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Hygienic Process Surfaces

- INVITATION TO SYMPOSIUM 2022 IN FINLAND
- WEBINAIR 2020 - THREE PRESENTATIONS WEBINAIR
- RAPPORT GRUNNKURS NORGE OCH CTCB-CERTIFIERING

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For those of you who would like further information in English about the magazine, articles, advertising or others, please contact the editor Alan Friis; alfr@force.dk

OMSLAGSBILD / COVER:
FOTO: Surface of stainless steel (Ingimage, Stock Photos)

Nytt renrumsuppdrag åt APL i Göteborg.

– Vi ser gladeligen fram emot att flytta vår sterila tillverkning till de nya lokalerna på Sankt Jörgen och starta vår verksamhet där i slutet av 2022, säger Malahat Pirjani, tillverkningschef APL i Göteborg.

Ventilator Renrum har fått i uppdrag att bygga renrum i klass B, C och D på totalt 320 kvm åt **Apotek Produktion & Laboratorier** (**APL**). Det är en totalentreprenad där det för Ventilators del ingår alltifrån projektering och byggnation av renrum till ventilation och vvs-arbeten. Renrummet ska användas för tillverkning av extemporeläkemedel.

Just nu projekterar Ventilator uppdraget och väntas gå i produktion i början på 2022. Ett halvår senare beräknas projektet vara färdigställt.

Ventilator har tidigare genomfört ett liknande projekt åt APL i deras anläggning i Kungens Kurva utanför Stockholm.

– Det är väldigt roligt att vi fått fortsatt förtroende av APL med att utveckla deras nya renrumsanläggning i Göteborg, säger Roland Lindblom, konstruktör på Ventilator Renrum.

Vi är experter inom renrumsteknologi och erbjuder byggnation, konsultation samt produkter för renrum. Vi har hög kompetens och mångårig erfarenhet av renhets teknik och byggnation av renrum inom bl.a. läkemedels och elektronikindustrin. Konsultation/byggnation av kontrollerade miljöer. Besök oss på **ventilator.se**

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KALENDER

2022

Feb

2 Sjukhusdag i Uppsala

May

9-11 R^3 Nordic Symposium and Exhibition 2022
Naantali Spa, Finland

Nästa nummer
beräknas utkomma den 17 mars 2022

Manusstopp / Annonsbokning:
15 februari 2022

Företag och medlem som vill delta med artikel eller release, skall sända detta i god tid före manusstopp till redaktör Alan Friis.

LEDARE

Dear members

The year 2021 head to an end and even we are not back where we were in 2019 but it has been possible to have a few physical events during the late summer/early autumn 2021 in R^3 Nordic, which were held with great success. Hopefully 2022 will bring us more like this. The events we have conducted are duly reported in this issue.

RenhetsTeknink (RT) has brought selected scientific papers from the on-line symposium in May which have contributed to the general spread of knowledge. It is the aim and hope of R^3 Nordic that we can maintain a strong scientific profile of RT as we soon embark on a new year.

Every autumn ISO TC 209 and ICCCS meeting are held, this year as a Zoom meeting hybrid Zoom-physical meeting, you can read more about these meetings and the outcome in this issue.

With the best wishes for the 2022 Merry Christmas and Happy New Year to all

Best regards

LENE BLICHER OLESEN
CHAIRMAN

ALAN FRIIS
EDITOR

How are hygienic process surfaces chosen?

BY NICOLE CIACOTICH, THOMAS FICH PEDERSEN AND ALAN FRIIS, FORCE TECHNOLOGY

The surface characteristics of product contact areas impact the cleanability of the materials that are in contact with, for example, foodstuffs. This is evident from a number of published studies. However, a clear correlation between surface topography and cleanability has not yet been established. FORCE Technology is working to achieve this through the development of a hygiene factor

The statutory requirements are the same regardless of whether you consult the Machinery Directive (2006/42/EC) or EU regulation 852/2004 on the hygiene of foodstuffs.

It is specified that surfaces in contact with products must be smooth and free from cracks and crevices and must not exchange substances with the products. Furthermore, they must be cleanable at a level that ensures that they are clean and free from substances that may contaminate the products before process plants are commissioned in production. In practice, random sampling is used in production to verify that the product contact areas are clean. It is, of course, a prerequisite that good materials have been chosen with cleanable surfaces in the construction phase of machines and process lines.

These general specifications are, however, of little practical use for manufacturers of process equipment. They need specific knowledge about material qualities and surface characteristics to be able to make the right choices.

The current guidelines and rules of thumb are based on the characterization of surface roughness given by the Ra value. This is a measure of the mean distance between top and bottom over a distance of six mm on the surface (according to ISO 4287), and it is often measured only in one direction. Traditionally, this measurement takes place with a physical pickup, which is moved across the surface. The characterization of the surface characteristics by only one number is a major simplification, which is quite easy to infer by observing a typical surface topography for a steel surface, as shown in figure 1. Typical surface profile for stainless steel is shown in figure 2.

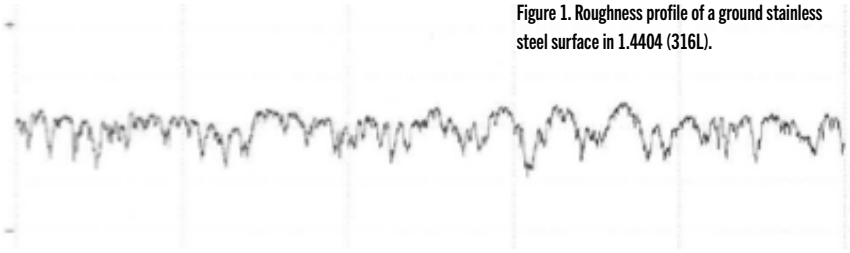


Figure 1. Roughness profile of a ground stainless steel surface in 1.4404 (316L).

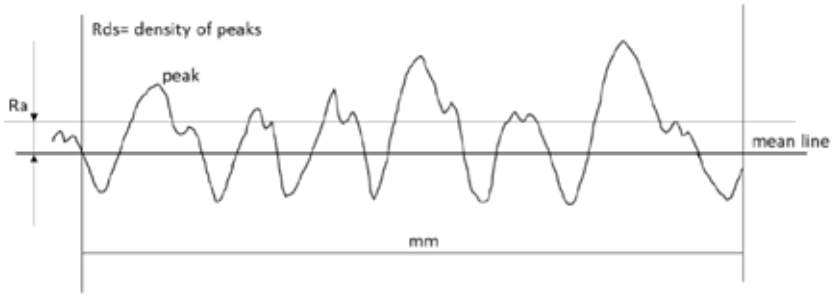


Figure 2. Measures roughness profile with indication of relevant characteristics (Ra and Rds).

HYGIENE FACTOR

To obtain a more adequate description of a surface like the one in figure 1, FORCE Technology has been working on the development of a hygiene factor (HF), which aims to better assess the hygiene quality of a surface. This measure also includes the number of peaks. The idea behind the hygiene factor is for the entire assessment to be carried out using an optical 3D microscope.

The formula for calculating the hygiene factor is shown below. Ra is the geometric mean distance from the mean line in a roughness profile, and Rpd is Peak Density (number of peaks per cm on the roughness profile):

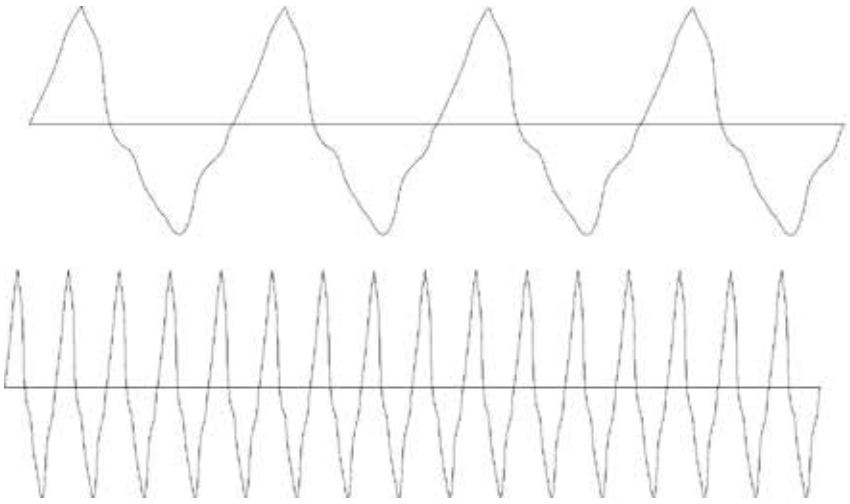
$$HF = \frac{1}{R_a \cdot R_{pd}}$$

A modification is used in that the parameters are not measured on a fixed roughness profile, as defined in the ISO 4287 standard, which is the raw profile filtered through a high pass and a low pass filter with typical lengths of lc and ls, respectively. Instead, ls= 2.5 µm and lc= 25 µm is used.

When determining the roughness profile for the profiles shown in figure 3, it appears that the distance between top and bottom in the profiles is the same, and the Ra value will therefore be the same. It is, however, evident that there is a difference between the distance between the peaks, and in practice translates in a different topography.

It may therefore be relevant to include a measure of the peak density, which is Rpd.

Figure 3. Surface profiles with different appearance but the same Ra value.



In this way, it is possible to describe whether the surface has a soft and open shape with relatively few peaks or it is closed with multiple peaks and a short distance between these. Thus, it is possible to differentiate between the profiles shown in figure 3.

The goal is to use the hygiene factor as a tool to assess the hygiene quality on all types of material without carrying out experimental work.

REQUIREMENTS FOR HYGIENIC STAINLESS STEEL SURFACES

Historically, a lot of work has been done to investigate the hygiene quality and cleanability of stainless steel, and the established dogma for hygienic surfaces is an Ra value below 0.8 µm. This is supported by recognised organisations such as European Hygienic Engineering and Design Group (EHEDG) and 3A-Inc in the United States, and it is therefore often the requirement for stainless steel for food contact. There are few examples of how the pharmaceutical industry has its own requirements for surfaces with a lower roughness, e.g. Ra values below 0.3 µm.

