

Cleanzone establishes itself as a platform for international exchange in the cleanroom community

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Hans J. Michael GmbH

MT-Messtechnik









EU project "MetAMC" and ICCCS international cleanroom association at Cleanzone for the first time **@**

27th - 28th Oct. 2015: Cleanzone, Frankfurt am Main (D)

Cleanzone is becoming even more international. For the first time, the international cleanroom association ICCCS (International Confederation of Contamination Control Societies) will be appearing at the trade fair and congress for cleanroom technology on 27 and 28 October 2015 in Frankfurt am Main. In addition, various national research institutes will be presenting the findings of "MetAMC Metrology for Airborne Molecular Contamination in Manufacturing Areas", a European project that is focused on methods for measuring chemical contamination in micro-production. Ruth Lorenz, Vice President Technology & Production at Messe Frankfurt, is pleased by the international response: "The high level of international interest in Cleanzone shows us just how important it is to have a platform that brings together the global players in the field of cleanroom technology."

Even minuscule chemical impurities, such as ammonia, acids or organic compounds, can bring production to a standstill in fields such as nanotechnology and in the manufacture of semiconductors, photovoltaic cells, LEDs and OLEDs. In an effort not only to develop new laser-based measurement methods, but also to gain a better understanding of the origin of chemical particles, in 2013 "MetAMC" was launched as a three-year EU project. On Monday, 26 October 2015, the participating institutes will present their latest findings in a workshop in advance of Cleanzone. Trade fair attendees will be able to find out about the progress of their research at the project's stand at Cleanzone. According to Tuomas Hieta, a scientist at Finland's national institute for metrology, Mikes: "Cleanzone, as a key cleanroom technology event in Europe, is a natural choice for our MetAMC EU project to present its findings related to emerging cleanroom contamination. As representatives of the scientific community, it is vital for our project consortium to get in touch with cleanroom operators and experts to find out what is really needed in future in terms of services and instrumentation."

Koos Agricola, General Secretary of the ICCCS, also believes that Cleanzone is an ideal place in which to present the association's efforts to an international audience: "We want to take this opportunity to inform a large international audience of the new road ICCCS will be taking. In Frankfurt, we can encourage people from countries that are not yet members to set up their own national societies." The ICCCS is planning to offer its member associations even greater support in order to foster the international exchange of expertise in the field of cleanroom technology. For example, the association would like to provide its members with standard courses they can offer in their own countries.

Approx. 80 exhibitors are expected at Cleanzone 2015, roughly one-third of whom are from outside Germany. Their ranks include manufacturers from Finland, Great Britain, France, Italy, Switzerland and Austria. The range of products on offer at the trade fair includes construction, planning, ventilation and air-conditioning technology, consumables, clothing, monitoring, quality control, and basic and advanced training.

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cleanzone Ludwig-Erhard-Anlage 1 D 60327 Frankfurt am Main Telefon: +49 69 7575 6290 Telefax: +49 69 7575 96290 E-Mail: anja.diete@messefrankfurt.com Internet: http://www.messefrankfurt.com

Easily accessible technical support

Cherwell Launches Refreshed Website for Cleanroom Microbiology Solutions

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Cherwell Laboratories, specialists in cleanroom microbiology solutions for the pharmaceutical and related industries, have announced the launch of a refreshed website (www.cherwell-labs.co.uk). Designed to make it even easier for customers to find relevant product information, expert advice and technical information; the updated and fully responsive website also provides access to example product applications, testimonials and industry news via tablets and smartphones.

"Over the past 40 years, we have developed a reputation for offering expert technical advice and support," commented Andy Whittard, Managing Director, Cherwell Laboratories. "To make this information more accessible, our refreshed website includes a number of new features such as frequently asked questions, a glossary and a Cherwell blog to ensure we can keep our customers up-to-date on the latest company and industry developments." room microbiology products, developed to meet the specific requirements of the industrial microbiology sector. The product range incorporates Redipor[®] prepared microbiological media for environmental monitoring and process validation, SAS microbial air samplers for active environmental monitoring in a variety of applications and the Mar Cor[®] range of cold sterilants and Dry Fog technology for cleanroom bio-decontamination. In addition to product specific information, the website also offers access to regulatory updates and industry events.

