-Medisize not only because of the company’s technological skills but also because of its holistic approach to the project. The spray applicator is made of seven parts



Phillips-Medisize: Complete system solutions for pharmaceutical primary packaging – from design to the finished packed product. (Photo: Phillips-Medisize)

(the injection-stretch-blown PET container and the six injection-moulded parts made of PP or POM). The differently shaped parts require using multi-cavity tools of various sizes on injection moulding machines with clamping pressures of 50 to 200 tonnes. Extensive validation procedures were carried out prior to the production launch: from DQ (Design Qualification), to IQ (Installation Qualification), on to OQ (Operation Qualification) and PQ (Production Qualification). In the assembly process, the parts pass through 16 assembly stations before the so-called “subcomponent” is completed. The validation procedures also have the added ergonomics advantage that the amount of non-recyclable materials – that have to be discarded during production – is extremely low considering the fact that the various plastic parts have to intermesh precisely and that each part has different tolerances that must not exceed 0.03 millimetres at most.

Phillips-Medisize Corporation CH 8309 Nürensdorf



# Parts cleaning: as clean as necessary, as efficient as possible



- Increasing quality and efficiency with optimal cleaning solutions  
- parts2clean presents the latest technology and trends

**09 th - 11 th June 2015: parts2clean, Stuttgart (D)**

Cleaning parts and surfaces costs money – just how much money depends on the required result. Whether the job is simple degreasing or rather cleaning to meet strict technical requirements, achieving the necessary quality quickly, reliably and economically involves factors which go beyond the cleaning method used, including the selection of the proper cleaning media and containers and subjects like bath maintenance and packaging of the cleaned parts. You can explore all these aspects at parts2clean at the Stuttgart exhibition center from 9 to 11 June 2015.

“Whether we’re talking about the automotive industry and related suppliers, medical equipment, aeronautics, precision engineering, optics or electronics – today virtually every sector has strict requirements for component cleanliness, and this places significantly higher demands on cleaning,” says Olaf Daebler, in charge of the parts2clean show at Deutsche Messe. To play it safe, an “as-clean-as-possible” approach is frequently taken, which has an impact on cost and therefore on competitiveness. The remedy is to take a suitable cleaning approach that meets all requirements and to optimize cleaning results while reducing costs. “As the flagship trade fair for its sector, parts2clean presents a comprehensive scope of products and services that address every aspect of industrial parts cleaning, from systems and media to bath maintenance, analytics for cleanliness control, corrosion prevention, protection and packaging,” explains Daebler.

## Fine-tuning cleaning processes for reliability and efficiency

Wet chemical cleaning processes are the method of choice for the majority of industrial cleaning tasks. Here the dissolving capacity of the chosen cleaning media has a decisive impact on operating costs, quality and the stability of the cleaning process. The core principle that applies to media selection is “like dissolves like.” This means that solvents are normally used to remove oil-based (non-polar) contaminants such as cutting oils, grease and wax. Aqueous cleaners are generally used to remove water-based (polar) contaminants such as cooling and lubricating emulsions, polishing compounds, additives, salts, abrasion and other solids. Modified alcohols with balanced oil- and water-solubility are able to remove both non-polar and polar contaminants.

There is no magic formula for matching cleaning processes or system and process engineering to a particular scenario. They must be developed with a view to the overall manufacturing process. The following factors play a role: What materials are being treated? At what point in production do the parts get contaminated, and with what? Must this contamination be removed immediately, e.g. to ensure proper results in the next processing step? Does processing involve a variety of materials that can lead to cleaning problems if they are mixed? Does the cleaning of parts made of various materials such as aluminum, steel, titanium, carbide or ceramic create a risk of cross-contamination in the given facility? The answers to these questions can be used to arrive at a cleaning solution capable of optimizing both costs and results.

The parts basket or workpiece carrier also has a major impact on the cost and quality of the cleaning process. Effective filtration and separation systems such as oil separators, particle filters and membrane filters, as well as water treatment and in the case of solvents distillation capacity, also help to prolong bath service life and reduce disposal costs. For water-based media, continuous monitoring of cleaning agent concentration ensures that baths are not changed too quickly due to safety concerns, but instead only when insufficient component cleanliness can lead to problems in subsequent process stages.

## Component and surface cleaning know-how

As the only trade fair in the world focusing exclusively on industrial parts and surface cleaning, parts2clean not only reflects today’s market in its entirety, but also offers lots of added value in terms of its parallel three-day forum. Lectures on a wide variety of industrial parts and surface cleaning topics will be simultaneously translated (German-English/English-German).