It is, however, important to know how the product has been manufactured and its surface finish. Is it a ground surface or, for example, a 2B surface? Microscopic images of both surface types are shown in figure 4. It is obvious that the surface topographies differ, and it is therefore only natural to assume that the Ra value expresses something different in relation to each surface.

Both surfaces are available at hygienic quality and can easily be delivered with a surface roughness with Ra below 0.8 µm. The 2B surface is the direct product from the steelworks, which is cold-rolled and pickled while the ground surface is processed gradually until the requested surface roughness is obtained, which takes place on the basis of a surface that resembles 2B.

It has still not been concluded what the most hygienic surface is, but it is expected that it would be possible by correlating the hygiene factor and practical examinations of cleanability of different surfaces.

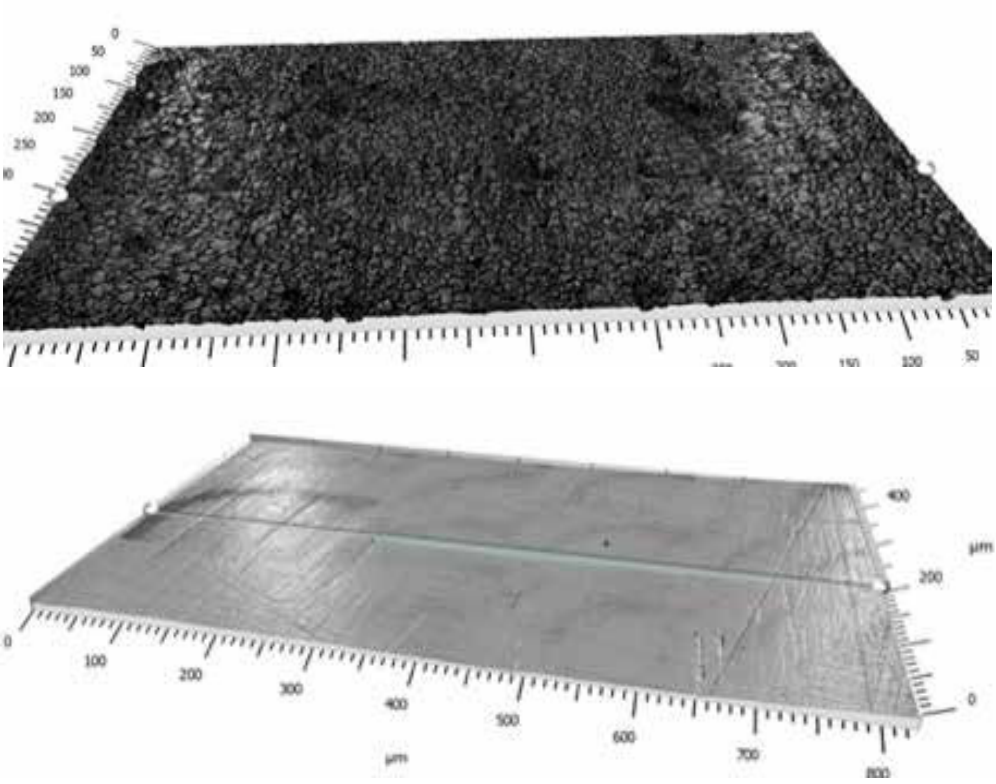


Figure 4. Microscopy image of surfaces on various types of stainless steel (2B and ground).

REQUIREMENTS FOR HYGIENIC SURFACES OF PLASTIC AND RUBBER

The same systematism has not been established for plastic and rubber as it has for stainless steel. In practice, a more subjective assessment is made to assess whether a surface is smooth enough to be used for food contact. The reason is that a number of products - such as packing made from rubber - must be more elastic and may therefore be more difficult to measure with the physical surface roughness gauge. The same applies to a number of plastic materials. Some plastic materials, for example PEEK, may, however, be so firm that it is possible to measure roughness.

Microscopy is already used to assess whether plastic and rubber surfaces have unevenness and irregularities. It is therefore natural to consider using 3D microscopy to determine the surface roughness, which also provides data for determining the hygiene factor.

The work with characterization of surface roughness and hygiene factors on plastic and rubber surfaces is a new area which has not yet proven its value in connection with the choice of material solutions with good hygienic quality.

FURTHER DEVELOPMENT OF THE HYGIENE FACTOR

Good preliminary results show that the hygiene factor is directly correlated with cleanability of both stainless steel and selected plastic materials.

The preliminary results and the further work with development of the hygiene factor are based on the activities within the result contract ”Competency centre for hygiene, health, and product safety”.

The goal is to develop a tool which may be used in industry to characterise materials with respect to their hygienic quality solely applying the hygiene factor determined by 3D microscopy. In this way, the hygiene factor may be of practical relevance for industry and be used, for example, to compare new surfaces and surfaces in use.

The future work will include correlation of the hygiene factor with cleaning time and testing of residual microbiological material on surfaces. This will take place partly in pilot plants and partly through field trials on components in industrial plants. Therefore, FORCE Technology would like to hear from companies interested in participating in case studies and practical testing.

WEBINAIR

Environmental contamination and risk of COVID-19 transmission at airports

ILPO KULMALA, VTT TECHNICAL RESEARCH CENTRE OF FINLAND LTD

INTRODUCTION

Air travel plays a major role in the global spread of infectious diseases like SARS-CoV2. Airports are potentially favourable places for disease transmission because of the numerous contacts among passengers, crowded places and frequently touched surfaces. In the recent PANDHUB project the presence of respiratory viruses in the passenger environment of an airport were investigated in order to identify risk points and guide measures to minimize transmission. Although the measurements were made before the COVID-19 pandemic, the knowledge gained from the presence of respiratory viruses in public places is highly relevant to the current pandemic situation

DISEASE TRANSMISSION MODES

The SARS-CoV-2 virus spreads mainly between people in close contact with each other through respiratory secretions containing the virus. Once expelled, SARS-CoV-2 can remain active up to 3 hours in the air and up to 2-3 days on room surfaces at common indoor conditions (Doremalen et al., 2020). The infectious material can be passed from person to person in different ways. The US Centers for Disease Control and Prevention (CDC 2021) categorises the SARS-CoV-2 transmission modes currently as

- deposition of virus on exposed mucous membranes,
- inhalation of virus, and
- touching mucous membranes with soiled hands contaminated with virus.

In general, virion-laden respiratory fluid droplets are released into the environment by infected people through expiratory events. When a person sneezes or coughs, a large number of droplets in the size range from < 1 up to > 1000 micrometer are sprayed in a cone-shape form. The droplets larger than 100 µm act like projectiles carrying high pathogen load. They are not inhalable but can hit target organs (eyes, mouth, nose) of an unprotected susceptible person in close range. Particles between 10 to 100 µm are inhalable but are deposited mainly in the head region and do no penetrate deeper in the respiratory tract (Figure 1).

Coughing and sneezing generates also small droplets <10 µm in size. When released in the air, water in the droplets evaporates quickly, in fractions of seconds leaving droplet nuclei. In indoor environments these particles are dispersed by air currents until removed by ventilation or gravitational settling. Recently it has been found that speaking and singing and even breathing produces aerosols also in the inhalable range and that the emission rate increases with the loudness of the voice (Alsved et al., 2020). When inhaled, the virus containing aerosols can penetrate deep in the lungs where much smaller dose is needed for infection than with deposition in the upper respiratory tract (DH 2011). Airborne aerosols can therefore pose an infection risk which has become more plausible with the new Covid-19 delta variant because of its high viral load in the respiratory secretions (Li et al., 2021). Like with droplets, the concentration

of aerosols is highest in close proximity to the infectious source and levels off within about 1.5 meters in indoor spaces (REHVA 2021).

The third mode of transmission is by touching eyes, nose or mouth with soiled hands contaminated with virus. Viruses can be collected on the hands by directly touching infectious person or indirectly by touching surfaces which have been contaminated by respiratory secretions.

ENVIRONMENTAL CONTAMINATION MEASUREMENTS AT AIRPORT

In the PANDHUB project environmental sampling was made at Helsinki-Vantaa airport to find areas where the risk of infection is at least temporarily increased. The sampling sessions were made during the peak flu season in 2015 well before Covid-19 pandemic. However, it is likely that the results can be generalised because the transmission pathways for SARS-CoV-2 are similar to the other respiratory infections.

Surface and air samples were collected weekly during three different measurement sessions in 2016. The measurements were made in a variety of sites along the passenger flow pathways in Helsinki-Vantaa airport from frequently touched surfaces. The samplings were immediately after the peak hours. Sampling time was tailored so that the surfaces sampled had not been cleaned after the most recent preceding traffic peak.

The surface samples were taken using nylon swabs, which were immersed in viral transport medium after sampling. The samples were analysed with real-time PCR using primers and probes for common respiratory pathogens (Ikonen et al., 2018). In total, 90 surface and 4 air samples were collected.

In total, respiratory viruses were detected in 10 % of the collected surface samples while one of the four air samples was positive for a viral pathogen. The positive sampling results are shown in Figure 2. Traces or respiratory viruses were found in samples from the children's playground, plastic trays at the security screening, buttons of the payment terminal at the pharmacy, at the passport control points, and the handrails of stairs. The used method did not tell whether the viruses were alive and the relatively high Ct values (from 36 to 42) suggest a low viral load on the surfaces that tested positive, and possibly not constituting the minimum infective dose.

