Renhets TEKNIK
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Virtual Reality Models in Cleanroom Design

- ISO 16890 NEW AIR FILTRATION STANDARD · SYMPOSIUM & EXHIBITION
- INTERNATIONELLA RAPPORTER · STANDARDISERING · INBJUDNINGAR

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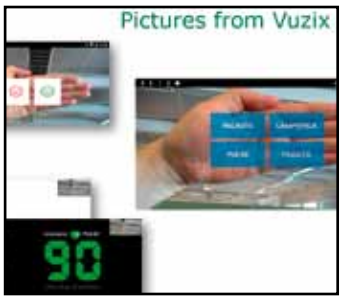
INNEHÅLL



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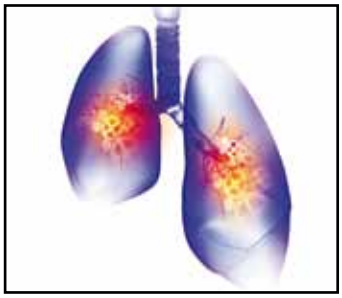

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Phone numbers and e-mail addresses you will find to the left, at page 2.

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ORDFÖRANDE HAR ORDET

Njuter av värmen i augusti månad. En helt otrolig värmebölja har hållit oss i ett fast grepp. Vilken enastående sommar vi har haft! Med så mycket ljusterapi har energidepåerna fyllts på, för att användas till att göra kreativa och utmanade saker resten av året

VAD HÄNDER RESTEN AV ÅRET?

Styrelsen kommer att träffas F2F i Åstorp (här ligger vårt nya kansli). Vi kommer att avhandla hur vi kan synas bättre på sociala medier och vad vi skall erbjuda våra medlemmar. Kan tyckas vara få punkter, men här finns mycket att förbättra. Vi tar tacksamt emot synpunkter från er medlemmar.

Planläggning pågår för vårt 50 årsjubileum med symposium i Stockholm.

Fem kurser är planerade att genomföras under kvarstående del av året

HUR SVÅRT KAN DET VARA ATT GÖRA RÄTT?

Detta fanns redan med i förra numrets ledare men kommer här igen, eftersom frågan är så viktig!

Jag såg två TV-program som sändes den 2/5 och 9/5, Dokument inifrån med titeln ”Den stora sjukhusstriden”. Programmen belyste en statlig utredning, ”Träning ger färdighet”, vilken har letts av Måns Rosèn. I serien ges inblick i konsekvenser av vad denna utredning leder till på mindre sjukhus, som tex Västervik, där man under ledning av doktor Magnus Fröstorp ser att det över tid kan bli svårt att bedriva akut kirurgiskt uppdrag på landsbygden. Denna utredning presenterades för regering och riksdag och en av slutsatserna var att man kunde spara 500 personers liv om man koncentrerade ”högspecialiserad kirurgisk vård” till färre kliniker. Rekommendationen var minst 50 operationer/år för att detta scenario skulle undvikas.

Alla riksdagspartier höll samstämmigt med om att utredningens förslag skulle genomföras. För inget parti eller ledamot vill ha på sitt samvete att man inte gör det bästa av vården. I TV-programmet belyses att det statiska underlaget, som presenterades i utredningen, var bristfälligt. De körningar som gjordes från Socialstyrelsens register var bristfälliga på flera punkter och underlaget som användes var märkligt valt, utifrån det man utredde.

Professor Ulf Gunnarsson menar att det inte finns något samband i volym och kvalité och professor emeritus Ulf Haglund menar att det finns inget stöd i forskningen, som visar att man måste utföra minst 50 operationer per år för att säkerställa kvalitén. Däremot kan man finna en förhöjd risk om man kommer ner till 3-5 operationer per år.

För cirka tio år sedan skrevs det i norska Dagbladet att tio personer dör varje dag p g a vårdrelaterade infektioner. Det var norska Folkhelseinstitutet, som konstaterade detta enligt beräkning av Professor Björg Marit Andersson, att 3 400 personer dör av sjukhusinfektioner årligen. Vidare i artikeln, ansåg man att 20-30 % borde kunna undvikas ”enkelt”, vilket betyder att 700-1 100 personer dör i onödan. (Publicerat 9 januari 2008 i Dagbladet)

Sjukhusinfektion är den fjärde vanligaste dödsorsaken i I-länder efter cancer, hjärtinfarkt och stroke. Gör man en, förvisso inte helt statistisk vetenskaplig jämförelse av detta, så skulle man kunna undvika cirka 2000 dödsfall om året i Sverige.

Varför diskuteras inte denna fråga i regering, riksdag, eller media? Var råder samsynen över denna utmaning? Här finns, enligt min mening, en frågeställning av mycket stor dignitet som inte hörs i debatten.

Vår förening har mycket att bidra med för att minska detta tal, höja vårdkvalitén och därmed säkerställa en högre patientsäkerhet. Släpp in oss på arenan!

LENNART HULTBERG
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”Vår förening har mycket att bidra med för att minska detta tal, höja vårdkvalitén och därmed säkerställa en högre patientsäkerhet. Släpp in oss på arenan!

KALENDER

2018

Sep

11 PHSS & UCL Annual Confenrence London, UK

12 Ventilation Solution Day, Camfil Trosa

12-14 Livsmedelsdagarna i Tylösand

23-26 ICCCS Internationellt Symposium Haag, Holland

Okt

2-3 CTCB-I Certifiering Associate Level

2-4 CTCB-I Certifiering Professional Level Göteborg

3-4 Grundkurs RenhetsTeknik Köpenhamn, Danmark

9-11 EHEDG Advance Course in Hygienic Engineering & Contamination Control, AlfaLaval, Tumba

15-17 13TH Annual PDA Conference on Pharmaceutical Microbiology, Bethesda, USA

Nov

2-4 CTCB-I Certifiering Glasgow, Scotland

29-30 Grundkurs RenhetsTeknik Chalmers, Göteborg

2019

Mar

11-13 PDA Annual Meeting 2019, Conference and Exhibition Marriott Marquis San Diego, CA

Maj

6-7 R³ Nordic 50:e Symposium & Exhibition på Hotel Birger Jarl, Stockholm

Nästa nummer
beräknas utkomma den 6 december 2018

Manusstopp / Annonsbokning:
6 november 2018

Företag och medlem som vill delta med artikel eller release, skall sända detta i god tid före manusstopp till redaktören Berit Reinmüller.

REDAKTÖRENS SPALT

R³ Nordic är en ideell och samhällsnyttig organisation med uppgift att informera, aktivera, engagera och öppna kontaktvägar. Det sker både på nationellt och internationellt plan. Genom att engagerade medlemmar berättar om t ex konferenser och utställningar, kan andra intresserade, som kanske inte haft möjlighet att delta, få information om tankegångar och synsätt utanför Norden samt tips om kontakter. Har du deltagit i en givande konferens eller ett evenemang som kan intressera föreningens övriga medlemmar. Skriv till oss och berätta om det. Utbyte av idèer över verksamhetsgränser kan vara mycket givande. Det går också att söka resebidrag/stipendier från föreningen för att delta i en mässa eller en konferens. Skicka din ansökan till styrelsen!

Föreningen har också som uppgift att samarbeta med myndigheter t ex standardiserings-organisationer som SIS men också lämna framställningar till myndigheter nationellt och internationellt. Ytterst är det dock enskilda medlemmars aktiva engagemang i sektioner, arbetsgrupper och utskott som ger resultat. Kontakter med kontrollerande myndigheter för att diskutera renhetstekniska aspekter och få ta del av deras synsätt och tolkningar är synnerligen viktigt.

I DETTA NUMMER...

I detta nummer finns två huvudartiklar, en om virtual reality i renrum och en om en ny filterstandard, som utgår från människans skaderisker. Virtual Reality, robotisering i industrin, datorhantering av ”big data” och snabba omställningsprocesser är saker vi får se mer av i framtidens tillverkning.

KOMMER

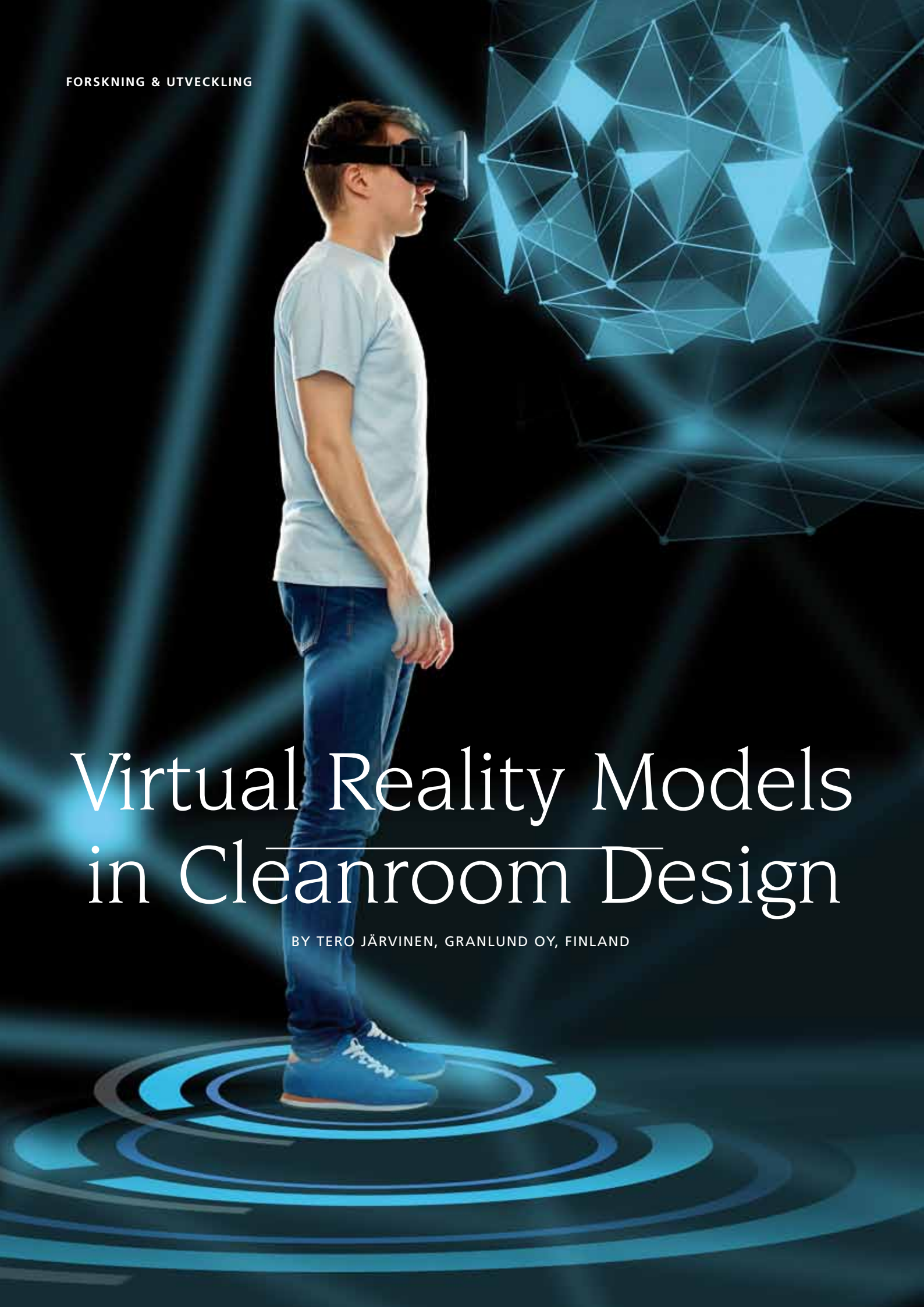
Nudging - en beteendevetenskap, som innebär att man på ett vänligt sätt puttar eller försiktigt påverkar personer i målgruppen i en annan riktning än den de annars skulle ha tagit. Nudging fungerar ofta bättre än både piska och morot. Förhoppningsvis kommer vi att få mer information om hur nudging tillämpats inom bl a läkemedelsindustrin i ett kommande nummer.

I nästa nummer kommer också en rapport från 2018 Cleanroom Guangzhou Exhibition, en av de stora utställningarna inom området. Givetvis kommer rapporter från föreningens genomförda kurser och certifieringar.

Ytterligare information inför föreningens 50:e symposium, med abstracts mm kommer i nästa nummer och i det första numret 2019 kommer bl a att belysa föreningens historia och framtid.
Efterföljande nummer, 2:2019, kommer mest att handla om det då genomförda 50:e symposiet.