## Deutsche Messe surface technology fairs : upcoming dates

The next surface technology fair in Germany is SurfaceTechnology at HANNOVER MESSE from 13 to 17 April 2015. The next parts2clean is scheduled from 9 to 11 June 2015 in Stuttgart, Germany. O&S and parts2clean 2016 are planned to run from 31 May to 2 June. Upcoming fairs abroad with a surface technology component are SurfaceTreatment EURASIA with a parts2clean pavilion from 12 to 15 February 2015 in Istanbul, Turkey, and also the very first Surface Technology.

Deutsche Messe AG D 30521 Hannover

Schreiner MediPharm's Specialty Labels Increase Patient Safety

# Flexi-Cap and Autoinjector-Labels



Pharmaceutical products must be clearly labeled, and protected against counterfeiting and manipulation to increase patients' safety. From February 11 to 12, 2015, Schreiner MediPharm will showcase its innovative Flexi-Cap security concept at Pharmapack Europe in Paris. Flexi-Cap clearly indicates first opening of containers. Schreiner MediPharm will also present new features for Autoinjector-Labels, such as NFC chips for electronic tracking as well as patient communication.

**11 th - 12 th February 2015:  
Pharmapack Europe, Paris (FR)**

## Flexi-Cap: Preventing Illegal Re-Use of Empty, Original Containers

Dumpster diving involves removing empty medicine containers from waste containers, in order to refill them with counterfeit substances and sell them as alleged original products. With Flexi-Cap, Schreiner MediPharm has developed a security solution that clearly and irreversibly shows first opening of a primary container. Flexi-Cap features an innovative combination of a label and a film cap. The bottom portion of the cap and the label adhere to the container when it is unsealed. Attempting to remove the rest of the cap destroys the label.

The security concept enables flexible use with different container types, forms and sizes. In contrast to shrink-wrap solutions, the label design is applied without using heat, which also makes it suitable for temperature-sensitive medicines. Integrated extra security features such as holograms, color-shifting inks, guilloches or hidden features such as a void effects or covert color pigments give suppliers, pharmacists, healthcare personnel and patients extra reassurance that the product they are holding in their hands is genuine. In addition, Flexi-Cap's top provides space for bar code printing or NFC chip integration. Thus, important user information can be communicated or patient compliance documented.

## Multi-functional Labeling for Pens and Autoinjectors

User safety is paramount when developing pens and autoinjectors for self-injection. Schreiner MediPharm's multi-functional label solutions support injection systems' high demands in terms of quality and reliability. The label functionalities can be individually combined to increase user comfort and patient safety.

For instance, the integration of NFC chips enables electronic tracking, patient communication or monitoring patient compliance. A printed QR code leads users to a website and important, additional information. Double-layered, reclosable labels protect the contents from UV rays if the pen is equipped with an inspection window to check the medicine. The label that encloses the cap features a perforation to indicate first opening of the autoinjector. The authenticity of the pen can be checked by means of various overt and covert anti-counterfeiting features. In addition, a special anti-slip varnish en-

ures safe handling, while an integrated temperature indicator shows the correct ambient temperature for injection.

Schreiner MediPharm, a business unit of  
D 85764 Oberschleissheim



SMP Flexi-Cap



SMP Musterlabel fuer Pens und Autoinjektoren

Sophisticated applications and Freeformer premiere



# Arburg at the NPE

- Allrounders and Freeformers: the entire range for cost-effective plastic parts production
- Injection moulding highlights: Lightweight construction, Industry 4.0, medical and packaging technology
- Additive manufacturing: Sales launch and American premiere for the Freeformer

At the NPE in Orlando from 23 to 27 March 2015, Arburg will present a total of ten exhibits on high-end injection moulding technology and industrial additive manufacturing to cover the entire production spectrum from one-off parts through to mass-produced items. At the 650 square-metre exhibition stand W3729 (Level 2) in the West hall, five Allrounder injection moulding machines and two Freeformers will demonstrate sophisticated applications and innovative processes covering topics such as lightweight construction, multi-component injection moulding, automation and LSR processing. Five further Allrounder machines will be featured on partner stands. In the context of accompanying conferences, Arburg will also hold several presentations on the topic of additive manufacturing.