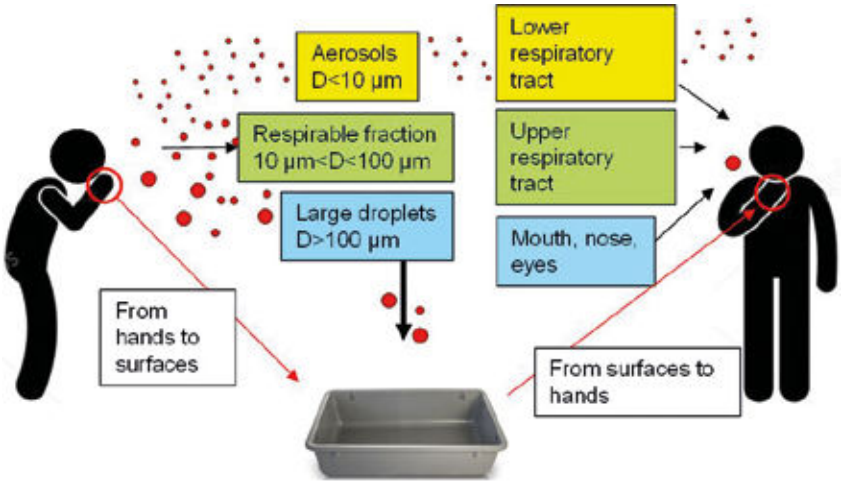


Figure 1.
Transmission pathways of respiratory pathogens.

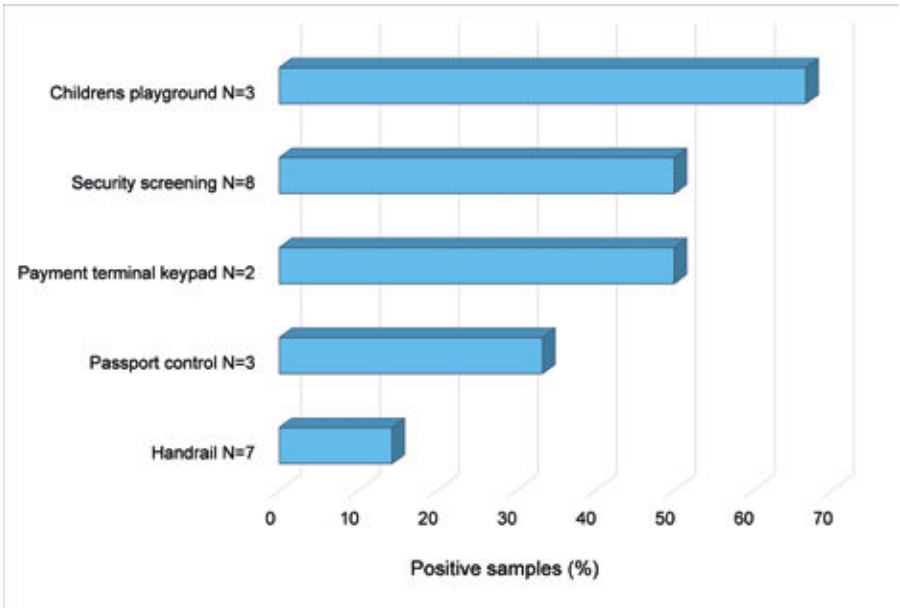


Figure 2.
Presence of respiratory viruses in positive samples.
N=number of samples collected.

CONTROL OF INFECTION RISK

The environmental survey confirmed that infected persons shed viral pathogens which will spread in the airport environment. Furthermore, it can be concluded that there are areas where the risk of disease transmission is elevated at least temporarily.

The infection risk can be controlled by inferring the relevant transmission routes. A summary of measures is shown in Table 1 at next page. Achieving a safe indoor environment requires the involvement of both airport operators as well as passengers and other persons working in the airport.

	Control measure	
Infection transmission mode	**Source control**	**Exposure control**
Droplet deposition tect	Use of face masks to reduce the emission of droplets. Coughing and sneezing hygiene	Use of surgical mask as a barrier pro- mouth and nose from droplet sprays Use of googles to protecy eyes Social distancing >1.5 m Plexiglas shields
Inhalation	Avoiding loud voice activities to minimize emissions Dilution with general ventilation Mobile air purifiers with high efficiency filtration in congested areas with poor ventilation	Use of FFP2 respirators to remov airborne particles ocial distancing >1.5 m
Contact via hands	Enhanced cleaning or disinfection of high touch surfaces Used tissues in dust bins Use contactless payment terminals; avoid keypads Contactless operations (faucets, doors)	Avoid physical contacts between individuals Good hand hygiene Washing or disinfecting hands after security screening Avoid touching the face

Table 1.
Disease transmission modes and prominent control measures.

In general, the risk of infection increases with time spent in indoor spaces with potentially infective individuals. Therefore it is advisable to check in online before the departure to avoid the queues on the counter. At the airport all passengers are funneled through the same security screening checkpoints which often means long queues and touching the security bins where personal belongings are put in for x-raying. The passengers are then often directed through duty free shopping areas before walk to the gate. Passengers board the plane through a loading bridge or by bus. Upon arrival, there is usually congestion on the plane and on buses, and at baggage claim.

The airport operator should ensure that the passenger flows move smoothly, there is good housekeeping with regular cleaning of high touch surfaces, and that the technical solutions are in place and operational. In addition, there should be clear instructions for passengers how to act to avoid infection risk. These instructions are usually prepared in cooperation with health authorities.

All the different phases in passenger process include high-touch surfaces and congestions where it may not be possible to maintain physical distancing. In such situations, the passengers should follow relevant precautions to minimise the exposure to the SARS-CoV-2:

- Use contactless payment instead of key-pads when shopping
- Wash your hands with soap and water for at least 20 seconds or disinfect them sanitizer with at least 60 per cent alcohol after the security screening and shopping
- Use tight-fitting FFP2 respirators in congested places or in areas with poor ventilation to protect from airborne pathogens.
- Avoid knowingly face-touching until you have cleaned your hands.

The relative importance of the different transmission modes of COVID-19 is still uncertain and probably varies depending upon the setting, the characteristics of the viral strain, environmental conditions, and other factors. To be on the safe side it is essential to cut all transmission pathways by following the relevant precautions.

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WEBINAIR

GMP Annex 1 – Selection Criteria for Protective Cleanroom Garments

STEVE MARNACH, DUPONT PERSONAL PROTECTION, LUXEMBOURG

INTRODUCTION

For the first time since 2008, the GMP Annex 1 for the manufacturing of sterile medicine products is undergoing a profound revision. The 2nd draft, published in February 2020, revealed that is more than a simple update: the actual guideline has completely been rewritten. Not only has the length of Annex 1 been increased from 16 to 50 pages, but the whole approach has changed, which will have repercussions on the technologies and the procedures used in pharmaceutical manufacturing.

The following excerpt from the very first page of the 2nd draft summarizes the new approach: "Processes, equipment, facilities and manufacturing activities should be managed in accordance with QRM (Quality Risk Management) principles that provide a proactive means of identifying, scientifically evaluating and controlling potential risks to quality."

It anticipates that all pharmaceutical manufacturing activities will be governed holistically by the QRM principles and documented in the contamination control strategy (CCS). The CCS will become a living document, based on a data-driven scientific approach, which should be continuously updated and improved in order to control potential risks to quality.

The new draft is calling for a proactive approach: simply reacting to and correcting detected contamination will no longer be enough. Manufacturers will be expected to fully understand their processes and procedures, so that they can identify the potential risks to quality, put in place all the technical and procedural means to control these risks and aim for continuous improvements. Since cleanroom garment systems are a critical part of sterile and aseptic manufacturing, they need to be managed under QRM principles too.

QRM PRINCIPLES FOR CLEANROOM GARMENTS

Quality risk management starts with an analysis and understanding of all the risks to quality associated with cleanroom operators wearing cleanroom garments. A complete databased analysis will allow for design certification, qualification, validation and monitoring procedures, which have quality built into them, thus being part of a holistic contamination control strategy.

A risk analysis is needed to understand the contamination risks coming from operators wearing cleanroom garments. Operators represent the biggest source of contamination inside cleanrooms, responsible for 75% of all contaminants (Ramstorp, 2000). This contamination is coming both from the operators themselves and from their cleanroom garments (Ljungqvist & Reinmüller, 2005).

Operator contamination is due both to our human nature (an average person sheds 40 000 particles per minute and 10% of them carry microorganisms) and human behaviour. While it is possible to mitigate the latter aspect through careful operator selection, training, slow movements or impeccable hygiene, the fact is that operators will always be shedding particles, as multiple studies have proven. There is just one way to prevent particles generated by operators from contaminating the cleanroom: use cleanroom garments. They are the only barrier between the operator and the production environment. The 2020 draft of Annex 1 clearly points this out: "the cleanroom garments should) retain particulates shed by the body".

Cleanroom garments themselves may be a source of contamination and this risk needs to be assessed too. For example, the material used for making the garments (non-woven for single-use garments or woven for reusables) can shed more or fewer particles depending on the nature of the fibres or filaments used, their resistance to abrasion or their construction. The trims (zipper, buttons, elastic or sewing threads) may also be a source of contamination. The design of the garment also plays a role and should be evaluated. One detail which is often neglected is the packaging in which the cleanroom garments come, which could be an additional source of contamination i.e. paper-bag vs. plastic bags.

MAIN STAGES OF VALIDATION

Once the risks have been evaluated, they should be removed or replaced by technical or organisational means as far as possible, and the residual risks mitigated as much as possible using a validated cleanroom garment system. The EU general guidance on validation (GMP Annex 1519) provides the general framework that can be applied to the qualification of cleanroom garment systems as well. This validation approach consists of five steps: the definition of User Requirements Specification (URS), the Design Qualification (DQ), the Installation Qualification (IQ), the Operational Qualification (OQ) and the Performance Qualification (PQ). While the DQ and IQ have the highest impact on the quality achieved, the other stages should not be neglected, and it is important to proceed systematically. (Pavičič & Wagner, 2019)

USER REQUIREMENTS SPECIFICATION (URS)

While they are not formally part of the validation process, it is important to define upfront the requirements on the cleanroom garments system from the users and the environment they work in. The URS will define the critical requirements against which the garment system needs to be assessed so that they will be in line with the risk assessment. For example, a trained operator may have to be able to work at least 3 hours in the same set of cleanroom garments without causing unacceptable (cGMP) levels of contamination of the garments and the aseptic working environment. The garment's packaging system may have to be suitable for the layout of the cleanroom and its material pass-through systems, or may have to be suitable for manual spray disinfection. Sometimes, the operator may also need chemical or biological protection against the substances they are handling inside.