Berit Reinmüller

BERIT REINMÜLLER
REDAKTÖR



Virtual Reality Models in Cleanroom Design

BY TERO JÄRVINEN, GRANLUND OY, FINLAND

The use of Virtual Reality (VR) possibilities has increased in recent years due to technology improvements. The driving force has been the gaming industry. The construction sector has been able to benefit from the technology leaps carried out by other industries. Building Information Models (BIMs) have been in use by architects and structural and mechanical designers since the early 2000's. In the Nordic countries, using BIMs is a normal way to design and the construction companies are able to utilize these models quite easily. By combining BIM processes and current VR technologies we are in the situation that the use of VR glasses can be a common means with which the design in construction projects can be promoted (Figure 1). When combining the VR glasses with models, the end users can obtain a better understanding of what architects and engineers are designing than based only on combined models on a computer screen. With VR glasses on, the users can walk inside the rooms and see objects in real scale. When the construction process goes further and we have a real environment built up, we can start using Augmented Reality (AR) possibilities. With AR, you can add objects to the camera view of tablets, phones or smart glasses. AR models can utilize the same BIMs as VR is using. Unfortunately, technology in AR systems and software still needs improvements. VR models are easy to set up but AR models need a lot more preparation to work in real-life use cases. Examples of possible use cases with VR models in the design and construction phases:

- Checking process functionalities inside a cleanroom, moving things in VR
- Checking service/maintenance possibilities
- Checking equipment/device locations in the design phase
- End user approvals/rejections to design team
- Visual inspection of different lighting environments
- Multi-user meetings inside a cleanroom (attendance from multiple locations)
- Training of people (device maintenance or processes etc.)

Examples of possible use cases with AR models:

- Seeing through walls/ceilings (using BIM)
- Locating equipment/devices (with indoor location or tags attached to devices)
- Serving additional information to end user for operating devices/to follow protocols (with preloaded material in the cloud)
- Seeing additional information on top of gauges etc. (using object recognition)
- Seeing and operating virtual user interfaces on top of QR code etc.
- Using voice commands for operating AR software (if you need both hands)

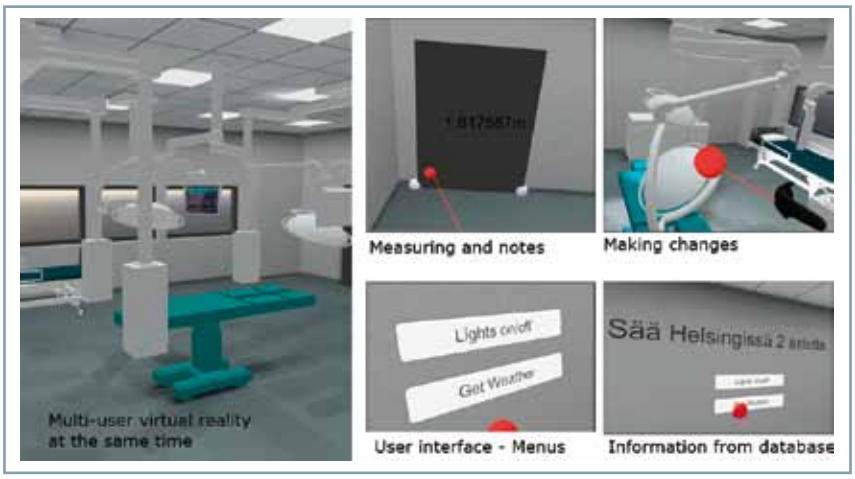


Figure 1. Examples of functionalities in VR models

PROCESS

The construction process produces BIMs in multiple different formats. Efficient use of VR needs straightforward processes. Access to BIM information is available through an open BIM format called Industry Foundation Classes (IFC). All native BIM modeling software can export IFC-models and these models can be viewed through numerous other software. Using IFC models as the basis of a VR environment is the most powerful way to create and update VR information during a construction project. With IFC, different disciplines can combine each other's models and make their own VR models for other use cases from the same source and content (Figure 2). If the whole design team is using the same native BIM software, IFC is not needed in the process. But in Finland, that's not a normal case by any means.

Figure 2. VR/AR models are created from a single source

DEVICES

VR/AR devices are developing rapidly nowadays. Oculus Rift and HTC Vive have been the best VR glasses

Figure 3. Examples of Windows Mixed Reality Glasses

Figure 4. Example of Smart Glasses, Vuzix M300 with Android operating system

Figure 5. Screenshots from AR Smart Glasses

for a couple of years. Microsoft launched its "Windows Mixed Reality" platform at the end of 2017 and the cost of VR headsets decreased dramatically. Now there are multiple hardware manufacturers in the market. In the AR sector, there are many different approaches to utilize models. The easiest way is to use your phone or tablet but in the cleanroom environment that's not always possible. There needs to be a technology that brings the AR view to your visor or smart glasses. One working and tested solution is using smart glasses (Figures 3-5).

In Granlund, we made prototype software using smart glasses with a virtual dashboard. With that technology, the user can give a simple command using only hands to operate AR functionalities. Functionalities were made for Facility Management purposes, using cloud FM database information, but can also be made with any cloud information that has an interface to connecting data sources. The software recognizes the hand of the user and draws a virtual dashboard on top of the hand. The user can push the buttons on the virtual dashboard and see more information about the selected topic. The user can change pages by swiping a hand in the air or give "accepted/rejected" commands with a thumb up/down [1]. It is also possible to use voice recognition, but that was not tested in the Granlund prototype.

INFORMATION CONTENT

When using VR or AR models, the information inside BIMs is still very important. Therefore, access to BIM information is very important for use cases where the information of models is used. Using an open IFC format, information content is understandable to various software platforms. With IFC, you can build a BIM environment where you can see multiple discipline models in a single, coordinated model. This kind of environment is ideal for VR purposes. The downside of using the IFC format is that it contains static information. IFC is exported from designers' native BIMs and is therefore always "old" information, because designers are making updates to native BIMs. In the design and construction phases this is not a big problem, because these phases are used to having iterative information flow in their processes. The designer is publishing a new IFC model, for example, every week to the construction site. After the construction project – in the Facility Management phase – this kind of process is not possible. Updates to models must be done instantly when something has been changed. To achieve this, we need a Digital Twin of the building or cleanroom.

DIGITAL TWIN

Digital Twin is a representation of a real building, its components, systems, measurements and functionalities. Digital Twin can act as a user interface for AIM (Asset Information Model) [2]. With static asset information from BIMs and a dynamic IoT-sensor or system information from manufacturers' environments we can build up a system that can be monitored and updated through cloud services. Information from multiple different systems can be seen and operated through a single interface. With possibilities in cloud software, there is a possibility to update the information in the IFC model seamlessly,

without the need of opening complex native BIM software. Native BIM software is needed only when there is a change in graphical objects – you need to move a wall etc. Using REST API technology, there is a possibility to connect multiple different systems and gather dynamic information from them. With Digital Twin, there are more VR and AR use cases in the future. The digital model comes alive when the user can see dynamic information of cleanroom in the visor or smart glasses (Figures 6–7).

Figure 6. Example of Digital Twin user interface to monitor temperature, humidity and space performance, information available through REST API for VR/AR environment

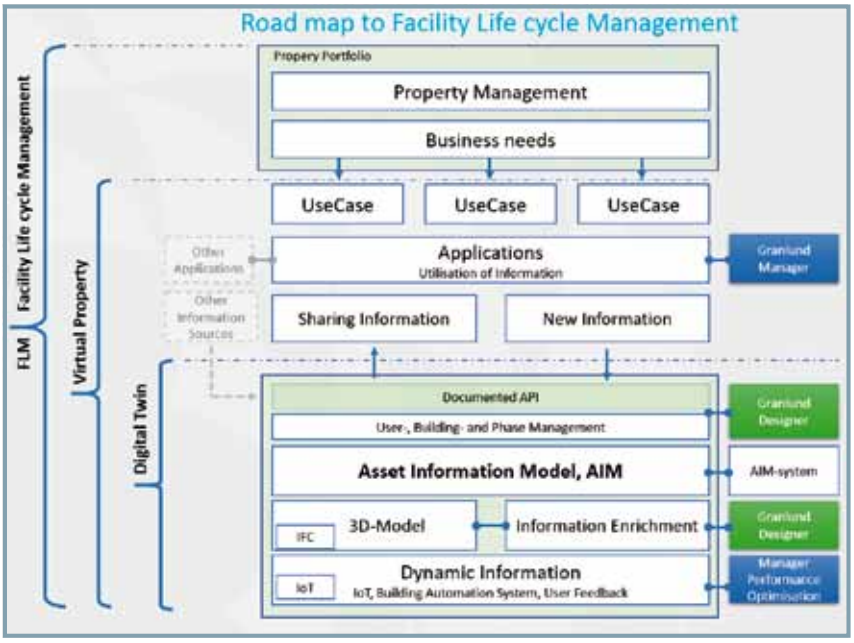
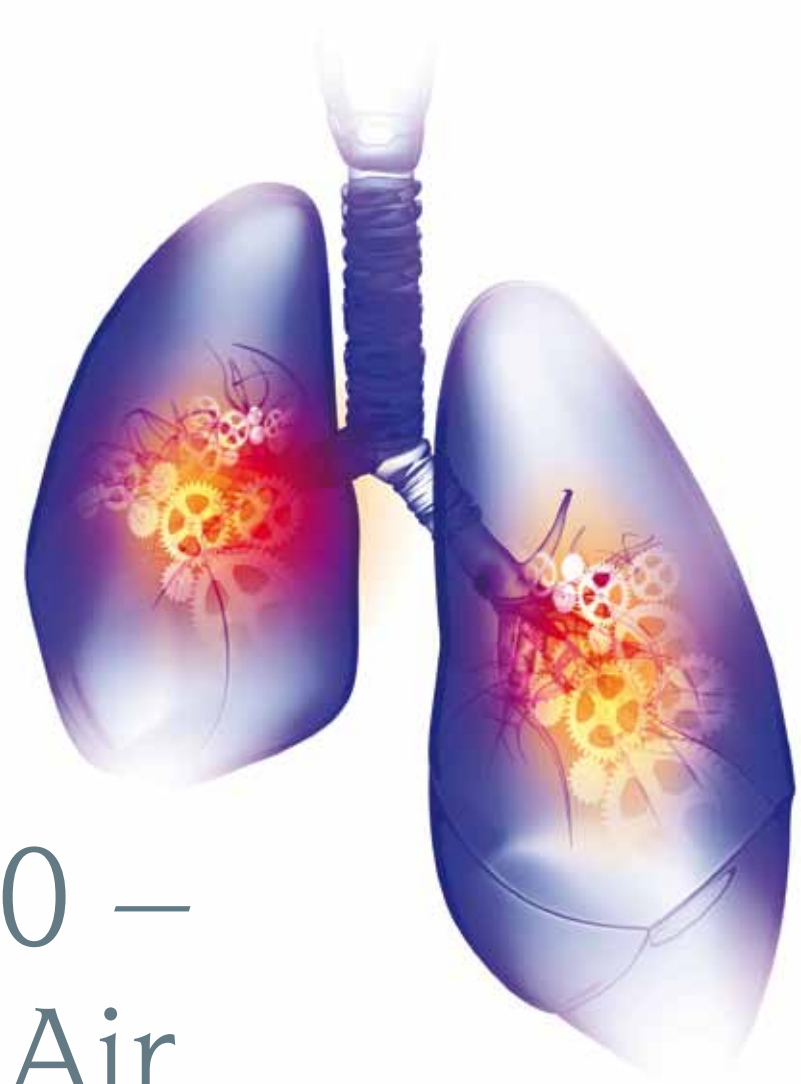


Figure 7. Concept of Digital Twin during facility lifetime

REFERENCES

1. Demo how to use smart glasses with hand gestures (in Finnish): https://www.youtube.com/watch?v=EixdlYRRvAc&t=1s

2. PAS 1192-3, AIM; "Asset Information Model". Defined for guideline of using BIM models in operational phase of construction project by BSI, British Standards Institute. https://www.designingbuildings.co.uk/wiki/Asset_information_model_AIM



ISO 16890 – The New Air Filtration Standard –Protecting your Indoor Air Quality

BY ROSS DUMIGAN, CAMFIL IRELAND, IRELAND

After a long process over several years all involved countries in the world have finally come to a common decision. The future global test standard for air filters is called ISO 16890 and it will replace the existing standards, EN779 (Europe) and ASHRAE52.2 (USA, Asia and Middle East). EN779:2012 will be deleted in the end of August 2018 and until then, both standards are valid. ISO16890 has a completely new way of classifying air filter products. All manufacturers must make new tests and adapt all their products accordingly. With the new ISO16890 standard we can get a relation between the outdoor air particles and the effect of the inlet air in regards of filter efficiency. The old (but still existing) EN779:2012 is based on filtration efficiency focused only on 0.4µm particle size, but new ISO16890 gives more intuitive filtration performance related to particulate matters PM10, PM2.5 and PM1. Clean air is one important ingredient - the "invisible raw material" in sensitive Food, Beverage, Biotech and Biopharma manufacturing processes. Hygienic aspects and standards must be considered at new product stages, which will maintain and possibly also improve the product safety.
It is the responsibility of designers and each manufacturer to establish GMP framework and requirements for each product type or family that will result in quality products that are safe, from raw material handling through production and warehousing all the way to distribution. It is a complex task balancing costs, safety regulations and user requirements. However, with step-by-step project management, EHEDG hygienic engineering guidelines, equipment suppliers and contractors that are familiar and experienced in GMP and with appropriate validation and verification activities, our joint preventative and predesigned efforts will secure food products that meet the quality and hygiene system requirements and attract consumers now and in the future.