"We were keen to ensure that our contact details remain very visible as we are always happy to discuss applications and solutions with new users," continued Andy Whittard. The new website also has easier access to downloadable content, newsletter sign up and links to Cherwell's growing network of European distributors.

Cherwell's website provides information on their range of clean-

Cherwell Laboratories Ltd OX26 4XB BICESTER



Dear readers, dear subscribers,

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

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





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.



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

cleanroom

Markus Lusser is New President of Leica Microsystems



Markus Lusser is the new President and Director of Leica Microsystems, headquartered in Wetzlar, Germany. This appointment became effective July 1, 2015. He succeeds Andries Peter Jan van den Broek who has left the company.

Before joining Leica Microsystems, Markus Lusser was Vice President Global Sales and Customer Support with Sciex. Sciex produces analysis instruments and, like Leica Microsystems, belongs to the U.S. company, Danaher Corporation. Lusser holds an Electrical Engineering Degree in Telecommunications and Electronics from the College of Electrical Engineering in Innsbruck, Austria (HTBLA). His professional career includes a 20-year tenure at Siemens Healthcare, most recently as Vice President Global Sales and Marketing for Siemens' Molecular Imaging business.

In his new role with Leica Microsystems, Lusser assumes leadership over a major worldwide developer and manufacturer of microscopes and scientific analysis instruments. The company offers innovative, application-oriented solutions for the inspection and evaluation of micro- and nano-structures in a wide range of markets. Products such as the new Leica DVM6 digital microscope help users improve efficiency when performing quality control in the industrial field, while high-end surgical microscopes offer neurosurgeons outstanding functionality and ergonomics. In life science research, the most recent innovation, the Leica TCS SP8 DLS, unites the world of confocal and light sheet microscopy to reveal development processes in living organisms.

"We are pleased that Markus Lusser has taken on this challenge within the Danaher group," says Dan Daniel, Executive Vice President, Danaher Corporation. "He and his team will focus on Leica Microsystems' further growth. I am convinced that also in the future Leica Microsystems' customers will benefit from innovative products and solutions."

"I'm delighted with my new assignment at Leica Microsystems," says Markus Lusser. "This company has set standards within Danaher. Over the past few weeks I have experienced the innovative strength of Leica Microsystems. And I have seen the passion with which our team fulfills customer requirements in industry, medicine, and research, collaborating with them to develop solutions. I am looking forward to being part of the successful future of the company."

Leica Microsystems GmbH D 35578 Wetzlar

ISO Class 7 Cleanroom Extension for Loyal Manufacturing Client



- Size: 208m²
- Type: Hardwall

What did the client need?

The existing client approached Connect 2 Cleanrooms as they needed to extend their existing cleanroom due to a rise in demand for their products. This was the 4th extension that the Connect 2 Cleanrooms Team undertook for their loyal client; their cleanroom was originally installed in 2008.

How did Connect 2 Cleanrooms help the client?

The team designed a 'goods in' area to encourage best practice and relocated the change area so new machinery could be accommodated. Furthermore they added in energy efficient LED lighting & air conditioning to create a stable production environment and improve operator comfort. Connect 2 Cleanrooms even created a ,white area' without any HEPA filtration, which could be upgraded to a cleanroom environment, to future-proof growth.

How did the client benefit from this solution?

The cleanroom extension lead to an increase in production output, as more machinery could be used. The client is also benefiting from better practice through the creation of a 'goods in' area and there is an overall improved workflow.



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





Bringing Cleanrooms Online, Initially and After a Worst Case Event **(20)**

Author: Jim Polarine & Beth Kroeger

Introduction

Environmental control of classified areas within a biopharmaceutical facility is maintained by systems controlling humidity, air temperature, air exchanges, filtration and pressure differentials and by practices such as room cleaning, limited access and facility flow. When any of these systems or practices fail, it's considered a "Worst Case Event" which has the potential to impact the clean state of a Classified Area.

Many facilities have procedures in place to conduct the day-today operations but fail to have procedures in place to handle catastrophic or non-routine events. These disturbances should be defined as part of the Facility Cleaning Procedures in order to provide guidance to operators if issues occur during off-shift or to provide a routine response to a non-routine event.

Is action always necessary?