DESIGN QUALIFICATION (DQ)

The compliance of the cleanroom garment system with cGMP must be demonstrated and documented during the DQ, which aims to confirm that the selected cleanroom garment is qualified for the intended use. As the new Annex 1 will require a data-driven scientific approach, the DQ should include tests to simulate the intended use and the performances of the garments. As recommended by ISO 11607-1, the DQ should be split into four key areas: Material qualification, Performance testing, Stability testing and Usability evaluation. For reusable garments, this needs to be extended to the garment maker's subcontractors, suppliers and service providers.

In this article, only a couple of these properties will be highlighted to show their importance and the scientific test methods that may be used to assess the performance of cleanroom garment systems (Table 1).

1) Material qualification

- In order to ascertain whether the garments are truly sterile, it is important to check if the manufacturer is following a validated sterilisation process and can guarantee a sterility assurance level of 10-6 as per ANSI/AAMI/ISO 11137-1 and document this in a certificate of sterility. A simple certificate of irradiation or a document attesting an internal autoclaving process are not enough. Since the cleanroom garments need to be a barrier against the human contamination generated by the operators, it is important to assess the filtration efficiencies of the materials (non-woven or reusable polyester fabrics) used for making the garments. The particle filtration efficiency (PFE) against dry particles can be assessed with the test method EN 143 (TSI 8130), which measures the filtration efficiency using salt particles having a diameter of 0.3 µm. While the bacterial filtration efficiency (BFE) can be assessed with the test method ASTM F2101.

2) Performance testing

- The Helmke Drum test method as per IEST-RP – C003.4 is a good way to assess the particle

Table 1.
Properties to be checked, when evaluating the performance of cleanroom garment systems (Pavičič & Wagner, 2019)

MATERIAL QUALIFICATION	PERFORMANCE TESTING	STABILITY TESTING	USABILITY EVALUATION
Cleanroom garments	*Cleanroom garments*	*Single-Use garments*	*User scenarios*
• Fiber and particle shedding • Sterilization compatibility • Sterility assurance level • Pyrogenicity • Particle filtration efficiency • Bacterial filtration efficiency • Porosity • Surface resistivity • Perforation resistance • Mechanical resistance • Protection against biological agents	• Body box testing • Helmke drum test	• Properties and characteristics at the end of shelf-life *Reusable garments* • Properties and characteristics after maximum number of laundering and sterilization cycles	• Transfer to classified storage area • Readability of label • Easy opening of packaging • Aseptic unfolding of garments • Gowning • Donning additional accessories (e.g., sterile gloves, face mask, goggles) • Work situations • Safety, biosafety • De-gowning
Packaging	*Sterile packaging*	*Sterile packaging*	*Packaging*
• Fiber and particle shedding • Bioburden • Penetration of commonly used disinfectants *Sterile packaging* • ISO 11607-1	• Influence of transport on integrity/sterility (ISO 11607-1)	• Packaging integrity/sterility at the end of shelf-life (ISO 11607-1)	• Aseptic presentation of garments (multiple layers)

Source: Pavičič M. & Wagner T., Risk and Science-based Validation of Cleanroom Garments

shedding of cleanroom garments, especially for garments that are washed multiple times.

- The Body box test (IEST-RP-CC003.4) is the only test method available to assess particle shedding when a garment is being worn by an operator. It allows evaluation of both the particle shedding of the garment and its PFE & BFE of the particles shed by the operator.

3) Stability testing

It is important to check how the garment characteristics and properties will change over time (due to ageing, wear, wash-dry-sterilisation cycles). Therefore, the performances listed above should be validated under worst-case conditions, i.e. for single-use garment assessing garments from different batches and at the end of their shelf life, and for reusable garments after 10, 20, 30, 40 and 50 wash-dry-sterilisation cycles to assess the end-of life of the garments (Romano et al., 2016).

4) Usability evaluation

It is important to go through the user scenarios and to assess the packaging of the garments to ensure that the cleanroom garments can be used with acceptable remaining contamination and safety risks. While this is typically done by the end-user, suppliers can also evaluate and supply data to users.

INSTALLATION QUALIFICATION (IQ)

Even though the IQ is a formal check to verify if all required elements of the cleanroom gowning system are present, it is important to check the following in order to eliminate unforeseen risks: Are the gowning and de-gowning facilities in order? Did the supplier provide the required certificates of conformance and/or analysis, supplier instructions, etc.? Have the Standard Operating Procedures for gowning and de-gowning been written or adapted? Have the logistical processes for garments and accessories been validated? Has the operators' training and qualification plans been established?

OPERATIONAL QUALIFICATION (OQ)

The OQ aims to qualify the gowning and de-gowning concept, including logistics & material pass-throughs, and the aseptic presentation of the garments (i.e. folding, packaging).

PERFORMANCE QUALIFICATION (PQ)

The PQ is typically done under worst-case conditions, which must be determined based on a risk assessment to validate the performance of the cleanroom garment system when it is used. The requirements specified in the URS must be complied with fully. They include the aseptic gowning qualification and the validation of the microbiological quality of the gowned personnel with the garments and other accessories during the actual work.

Of course, it does not end there: periodic revalidation of the garment system, constant monitoring and critical review of changes to the garments or the system are important to demonstrate the state of control.

CONCLUSION

Cleanroom garment systems are a critical part of the contamination control strategy and process validation. A Risk and Science-based Quality-by-Design approach and verification is the correct strategy to control contamination risks related to people and offer designed-in risk reductions. This approach is an adequate response to the latest regulatory requirements.

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WEBINAIR

Contamination Control Strategy for EU GMP Annex 1 compliance

JAMES L DRINKWATER; PHSS CO-LEAD IN DEVELOPMENT OF CCS GUIDANCE. F ZIEL GMBH HEAD OF GMP COMPLIANCE.

The requirement for control strategies in Good Manufacturing Practice (GMP) are not new. What is new is the requirement of a Control strategy in EU GMP Annex 1 specific to contamination called a CCS: Contamination Control Strategy. Annex 1 in principle applies to manufacture of sterile medicinal products but (as Annex 1 states) the principles and requirements within can also be leveraged for low bioburden processes including those applied to manufacture of non-sterile products. Annex 1 sets out the requirement of a CCS as a principle without details of application, scope and format. Guidance is in development to assist converting this principle requirement into practice and this article explains the considerations and guidance in development as a joint initiative by the PHSS (UK) and A3P (France).

Fig 1
Building blocks in the Contamination Control Strategy (CCS).

CONSIDERATIONS OF CCS SCOPE AND CONTENT - BUILDING BLOCKS OF A CCS

A CCS is considered to be developed based on a number of building blocks, represented in the CCS pyramid Fig.1.

CCS SCOPE

Medicinal products and advanced therapeutic medicinal products that require contamination control including sterile products (Aseptically processed and terminally sterilised), Non-sterile product that require microbial/ bioburden control.

Scope of contaminants to include total particulate (non-viable), microbiological/ pyrogens including endotoxins and for biological products where prions and mycoplasma are present. In addition chemical contamination from disinfection residues (disinfectant agents and gaseous agent residuals e.g. VHP) and SUS product contact parts leachable and extractable contamination together with extraneous cleaning residues; soiling, lubricants etc.

CCS GUIDANCE CONTENT

Guidance on a holistic approach and principles to apply when preparing a (CCS) with case studies that show interpretation of guidance principles into application. A template of contents is provided as part of the guidance initiative to facilitate a harmonised approach. Points to be considered in Q&A according to the PHSS-A3P CCS focus group follows below.

OVERALL - WHAT SHOULD A CCS LOOK LIKE?

The CCS is a document which outlines a sites approach to contamination control through its existing quality systems, processes etc. Where a validation master plan addresses the approach to verification of the developed processes and systems at a site and makes reference to existing lower level individual system plans which address individual topics in more detail. For a CCS each of the systems is viewed from the focus of contamination control. Where a site has many different areas then the CCS will outline the approach to contamination control at the systematic level and at the line/ area level the detail as it applies to that line are captured in lower level documents.

The CCS needs to cover the site's approach to design, control, monitoring, trending, response processes and governance and life cycle in the context of contamination control. Each of the elements of facility, utilities, equipment, process (including materials), personnel and waste needs to be addressed from the design, control, monitoring, trending, response, governance and life cycle perspective.

CONTEXT SETTING - SITE AND INDIVIDUAL LINE LEVELS

When setting the context for the reader of the CCS, the products manufactured and the processes used at a site are described at very high level. At the individual line or product level, a high level description is given e.g. X product in pre filled syringes. Y product in vials etc. If several products of the same basic format are manufactured then these are referred to.

Details of the critical quality attributes (CQAs), critical process parameters (CPPs), critical process steps (CPS), in process controls (IPCs) from a microbiological perspective are also described, typically in tabular form. Such information i.e. the what, how and why products were designed the way they were from a microbiological contamination control perspective is supported by the information in the 3.2.P section of the common technical document (CTD). Other microbiological aspects e.g. Grade A environmental monitoring requirements may also be described at this point. Where this gets too cumbersome the detail may also be captured in appendices.

APPROACH TO VALIDATION, THE LINK BETWEEN PROCESS DESIGN, OPERATION AND QUALITY RISK MANAGEMENT

The link is then made between the CQAs, CPPs, CPS, IPCs and the validation approach bringing in the details of the site quality risk management (QRM) processes and how they are leveraged in the validation process. This will also encompass the approach to sampling and analysis and the use of validated methods of microbiological analysis.

Areas of focus for QRM include design of facility, utility, equipment etc., controls for utilities, facilities, process etc., application of procedural controls to operator aseptic behaviour and technique, aseptic processing QRM, what control levels are applied to environmental monitoring, response to deviations, change control, self-appraisal, outsourced activities, vendor approval, material management and the link to continuous improvement etc. The point here is that there are many existing applications of QRM within site quality systems and the CCS presents the link between them for the purposes of contamination control.

QUALITY SYSTEM DESCRIPTION AND ITS APPLICATION TO CONTAMINATION CONTROL

The CCS then describes those further elements of the quality system and how they function and are structured to address contamination control.

APPLICATION OF PRINCIPLES OF ANNEX 1 TO NON-STERILE PRODUCTS

Where a site manufactures non sterile products and the site has adopted principles and guidance from Annex 1, which ones they are using are addressed too?