Air Filtration is primarily designed to help improve Indoor Air Quality. Indoor air quality refers to the quality of the air inside buildings as represented by concentrations of pollutants and thermal conditions that affect the health, comfort and performance of occupants.

Before discussing the new Global Air Filtration standards it's important to understand the air you breathe. By understanding the air you breathe it is easier to determine your air filtration needs.

WHAT IS IN THE AIR WE BREATHE?

Did you know that with Every breath we take we breathe in over 25,000,000 Particles? These particles can come from a range of different sources including Diesel Exhausts, Dust Particles, Asbestos etc. When Classifying these particles ISO 16890 divide these up into 4 main categories – PM1, PM2.5, PM10 and Coarse Particles:

PM_1 Mass concentration of particles, aerodynamic diameter less than 1,0µm expressed in µg/m^3

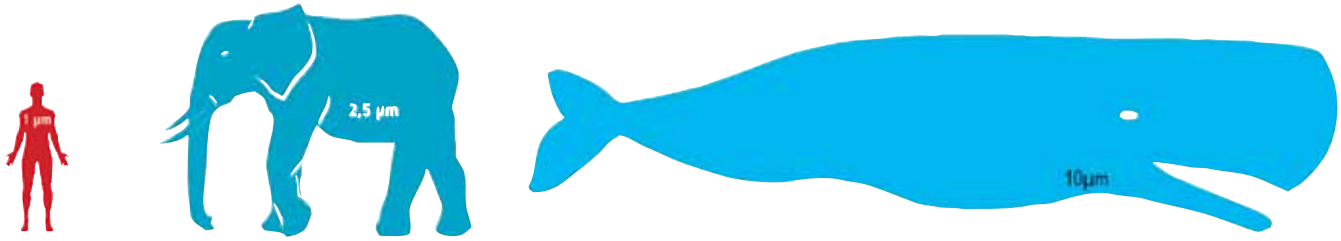
$PM_{2.5}$ Mass concentration of particles, aerodynamic diameter less than 2,5µm expressed in µg/m^3

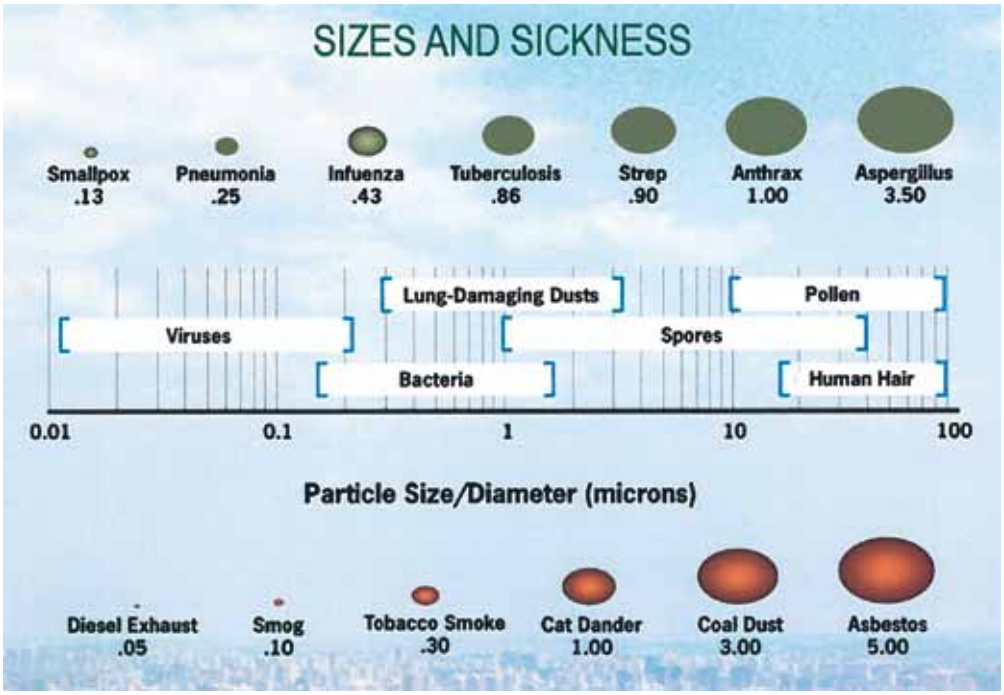
PM_{10} Mass concentration of particles, aerodynamic diameter less than 10µm expressed in µg/m^3

Coarse Particles–This refers to all particles that are above the PM_{10} Value.

To put these into real life scale comparisons – If A Human was 1,0µm then an Elephant would be 2,5µm and a sperm whale would be 10µm.

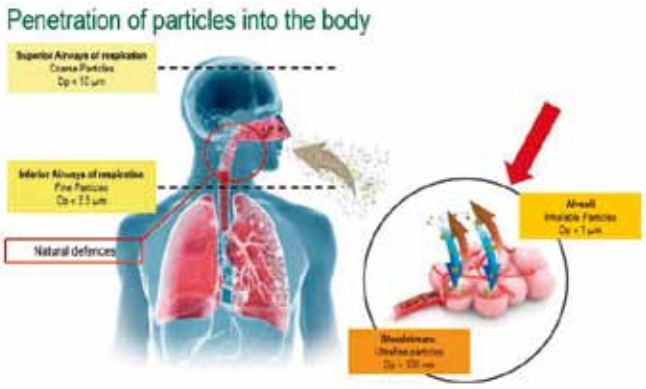
The chart on next page highlights some of the key contaminates that we are trying to stop entering our buildings and their corresponding Particle size.





HOW DO THESE PARTICLE SIZES AFFECT OUR BODY?

Our Bodies have natural defences that help us protect ourselves from different particle sizes. The picture shows how particles greater than 10µm can be stopped in our Nasal passage, Particles greater than 2.5µm in the throat while the smallest particles can penetrate our Alveoli and even enter our Blood Stream.



According to Magnus Svartengrens (Professor in the KI institute) report on Mortality and particles, he shows that particles smaller than 10 and 2.5 microns is linked to increased mortality.

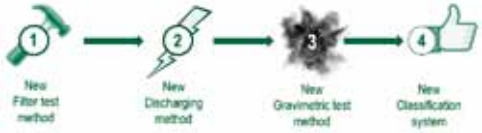
ABOUT ISO 16890

The International Organization for Standardization (ISO) has published a landmark standard for the air filtration industry. ISO16890 defines testing procedures and a classification system for air filters used in general ventilation equipment. This new standard provides the first opportunity for global harmonization as it proceeds to replace the two existing localized standards; ASHRAE 52.2 which is dominant in USA and EN779:2012 which is dominant in Europe. Both standards coexist in Asia and the Middle East.

There are important differences between the ISO16890 standard and Preceding standards.

- In several aspects, the new test procedures are more demanding than the existing standards. This will lead to higher filter performance, improved indoor air quality (IAQ) and greater protection of human health.
- The new test procedures are more closely related to real-world filter performance.
- The classification system is related to filter performance against three different sizes of particles.
- Importantly, the smallest particle fraction of the three, so called PM1, best represents the very fine particles that are known to be the most harmful to human health.

WHAT IS NEW ABOUT ISO 16890?



WHAT DO THESE CHANGES MEAN?

The new filtration standard has been designed around real-life conditions. Previously your Air Filter was categorised into 9 different

PM1 Classification	PM2,5 Classification	PM10 Classification	Coarse
ePM1 [95%]	ePM2,5 [95%]	ePM10 [95%]	Arrestance reported in 5% increments
ePM1 [90%]	ePM2,5 [90%]	ePM10 [90%]	
ePM1 [85%]	ePM2,5 [85%]	ePM10 [85%]	
ePM1 [80%]	ePM2,5 [80%]	ePM10 [80%]	
ePM1 [75%]	ePM2,5 [75%]	ePM10 [75%]	
ePM1 [70%]	ePM2,5 [70%]	ePM10 [70%]	
ePM1 [65%]	ePM2,5 [65%]	ePM10 [65%]	
ePM1 [60%]	ePM2,5 [60%]	ePM10 [60%]	
ePM1 [55%]	ePM2,5 [55%]	ePM10 [55%]	
Requirements: > 50% inital efficiency > 50% discharged efficiency	Requirements: > 50% inital efficiency > 50% discharged efficiency	Requirements: > 50% inital efficiency	No discharge requirements

categories from G1 up to F9. In this standard, Medium and Fine Filters (M5-F9) were tested against one particle size - 0.4micron. Now your filters are categorised into over 30 different categories (Outlined in above chart). Each filter is now tested against all four particle ranges. The filter is tested with its charge and without its charge. The filter is classified based on the mean efficiency. When a filter is being classified by a manufacturer it must achieve a minimum of 50 % efficiency in its decided category from its charged and discharged test report.

SO HOW DOES THIS AFFECT OUR FILTRATION CHOICES?

With the new air filtration standard changing the classification of filters its extremely important for you to understand how the old standards correlate with the new standards and what filter should replace your old "Specified Air Filter". In most HVAC systems, where a clean room environment is not required, it was recommended that your final filter should be F7-F9 in efficiency according to EN779:2012. The chart below helps you identify where these filters are placed regarding the new ISO 16890 standard.

CHOOSING YOUR NEW ISO 16890 CLASSIFIED FILTER

In areas where there are no sensitive processes, it is recommended that ePM1 classified air filters should be the minimum requirement. ePM1 60%+ filters are best equipped to protect the health of your building occupants. By Choosing ePM1 60%+ filters you are ensuring that over 60% of the smallest par-

FILTER CLASS	PM1	PM2,5	PM10
M5	< 20%	< 40%	≤ 50%
M6	< 40%	≤ 50%	≤ 60%
F7	≤ 50%	≤ 70%	≤ 80%
F8	≤ 70%	≤ 80%	≤ 90%
F9	≤ 80%	≤ 90%	≤ 95%

ticles are removed from the air you breathe (ePM1 filters will also ensure higher levels of the larger particles are removed also).

In sensitive processes old F7-F9 rated air filters (EN779:2012) were used to protect the HEPA filter and improve its product Life Cycle. The idea was simple – The fewer particles your HEPA filter had to deal with the longer it would keep its efficiency and lower pressure drop. The problem with the old standard was that there was a wide variation in efficiencies when dealing with each filter classification. F7 encompassed all filters that had a minimum efficiency between 35 % and 54 %, F8 encompassed all filters that had a minimum efficiency between 55 % and 69 %, while F9 encompassed all filters with a minimum efficiency 70 % and above. This meant that there could be a huge disparity between different F7 Air Filters. Because of this, companies that changed filter supplier may have noticed an increase in HEPA filter changeouts when they were "Using the Same Classification air filter".

The new standard allows for better visibility when changing from one filter to the other. With over 30 different categories the end user can now ensure that when fine filters are changed out a like for like or filter upgrade should be provided. This is to ensure a longer life of your costlier HEPA filter.

To learn more about the ePM1 filters visit www.camfil.com/takeabreath/.

WHAT OTHER CONSIDERATIONS SHOULD BE MADE WHEN CHOOSING YOUR AIR FILTER?

Choosing an ePM1 Certified Air Filters to protect the health of the people in your building from outside contaminants is always the first step. The problem with just choosing an ePM1 filter is that "not all filters are created equally". Other considerations that need to be considered would include:

1) Energy Rating: All Certified Fine Filters are accompanied by an Energy Rating. These ratings are calculated using a calculation that has been highlighted by Eurovent Document 4/21. In this rating system all Air Filters are rated from A+ to E. Choosing the Most Energy efficient solution is key to help save your company money. (With the introduction of ISO16890 the classification system is changing. This is the most recent energy standard in operation).

2) Sensitive Manufacturing Processes: In different Manufacturing Facilities there are different Hygiene zones and different Air Contamination threats to factor in. For Instance, in sensitive areas where Cross Contamination and Food Contact are a concern, there is a larger emphasis on Quality Control and Compliance. Consider what environment the filters are supposed to operate in and make sure that they are suitable for that. Choosing Air Filters that are fit for Product Contact, Fully Traceable and do not support Mould Growth are key to ensuring these areas are prepared for Quality Audits. To find out more how to comply with the stringent requirements of Life Science and Food & Beverage visit www.camfil.com/prosafe

3) Total Cost of Ownership: There are many factors that influence the overall costs for air filters over a long period of time. One of these factors is Frequency of Filter change out Vs Energy consumption. Choosing an air filter that maintains a low pressure drop over a longer period of time is key to reducing costs. When saying "Not all filters are created equally" operational lifetime is a key factor. Some air filters get changed twice a year, some yearly and some can last even longer when focussing your filter changeouts around your Economical Change point. Choosing a longer life filter can help reduce labour costs, Disposal Costs, Long term filter costs and more.