**23rd - 27th March 2015: NPE 2015,  
Orlando (FL, USA)**

“For us, the NPE is the most important trade fair in the US, at which we will present product premieres, innovative processes and sophisticated applications to the trade visitors. The sales launch of the Freeformer for industrial additive manufacturing in America will also coincide with the exhibition,” says Friedrich Kanz, Managing Director of the North American Arburg subsidiary. “With our offerings, we cover the entire production spectrum – from the industrial additive manufacturing of one-off parts and multi-variant small batches, through to cost-effective injection moulding of mass-produced articles.” He went on to say that production efficiency is the focus with regard to all of the exhibits.



Friedrich Kanz, Managing Director of Arburg Inc.: “At the NPE, we will be exhibiting the Freeformer for industrial additive manufacturing for the first time overseas. The sales launch for our American customers will take place at the same time.” (Photo: Arburg)

## Freeformer for two-component additive processing

With two Freeformers, Arburg will demonstrate how fully functional plastic parts can be additively manufactured from standard granulate using the patented Arburg Plastic Freeforming process based on 3D CAD data, without a mould. As with injection moulding, the granulate is first melted in a plasticising cylinder. Plastic droplets are applied layer-by-layer onto a moving part carrier via the nozzle of a stationary discharge unit by means of high-frequency piezo technology at a specified duty cycle of 60 to 200 Hertz.

The second discharge unit can be used for an additional component in order to produce, for example, a part in different colours, with special tactile qualities, or as a hard/soft combination. At the NPE, a Freeformer will combine an elastic standard TPU material with a special support material – a first in additive manufacturing. Possible applications include e.g. bellows, hoses, sleeves, or flexible components for robotic grippers. The supporting structures can subsequently be removed in a water bath.

## Industry 4.0: individualised toy buggies

At the NPE 2015, Arburg will demonstrate its practical capabilities with regard to the topical subject of Industry 4.0 using an electric Allrounder 370 E, based on the example of a toy buggy. The Arburg host computer system (ALS) is of central importance here, networking various independent stations, recording all the parameters and transmitting them to a web server.

First of all, a personalised chip card is read in by the Selogica control system of the production cell. During the following cycle, the corresponding buggy is injection moulded and an individual code is applied onto its roof by laser. A linear Multilift Select robotic system performs handling and assembly of the buggy, and removes it from the

machine via a chute. Next, the toy car can be checked, e.g. for correct operation. The code on each individual buggy can be read out using a mobile device. It leads to a part-related web page containing all the process data for the moulded part. All the work steps are seamlessly documented, error-free. This ensures transparent, 100 percent traceable production.

## Industry specific: Allrounder “Packaging” version

In Orlando, Arburg will be exhibiting an injection moulding machine in the “Packaging” version especially designed for the packaging industry. The hybrid Allrounder 630 H (P) has been specially configured for thin-wall applications. It produces four round lids per cycle, made from a transparent PP with a label from Verstraete IML that is printed on both sides. The mould was built by the Canadian partner Stack Teck and an IML system from Yudo is used for the automation. The cycle time is around four seconds.

## Medical technology

Thanks to their high precision, speed and low-emission operation, electric machines are ideal for the production of medical items. At the NPE 2015, Arburg will exhibit a representative of its electric high-end Alldrive series. The GMP-compliant, stainless steel Allrounder 520 A machine version uses a high-performance mould from Tanner to produce 64 pipette tips in a cycle time of around 4.8 seconds. For removal, a Hekuma robotic system is used.

## Lightweight construction: long-fibre direct injection moulding combined with organic sheet

Arburg presents an innovative lightweight process that is marked as an exhibit as part of the Blue Competence initiative of the German Machinery and Plant Manufac-

## Arburg at the NPE

turers Association (VDMA): Using long-fibre direct injection molding a side feeder incorporates the fibres in the liquid plastic melt. The advantages of this innovative process include flexibly adjustable fibre lengths of up to 50 millimetres, a low incidence of fibre damage in the plastic melt and significant cost advantages compared to fibre-reinforced standard granulates.

The process will be demonstrated on a hydraulic Allrounder 820 S, operating with a mould from company Georg Kaufmann Formenbau. Through the overmoulding of continuous-fibre reinforced thermoplastic inserts (organic sheets), high-strength, resilient composite parts are created, which weigh less than 200 grams at a length exceeding 500 millimetres. A six-axis robotic system picks up two organic sheets of different

thicknesses from a magazine. The flat inserts are gently heated, process-reliably, using a new technology in the gripper system and transferred to the LIPA (Lightweight Integrated Process Application) mould at a precise forming temperature. Here, forming of the inserts and injection moulding of the functional and reinforcement elements are performed simultaneously in a cycle time of around 55 seconds. The composite part produced provides a good illustration of how lightweight parts can be manufactured, e.g. for the automotive industry, with a high level of functional integration and short cycle times by combining organic sheets and long-fibre direct injection moulding. Thanks to the servo-hydraulic system, the hydraulic Allrounder ensures particularly energy-efficient and low-emission operation.