INDIVIDUAL LINE/AREA OR PRODUCT CCS

Once the high level site systematic approach has been outlined the individual lines/areas in which a common approach to contamination control is used are then addressed. This is where

the 'what' outcome of the application of the high level systematic approaches is described.

These lower level CCSs provide reference to the detailed documents again focused on contamination control, including validation protocols and reports, QRM documents for EM, aseptic processing, media fills for aseptic processes, management of campaigns, line and process change over.

Material selection (excipients, API, consumables (e.g. sterile low lint wipes, sterile gloves, sterile disinfectants), critical processing aids (e.g. filters, single use systems), approval, details of vendor approval, the management of etc). Where possible existing documents are used e.g. site master file for facility layouts, automation system descriptions, URS, DQ, IOQ, PQ, Annual Product Quality Reviews, periodic trend reports for building monitoring system alarms, process monitoring, etc.

A fundamental point in transitioning to CCSs as a new class of documents is that many elements of contamination control strategy already exist. The added value of a CCS is linking them together for the purposes of focusing efforts and critical thought to a systematic holistic approach to contamination control.

CCS Q&A'

What's new and different about a CCS as specified in Annex 1 as requirements for a Control strategies have been around for some time e.g. Control strategy for biological products (Annex 2), Automation Control Strategy (Annex 11 computerised systems)?

What's new is the overarching and detailed nature of the holistic focus on contamination control for sterile products.

- Is a CCS just an over-arching list of documents that already exist and cover contamination control in a facility so an easy document to prepare without too much additional burden to routine work?

As indicated previously, there are elements that can be leveraged but their critical appraisal as to 'why' what is done, is done, the 'how' it is done is different for sterile products and unless this is carefully considered, misses the point entirely. The easy bit is the 'what' is done... this is in place already.

- What is the connection with other GMP chapters/ GMP requirements/ risk assessments/ Site Master file?

As previously outlined – the CCS leverages all of the existing GMP chapters, requirements, risk assessments, APS/SMF etc for the purposes of capturing the systematic approach to contamination control but the added element in the CCS is the 'why' and the 'how' these existing elements function to support contamination control.

- What if my product is toxic how do I prepare a CCS for Annex 1 compliance that mainly considers sterility?

Management of cross contamination, containment and segregation process have been in existence for a considerable time – marrying them to contamination control is an added context and again the site quality system approach as with other systems is leveraged to link what is relevant at the site and line level. Separate guidance is in preparation by the PHSS covering an Aseptic-Containment Strategy (ACS) based on Health based exposure limits and approaches to contain hazardous and toxic products that are aseptically manufactured.

- How far do Annex 1 requirements apply when applied to a non-sterile product or sterile API/ ATMP substance?

Manufacturers are concerned about the potential for the mis-application of Annex 1 requirements to non-sterile products and the scope for misunderstanding especially from less mature regulatory authorities so there is hesitancy to explicitly commit to their application. Safe, effective and controlled processes have been in place for many years at such facilities so it is not clear where the risk may lie which has not already been addressed. As a context USP <1115> outlines very similar methodology but as a guidance it seeks to influence approaches to contamination control. For sterile APIs, ATMPs and clinical products – it is clear that Annex 1 applies. The degree of detailed application may be a topic for further exploration for clinical products.

- If my process uses new technology, new (RMM) EM methods that do not fully align with generic GMP expectations but instead apply alternative approaches how do I apply QRM? Do I use the CCS as the document to put forward the alternative approaches to the regulatory authorities or use different submissions/ rationale documents?

Any manufacturer with significant capital bound up in a new projects will adopt a cautious approach to the use of new technology for whatever purpose RMM EM or not. The ability of that technology to achieve it's function will be subject to QRM in the normal way but it certainly makes sense to ensure that early engagement with the regulator as part of routine GMP inspection / 'Engineering' type inspection or other alternatives are explored.

The implications of the use of new technology for processes and how that may result in further enhancement of process controls and the potential to restrict practice is a real concern for manufacturers and limits consideration of its adoption. Representation by industry bodies to regulators and pilot application in an agreed approach to understanding how the new technology will perform is one avenue for potential success.

Where such technology needs to be built in the machine / filling line fabricators may also wish to be convinced of the 'workability' of any such new technology. Once the principle has been agreed with the regulator and preliminary data indicates significant potential for success then the details will have to be submitted as part of a CTD in the normal way. It is not clear how a regulator could give agreement for application of new technology without a CTD submission following existing processes. To accelerate adoption of new technology may require enhanced co-operative processes between the regulators and industry.

- If my project is not new and an older facility how do I go about CCS preparation and do GMP inspectors expect a CCS for older and established processes/ products in manufacture?

As outlined above – there is no reason why a CCS cannot be developed using a standardised approach for existing products and lines. After all the vast majority of processes in existence need to be brought into scope of a CCS. It may indeed be the case that as a CCS is built for a site that differences in approach between different lines and products are identified and will need to be evaluated and addressed as appropriate.

CCS DOCUMENTATION STRUCTURE RECOMMENDED IN PHSS-A3P GUIDANCE

It is recommended to prepare a site Master CCS that covers site policies and principles and centralised areas that contamination control applies to. Referenced from the site Master CCS individual Area-Unit operations CCS's can be linked (cross referenced as required). For a small operation it may be possible to justify a single CCS but it is recommended to follow the same structure starting with policies and principles applied to site operations followed by specifics on unit operations. See the CCS matrix and its connection with the PQS in Fig 2.

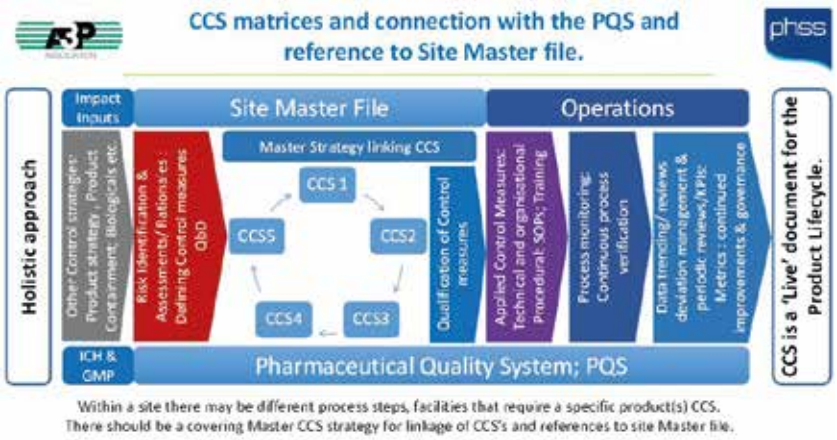


Figure 2
Contamination Control Strategy (CCS) matrix

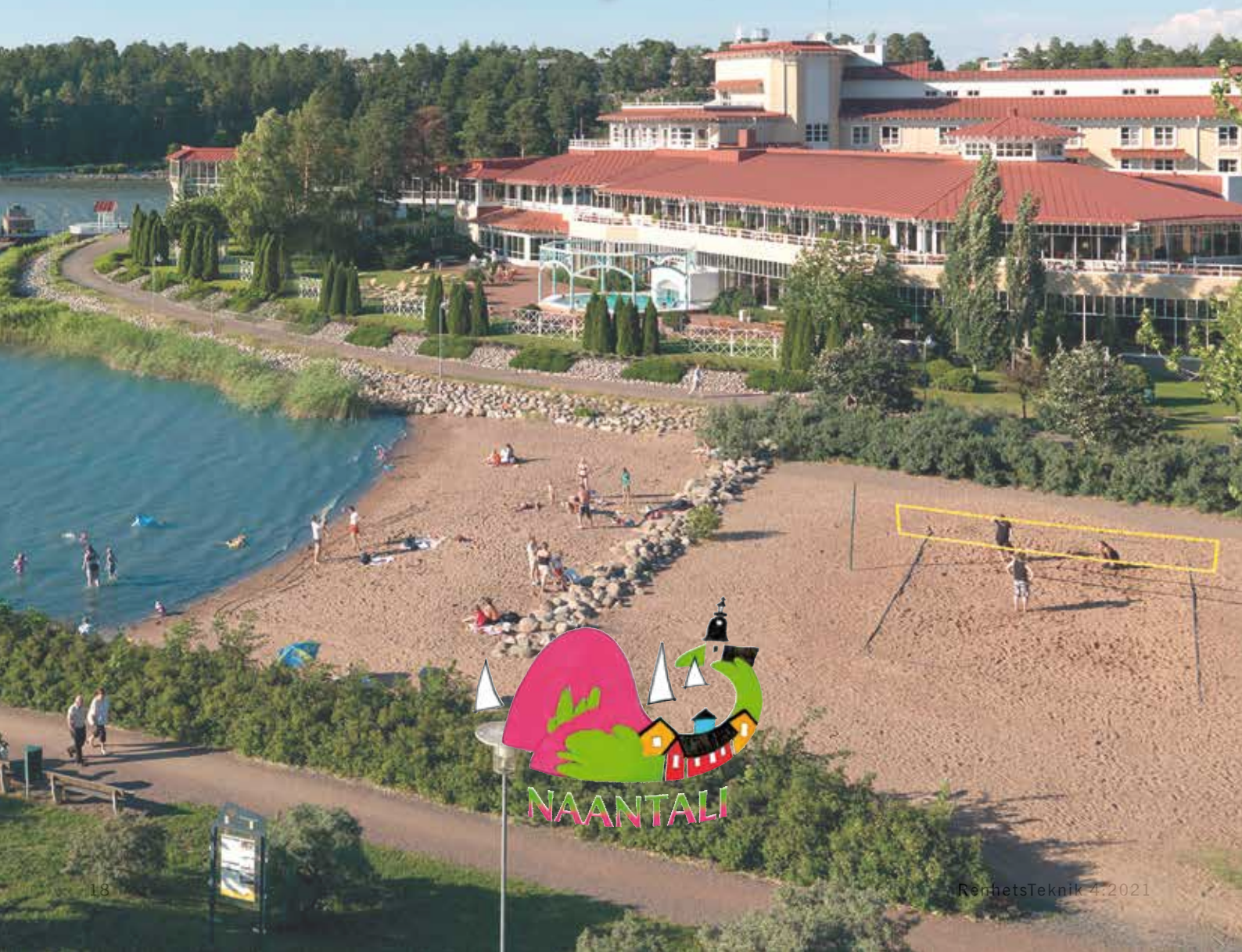
PHSS-A3P CCS GUIDANCE PUBLICATION

The PHSS-A3P CCS Guidance is in preparation with publication expected by year end 2021. The joint initiative of PHSS-A3P society-association are also connecting with collaboration partners, including R^3 Nordic to share guidance when developed.