References

Svartengrens, M.(2004) Air Quality and Morbidity: Concentration-response Relationships for Sweden. Working Paper Number 87 Stockholm: The National Institute of Economic Research

ISO Standards Update of ISO/TC209

ISO 14 644 "CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS"

ISO Part	Name	Year
14 644-1	Classification of air cleanliness by particle concentration	2015
14 644-2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015
14 644-3	Test methods	DIS 2016
14 644-4	Design, construction and start-up	2001
14 644-5	Cleanroom operations	2004
14 644-7	Separative devices (clean air hoods, glove boxes, isolators and minienvironments	2004
14 644-8	Classification of air cleanliness by chemical concentration (ACC)	2013
14 644-9	Classification of surface cleanliness by particle concentration (SCP)	2012
14 644-10	Classification of surface cleanliness by chemicals concentration (SCC)	2013
14 644-12	Classification of air cleanliness by nanoscale particle concentration	DIS 2016
14 644-13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical concentrations	2017
14 644-14	Assessment of suitability for use of equipment by airborne particle concentration	2016
14 644-15	Assessment of suitability for use of equipment and material by airborne chemical and surface chemical concentration	2017
14644-16	Code of practice for improving energy efficiency in cleanroom and clean air devices	DIS 2018
14644-17	Particle Deposition Rate Applications	PWI

ISO 14 698 "CLEANROOMS AND ASSOCIATED CONTROLLED ENVIRONMENTS – BIOCONTAMINATION CONTROL"

ISO Part	Name	Year
14 698-1	General Principles	2004
14 698-2	Evaluation & Interpretation of Biocontamination Data	2004
EN17141	Biocontamination – Microbial cleanliness levels	DIS 2017

Från filterscanning test på CTCB-I Professional Level i testanläggningen på Chalmers Installationstekniska lab.

CTCB-I certifiering & årsmöte i UK

TEXT OCH BILD: LARS EKBERG

CTCB-I står för CleanroomTesting and Certification Board International och är en internationell sammanslutning. Sedan 2011 hålls de Nordiska certifieringskurserna på Chalmers, vid avdelningen för Installationsteknik. CTCB-I´s certifiering av renrumskontrollanter och innefattar krav på kunskaper om fysikaliska grunder, mätteknik samt regelverk och standarder. Dessutom ställs krav på praktiska färdigheter när det gäller mätteknik, framförallt beträffande luftflöden och funktionskontroll av HEPA filter för certifiering på Professional Level.

Den 19-21juni var det dags för The Scottish Society for Contamination Control (S2C2) att arrangera en certifieringskurs i Letchworth Garden City, Hertfordshire, strax norr om London. Kursen hölls i laboratoriet hos Air Techniques International (ATI). Dagen efter att kursen avslutats höll styrelsen i CTCB-I sitt årsmöte.Vid mötet fanns representanter från Holland, England, Skottland, Irland, Turkiet och de Nordiska länderna. Vid mötet ägnades mycket uppmärksamhet åt hur man på bästa sätt säkerställer att certifieringen är likvärdig oavsett i vilket land den genomförs. För att säkra kvaliteten på certifieringskursen styrs den av standard operating procedures (SOPs) för allt från praktisk planering och genomförande till krav och bedömningsgrunder.

Norden representerades av Lars Ekberg, som under de gångna åren successivt tagit allt större ansvar för genomförandet av de Nordiska certifieringskurserna. Från och med årsskiftet 2017/18 är Lars kontaktperson för CTCB-I i Norden. Under 2018 leder han kursen tillsammans med Berit Reinmüller, docent, och Bengt Ljungqvist, professor, samt i samverkan med ett flertal lärare från näringslivet. Den 2-4 oktober är det dags för nästa nordiska kurstillfälle på Chalmers i Göteborg.

PDA Europe 3rd Annual Meeting

Den 26-27 juni var det dags för PDA Europe 3:e Annual Meeting i Berlin under temat Global Healthcare of the Present & the Future. I samband med konferensen hölls möten i intresse grupperna (IG) för Quality System och Freeze Drying Technology.

TEXT OCH FOTO:
BERIT REINMÜLLER

Konferensen och utställningen hölls på Hotell Marriot vid Potzdamer Platz i Berlin. Drygt 200 deltagare, 35 föreläsare och ca 30 utställare samt ett antal posterpresentatörer fanns på plats. De flesta var från Europa, varav ett fåtal kom från Norden. Konferensen öppnades av Falk Klar, PDA Europe, och flera PDA utmärkelser delades ut. Konferensens två ordföranden, Jette Christensen, Novo Nordisk och Borke Van Belle, Jansen J&J hälsade alla välkomna. Keynote sessionen hade tre inlägg; Alex Glatz, Pfizer presenterade läkemedelsindustrins möjligheter och framtida inriktning ur ett globalt perspektiv, Markus Hayek och Marc Philipp, AccentureStrategy diskuterade hur industrin kan hantera den ökande komplexiteten i nya produkter. Jette Christensen gav ett patientperspektiv på debatten och gav exempel på hur utvecklingen av bl a diabetesmedicin sedan 60-talet underlättat det dagliga livet för patienter.

Efterföljande session diskuterade aktuella EMA Annex 1 och PDAs revision av denna med kommentarer från industrin. Performance of a pre-use, post-sterilization integrity test (PUPSIT) som krävs i Section 113 av Annex 1, gav upphov till en livlig diskussion. Efter lunch och utställningsbesök delades konferensen i två delar, Big Data och Manufacturing och därefter New Era of Manufacturing Technology med flexibla fabriker och robotar samt Digital Health & Precision Medicine Patient Centricity. En intressant första dag avslutades med ett networking event, var en uppskattad båttur på floden Spree genom Berlin. Dag två innehöll två spår, Smart Industri och ett nytt inslag Young Professionals, samt Regulatory Perspective och Data Integrity. Konferensen avslutades med en gemensam session där bla Reyk Horland, TissUse presenterade Healthcare of the Future: MultiOrgan Chip Technologies och ”Patient on a chip” en teknik för säkerhets och toxikologiska tester, som sparar tid och pengar.

Två högintressanta dagar med representanter från de största läkemedelstillverkarna, med diskussioner hur aktuella kontrollmyndigheters uppdateringar tolkas av industrin och hur morgondagens tillverkning kan se ut.

De flesta presentationerna och många bilder finns tillgängliga på nätet för deltagarna fram till den 26 september.

Tre två-dagars PDA-kurser var schemalagda direkt efter konferensen; Practical Approach to Quality Culture, Best Compliance Practice in a GMP Regulated Testing Laboratory och Test-Methods for Pre-filled Syringes.

Den 4:e PDA Europe Annual Meeting blir 25-26 Juni 2019 i Amsterdam, Nederländerna. Notera detta datum i din kalender.

Richard Johnson, PDA president
Photo: Jens Llebchen

Potzdamer Platz, Berlin

ICCCS

The International Confederation of Contamination Control Societies (ICCCS) is an international community for national society on cleanrooms and contamination control. From each country only one society can be a member and represent their country. At the moment there are 19 members.
One member R3Nordic even represents 4 countries (Denmark, Norway, Sweden and Finland).
ICCCS members organise an international symposium every 2 two years in the even years.
ICCCS stimulates the development and exchange of cleanroom technology and contamination control courses and provides international accreditation to courses of members that fulfil the IEC guidelines.
ICCCS has an liaison with the TC209, the Technical Committee of cleanroom standard International meetings of ICCCS, IEC and TC209 are aligned yearly.
Any group representing a Contamination Control society in one country and which subscribes to the aims and mission of ICCCS can apply for membership.
ICCCS provides a network for specialists in cleanroom and contamination control

IEC

The IEC is an integrated part of the ICCCS with the goal to harmonize and share cleanroom courses. The IEC promotes the preparation and accreditation of internationally-recognized educational courses for people who design and test and monitor, operate, and work as operators in cleanrooms.
The IEC accredits Cleanroom and Contamination courses that treat subjects according to the relevant **ISO standards**. Courses are accredited within an Accreditation Guidelines' set down by the IEC.
People attending courses will be certified by examination and each successful candidate is awarded a certificate with the ICCCS Education logo, and has their name placed on the website.
The history of IEC:

- Since 2015 the ICEB activities are taken over by the ICCCS Education Committee.
- In São Paulo the ICCCS Education Committee presents its business plan.
- The IEC proposes to replace all new ICEB accreditations by ICCCS Education Accreditations

ITC

The standards activities by the ICCCS are executed by the ICCCS Technical Committee (ITC). The ICCCS has a liaison with the ISO TC209 Cleanrooms and associated controlled environments.
This new committee ITC fulfils the ICCCS mission in standardization and stimulates international cooperation of the ICCCS member societies in the field of cleanroom and contamination control standards. The ITC serves as the international gateway to advance and harmonize cleanroom technology and contamination control standardization.
ITC still has to develop its activities to support the development of international standard on cleanrooms and associated contamination control aspects. The ITC will be the organization that can provide input and comments on cleanroom technology and contamination control standards as an international organization and through the experts of the member societies.
The ITC will provide expert knowledge and facilitate expert discussion on actual subjects in ISO working groups. The ITC will develop a roadmap for the standards activities the ICCCS should be involved in.
The present members of the ITC are Koos Agricola (chairman), Alexander Fedotov, Da Qian Wang and Conor Murray.
The committee wants to expand with interested and experienced younger members to ensure a good future. Experts that are willing to offer knowledge and/or discuss various subjects with experts of ICCCS members can join the ITC.

Clean Air and Containment Review

Clean Air and Containment Review (CACR) Issue 35, July/August 2018

- Comparison of the removal of macro-particles and MCPs in cleanrooms by surface deposition and mechanical ventilation, Bill Whyte, Koos Agricola
- Getting rid of 95% UCL calculations in ISO 14644-1:2015 standard: new weaknesses and possible solutions, Alexander Fedotov
- Removal of airborne contamination using hydrogen peroxide vapour (HPV), Shada Warreth, Michael Wood and John Chewins
- VHP (Vapour Hydrogen Peroxide) fragility, Andrew Hopkins
- Review of 'Advances in Cleanroom Technology' by Bill Whyte, Gordon Farquharson
- Cleanroom Technology Conference 2018, Murielle Gonzalez

Hela tidningen kan läsas av medlemmar på hemsidan genom att logga in med r32018

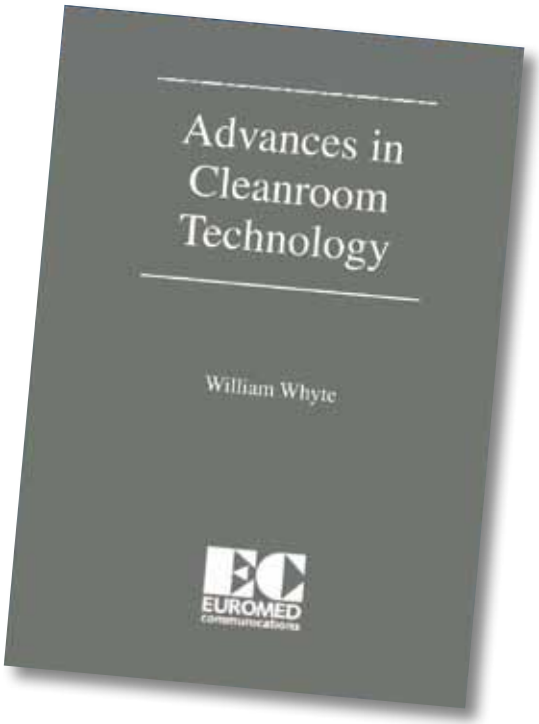
Review of 'Advances in Cleanroom Technology' by Bill Whyte

Clean Air and Containment Review

Printed with permission of CACR

By Gordon Farquharson.

The author Bill Whyte is a leading international expert in the field of cleanroom contamination control. He has published over 150 articles and papers through 50 years of research – an amazing compendium of work in the Contamination Control field. The 34 articles chosen for this new book cover immediate post war surgical operating rooms, through to the latest thinking on energy and sustainability in Cleanroom technology. Many of the papers have joint authors and virtually all of them have been subject to peer review. The book will be of great value across the Cleanroom community from academia, to specifiers and designers, test and certifiers, and of course users. The book is organised in seven logical technical groups rather than chronological order. This is a really helpful approach allowing the reader to review collections of articles covering historical subjects, application of the principles of risk management to contamination control, and five other subject areas. The one aspect of the book that really struck me was the way it explores improved understanding and explanation of the science supporting the operations of cleanrooms. Papers in sections 3, 4 and 6 are focused on understanding the strength and nature of contamination sources, and the control mechanisms and performance of non- unidirectional airflow cleanrooms. The book is bang up to date with the latest papers on particle deposition rate. Bill Whyte sees this as a really exciting development in the characterisation of environmental cleanliness by way of the particles that are likely to deposit on critical surfaces. Some consider that this cleanliness attribute is more valuable than the traditional consideration of airborne sub-micron particles. Finally, the quality and clarity of printing is exemplary. This is an essential point because most of the papers rely on diagrams, drawings, charts and formulae.