Not always. Air handling unit (AHU) shutdowns and pressure differentials excursions should have procedures in place for when events occur. Facilities should determine the amount of time a door may be open to not impact the pressures. Facilities should also establish a time limit that pressure differentials are allowed outside of the established range along with how long AHU shutdown is accepta-

cleanroom

Bringing Cleanrooms Online, Initially and After a Worst Case Event

ble without requiring a major clean and Environmental Monitoring. Acceptance criteria should include conditions such as no traffic in the room, doors remaining shut and time limit for pressure excursions or AHU shutdown.1

Procedures should define the most probable excursions and place acceptable criteria around such incidents so when an event does occur, there are some parameters in place to provide alternative responses that have been thought out and verified in advance.

Issues causing a Worst Case Event

Most probable causes for disturbances				
Air Handling Unit	 Power outage Planned shutdown for Maintenance Damper issues Temperature excursions Humidity excursions 			
Room pressure excursions	 Human error – Holding doors open Mechanical failure 			
Wet Conditions	 Mechanical failure with AHU/humidity control Mechanical failure with process equipment Fire suppression system failure Spill Human error 			
Reverse flow	 Equipment Personnel Raw materials			
Planned shutdown	 Construction activities Calibration activities Preventative maintenance Implementation of CAPA's 			
General	 Entry into area without proper gowning Weather causing interruption to power Exceeding alert/action limits 			

Immediate Actions

- Isolate the area.
- Notify appropriate personnel.
- Limit personnel working in the area. If access is required, change shoe covers, when exiting the area, to avoid contaminating adiacent area.
- Clean or cover equipment and materials as they are transported out of the area.
- Clean the area impacted by the event by first clearing any spill or debris using a HEPA wet/dry vacuum or other appropriate means such as wipes, mops or squeegees.
- Triple-clean the area.

Triple-clean - What is it?

- No unified definition
- PDA Technical Report: "Facilities should strongly consider having special start-up cleaning and disinfection programs in place following "shutdowns" or when significant construction is performed."2

1. Triple-clean definition:

Application of a disinfectant, followed by another application of a disinfectant using fresh solution and bucket/mop assemblies, followed by an application of a sporicidal agent.

2. 9 X clean:

Performing a triple-clean each day on 3 consecutive days.

Application of Disinfectants and Sporicides

Bucket assembly set-up					
Two-bucket routine	Disinfectant in front bucket or in bothBucket under wringer is rinse and waste				
Three-bucket routine	Disinfectant in front bucket or front two bucket Middle bucket is rinse bucket. Bucket under the wringer (third bucket) is for catching wrung out waste solution. Instructional video: http://youtu.be/ai75_OHErg				

Application technique

- Dip mop head into front bucket (bucket #1), let excess liquid drain off or wring. Apply to the surface.
- When mop head appears to be dragging on the surface, dip into rinse bucket (bucket #2), then wring out waste into bucket #3. - Repeat.
- Change out the use dilutions every 600 ft2 in ISO 5 and 1,000 ft2 in an ISO 6, 7 and 8.
- Mop in a grid pattern.
- Mop top to bottom and back to front.
- Unidirectional application.
- Overlap application by 20%.

New Cleanroom Operation

New Clean-rooms should be Certified following International Standard (ISO) 14644-2, Cleanrooms and associated controlled environments, Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.

Requirements for Certification

- 1. Particle concentration limits, which ensures the Classification of the cleanroom.3,4
- 2. Airflow volume or airflow velocity.3,4
- 3. Room differential pressures.3,4
- 4. HEPA filter Integrity leak tests and efficiency tests.3,4 (optional)
- 5. Smoke studies, including a video of smoke patterns. 3,4 (optional)
- 6. Laminar flow hood or Biological Safety Cabinet certification, if required.

Cleanroom specifications

- 30 60% relative humidity
- 16 24°C
- Air change rate: ISO 8: >20 air changes per hour, ISO 7: >50 air changes per hour
- Positive differential pressure 10-15 pascals (12.5 pas = 0.05 inches of water column ("w.c.)) between adjacent areas of different classifications.5
- Pressure differential of 0.02"w.c. between adjacent clean spaces.6

Bringing Cleanrooms Online, Initially and After a Worst Case Event



What cleaning is required for Certification?