Invitation to the 51st R³Nordic Symposium & exhibition

After two years suspension due to the COVID-pandemic the symposium will now be arranged

May 10-11, 2022 at Naantali Spa, Finland



PROGRAMME

The Program Committee 2022 (PK22) likes to inform You that arrangements of the 51st R³ Symposium are in good progress. The programme will cover applications in both cleanroom technology and contamination control in pharma and food industries, in hospitals as well as in the session on general knowledge/news in cleanroom technology. Both the scientific and the social programmes will be finalized in January and more information will be available in RT1:22. On page 21 you will find confirmed speakers..

Our keynote speakers cover topics on good manufacturing practices and contamination control in various types of cleanrooms. The abstracts of approved topics will be in focus in the next issue of Renhetsteknik (RT 1:22). Furthermore, the programme will regurarly be updated on R³Nordic's website from January 2022 onwards at https://r3nordic.org/symposium-exhibition-2022/. In this issue, we show confirmed speakers and their topics. More detailed will be available when the symposium programme is updated.

PARTICIPATION

For registration to the 51st R³Nordic Symposium, please, use the Registration Form, which you find in this issue or visit the homepage www.r3nordic.org/symposium-2022. In case you need accommodation at Naantali Spa and want to take part in the dinner(s), this information should be given at registration. Registration through the homepage have two possibilities for payment, these are either card payment or through invoicing. Tick the preferred payment before submitting the electronic registration. According to general data protection regulation (GDPR) we are publishing only the names by country. Note that photos are taken at the event. They will be published in RT2:22.

EXHIBITION

The annual exhibition is arranged in conjunction with the symposium. Some of the exhibition stands are already booked. Please, contact Gun Wirtanen at guliwi@luukku.com to find out which stands are available. You will find more information on the R³Nordic's homepage from January 2022 onwards.

SOCIAL ARRANGEMENTS & ACCOMMODATION

All participants are warmly invited to take part in the evening events, the Get-together party on Monday evening 9th of May and the banquette on Tuesday evening 10th of May 2022. The price information is available in the registration form.

Please, note that to obtain discounted prices of accommodation at Naantali Spa You should book the room(s) through the registration form at latest on 12th of March 2022. Thereafter PK22 cannot directly approve that there are rooms available, due to other events arranged at Naantali Spa and its vicinity.

Further information on the symposium including registration form is found on https://r3nordic.org/symposium-exhibition-2022/.

SPECIAL OFFER "GO 3 PAY FOR 2"

Our early-bird special offer "Go 3 Pay for 2" for industrial delegates is valid until the end of March 2022. Please, note that prices will raise from 1st of April 2022 onwards.

The participant fee for persons coming from hospitals, educational institutions etc. is given under "Public & Municipal" on the form.

The 51st R³ Symposium is waiting for you; come and enjoy the event! Welcome to Naantali - Nådendal!

PROGRAMME COMMITTEE MEMBERS

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Kari Leonsaari	Pharma & News	kari.leonsaari@santen.com
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Gun Wirtanen	Exbibition & Food	guliwi@luukku.com / gun.wirtanen@seamk.fi

Registration Form

Please return
this registration if you want us to send you an invoice.

R³ Nordic Office
info@r3nordic.org

To obtain discounted prices
please return the filled form at
latest on March 30, 2022

Registrate Online
and charge your credit card
The discounted prices Online are available until **March 31, 2022**, at

www.r3nordic.org

CONFIRMATION
A written confirmation will be sent by E-mail to each participant after we have received the registration form and payment of Grand Total Sum.

ON-SITE PAYMENT FEES are based on full prices for non-member.

PLEASE NOTE!
The number of rooms at Naantali Spa is limited due to other arrangemants in the Turku-area at the time of the R³ Nordic Symposium.
When the rooms are sold out we can only help you with addresses to hotels in the nearhood and the prices will be market prices, which you then pay directly to the hotel of our choice.

The Hotel accommondation must be booked through PK by the participant.

CANCELLATION
All participants cancellation must be submitted in writing. For cancellations received by **March 31, 2022**, all fees will be refunded except for a cancellation fee at 250 €.
No refunds will be made after April 1, 2022. We do not accept neither personal nor company cheques!

PLEASE take a copy of the filled form for your own records.

FURTHER INFORMATION
is avaiable from the members in the Programme Committee.

CONTACT INFORMATION *Please print!* **Only one participant per registration form!**

Family name	First name	
Company		
Mailing address		
ZIP code and City		
Country		
Telephone	Mobil phone	Telefax
E-mail		
Another Invoice Address		
Any reference or labeling		
ZIP code and City		

ATTENDANCE CATEGORY

Member of R³ Nordic: ☐ Yes ☐ No ☐ **Participant Commercial**

☐ **Participant Public and Municipal Services**

Exhibitor
Please contact Gun Wirtanen
+358 40 525 74 27 · guliwi@luukku.com

Speakers
are registered through your PK 20 contact

PARTICIPATION

I will participate: ☐ May 10 ☐ May 11 ☐ May 9-10 ☐ May 10-11 ☐ May 9-10-11

REGISTRATION FEES FOR PARTICIPANTS (€)	Commercial Before April 1	Commercial From April 1	Public & Municipal Before April 1	Public & Municipal From April 1	Total EURO
Registration fee (1) for members, 2 day	**840**	**960**	**670**	**770**	
Registration fee (1) for members, 1 day	**570**	**650**	**420**	**500**	
Registration fee for members (Go 3 Pay for 2), 2 days	**1680**	**1920**			
Registration fee (1) for non-members, 2 day	**960**	**1080**	**750**	**850**	
Registration fee (1) for non-members, 1 day	**650**	**730**	**500**	**580**	
Registration fee for members (Go 3 Pay for 2), 2 days	**1920**	**2160**			

The group offer "Go 3 Pay for 2" is available to the end of April. In case your register five (5) additional names, you should pay the "Go 3 Pay 2"-offer twice. For participants who are non-members you have to pay the non-member or register as members in advance (70 € non-member).

Below - Register the names of the colleagues in the Go 3 Pay for 2

Name 2: ..... *Name 3:* .....

Name 4: ..... *Name 5:* ..... *Name 6:* .....

SOCIAL PROGRAM	Amount	Price before April 1	Price from April 1	Total EURO
Get-together ticket (Monday May 25)		**75**	**90**	
Banquet ticket (Tuesday May 26)		**110**	**125**	
HOTEL ACCOMONDATION	**Nights**	**Price before April 1**	**Price from April 1**	**Total EURO**
Naantali Spa, Singel room		**155**	**160**	
Naantali Spa, Double room		**170**	**180**	

Check-in: ..... / ..... **Check-out:** ..... / ..... I will shared the double room with: .....

GRAND TOTAL **EURO**

COPY · FILL IN · SIGN · SEND (All payments i Euro)

.....
Signature of authorized signatory

According to GDPR we are publishing only the names of the participants by country; no further information on the participants will be published in the participant list.

Speakers at this Symposium are amongst others:

1) *Dr. Veli-Jukka Anttila*, Helsinki University Hospital
2) *Frans Saurwalt*, Kropman
3) *Mervi Saukkosaari*, FIMEA
4) *Dr. Berit Reinmüller*, Chalmers
5) *Simone Biel*, Merck Life Science
6) *Rüna Brade*, Elomatic Oy
7) *Esa Högel*, Valtria Swiss AG
8) *Aku Karvinen*, VTT Ltd
9) *Teijo Paavilainen*, Bayer Oy
10) *James Drinkwater*, Franz Ziel GmbH
11) *Steven Derez*, CRDB
12) *Prof. Bengt Ljungqvis*t, Chalmers
13) *Sanna Tietäväinen*, JIK ky
14) *Alan Früs*, FORCE Technology

We are allowed to use photos from Naantali Spa's image gallery (www.naantalispa.fi)

The PDA Annual Meeting Returns to In Person! Taking place in 04-06 April in Dallas, TX, the 2022 PDA Annual Meeting will focus on the theme, Level Up: Agility in the New Normal. Through interactive sessions across multiple tracks, you will see how companies are developing new modalities and adapting to the current manufacturing environment through modernization and innovation.

PDA Letter Europe, April 2021 presents e.g., "The Moldy Nightmare: Questions and Answers", Part 1 by Ziva Abraham, Microlite, Inc.

PDA September/October 2021; Volume 75,Issue 5, contains among other articles

- Contamination Control Strategy: Implementation Road Map, *by Walid El Azab*
- Statistically Significant versus Practically Relevant Trend in Stability Data, *by Bernhard Schmelzer, André Mischo and Franz Innerbichler*
- Wanted: Dead or Alive, *by James P. Agalloco*
- Re: Annex 1 Of Manufacture Of Sterile Medicinal Products - Final Document NOT Yet

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PHSS have been asked to distribute the following message to members from European Medicines Agency

Dear Industry Stakeholders,

EMA and its working party GMDP IWG are is in the process of finalising "Annex 1 of Manufacture of Sterile Medicinal Products 2008_11_25_gmp-an1.doc (europa.eu) and publication will follow in due course.

Once available, all stakeholders will be informed accordingly.

Any draft version of the previously mentioned document which may become available by other routes should neither be regarded nor considered as EMA official final document.

Thank you for forwarding this message to whom you think appropriate within your respective organisations.