For further information and to order see the Euromed Communications website at: www.euromedcommunications.se

ISCC'18 Announces Final Programme

From 23 to 26 September 2018 VCCN, the Dutch contamination control society, hosts the International Symposium on Contamination Control and cleanroom technology in the Hague.
ISCC'18 is pleased to announce the final symposium programme, including our keynote speakers. The symposium starts with a social programme, followed by a two day conference programme, including tutorials and workshops. The symposium closes with technical visits to companies as Philips, ASML and ESA/ESTEC/Space-Expo.

The total conference programme consists of four keynote speakers and 27 speaker sessions with 72 speakers. The keynote speakers are:
Opening keynote speaker prof.dr.ing. Dave Blank
Health Care keynote speaker dr Bas Zaat
Micro Nano Tech keynote speaker prof.dr. Vadim Banine
Closing keynote speaker Peter Ros

For more information, the complete conferense programme and registration, vist www.iscc2018.com

Call for papers

R³ Nordic Symposium & Exhibition
Hotel Birger Jarl • Stockholm
6-7 May 2019

Main subjects

The latest development in cleanrooms, controlled environments and contamination control areas.

Pharma manufacturing and monitoring

Current standards and ongoing standardisation work, such as e.g., Annex 1 of the EU GMP

Hospital - cleanliness requirements. Requirements of today and tomorrow

Call for Papers

The program committee is open to New ideas and proposals - What do you want to learn more about?

The symposium will be arranged in two parallel blocks;

Pharma
- Annex 1 - Perhaps the most important issue for everyone in the industry
- PDA - "What happens today around the world"
- Risk Analysis - Good examples of how to use the tools?

Hospital
- Tissues - GMP and regulations
- Premises and installations from a cleanliness point of view
- Trends in the Nordic countries and Europe

Presentations are accepted in English or in the Nordic Languages.

Send Your proposals to the Programme Committtée - see next page!

Complete programme, invitation and registration information will be included in the next issue of RenhetsTeknik

Exhibition

Exhibiton area

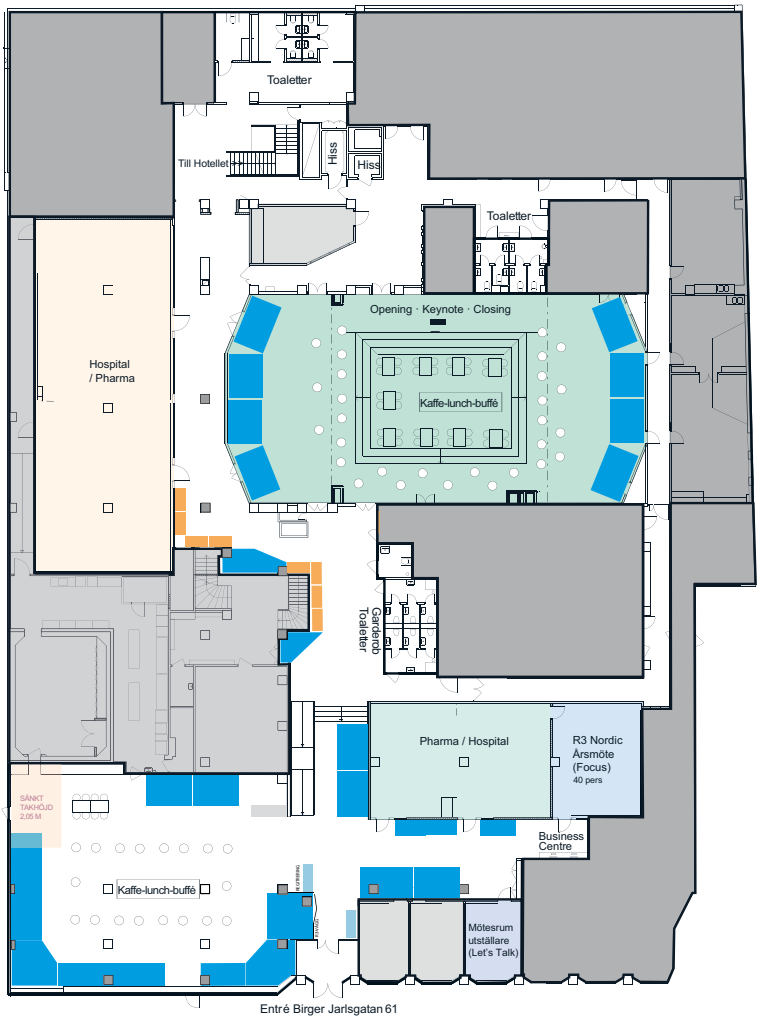
Unfortunately, we have not quite finished the layout and the number of places for the 2019 exhibition. The requirement is to increase both the number and at the same time create a number of larger areas than what we had in 2017.

The facilities at Hotel Birger Jarl are in all aspects perfect for the R³ Nordic's exhibition and of course we hope that the jubilee will attract more exhibitioners and provide you all with the very best options for exposing your services and products.

Apply today!

You can announce your interest to participate today by contacting Anders Jarl. All applications will be handled chronologically.

Anders Jarl, AJ Consulting
+46 (0)70 650 82 30 · anders@aj-con.se



Welcome to the R3 Nordic Symposium & Exhibition in Stockholm on 6-7 May 2019

Programme Committée

Further information and questions, please contact

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Bild: Jan Gustén, Catinka Ullman, Evelina Zettervall och Lennart Hultberg

Under sommaren rapporterade European Food Safety Authority (EFSA), FDA i USA och Folkhälsomyndigheten i Sverige om livsmedelsburna utbrott av Listeria, Salmonella och ehec i livsmedel, som normalt inte kopplas samman med mikrobiologiska risker. Omfattande indragning av varor blev följden.

EFSA EUROPEANFOODSAFETYAUTHORITY AND FDA
WWW.EFSA.EUROPA.EU/EN/PRESS/NEWS/180703
WWW.FDA.GOV/SAFETY/RECALLS/UCM614253.HTM
WWW.FOLKHALSOMYNDIGHETEN.SE/

Livsmedelsburna infektioner

July 2018 - Listeria monocytogenes: update on foodborne outbreak

Experts used whole genome sequencing to identify the food source, which initially was thought to be limited to frozen corn. As of 15 June 2018, 47 cases including nine deaths had been reported. The same strains of L. monocytogenes have been detected in frozen vegetables produced by the same Hungarian company in 2016, 2017 and 2018. This suggests that the strains have persisted in the processing plant despite the cleaning and disinfection procedures that were carried out.

The available information confirms the contamination at the Hungarian plant. However, further investigations, including thorough sampling and testing, are needed to identify the exact points of environmental contamination at the Hungarian plant. The same recommendation applies to other companies belonging to the same commercial group if environmental contamination is detected.

On 29 June 2018, the Hungarian Food Chain Safety Office banned the marketing of all frozen vegetable and frozen mixed vegetable products produced by the affected plant between August 2016 and June 2018, and ordered their immediate withdrawal and recall. This last measure is likely to significantly reduce the risk of human infections and contain the outbreak. All freezing activity at the plant has been stopped.

New cases could still emerge due to the long incubation period of listeriosis (up to 70 days); the long shelf-life of frozen corn products; and the consumption of frozen corn bought before the recalls and eaten without being cooked properly.

To reduce the risk of infection, consumers should thoroughly cook non ready-to-eat frozen vegetables, even though these products are commonly consumed without cooking (e.g. in salads and smoothies). This applies especially to consumers at highest risk of contracting listeriosis – such as the elderly, pregnant women, new-borns and adults with weakened immune systems.

Frozen corn and possibly other frozen vegetables are the likely source of an outbreak of Listeria monocytogenes that has been affecting Austria, Denmark, Finland, Sweden, and the United Kingdom since 2015.

July 2018 - FDA Investigating Multistate Outbreak of Salmonella Mbandaka Infections Linked to Kellogg's Honey Smacks Cereal

The FDA, CDC, along with state and local officials are investigating a multi-state outbreak of Salmonella Mbandaka infections linked to Kellogg's Honey Smacks sweetened puffed wheat cereal. The FDA and CDC, along with our state partners contacted The Kellogg Company and as a result of discussions, the company has voluntarily recalled Kellogg's Honey Smacks to prevent further distribution of potentially contaminated products. The recalled products were distributed across the United States including Guam and Saipan, and internationally in certain countries.

There are 100 people ill with this strain of Salmonella in 33 states of USA

July 2018 - Multi country Salmonella Agona outbreak possibly linked to ready-to-eat food

Five European countries have reported 147 people infected with the strains of Salmonella Agona – with 122 cases occurring since the beginning of 2017 and the remaining 25 identified retrospectively between 2014 and 2016. The number of affected people reported in each country is: United Kingdom (129), Finland (15), Denmark (1), Germany (1) and Ireland (1).

Based on available information, experts from EFSA and ECDC suggested that ready-to-eat products containing cucumbers and prepared in the United Kingdom may be the source of infection. However, they could not identify the specific point in the production chain where contamination took place.

Experts warned that new cases might occur until the source of infection and the specific point of contamination in the production chain are identified.

July 2018 - Ritz and Goldfish crackers, Swiss Rolls - they've all been tied to possible salmonella contamination through a common ingredient, dry whey powder, U.S. officials say.

"There are no confirmed illnesses related to these products," commissioner Dr. Scott Gottlieb stressed in a U.S. Food and Drug Administration news release on Thursday. "But we know these products are consumed daily across our country, often by children, which is why we're alerting consumers now."

Gottlieb also said, "Our team is onsite investigating the facility that processes the dry whey used in the recalled products and we're working to identify what other companies may have used this ingredient to determine what, if any, food may be contaminated with salmonella." Mondelez International Inc., Pepperidge Farm Inc. and Flowers Foods Inc. have already recalled Ritz cheese sandwiches and Ritz Bits cheese products, Goldfish crackers, and various brands of Swiss Rolls, respectively, because they contained the suspect whey powder.

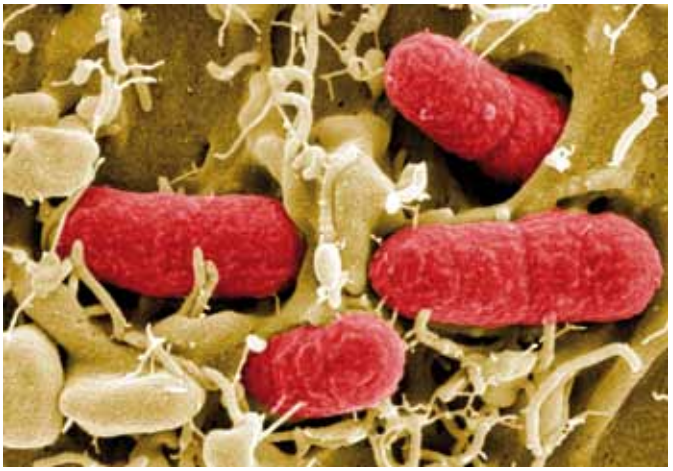
Nationell spridning i Sverige av ehec utreds

Sedan början av juli har antalet fall av ehec-infektion ökat i Sverige. Analyser visar att majoriteten är av samma typ och fallen har rapporterats in från flera län, främst Uppsala och Västra Götaland. Enligt utredningen rör det sig om ett nationellt ehec-utbrott som har en eller flera gemensamma smittkällor.

Hittills har ehec-infektionen hos ett femtiotal personer som insjuknade under juli månad kunnat kopplas samman med hjälp av molekylärbiologiska analyser av bakteriernas arvsmassa. Ytterligare ett femtiotal personer misstänkts också vara drabbade. Bland de insjuknade finns både barn och vuxna.

Eftersom den aktuella typen av ehec, O157:H7, har spridits till olika delar av landet rör det sig sannolikt om en livsmedelsburen smitta. Lokalt kan smittan även ha spridits från person till person via badvatten.

– Det här ser ut att vara ett av de största utbrotten av ehec som vi haft i Sverige. Den bakteriestam som spridits kan orsaka allvarlig sjukdom, framför allt hos barn. Tillsammans med berörda smittskyddsenheter och kommuner, Livsmedelsverket och Statens veterinärmedicinska anstalt, arbetar vi för att utreda utbrottet och framför allt försöka identifiera smittkällan och förhindra vidare smittspridning, säger mikrobiolog Cecilia Jernberg.