- 1. Removal of construction debris: Remove debris, corrugate and unnecessary items.
- 2. Vacuum and then wipe or mop all surfaces: Use approved disinfectants, utensils and assemblies
- 3. Uncover/expose air returns. At this point in new construction, the air returns may have been covered by the contractors as a precaution.
- Non-invasive construction work may still be in progress.
- Certify while construction activities are ending with personnel on site to remediate issues, if discovered.
- It's not necessary to have cleanrooms 100% operable with full gowning, routine cleaning and Environmental Monitoring implemented.
- A triple-clean may be performed, however, it's not necessary for Certification. The goal should be to remove particulates in order not to obstruct the filters when the system is in operation.

Triple-cleaning results

Aseptic Viable Particulate Surface Sampling Results – post Triple-clean (ISO 8, 554 ft ² room) – case study						
Sample	Action limits	Pre Triple-clean	Post Triple-clean			
Rodac	2 cfu/plate	3 cfu/plate	< 1 cfu/plate			
Rodac	2 cfu/plate	31 cfu/plate	< 1 cfu/plate			
Rodac	2 cfu/plate	3 cfu/plate	< 1 cfu/plate			

General Recommendations

 No cleaning should take place in an area during open operations and/or during environmental monitoring.

Routine cleaning frequencies

	Daily	Weekhy	Monthly	Voarly			
	Daily	Weekly	wontiny	really			
Controlled Area							
Floors	Х	X					
Ceilings				Х			
Walls			X				
Fixtures/Equipment			X				
Class 100,000 (ISO 8)							
Floors	Х						
Ceilings				Х			
Walls			X	1			
Fixtures/Equipment		X	X				
Class 10,000 (ISO 7)							
Floors	Х						
Ceilings			X	Х			
Walls		X					
Fixtures/Equipment	Х						
Class 100 (ISO 5)							
Floors	Х						
Ceilings	Х						
Walls	Х			1			
Fixtures/Equipment	Х						

 Rooms divided by lines of demarcation, separating two classes in the same room should be cleaned and monitored per the stricter classification.

- Do not use solutions and equipment from a less strict classification to clean a stricter classification of room.

Summary

Worst case event response should be detailed as part of the Facility Cleaning Standard Operating Procedures. Action is not always necessary, provided there are proven acceptable limits and procedures surrounding AHU shutdowns and pressure differential excursions. When an event occurs that requires action, rooms should be isolated with personnel access to the area restricted and additional gowning procedures in place to avoid contaminating adjacent areas. Area should be triple-cleaned after a worst case event and monitored prior to release of room. New cleanrooms should meet ISO 14644-2 requirements, however, new construction cleaning is more concerned with particulate removal rather than microbial control for certification. Final triple-clean prior to room release is required along with environmental monitoring and Quality release of room based on micro results.



STERIS Deutschland GmbH Eupener Strasse 70 D 50933 Köln Telefon: +49 (0)821-56996494 Telefax: +49 (0)821-56996496 Mobile: +49 (0)172-5201338 E-Mail: Andrea_Haselmayr@Steris.com Internet: http://www.sterislifesciences.com

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ZAHORANSKY Z.SIROC, the mobile extension unit for automated extraction in operation at FAKUMA (2)



Mobile Z.SIROC Entnahmeeinheit

13th - 17th Oct. 2015: Fakuma, Friedrichshafen (D)

Normally, take-out units are firmly fixed at clamping plates of the machine. The Z.SIROC extension unit built by ZAHORANSKY allows a much more flexible and universal use.

This is a standardized unit for the automatic feed-in, assembly and removal directly at the injection molding machine, used exactly where it is necessary for part removal. This module including its safety housing can be easily moved by hand lift truck and be adapted to any appropriately equipped injection molding machine.

The take-out unit is currently available in three different versions: the overhead or vertical unit fitted with a 6-axes robot made by Kuka, and the unit with sideload using a linear robot. The three variants of the Z.SIROC removal unit have been designed for use for injection molding machines made by different manufacturers and with clamping forces ranging from 500 to 2,000 kN.

The use of the units is only limited by the available working space in and around the injection molding machine. Owing to the extra



SCPS-Light Werkzeug

eedom of movement, the 6-axes robot integrated as standard easily moves even the most complex of parts.

Rapid and easy communication with the machine control is enred from the autonomous robot control systems via an interface cording to Euromap 67. This will convert the complex 6-axes sysm into a user-friendly Cartesian System of coordinates which will ow the operator or fitter to move within the familiar and usual mensions. The robot's intelligent control makes the appropriate interpretation into the 6-axes system. The Euromap 73 interface is available for integration into the safety circuit of the injection molding machine.