With best regards

Congratulations to the winners of this years George Sykes Memorial Award and John Sharp Memorial Award

Every year PHSS nominate the most read article for both Peer Review and Opinion, we believe this is quite an achievement. We are sure you wish Congratulations to both authors for their fantastic contributions this year.

Tim Sandle - George Sykes Memorial Award Winner 2021 - *A global disinfectant standard for cleanrooms: Presenting a harmonised approach*

Alan Heavey - John Sharp Memorial Award Winner 2021 - *Wet loads - a phenomenon or by design?*

The latest issue of Clean Air and Containment Review, Issue 45:2021, number one, can be found at R^3 Nordic members´page. Number one contains in addition to John Neiger´s Editorial, Pearls of wisdom and Live lines the following:

- Main features Individual closed isolators for cell therapy *by Didier Meyer*
- Cleanroom - known unknowns: 5. Separative devices and biological safety cabinets *by Andrew Watson*
- Innovations New hydrogen peroxide bio-decontamination method enhanced with ultrasonic wave energy *by Koji Kawasaki and Gordon Farquharson*
- Regulatory reflections Partnering with suppliers to get the best out of your Contamination Control Strategy (CCS) *by David Keen*
- Advertorial Next generation integrated isolators for pharmacy production processes from Envair Technology
- News, Events and Training courses

Latest issue of European Journal of Parenteral & Pharmaceutical Sciences, Vol 26, issue 3, presents two peer-reviewed papers, two opinion papers, editorial comments, PHSS news, one book review and the monthly update by *Malcolm Holmes* (EJPPS Online).

Peer Review Papers

- Microbial Air Samplers for Meaningful Cleanroom Environmental Monitoring by *T Eaton*, AstraZeneca, Macclesfield, UK
- A Comparison of the Bacterial Contamination of the Surface of Cleanroom Operators' Garments following Donning with and without Gloves by *Dr Laurie M. Smith, Dr Noëlle H. O'Driscoll, Prof Andrew J. Lamb*

Opinion Papers

- Environmental Sustainability in the Life Sciences Sector: Embedding Change by *Cliodhna McDonough, Hugo Lidbetter*
- Recommendations of scientifically sound and appropriate sampling plans for parenteral drug products by *Ian Aled Jones*, Alex Bird and Nathaniel Lochrie*

Editorial

- Disinfectant resistance: The next threat to pharmaceutical contamination control?

Guest editorial by Tim Sandle

- PHSS News by Jenni Tranter, chair of PHSS
- Introductions to new Editorial Board Members

Regulatory Update by Malcolm Holmes

- July 2021
- August 2021
- September 2021

Book Reviews by Tor Gråberg

- Advances in Practical Safety Ventilation -- Pharmaceutical Cleanrooms and Hospital Operating Rooms by *Bengt Ljungqvist* and *Berit Reinmüller*.

ICCCS Meeting

The meeting was held as a hybrid meeting, with attendees connected by Zoom and by physical attendance in Woerden (NL).

Frans Sauerwalt has served as chairperson for ICCCS for the last six years, and therefore a new chairperson must be elected. Conor Murrays was elected as the new charperson for 2022, 2023 and 2024.

The year passed were discussed. As other organisations have experienced it has been a very difficult year to have physical conferences and training courses. This means that the expenses on having courses and the income on having courses are both limited the philosophy of ICCCS is to support the member organisations (as R³ Nordic is), the economy of the ICCCS is very well even this is not the primary focus of this organisations

Next year (2022) ICCCS will have 50 years anniversary and photos, anecdotes etc. from yearly times ware called to try to cover the story of ICCCS. If you have anything, please send it to the R³ Nordic or directly to the ICCCS Board.

The ISO TC209 meeting was held for the 2nd time as Zoom meeting 1st - 4th Nov 2021. The attendance were broad represented by the member countries, from the Nordic countries Finland and Denmark participates. On the ISO TC 209 meeting the new chairperson, Gordon Ely was introduced. Gordon is the successor of David Ensor who former served as chairperson for TC 209

The meeting went well and as scheduled and six resolutions as follows, were approved:

- To dissolve WG 14 as the work on ISO 14644-17; Particle Deposition Rate was completed and the standard published.
- To include the proposed microbiological control standard (based on EN 17141) in the ISO 14644-series and start the work in WG 2 with Conor Murray as convenor
- To confirm Frans Sauerwalt to continue as convenor of WG 4; Design and construction
- To form a new WG convened by John Hargreaves, to perform a Technical Report on Particle Sampling Techniques (see below)
- To prepare a technical report on clarification of issues associated with Particle Sampling Techniques
- To establish a liaison with IEC/TC 101 Electrostatics with Larry Levit as responsible

Pågående arbeten inom standardisering

Under de senaste två åren har arbetet med nationella och internationella standarder förändrats. Det har blivit möten via Webex, Zoom och Teams och med deltagare från kontor och hemarbetsplatser. Plötsligt har det varit möjligt att deltaga i möten utan att resa. Men den personliga kontakten och diskussionerna vid pauserna har försvunnit och inte helt ersatts av chatfunktionen. Teamkänslan har minskat.

INTERNATIONELLT

Arbetsgruppen för revision av **ISO 14644-4 :2001**, Cleanrooms and associated controlled environments - Part 4: Design, construction and start-up, har nu publicerad en ISO/DIS 14644-4 :2021 och kommentarer ska lämnas av respektive lands standardiseringsorgan. Mellan de olika versionerna CD ISO 14644-4 2019, ISO 14644-4 2020 CD stage och ISO/DIS 14644-4 :2021 har många ändringar skett och nya punkter har tillkommit.

Det är viktig att kommentera standarden nu, då man i senare steg av ISO processen inte accepterar tekniska kommentarer.

Arbetsgruppen för **ISO TC 209 WG 11** Cleanroom and associated controlled environments – Part 18: Assessment of suitability of consumables, har hållit flera virtuella möten under året, det senaste under augusti. Inkomna kommentarer har diskuterats och ändringar i texten har gjorts. Det färdiga dokumentet ska ge vägledning krav på förbrukningsvaror tiil renrum, av både engångs- och flergångstyp, som t ex renrumskläder, handskar, städmaterial. För närvarande behandlas renrumskläder i ISO 14644-5:2004 Operations. När denna standard ska revideras kommer frågan om renrumskläder att diskuteras igen. WG 11 hoppas kunna presentera en CD under 2021.

Arbetet Inom **CEN TC 156/ WG 18** Ventilation in hospitals, har pågått under året och ett nytt möte planeras in under våren 2022. Genom tillägg i bilagor och vissa ändringar och tillägg tycks man komma närmare en teknisk specifikation som kan accepteras av hela Europa.

Arbetsgruppen **CEN TC 205/WG14** Surgical clothing and drapes, and medical face masks, har haft ett första projektmöte kring revisionen av EN 13795-2 Surgical clothing and drapes -Requirements and test methods – Part 2 Clean air suits.

NATIONELLT

Inom **SIS TK 333** Operationstextilier, har tillsatt två arbetsgrupper under året, en grupp för vägledning på svenska till EN 13795:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits. och en grupp för översättning till svenska av EN 13795:2019. Arbetet med vägledningen år i det närmaste klart och beräknas presenteras efter årsskiftet och ett seminarium kring vägledning är planerat till våren.

En översyn av gemensamma termer i vägledningen till SS-EN 13795, SS-EN 13795 och SIS TS-39 har påbörjats av en grupp med deltagare från **TK 527 och TK 333**.

SIS TK 527 Renhet i operationsrum, har tillsatt en grupp för revidering av TS 39:2015. Det reviderade dokumentet beräknas gå ut på en allmän remiss under våren 2022.

SIS TK 108 Renhetsteknik, har bytt tillhörighet nom SIS från verkstad till hälsovårdsektionen. Standarderna inom ISO 14644-familjen behandlas av denna TK.

New FDA Draft Guidance

MICROBIOLOGICAL QUALITY CONTROL OF NON-STERILE MEDICINAL PRODUCTS

Based on the experience of the past years, the FDA has published a new draft guidance that deals with the microbiological control of non-sterile medicinal products and clarifies it by means of case studies.

As a part of the news from CBER, the FDA published a new draft guidance on 30 September that is intended to help manufacturers of non-sterile medicinal products with microbiological quality control. It covers non-sterile solid, liquid and semi-liquid dosage forms (NSDs) such as topically applied creams, lotions and swabs, as well as oral solutions and suspensions. These may be prescription or non-prescription medicines as well as new drugs.

The New Guidance reflects the lessons learned from the FDA Adverse Event Reports (FAERs) and recalls due to contamination. From 2014 to 2017, 197 FDA Adverse Event Reports were recorded that were related to bacterial or fungal contamination, of which 32 were classified as serious adverse events. As the reporting is voluntary, the FDA assumes that the number of unreported cases is significantly higher.

For more details, please refer directly to the draft guidance Microbiological Quality Considerations in Non-sterile Drug Manufacturing, which is open for comment until 29 November 2021 via the FDA's dedicated website.

CTCB-I certifiering 2021

AV LARS EKBERG, CIT

I mitten av oktober, på Chalmers i Göteborg, hölls CTCB-I:s certifieringskurs i Norden för mätspecialister och beställare/granskare/utvärderare av mättjänster för renrum. Certifieringen utfördes enligt CTCB-I:s internationella riktlinjer, på två olika nivåer. Ett certifikat på Associate Level visar att man förstått teorin bakom renrumsmätningar och kan bedöma och förstå dokumentation från sådana mätningar. Ett certifikat på Professional Level intygar att man dessutom behärskar mättekniken och självständigt kan genomföra kontroller. I år kom deltagarna från Norge och Sverige.

Under dag 1 hölls en genomgång av det utsända kursmaterialet av Lars Ekberg, varvid deltagarna gavs möjlighet att ställa frågor kring kursmaterialet samt diskutera mätteknik, mätutrustning och mätproblem. Det skriftliga provet dag 2 med 60 frågor på kursavsnitten, genomfördes under ledning av Berit Reinmüller och Bengt Ljungqvist.

I försökshallen hade Håkan Larsson, Chalmers, tillsammans med Lars Jansson, MyAir, och Stefan Aronsson, CIT Energy Management, förberett allt inför eftermiddagens demonstration - där såväl mätutrustning som mätteknik visades och diskuterades.