Companies awarded at the R³ N

TEXT: GUN WIRTANEN

The 49th R³ Nordic symposium in May 2018 in Naantali gathered an interesting set of participants sharing a passion and expertise for pharmaceutical and hospital pharmacy solutions. The symposium programme covered also Food and Biotech themes related to hygienic design and contamination control. The two-day programme was an excellent mixture of challenges and available solutions for both food and pharmaceutical sector operators. Main themes were, as expected, clean room technology and applications & regulations (EU GMP Annex 1 draft) and practices. In addition, clean room management and BIM management were tackled.

Riina Brade states that "For her as a food safety professional focusing nowadays on industrial investment services (consulting and engineering relating to revamps, expansions and greenfields), it was slightly surprising to see how much focus air filtering & ventilation receives in pharmaceutical design. Camfil's presentation in relation to the new ISO 16890 for air filters supported by Granlund's presentation were very interesting. Thus, after this venue, I am updated on these risks and their current management practices as well."

Overall, in both food and pharmaceutical sectors, the fundamental principle of good manufacturing practice is to ensure that product contamination is minimised and products are consistently produced, traceable and controlled according to the relevant quality and safety standards. The biggest challenge is how to interpret the GMPs, because they are not, in most cases, very prescriptive. GMPs are deliberately general to allow for individual variations by manufacturers to implement the requirements in a manner that best suits their needs. Product safety is a joint effort with safety on one side, and cost efficiency and usability on the other. Balancing costs, safety regulations and user requirements is a complex task. However, with step-by-step project management, EHEDG hygienic engineering and design guidelines, competent equipment suppliers and contractors, and with appropriate validation and verification activities, we can secure food products that meet the quality and hygiene system requirements and attract consumers now and in the future.

Elomatic - the participants' favorite

Mr Markku Mäkinen, Elomatic Oy, gave an information-packed lecture on a practical approach to designing and constructing GMP clean rooms and clean room HVAC. The main messages discussed were concepts such as regulatory authorities, the standard V-model including its various phases, selection of contractors and equipment suppliers, and finally handover.

Quality Risk Management as a basis for project execution was also discussed. A basic understanding of all these gives an understanding of what needs to be considered in a GMP clean room and clean room HVAC project. It isn't rocket science, but this systematic approach facilitates a successful project. Globally there are six major GMP regulatory authorities, which can have different GMP requirements. Key terms like "Direct Impact System, Indirect Impact System and No Impact System" are always present in every GMP clean room project and therefore one needs to understand how those differ from each other. The URSs are basic documents in every GMP project, and the persons who are writing them should have sufficient competence. The impacts from type of production, isolators, RABS, room classifications, heat loads, air changes, ATEX, OEL etc. need to be considered.

The most suitable way of constructing the GMP clean rooms should be decided for each individual project. HVAC and utility systems require lot of space, which should be kept in mind. Consideration should also be given as to whether BMS or EMS or a combination of these should be used. In general, the design project consists of three phases (Conceptual Design, Basic Design, Detail Design), which all produce essential information for decision-making. Building Information Modelling BIM is a must in modern GMP clean room and clean room HVAC design. Selecting the right contractor or equipment supplier requires careful consideration. Design Review (DR) is perhaps the most important phase in every GMP clean room project and can be very rewarding if done correctly. If not, a lot of things can go wrong. The construction phase is subject to its own specific rules and guidelines, and therefore differs from so-called normal construction sites. Verification activities like commissioning, installation qualification (IQ) and operational qualification (OQ) are all inseparable parts of GMP clean room projects. Mäkinen ended his presentation with a short description of to handle the handover.

ordic Exhibition in Finland 2018

Cletec – the best news

Cletec received the award for its innovative service concept launched in May, which enables the sterilisation of laptop computers. The company's co-founder Sakari Heyno has developed the laptop sterilisation process based on gas plasma. It enables the comprehensive sterilisation of a computer, including its circuit board, without impairing on the functions and usability of the device.

UNIQUE STERILISATION PROCESS

The sterilisation process is cutting edge; apparently nothing like it has been achieved anywhere else in the world. It offers a solution to a daily issue in facilities that need to be free of microbes.Laptops are often used in rooms that require absolute cleanliness, e.g. a cleanroom. The cleanliness is difficult to assess especially in keyboards and hardware ports, where microbes can be accumulated. Without proper sterilisation the use of laptops in these types of spaces are thus risky.

"Digitalisation and its related technologies create new challenges in the cleanliness e.g. of health care work and operating environments. Our new sterilisation process for laptops is a part of a wider development process in which we are designing sterilisation procedures for equipment requiring absolute cleanliness but which sterility cannot be guaranteed at present." explains Petteri Puntala, Managing Director of Cletec. He states that "There is a growing demand for this type of service."

Cletec's service selection to expand to laptop sterilisation

In future, Cletec will in addition to its other services offer sterilisation of laptops for use in high hygiene facilities. Cletec's total service concept will ascertain which equipment will best suit the space, purpose and sterilisation, and take care of the sterilisation process. In this procedure a specific type of laptop, which can tolerate the planned sterilisation, will be selected. According to Heyno, the sterilisation cannot, at the moment, be applied to just any kind of laptop. For more information on the service concept, please contact Sakari Heyno:
sakari.heyno@cletec.fi / +358 40 509 3210.

Cletec Oy was represented by Heidi Holminen, Head of production, and CEO Petteri Puntala.

FläktGroup - the best stand

FläktWoods introduced a completely new stand at the Exhibition. The stand's appearance was designed in accordance with the new FläktGroup brand, and it was selected as the best stand of the exhibition. The stand introduced FläktGroup's solutions for hospital ventilation systems and clean room facilities.

FläktGroup provides specific solutions for the needs of healthcare facilities, and it has over 300 project references in 18 different countries. FläktGroup has solutions for both healthcare and for clean room facilities, as well as solutions against risk of transfer of bacteria or pollution. FläktGroup's systems offer by far the best applications for example operating theatres.

The long-term development of the equipment guarantees patient safety, high energy efficiency and extremely low life cycle costs for the whole building. All parts of the ventilation systems, such as for example ducts, fulfil the qualifications for M1 label of Cleanliness Classification by the Finnish Building Information Foundation RTS. In addition, FläktGroup has a patented E3-concept, which helps to produce the best possible indoor air quality and adds safety by protecting common environment, by developing energy efficient and cost-effective ventilation systems and by offering solutions that are optimized for the needs of the client.

FläktGroup supplies ventilation and fire safety solutions for the industry sector, business- and office buildings, public spaces and residential ventilation. In addition to the ventilation systems in hospitals, our expertise includes the demanding ventilation and extraction of fumes in underground spaces, such as tunnels and car parks.

TAKK ARILD FOR ALLA ÅRENE I R3 NORDIC

ARILD SVENDSEN

Arild Svendsen har nå gått ut av LAU Norge, og er dermed ikke lenger aktiv i R^3 Nordic. Arild har en svært lang historie i foreningen og han har vært med siden tidlig på 1960 tallet. Først deltok han som utstiller med firmaet Berdal som forhandlet Millipore. Han kom raskt inn i foreningens indre liv.

Arild har vært medarrangør i de fleste grunnkurs som har vært holdt i Norge og også de norske symposier. Utover det har han sittet i styret i foreningen og det norske LAU.

Arild er hedersmedlem i R^3 Nordic.

Det er dermed mye historie som forsvinner ut med Arild. Det norske LAU hadde en markering sammen med ham 5. juni.

Redaktionen för Renhets-Teknik vill också tacka Arild för hans stora insatser under alla år och framförallt önska honom all lycka som pensionär, nu när han kan ägna all tid åt sig själv och sina egna intressen!

GEIR NY LEDAMOT I STYRELSEN OCH LAU NORGE

GEIR VALEN PETTERSEN

Etter noen år i det militære, tok jeg radiografutdanningen i Oslo og arbeidet deretter som radiograf i Kristiansand i fem år. Deretter tok jeg en videreutdanning i strålebehandling og arbeidet som stråleterapeut ved Radiumhospitalet og i Kristiansand. Siden arbeidet jeg som høgskolelærer for radiografer og stråleterapeuter og studerte fysikk ved Universitetet i Oslo.

I 2010 startet jeg som syklotronoperatør ved Norsk medisinsk syklotronsenter as (NMS), ved siden av studiene. Dette var primært nattarbeid. Deretter arbeidet jeg ett år på nukleærmedisinsk avdeling, til jeg begynte hos NMS på fulltid som produksjonsingeniør i 2012, og hvor jeg fortsatt arbeider. Jeg er også fra 2018 valgt som leder for den lokale R^3-gruppen (LAU) i Norge.

NMS er et farmasøytisk firma som produserer radioaktive kontrastmidler til bruk i forbindelse med PET-undersøkelser. Vi har en syklotron – en partikkelakselerator, som vi benytter til å produsere kortlivede radioaktive isotoper. Produksjonen skjer i hotceller inne på renrommene og i tillegg kvalitetstestes alle produktene vi produserer. Forskning og utvikling av nye produkter er også en viktig del av virksomheten.

Min jobb er å produsere de radioaktive legemidlene på renrom, ha ansvaret for all opplæring av personalet som skal arbeide inne på renrom, og at rommet blir vasket og holdt i orden slik at kvalitetsnivået opprettholdes. Dette innebærer blant annet opplæring av personalet i påkledning og håndvask, og hele tiden være oppdatert på hva som skjer innenfor området renrom og hva som finnes av vaskemidler, hjelpemidler og annet. Kvalifiseringen i aseptisk metode foregår blant annet i en sikkerhetsbenk som holder klasse A. Selve renrommet og hotcellene har klasse C, men vi behandler hotcellene som klasse B.

I tillegg til min jobb i produksjonen og arbeid med renrom, er jeg også HMS ansvarlig. Dette innebærer blant annet oppfølging av alle HMS relaterte saker som avvik, opplæring med mer. Jeg er også Sikkerhetsrådgiver og har ansvaret for all transport av farlig gods (ADR transport), noe som innebærer transport av radioaktivt materiale.

Utenom jobb er jeg gift og bor i Oslo. Noe av fritiden går med til Nettverk etter soning. Dette er i regi av Røde kors, hvor jeg er gruppeleder. Dette er en del av røde kors som hjelper personer som har sittet i fengsel eller personer som sitter i fengsel og som snart skal slippes ut.

Nytt centrum för framtidens teknologier

Pressmeddelande • Aug 21, 2018 14:00 CEST

Idag invigdes Testa Center i Uppsala, ett innovationscenter där teknologier och produkter för framtidens läkemedel utvecklas. Region Uppsala är en av många aktörer som bidragit till att satsningen kan bli av.

– Det är fantastiskt att en av de viktigaste satsningarna inom life science i Uppsala någonsin nu har blivit verklighet. Detta kommer ytterligare stärka Uppsalas roll inom life science och bidra till utveckling och hållbar tillväxt i Uppsala län. Det är precis den här sortens samarbeten som vi eftersträvar i vårt regionala utvecklingsarbete, säger Jenny Lundström (MP), ordförande för den regionala utvecklingsnämnden.

Anläggningen ligger i Boländerna, drivs av GE Healthcare, och är en öppen plats för företag och forskare från hela landet. I centret finns bland annat fyra bioprocesslaboratorier där nya produkter ska kunna testas. Centret ska göra det lättare att omsätta forskning i kommersiellt gångbara produkter.

En rad aktörer har bidragit till satsningen, däribland regeringen, som gått in med 100 miljoner kronor. Region Uppsalas bidrag uppgår till 3 miljoner kronor, som ska användas till bland annat marknadsföring och att utveckla samverkan mellan olika aktörer.

För ytterligare information kontakta Jenny Lundström (MP), ordförande regionala utvecklingsnämnden, tel 070-399 24 93 eller
Erik Asplund, näringslivsstrateg, Region Uppsala, tel 0733-99 94 88

Nytt uppdrag för Ventilator på Karolinska

Ventilator har fått utförandeentreprenaden när Thoraxlokalerna i en av de äldre byggnaderna på Karolinska Universitetssjukhuset renoveras. Uppdraget inbegriper ny luftbehandling i patient- och behandlingsrum. Ventilator startade montagearbetet i februari 2018 och allt beräknas vara färdigt i början av 2019.

Byggherre: Locum Beställare: In3prenör

Ny renrumstrumpa för bättre komfort och nya krav enligt GMP Annex1

Sedan länge används antingen hårda Polyamidfibrer eller bomullsblandningar av olika slag i renrumsanpassade strumpor – och inget av alternativen är optimalt ur komfort- eller partikelsynpunkt. Under det senaste året har Berendsen därför, tillsammans med strumptillverkaren Bola, utvecklat en ny strumpa som är specialanpassad för en arbetsdag i renrummet.

I utvecklingen av renrumsstrumpan har såväl olika stickningar som materialblandningar provats och utvärderats – med hög komfort och låg partikelavsöndring som främsta fokus. ”Strumpans slutliga materialkomposition, design och stickning ger riktigt sköna och behagliga strumpor som är anpassade för en arbetsmiljö med speciella förutsättningar och krav.” säger Mats Nilsson, VD Bola.