The mobile Z.SIROC extension unit is on display at the FAKUMA on the Ferromatik Milacron stand in combination with an injection molding machine of the F-Series, model 120 with 1,200 kN clamping force.Z.SIROC takes out the ready injection molded handles from the mold. The pre-moldings are placed into the second cavity by means of an internal handling unit. The modular two-fold platform line mold demonstrates the flexible production of different handles in a single mold.

Using a three-station mold at its own booth n° 2309 in Hall A2, ZAHORANSKY shows options for integrated automation solutions inside the mold. Another exhibit on display at the ZAHORANSKY stand is an SCPS-Light mold. The outstanding features of this modular two-plate mold are the two assembly platens mounted outside the mold which allow complex assembly processes to be realized without longer cycle times.

ZAHORANSKY Formenbau GmbH D 79108 Freiburg

Gerresheimer at MedTec China



Production technology for even the smallest parts

cleanroom

Miniaturization is one of the most important technology trends in medical technology. Increasingly smaller and more precise components are required for the construction of medical devices. The conventional injection molding technology reaches its limits when it comes to the production of such parts. Gerreheimer Medical Systems therefore uses a special micro injection molding technology, with which extremely small parts can be produced in a precise and economic manner.



22nd - 24th Sept. 2015: MedTec China, Shanghai (China)

Some micro-injection-molded parts are smaller than the tip of a pen. When producing such products in accordance with the specifications, we have to master challenges in the areas of tool systems, injection molding technology, and measurement technology. Molds must, for example, adhere to much smaller dimension tolerances than the parts produced in them. The mold making department at Gerresheimer therefore uses very special machinery, which is capable of milling and polishing up to a precision of 2 micrometer. In addition, it is ensured that the developed mold solutions can easily be scaled in series production from small platforms for micro-injection molding machines to larger platforms for standard injection molding machines.

Due to the small shot volume, traditional injection molding machines cannot easily be used for micro-injection molding. If the plastic remains too long in the plasticizing aggregate and in the hot runner system of the mold, the material may degrade. In addition, the required mechanical precision is difficult to achieve with technology designed for much larger parts. Gerresheimer offers two solutions for this challenge. Large series are manufactured on modified standard injection molding machines. Heavily utilized molds ensure a shot volume which prevents any material degradation. Optimized special screws and non-return valves ensure the required precision. When producing small to mid-sized series, as well as products with particularly high precision requirements, Gerresheimer then uses special micro-injection molding machines. Here, the screw is only responsible for the plasticization of the plastic; the injection is performed by a piston in an extremely precise manner.

The third challenge is possessing the measuring technology suitable for micro-injection molding parts. At the Technical Competence Center in Wackersdorf (Germany), Gerresheimer has a computer tomograph at its disposal. A special technology is used there for the measurements. The technology is able to reliably fixate and display even the smallest objects during the measurement. Similar equipment is used for the optical measurements as well. In addition, the measured geometry must be freely accessible. With these two measuring technologies, it is possible to obtain measurements for the validation of molds and to manage quality quickly during the ongoing manufacturing process with the necessary speed.

Gerresheimer will be represented at MedTec in Shanghai from September 22-24 at the Shanghai World Expo Exhibiton & Convention Center, booth no. P301.

Gerresheimer AG D 40468 Düsseldorf

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Smart Solution for Indoor Climate Control

Room Transmitter for CO2, Humidity and Temperature

The EE800 transmitter from E+E Elektronik measures CO2, temperature and relative humidity and calculates the dew point temperature. The versions with Modbus RTU or BACnet MS/TP interface also calculate absolute humidity, mixing ratio, specific enthalpy, frost point temperature and partial water vapour pressure. In addition, they can be easily integrated into a bus system for building automation or automatic indoor climate control.

The CO2 infrared measuring principle (dual wavelength NDIR*) used on the EE800 is characterized by high resistance to contamination. The auto-calibration compensates for ageing effects, which leads to exceptional long-term stability. A multi-point CO2 and temperature factory adjustment ensures excellent CO2 measurement accuracy across the entire temperature working range.

The EE800 versions with analogue output (current or voltage) also feature also an optional passive temperature output.