Arburg is presenting the innovative long-fibre direct injection moulding process at the NPE 2015 with an energy-optimised hydraulic Allrounder 820 S in combination with the overmoulding of a continuous-fibre reinforced thermoplastic insert (organic sheet). The composite part weighs only around 200 grams at a length exceeding 500 millimetres. (Photo: Arburg)

## Multi-component technology: Suction pad made from thermoplastic and liquid silicone

As a multi-component application, Arburg will demonstrate the production of vacuum suction pads made from thermoplastic and liquid silicone (LSR). For this purpose, an electric Allrounder 570 A is equipped with two injection units in L-position and a 4+4-cavity mould from Rico. Thanks to its horizontal configuration, the Multilift Select robotic system is able to enter the clamping unit from above. It transfers the pre-moulded PBT parts to the LSR cavities and sets the finished parts down onto a conveyor belt. Four vacuum suction pads (used e.g. for moving bulky or heavy loads in handling equipment), are produced in a cycle time of around 40 seconds.

## Arburg presentations round off trade fair appearance

Arburg will not only be represented by its exhibition stand at the NPE, it will also contribute with keynote presentations on the topic of additive manufacturing: Managing Director Sales, Helmut Heinson, will provide an outlook on the global and US markets at the special NPE3D event. At the Antec Technology Forum, Managing Director Technology & Engineering, Heinz Gaub, will give a presentation on how additive manufacturing is changing the plastics industry.

ARBURG GmbH + Co KG D 72290 Loßburg



Industrial additive manufacturing: with the Freeformer and Arburg Plastic Freeforming, functional parts can be produced efficiently from standard granulate, without a mould. (Photo: Arburg)



Production process with know-how: complete suction pads can be produced from LSR and thermoplastic in a single operation. (Photo: Arburg)

Safe Measurement in Gas and Dust Hazard Areas

# The EE300Ex Humidity & Temperature Transmitter Conforms to International Standards for Intrinsically Safe Applications



The intrinsically safe EE300Ex humidity & temperature transmitter from E+E Elektronik conforms to the European ATEX Directive and now also to the international IECEx and the FM classification specifically relevant to the USA and Canada. This makes the device suitable for worldwide usage in explosion hazard areas.

The EE300Ex was developed for use in explosion hazard environments and can be mounted directly in both gas and dust hazard areas of zone 0 / Div1. Precise humidity and temperature measurements from 0...100 %rel. hum. and -40...180 °C (-40...356 °F) are also possible in applications under pressure up to 300 bar (4351 psi). Just as with humidity measurement in air, the EE300Ex can also be used for moisture measurement in oils.

Various models of the EE300Ex offer a high degree of flexibility. As a compact variant - with or without display - the transmitter can be mounted directly in the hazard area. With a remote probe, temperature classifications up to T6 can also be achieved. Depending on requirements, an EE300Ex model for combined humidity and temperature

measurement or for temperature measurement only is available.

The two-part stainless steel housing (separate connection area and measurement unit) simplifies installation of the transmitter considerably. It also permits the rapid replacement of the measurement unit - such as for calibration - without time-consuming re-cabling.

The measured values are issued on two analogue outputs with 4...20mA. The power can be supplied via any intrinsically safe power supply device. In addition to the measured values for humidity and temperature, dew point, frost point, absolute humidity, mixing ratio and other calculated values can also be issued.

The configuration software permits cu-

stomized configuration of the transmitter outside the hazardous area and permits, flexible, simple and rapid adaptation of the analogue -outputs for the relevant application.



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Figure 2: A variety of different models of the EE300Ex offer a high degree of flexibility in application. (Photo: E+E Elektronik GmbH)

Figure 1: The EE300Ex humidity & temperature transmitter from E+E Elektronik conforms to international standards for intrinsically safe applications. (Photo: E+E Elektronik GmbH)

# DICTATOR Interlock Control System

Whether in laboratories, in the food industry, pharmaceutical industry or research, simply everywhere where there are needed special environments or clean rooms for the production or research an interlock control system is necessary. It controls the possibility to enter certain rooms in dependence of other doors.