Det utvecklade materialet är slitstarkt för att klara av hårt användande och många tvättar, och i kombination med stickningen transporterar strumpan effektivt fukt för snabbare torkning. Då fukt leder kyla och värme upplever vi en högre komfort om strumporna är torra - dessutom nöter inte en torr strumpa lika mycket på vare sig hud eller sko, vilket minskar partikelavsöndringen. ”Den nyutvecklade strumpan minskar mängden fukt och friktion, vilket i sin tur minskar partikelsläppet från textilier och hud.” säger Jonas Högman på Berendsen Cleanroom. ”Renrumsmiljöernas speciella förutsättningar och kundernas krav på komfort får oss att driva utvecklingen framåt, något vi gör med glädje. Därför är vi oerhört stolta över att tillsammans med Bola kunna erbjuda våra kunder en strumpa som är optimal för en dag i renrummet – en strumpa som tar hänsyn både till användare och de nya renhetskrav i Annex1.”

Revised Annex 1 (section 4.13)
”Outdoor clothing should not be brought into changing rooms leading to grade B and C. It is recommended that facility suits, including dedicated socks be worn before entry to change rooms for grade C and B. Where clothing is reused this should be considered as part of the qualification”

Kriget i jorden: Global studie visar hur mikroorganismer konkurrerar

Pressmeddelande 2018-08-01

Forskare vid Uppsala universitet, SLU, Tartu universitet och European Molecular Biology Laboratory (EMBL) i Heidelberg har tillsammans genomfört den första globala genomiska kartläggningen av bakterier och svampar i jord. Resultaten, som publiceras i tidskriften Nature, visar att bakterier och svampar kämpar konstant om tillgång till näring. Som vapen produceras en mängd olika antibiotiska ämnen samtidigt som resistenser utvecklas som motmedel. Vanlig jord är full av liv. Mikroorganismer bryter ner dött material, fixerar näringsämnen från luften och lagrar kol. Trots det är kunskapen om mikroorganismernas gener begränsad. För första gången har forskare nu genomfört en global kartläggning av genomet hos jordlevande bakterier och svampar.

Studien omfattar 58 000 prover från 1 450 olika platser på jordklotet som har noga valts ut för att minimera påverkan från människan som till exempel jordbruk. Vidare valdes 189 av provtagningsplatserna ut för särskilt noggrann analys, vilket täckte samtliga av jordens viktigaste miljözoner, från tundra till tropisk regnskog. Detta genererade 14,2 terabyte data. Totalt sett tog studien fem år att utföra.

Forskarna upptäckte att bara hälften av de gener som hittades överlappade med befintlig data från mikroorganismer i magen och i haven. De fann också att variationen av bakterier var lägre där det fanns fler svampar
- Vi hittade också en stark koppling mellan antalet gener som kodar för antibiotikaresistens och mängden svamp, speciellt svamp som kan producera antibiotika. Släktet Penicillum är exempel på antibiotikaproducerande svampar. Detta tyder på att antibiotika är ett vapen som svampar använder för att konkurrera och bara bakterier som utvecklat resistens klarar sig, säger Mohammad Bahram, forskare vid Uppsala universitet och biträdande lektor vid SLU och förstaförfattare av studien.

Kampen mellan svampar och bakterier påverkar mångfalden hos olika bakteriekulturer och styr den genetiska uppkomsten av resistens mot antibiotika.
- Den här informationen kan användas för att förutse hur resistens mot antibiotika sprids i olika ekosystem och hur bakterier som orsakar sjukdomar hos människor kan bli resistenta. Vidare kan de också bidra till att hitta platser där den naturliga förekomsten av resistens är stor, säger Mohammad Bahram.

Forskarna upptäckte också regionala skillnader i mängden svampar och bakterier. Bakterier finns överallt och den största mångfalden hittades i tempererade zoner med stabilt klimat. Miljöfaktorer som temperatur påverkar mest, bakterier föredrar varma och fuktiga platser. Svampar är mer förekommande på kalla och torra platser som tundra. De är inte lika utspridda och det finns stora skillnader mellan kontinenter. Det tyder på att bakteriers och svampars bidrag till näringsämnens kretslopp skiljer sig på olika platser i världen och att klimatförändringarna kan påverka deras sammansättning och funktion på olika sätt.
- De klimatmodeller vi har för Sverige, till exempel de som tagits fram av SMHI, visar att både temperatur och nederbörd kommer att öka i framtiden. Därför är det viktigt att ta reda på hur ett varmare och fuktigare klimat kommer att påverka svampar och bakterier i jorden, säger Jennifer Anderson, forskare vid avdelningen för systematisk biologi vid Uppsala universitet och medförfattare till studien.

När forskarna jämförde data från platser utan mänsklig påverkan med data från platser med mänsklig påverkan, till exempel jordbruksmark och trädgårdar, var förhållandet mellan bakterier, svampar och antibiotika ett annat. Forskarna menar att den här förändringen i balansen visar att människor påverkar mikroorganismerna i jorden. Konsekvenserna av detta är ännu okända. Däremot kan en ökad kunskap om hur svampar och bakterier interagerar med varandra i jorden hjälpa till att minska användandet av gödsel inom jordbruket, då man kan ge mikroorganismer en bättre chans till överlevnad i sin naturliga livsmiljö.

- Vissa av de här globala trenderna visade sig även lokalt, så det skulle vara intressant att se om jordbruk har förändrat balansen mellan svamp och bakterier i nordliga länder som Sverige, där det finns betydligt fler svampar än bakterier i naturen, säger Mohammad Bahram.

Referens: Bahram, M., et al. Structure and functionof the global topsoilmicrobiome. Nature, DOI: 10.1038/s41586-018-0386-6

ISBE Award to Vetter-Pharma

https://ispe.org/sites/default/files/foya/2018/2018-foya-spotlight-excellence.pdf

Judges´panel conclusion: Application of excellent and innovative design practices as well as superior planning led to the successful integration of this new facility into an existing operational campus.

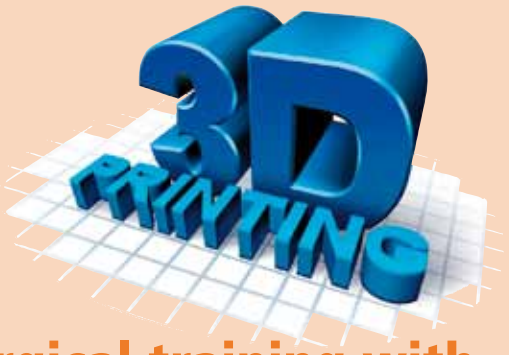
Facility of the Future Ravensburg Vetter West: The center for Visual Inspection and Logistics

Ny VD för AstraZeneca

AstraZeneca meddelar i juli att Katarina Ageborg utsetts till ny VD för AstraZeneca AB i Sverige. Hon tar över efter Jan-Olof Jacke den 1 augusti 2018 och kommer även fortsättningsvis rapportera till koncernchef Pascal Soriot.

Katarina Ageborg har suttit i bolagets koncernledning sedan 2011 och fortsätter även i sina nuvarande roller som hållbarhetschef och Chief Compliance Officer.
”Jag är väldigt glad att Katarina nu även kommer ansvara för att utveckla AstraZenecas starka position i Sverige. Samtidigt vill jag tacka Jan-Olof för hans insatser genom många år. Han har varit en framstående ambassadör och bidragit till att utveckla bolaget inte bara i Sverige, men även internationellt”, säger koncernchef Pascal Soriot som även är ordförande för AstraZeneca AB.

Jan-Olof Jacke lämnar bolaget under hösten för att börja som VD för Svenskt Näringsliv.



Surgical training with 3D-printed human body parts

3D-printed human body parts with lifelike bone, skin and muscle densities are being developed in South Australia as teaching aids for surgical training.

The medical devices can also be designed with built-in pathogens such as tumours, bone fractures or defective hearts to allow surgeons and students to practise specific procedures.

An experienced and respected conventional printer in Australia, Mark Roe founded Fusetec 3D in Adelaide in April 2017. After spending time researching in the United States and speaking to surgeons and academics in South Australia, Roe bought a state-of-the-art 3D printer in April 2018.

Roe said that although similar technologies were being used for research and patient specific modelling at universities and medical centres in North America and Europe, his system was the only purely commercial operation of its kind in the world.

“It was hard to get momentum, nobody was really taking us seriously so I had to take a great leap of faith in what I believed would be a good commercial market and buy the equipment with the theory of build it and they will come and that’s pretty much what is happening,” he said.
“We’re starting to get a lot of demand now, most of our demand is coming from export, driven by inquiries from China and ...

TO READ THE ENTIRE STORY - HTTP://BIT.LY/2KTW1FA

Regeringen vill säkerställa tillgången till antibiotika

Att kunna använda effektiva antibiotika vid bakterieinfektioner är helt centralt för sjukvården. Regeringen ger därför Folkhälsomyndigheten i uppdrag att genomföra en pilotstudie med syfte att säkerställa tillgänglighet till vissa antibiotika av särskilt medicinskt värde.

- Vårdens behov kan inte underordnas vinstmaximering. Detta är ett tydligt exempel på när staten behöver gå in och ta ansvar, säger socialminister Annika Strandhäll.

- Antibiotikaresistens är ett av de största långsiktiga hoten mot vår hälsa. Vi måste göra allt vi kan både på hemmaplan och internationellt för att säkra tillgången till antibiotika som fungerar, säger socialminister Annika Strandhäll.

Eftersom hälso- och sjukvården i Sverige har något mindre akuta problem med antibiotikaresistens än andra länder så kan det medföra att det ibland saknas ekonomiska incitament och logistiska förutsättningar för att på den svenska marknaden tillhandahålla vissa speciella typer av antibiotika. Detta kan i sin tur äventyra effektiv behandling av vissa bakteriella infektioner.

För att säkerställa tillgängligheten av effektiva antibiotika får därför Folkhälsomyndigheten i uppdrag att genomföra en pilotstudie för att utvärdera modellen för garanterad ersättning, som tagits fram under ett tidigare regeringsuppdrag om tillgänglighet till antibiotika.

Folkhälsomyndigheten ska i genomförandet av uppdraget samarbeta med Tandvårds- och läkemedelsförmånsverket (TLV) samt Verket för innovationssystem (Vinnova). Folkhälsomyndigheten ska redovisa uppdraget till Socialdepartementet senast den 31 december 2022.

Sverige är ett av de länder som driver antibiotikaresistens som en ödesfråga hårdast på den internationella arenan.

Kontakta Victor Harju, pressekreterare hos Annika Strandhäll
072-5043670 / victor.harju@regeringskansliet.se

INVITATION TO Ventilation Solution Day

17 september 2018 · Camfil Sweden, Trosa

R³ Nordic in corporation with Camfil, arranges a solution day with ventilation theme including following topics:

- New international air filter standard - ISO16890
- Basic ventilation principles
- Isolation rooms within healthcare
- Bio-decontamination by VHP (Vaporized Hydrogen Peroxid)
- VHP sterilization - new developments
- HEPA-filter handling during installation, filter change and how does it work in operation.

The solution day is held at Camfil Sweden head quarter in Trosa, Industrigatan 3, **17 september 2018 at 10 am - 5 pm.**
Maximum participants are 30 people and registration fee for members of R³ Nordic is SEK 2 500 including lunch and coffee. Non-members pays an additional fee of SEK 650 and become members for 1 year in the association R³ Nordic.

Registrate at info@r3nordic.org

Last day of registration will be the 3th of September and after this date the participant fee will be non refundable. In the event of written cancellation before the 3th of September the fee will be refundable minus a cancellation fee of SEK 250.

Some of the presentations will be in English, the rest will be held in Swedish.

For more information about the day contact:
Evelina Zettervall, board member of R³ Nordic, at
+46 70 344 20 96 or on evelina.zettervall@camfil.com

For participants that needs accommodation in connection to the solution day, Trosa Stadshotell could offer limited number off single room at a better rate of 1050 SEK including breakfast.

R³ NORDIC, CTCB-I OCH CHALMERS INBJUDER TILL CTCB CERTIFIERING

CTCB certifiering av Cleanroom Testers

2-4 OKTOBER 2018
INSTALLATIONSTEKNIK, CHALMERS, GÖTEBORG

Kursmaterialet för "Cleanroom Testing Certification" är på engelska och skickas efter inbetald registreringsavgift tillsamman med Question/Answers-häfte till kursdeltagaren för självstudier, senast en månad före kursstart.
Efter godkänt resultat erhålls ett certifikat. OBS. Certifikat på Professional Level är giltiga i endast 5 år.