The innovative snap-on design allows for fast mounting and minimizes installation costs. In order to meet various international standards the EE800 is available in two enclosure sizes. The measured or calculated values can be read on the optional display. An optional USB configuration adapter facilitates easy setup and adjustment of the EE800.

*non-dispersive infrared technology

Swiss Medtech Expo "Innovation Symposium": focus on additive manufacturing 🐵

The Swiss MedTech Expo will take place for the first time at Messe Luzern from 15 to 16 September 2015. The trade fair is the most important convention for Europe's third-largest medtech market. The two trade fair days are dedicated to innovation and additive manufacturing in the medtech segment. One of the highlights of the programme is the "Innovation Symposium" that will take a close look at current topics and trends.

15th - 16th Sept. 2015: SWISS MEDTECH EXPO, Luzern (CH)

On the second trade fair day, 16 September 2015, the "Innovation Symposium" will focus on the topic of "Additive manufacturing in medical technology". Additive manufacturing is already an important component of medical and dental technology. Clinical users, service providers and researchers will report on current and future-oriented projects during the "Innovation Symposium".

A beneficial series of lectures

Antonius Köster will get the symposium off to a good start. In his overview speech, he will demonstrate how medicine can benefit from 3D printing. Antonius Köster and his company, Antonius Köster GmbH & Co. KG, are pioneers in the field of 3D modelling and 3D printing of customised implants. The lecture from Dr Johannes Homa also promises to be very exciting. As the responsible manager for biomedicine at Lithoz GmbH, he will report on the 3D printing of biodegradable photopolymers and ceramics. Lithoz GmbH is world market leader in the generative manufacturing of high-performance ceramics. The talk by Thomas Gradl on regulatory requirements for implants made using additive manufacturing and their inclusion in the process chain will be another highlight. Thomas Gradl works in project sales at FIT AG, a service provider and innovator in the field of 3D printing and medical technology. The interesting series of lectures taking place on Wednesday 16 September is organised by Ralf Schumacher, Head of Medical AM at the School of Life Sciences FNHW, and by Dr Stefan Köstler and Ulrich Trog from Joanneum Research.

Competence centre for additive manufacturing

The Rapid.Area will also be on show at the Swiss Medtech Expo. Eight leading companies and institutes with long-standing experience and competence in additive manufacturing for medical technology will present their expert knowledge to trade fair visitors. The Rapid.Area is a mobile platform for additive manufacturing and 3D printing that is organised by Messe Erfurt. Other companies, networks and service providers will also present topics on additive manufacturing outside of the Rapid.Area.

Messe Luzern AG CH 6005 Luzern



Figure 1: EE800 room transmitter for CO2, humidity and temperature. (Photo: E+E Elektronik GmbH)



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

Novel Solution Developed by Schreiner MediPharm and Edelmann

The Future of the Package Insert: Booklet-Label on the Medicine Pack

Schreiner MediPharm has developed in a joint project with the packaging manufacturer Edelmann an innovative solution which makes important product information accessible without opening the pharmaceutical pack. The packaging solution is based on the requirements of the EU Falsified Medicines Directive 2011/62/EU.

Among other things, the said EU directive requires a security seal for the outer packaging of medicines, in order to prevent manipulations. Pharmacists can then only read the package insert after destroying the seal which is meant to form a barrier and to serve as a first-opening indication. In order to avoid this, Schreiner MediPharm as a leading manufacturer of specialty labels for the pharmaceutical industry has jointly developed with Edelmann, a leading supplier of folding boxes, a novel solution combining a folding box with a Booklet-Label applied to the outside.

Applied to the outer packaging, the multi-page Booklet-Label from Schreiner MediPharm makes even multi-lingual product information easily accessible and readily visible without damaging the original pack. It reliably adheres to the medicine pack and is easy to open and close again with the top layer of the film. The Booklet-Label is additionally equipped with a security color-shifting ink for integrated protection against counterfeiting.

"The solution that has been jointly developed with Edelmann maintains the integrity of the pack, while allowing easy access to the package insert," says Robert Unglert, Senior Sales Director at Schreiner MediPharm. The patient benefits from the booklet applied to the pack as well, because it is easy to open and close again. Since the booklet is firmly attached to the pack, it is also less likely to be misplaced.

Schreiner MediPharm D 85764 Oberschleissheim

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 Original texts and images

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