## There are available three different versions of the DICTATOR interlock control system:

- Peripheral system: The control boards where the relations between the doors are adjusted, are situated directly in the control terminals of the respective doors.
- Central system: The control boards are combined in a central casing. On the doors are mounted just simple operating terminals.
- Ex-proof system: Special execution of the central system for hazardous areas. Outstanding feature: the ex-proof terminals are as small and optically attractive as the "normal" operating terminals.

## What makes the DICTATOR interlock control system so unique?

- You need no knowledge of computer science or a complex PLC control system to

- adjust the relations between the doors. The „programming“ consists of adjusting simple DIP switches. At any time it can easily be modified by instructed persons (without special computer knowledge).
- With the peripheral and central systems all intra-system components are pluggable. For most connections are used flat cables with RJ45 connectors. All cables and their corresponding plug-in-positions are colour-coded so it is nearly impossible to make errors during connection.
- Even the power pack for supplying the components has a connection cable with safety plug and hasn't to be opened even for mounting.
- Simple installations can therefore be mounted without needing specialists.
- The system has a modular structure, i.e. it is extremely adaptable and flexible. The interlock control system can easily be linked to a facility management system and many special functions are possible, too. Among these are for example a time control unit to time the clearing of doors (e.g. only after a certain temperature or quality of the air has been achieved), the possibility to integrate and control door operators of different makes, to realize discretion circuits, to assume commands from a facility management system and



Most simple connection of the terminals by colour-coded flat cables with RJ45 connectors.

much more.

- The DICTATOR interlock control system has also available an approved emergency exit terminal to integrate doors in emergency exits - of course meeting all corresponding requirements.

## DICTATOR

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# Spetec Laminar Flowbox FBS

In industrial manufacturing in science and research the need for a clean particle and germ free environment plays an ever important role.

For this purpose elaborated clean room facilities are being designed at great expense not only upon purchase but also for their upkeep. In many instances it is absolutely excessive to install oversized, technically complex, and expensive clean room facilities. Often the economy of an exclusive clean room does not justify for it. In many instances it is quite sufficient to create a localized clean room environment.

The Spetec Flow Box FBS has been developed exactly for this purpose.

The use of a Laminar Flow Box establishes clean room conditions at the location where they are needed. The effective clean room space of the FBS covers a size between 2,16 square feet and 10,08 square feet.

For the manufacturing of the Flow Box FBS only high quality materials such as acrylic glass and stainless steel are being applied.

For installation in an acidic atmosphere a special protective coating will be offered as an option.

The Flow Box is equipped with a filter of the type H 14. This filter is capable of removing 99,995 % of all particles having a size larger than 0,5 µm (EU 14). Even for particles larger than 0,21 µm the degree of filtering is still 99,95 % . In this case the retention factor is 103



which means that the air quality in the Flow Box versus the outside air will improve by a factor of 1000. For particles larger than 0,5 µm an improvement by a factor of 90,000 will be obtained . At an air flow velocity of 0,45 m / sec. the air stream occurs laminar which means that the air moves as a parallel stream.

## SPETEC

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These are the two key product characteristics of Aluminium pallets, -tops, -containers and -skeleton boxes, which are offered by the HURTZ company.

# Clean and safe - in production and storage

Transport and storage devices made of Aluminium are the first choice, when packaging, transport or storage of sensitive hygiene products according to the GMP, and HACCP regulations are concerned. Pallets, tops, containers and boxes made of Aluminium are minimizing the risk of physical, microbiological or chemical contamination to an absolute minimum.

Goods produced in a GMP environment are safely protected, e.g. with containers of aluminum by influences from outside and manipulation. Another advantage of using aluminum products is the low weight by high stability.

So aluminum solutions are clearly superior against other products.

## All HURTZ Aluminium products have special advantages of the material:

They are rustproof, lightweight, odorless and tasteless, 100% recyclable, anti-static and long-lasting. In addition, aluminum costs significantly less than, e.g. stainless steel and has a much lower weight and high torsional rigidity. Aluminum is very easy to clean, due to the fact of his very smooth and compacted surface.

So aluminum is the best material for storage & transport in hygienic areas.

**Who wants to use pallets and containers for many years and who attaches great importance to their serviceability, should look for to the following quality characteristics:**

- the clean design of the welds
- the quality of the profiles (torsion, rigidity, dimensional accuracy)
- the flatness and a slight deflection of pallets.

HURTZ offers aluminum pallets in many different standard designs (euro and industrial format). Thanks to its expert knowledge, a very flexible production and the advantages of aluminum, the company is able to produce special solutions and special designs.

All products are naturally suited for use in high racks and on roller conveyors.

ANTON HURTZ GMBH & CO. KG  
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