First Day Lecture Course:
Associate and Professional candidates

- **Lecture course** revising the course notes
- **Tutorial** revision

Second Day Written Exam and Practical Training:
Associate and Professional candidates

- **Written Exam:** This will examine the candidate's knowledge of the course notes. The questions will be short and of the type that can be answered by no more than 10 words; no essays are required. The questions will be similar, or identical, to those given in the question and answers handbook. The pass mark is 55%.
- **Installed filter leakage testing**. Information will be given on an aerosol smoke generator and photometer, and how these are used to test filter integrity.
  The technique will be demonstrated and each student will have an opportunity to use the method.
- **Air velocity and volume flow measurement**. Information will be given on how to carry out testing using an anemometer, hood capture method, averaging pressure flowmeter, and Pitot-static tube. The techniques will be demonstrated and there will be an opportunity for each student to use the methods.
- **Microbiological airsamplers and documentation requirements.** Information will be given on common instruments and their characteristics. The requirements on adequate documentation will be discussed.
- Possibility to **Hands-on**. Associate candidates only. Work two an two on installed filter leakage test and air velocity and volume flow measurements with comments from teachers.

Third Day Practical Exam:
Professional candidates only

- The candidate will be required to show their ability to carry out the following important tests:
  - Determine the average air velocity and uniformity, as well as the volume of air passing through a HEPA fan/ filter unit by use of an anemometer. The use of the hood capture method must also be demonstrated.
  - Demonstrate that they can operate a smoke generator and photometer to find leaks in a filter and filter gasket.

The candidate will be required to competently write up reports on the two tests. Professional candidates are expected to carry out the above tests competently, and accurately measure the airflow and find filter leaks.
The exams will be marked in two parts i.e. practical and theoretical, so that it is possible to pass none, one or both exams. It is necessary to pass both exams to be certified on professional level.
The candidate's exam results are assessed by an Examination board. It is anticipated that about 70% of the candidates will pass their exams in the first attempt. The CTCB has an examination appeals procedure.
Anyone failing an exam can re-sit it at the next examination within a year. This can be done in Sweden, or at another CTCB Cleanroom Testing Certification course in Ireland and UK.
Certificate on Professional Level valid for 5 (five) years!

SISTA ANMÄLNINGSDAG 2018-09-15

CTCB Associate Level - 2 days, 2-3/10 2018
Registration: SEK 3 950 · Course and exam: SEK 10 250
Lecture course. Written exam. Practical training and hands-on.

CTCB Professional Level - 3 days, 2-4/10 2018
Registration : [illegible] · Course and exam: SEK 13 500
Lecture course. Practical training. Written and practical exams.

Fullbokad!

Exam Re-sit and Upgrading (Assoc to Prof) 4/10 2018
Candidates can re-sit their or upgrade their exams within a year. **Registration SEK 2 950. Practical exams will be SEK 2 500 for one exam and SEK 5 000 for two.**

Fullbokad!

CTCB Prof Level Recertifikation - 3 days, 2-4/10 2018≈
Registration: SEK 3 950 · Course and exam: SEK 11 500
Lecture course. Pracital training. Written and practical exams.

Note: Candidates who are not already members of R³ Nordic or another ICCCS affiliated society will also be charged the cost of one year's individual membership - currently SEK 650,- in R³ Nordic.
Note: Any costs required for accommodation are the responsibility of the candidate.
Moms tillkommer på samtliga angivna priser.

Questions and application form: +46 (0)703 15 11 55
Lars Ekberg, e-post: lars.ekberg@cit.chalmers.se
Information also available at www.safetyventilation.com

LAU DANMARK INBJUDER TILL

Grundkursus i renhedsteknik

3.-4. oktober 2018
København

PREL PROGRAM DAG 1

09.00 – 09.10 Velkomst
09.10 – 10.00 Arbejde i et rent miljø, særlige krav og forudsætninger
10.00 – 11.00 GMP/Mikrobiologi og Dokumentation - SOP
11.00 – 11.15 Kaffepause
11.00 – 12.15 Standarder for klassificerede rene områder, ISO/CEN/GMP
12.15 – 13.00 Frokost
13.00 – 14.00 Design af rene rum, design, layout, sluser og materialer
14.00 – 15.00 Beklædning og omklædningsprocedurer i rene miljøer
15.00 – 15.15 Kaffepause
15.15 – 16.15 Eksempler på renrumsprojekter bl.a. i hospitalsmiljøer, fokus på konflikter og synergier inden for GMP forhold

PREL PROGRAM DAG 2

09.00 – 10.00 Design af ventilation i rene miljøer, herunder forskellige former for ventilation, LAF, UDF, opblanding mm.
10.00 – 11.00 Besøg i klassificeret miljø / renrum
11.00 – 11.15 Kaffepause
11.15 – 12.15 Test og kvalificering af renheden i rummet
12.15 – 13.00 Frokost
13.00 – 14.00 Sterilisation – Validering og monitorering
14.00 – 15.00 Desinfektions- og rengøringsprocessen i rene miljøer
15.00 – 15.15 Kaffepause
15.15 – 15.30 Evaluering og afslutning

Kursusafgift DKK 5.100,- (R^3-medlem 4.600,-)
Inkluderer kursusmateriale, diplom, frokost og kaffe.

Information/kursansvarig: Alan Fries, R^3 Nordic
+45 42 482 482 · info@tech4bizz.dk

Tilmelding
www.r3nordic.org

R^3 NORDIC INBJUDER TILL

Grundkurs i renhetsteknik

29-30/11
Chalmers, Göteborg

Med fokus på Läkemedeklstillverkning, Sjukhusmijöer och GMP

PROGRAM DAG 1:

09.00-11.00 Kontaminanter, partikelmätning och grupparbete
11.00-12.00 Mikrobiologiska testmetoder
12.00-13.00 Lunch
13.00-13.30 Mikrobiologiska testmetoder
13.30-14.30 Standarder (Renrum)
14.30-15.00 Kaffe
15.00-15.30 Standarder (Renrum)
15.30-16.30 Luftrörelser

PROGRAM DAG 2:

09.00-10.00 Konstruktion av ren rum, ventilation och design av utrustningar (maskiner, kärl, kranar och ventiler).
10.00-12.00 Människan i renrum, arbetssätt och kläder
12.00-13.00 Lunch
13.00-14.30 Kläder, tvätt och rengöring
14.30-15.00 Kaffe och grupparbete
15.00-16.00 Genomgång av grupparbete och avslutning.

Kursavgift SEK 6.150,- (R^3-medlem 5.500,-)
Inkluderar kursmaterial, diplom, lunch, kaffe fm och em.
Information om kursen lämnas av Lennart Hultberg (se nedan)

Kursansvarig:
Lennart Hultberg, R^3 Nordic
+46 (0)760 399 500 · lennart@processhygien.com

Anmälan
www.r3nordic.org

Anmälan till kursen skall vara skriftlig och är bindande. Avbokning skall ske skriftligen och inkomma minst en månad före kursstart för att kursavgiften, minus avdrag med 500 kr, skall återbetalas. Vid avbokning senare, minst 14 arbetsdagar före kursstart, återbetalas halva kursavgiften. Vid avbokning senare än 14 arbetsdagar före kursstart sker ingen återbetalning. Ersättare kan registreras fram till och med första kursdagen. R^3 Nordic förbehåller sig rätten att ändra kursinnehåll och föreläsare utan att meddela deltagare eller att ställa in kursen. Föreningen ansvarar inte för merkostnader i samband med kursens inställelse. Vid inställelse återbetalas kursavgiften i sin helhet.

R³ NORDIC AND ALFA LAVAL INVITES TO

EHEDG advanced course in Hygienic Engineering & Contamination Control

9th - 11th of October 2018

Alfa Laval Tumba AB, Hans Stahles väg 7, Tumba, Stocklholm

Aim

The advanced course gives knowledge and insight in hygienic design of process equipment, lines and facilities in food, biotech and pharma industry as well as their suppliers. Investment in hygienic design can when optimally used give optimal product safety and constant product quality as well as lead to diminished down time, maintenance costs, cleaning costs and environmental impact. It deals with how to fulfil present legislation and standards and anticipate future changes.

Participants

The advanced course is originally targeted for service producers in food, biotech and pharma industry e.g. mechanical engineers. It is also meant for managers and supervisors, constructors, project managers as well as sales engineers, who are active in using, building or servicing equipment for industries relying on hygienic or aseptic processing. The advanced course is excellent for the technical and quality assurance staff, who needs knowledge in hygienic engineering, in these industries.

Previous training and working experience

Participants should have 2 years of relevant practical experience. Participants with equivalent training/experience can also participate.

Content

The course is given from a practical point of view. The theoretical fundamentals of the different subjects are given in a concise way, continuously relating these to practice through pictures or examples. Design guidelines are dealt with in terms of the basic properties experimental evidence. The course gives you tools to solve hygienic problems within your own organization. The course is interactive due to training in small groups. On the last course day, there will be an Exam (course material allowed as aids). EHEDG certificate will be mailed to approved participants attending the full course.

Kursen är Fullbokad!

Course Fee

The course fee is 1950 € / participants. EHEDG company members get 10% reduction of the fee. The fee comprises course material, course certificate (posted to approved participants attending the whole course), coffee/tea, lunches and dinners mentioned in the programme. The prices are excl. VAT.

For more information, please, contact Dr. Gun Wirtanen by e-mail.

Cancellations must be sent in writing to guliwi@luukku.com. Participation in this training course can be cancelled free-of-charge (except for an administration fee of 100 € for already invoiced course fees) four weeks prior to the event (last day is 10th of September). In cancellations, thereafter, we will charge 50 % of the participation fee and one week or less before the event the full participation fee will be charged. (Note: the name of the participant can be changed until one week before the course start).

Bli stödjande medlem i R³ Nordic
Läs mer på www.r3nordic.org

MARKNADSGUIDE

FÖRETAGS- & BRANSCHREGISTER ÖVER STÖDJANDE MEDLEMMAR I R³ NORDIC

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FÖRBRUKNING FÖRPACKNING PROCESS

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Tel 08-59080720 / info@inrem.se

LABOREN (DK)
Totalleverandør til renrum- og ESD-miljø.
Tel 4045 1609 / jq@laboren.dk

INSTRUMENT ÖVERVAK VALID KALIB

BROOKHAVEN INSTRUMENTS AB (SE)
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NINOLAB, AB (SE)
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Tel 08-59096200 / cja@ninolab.se

PARTICLE MEASURING SYSTEMS (DK)
Partikelräknare, sensorer och system.
David Hall / dhall@pmeasuring.com
Tel: 7774 987442 / Skype: DrDave0012

MIKROBIOLOGI STERILISTERING

GETINGE FINLAND OY (FI)
Peter Holmberg
Tel 040 900 4620 / peter.holmberg@getinge.fi

MICLEV AB (SE)
Biologiska indikatorer, färdigberedd media, sterilisering, luftprovare, mikroorganismer.
Tel 040-365400 / info@miclev.se

NINOLAB, AB (SE)
Inkubatorer, värmeskåp, class100 sterilasatorer. Autoklaver - diskmaskiner. Christian Janson
Tel 08-59096200 / cja@ninolab.se

CRC CLEAN ROOM CONTROL AB (SE)
Kvalificering av renrum, LAF, säk-bänkar och skyddsventilation. Mikrobiologiska tester. Rök.
info@cr-control.se / www.cr-control.se

KONSULTER PROJEKTERING

CIT ENERGY MANAGEMENT AB (SE)
Teknisk utveckling, validering och funktions-kontroll inom luftrenhet, klimat och energi.
031-772 11 51 · stefan.aronson@cit.chalmers.se

CRC CLEAN ROOM CONTROL AB (SE)
Rådgivningar, förstudier och projektering. Utbildning. Tel 018-246460 / 070-5926604.
info@cr-control.se / www.cr-control.se

EXENGO INSTALLATIONSKONSULT (SE)
Automation, kommunikation och säkerhet, VVS och elteknik mot bygg- och fastighetsmarknad
08-120 038 00 / Anders Wester / www.exengo.se

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Tel 070-9711454 / bernt.karlsson@ventilator.se

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Tel 070-9711454 / bernt.karlsson@ventilator.se

RENGÖRING STÄDNING

PHARMACLEAN AB (SE)
Konsultation, lokalvårdsutbildning och lokalvård för renrum. Regina Björnsson.
Tel 0708-986428 / www.pharmaclean.se

PIMA AB (SE)
Bemanning - Entreprenad - Konsultation
www.pima.se
Tel 08-55424610 \ kontakt@pima.se

RENRUMSKLÄDER TEXTIL TVÄTTNING

DFD CLEAN ROOM (DK)
De Forenede Dampvaskerier A/S
V. Henriksens Vej 6, 4930 Maribo
Tel 5476 0509 / crmar@dfd.dk

NINOLAB AB (SE)
Säkerhets- sterilbänkar. LAF-tak o luftduschar (ScanLaf), Thermo Partikelräknare (MetONE)
Tel 08-59096200 / cja@ninolab.se

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VENTILATION FILTER

CAMFIL SVENSKA AB (SE)
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