Under dag 3 genomfördes de praktiska proven, som bedömdes av totalt sju examinatorer, Mari-Liis Maripuu, Lars Ekberg och Stefan Aronsson från CIT Energy Management, Lars Jansson, MyAir, Nils-Johan Björklund, CRC Clean Room Control samt Daniel Laggar och Johan Ahnfeldt, båda från Brookhaven.

När de praktiska proven avslutats samlades lärarna för att gemensamt gå igenom och sammanfatta resultaten under ledning av Lars Ekberg. När Berit Reinmüller rättat teoriproven stod det klart att tjugo personer var godkända och därför erhöll certifikat; sju på nivån Associate, tretton på nivån Professional. Ett extra tillfälle hölls i maj 2021 varvid ytterligare två kandidater certifierades på nivån professional. Detta betyder att totalt 22 personer har CTCB-certifierats under året. Ett stort tack riktas till alla lärare och företag som stöder CTCB-I certifieringen genom att medverka på plats under kursdagarna, genom att skänka filter och genom att låna ut mätutrustning till de praktiska proven.

Nya kurstillfällen för certifiering i Göteborg planeras till våren och hösten 2021. Detaljer om detta publiceras efter hand i kommande nummer av RenhetsTeknik, på föreningens hemsida samt på www safetyventilation.com. Planerade kurstillfällen i de andra medverkande länderna kan du läsa om på www.ctcb-i.net/courses.php.

Tänk på att antalet deltagare på Professional Level är begränsat, varför du som ska förnya ditt certifikat efter fem år bör anmäla ditt intresse så snart som möjligt till Lars Ekberg. För Associate Level är antalet inte lika begränsat. Anmäl ditt intresse på mailadressen: lars.ekberg@cit.chalmers.se. Certifierade kandidater presenteras på nästa sida.

Bild 4. Årets lärare och examinatorer, från vänster Berit Reinmüller, Daniel Laggar, Lars Jansson, Bengt Ljungqvist, Johan Ahnfeldt, Nils-Johan Björklund, Lars Ekberg och Stefan Aronsson (ej med i bild Mari-Liis Maripuu).







CTCB ASSOCIATE

Ovan fr v: Ola Forn. Kristian Waernes, Karoline Bondö Haug, Henrik Eriksson, Sturla Ingebrigtsen, Jonas Rask och Anders Moström Nilssen.

Ytterligare information om kandidaterna finns att läsa på www.safetyventilation.com










CTCB PROFESSIONAL

Ovan fr v: Erik Ristorp, Mikael Johansson, Johan Karlsson, Finn Tollef Hensrud, Per-Erik Karlsson, Per Johnny Hovin, Jan Terje Ytterstad, Einar Frengen, Bjørn Norberg samt Jan Mottlau och Jaz Christian Peoples.

Ytterligare information om kandidaterna finns att läsa på www.safetyventilation.com

EHEDG Advanced Course in Hygienic Engineering and Contamination Control

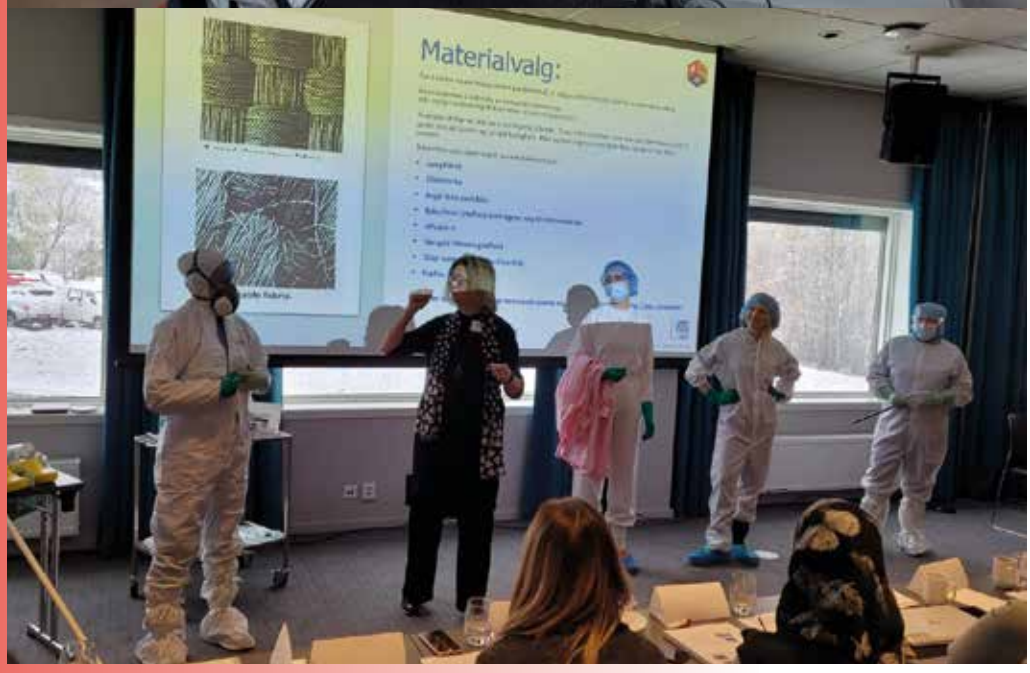
BY ALAN FRIIS, FORCE TECHNOLOGY

After a unvoluntary break on over two years we were finally able to gather people for a physical attendance course. The course was conducted by Gun Wirtanen, Firma Lövås and Alan Friis, FORCE Technology.

I was great to see that 14 participants from Finland, Sweden, and Denmark all with great interest in hygienic engineering and control of contamination had found their way to Brøndby on the outskirts of Copenhagen. The course is three day long and packed with an intense series of presentations and group works. Selected topics are legislation, hygiene hazards, pumps, valves, construction materials, cleaning, hygienic integration and maintenance. The participation is crowned with an exam just before lunch on the last day. And by the way all participants passed.

The participants were very active during the course and we had many good discussions over the three days.

GRUNNKURS NORGE



Endelig ble det mulighet for å holde vårt årlige R³ grunnkurs etter et opphold grunnet pandemien. Kurset ble holdt i regi av det norske LAU (Landets Arbeids Utvalg) i R³ Nordic som består av følgende personer: Barbro Reiersøl (AET), Phuong Ngoc Huynh (Sykehusapoteket Drammen), Hong Thanh Thi Nguyen (IFE) og Geir Valen Pettersen (NMS).

LAU Norge (fr v):
Phuong Ngoc Huynh, Barbro Reiersøl, Hong Thanh Thi Nguyen og Geir Valen Pettersen.

Årets «Grunnkurs i renromsteknikk» ble holdt 18 og 19 oktober 2021 på X Meeting Point som ligger på Skjetten. Vanligvis holdes kurset på Olavsgaard Hotell, som også ligger på Skjetten, men siden dette hotellet ble beordret som et beredskapshotell vedr. Corona karantene, måtte vi kort tid før kurset endre sted. Vi hadde planlagt å holde kurset for ca. 50 stk. på Olavsgaard Hotell, men siden vi kunne ta imot flere på det nye hotellet og pågangen var stor, endte vi opp med 73 deltagere. Deltagerne kom både fra det private og det offentlige næringslivet. Det ble en god spredning fra ulike bransjer. De som ønsket det, fikk bo på hotellet, noe man kunne velge ved påmelding.

Den første dagen startet med en kort introduksjon og presentasjon av kurslærere og deltakere. Deretter loset Kari Solem (COWI) oss gjennom de første timene. Hun tok for seg temaer som standarder i renrom, ventilasjon og luftbevegelse, konstruksjon og kvalifisering av renrom. Den siste forelesning om kontaminasjonsbegrepet ble holdt av Barbro Reiersøl (AET).

Dagen ble avsluttet med en felles middag for de som ønsket det. Under middagen hadde vi et musikalsk innslag av Mari og John Kenneth Melby

Den andre dagen ble startet av Barbro Reiersøl (AET) hvor temaet «Mennesket i det rene rom, arbeidsteknikk og påkledning» ble utredet. På slutten av denne forelesningen, fikk vi en mannekengoppvisning av fire personer av deltagerne som hadde iført seg ulike typer renromstøy. Her fikk publikum mulighet for å koble de ulike påkledingene til de ulike renromsklassene. En av disse hadde kledd seg på en slik måte som man ikke skal kle seg i renromsmiljø. Dette ble et populært innslag. Deretter overtok Kjersti Aulie (GE Healthcare) med en gjennomgang av mikrobiologi i renrom og ulike mikrobiologiske testmetoder. Kurset ble avsluttet av Barbro Reiersøl med temaet «Klær, vask og rengjøring».

Det var en jevn strøm av spørsmål under alle forelesningene og tilbakemeldingene fra kursdeltagerne var veldig bra. Vi hadde noen små problemer under kveldsmiddagen, men ellers ble kurset gjennomført på en bra måte.

Uppdrag: Innovationshubb för produktion av vaccin och avancerade läkemedel

Vinnova har fått i uppdrag av regeringen att etablera en innovationshubb för att möjliggöra produktion av avancerade läkemedel och vaccin i samverkan med företaget NorthXBiologics i Matfors.

- Konkurrenskraft skapas genom att bidra till lösningar på viktiga utmaningar - och pandemin har påmint oss om betydelsen av forskning, innovation och internationell samverkan på hälsoområdet, säger Darja Isaksson, generaldirektör för Vinnova.

Uppdraget att etablera innovationshubben för att gynna kompetens- och kapacitetsutveckling är ett tydligt steg i den riktning som vi pekade ut i rapporten om Sveriges kapacitet att producera vaccin. Rapporten lämnades till Regeringen i våras

- Vi ser fram emot att bidra till en öppen innovationsmiljö för avancerad läkemedelsproduktion i Matfors till nytta för svensk konkurrenskraft, vår beredskap för framtida utmaningar och internationella samarbeten. Det här är en viktig pusselbit som kompletterar Sveriges redan starka life science-sektor.

www.vinnova.se/nyheter/2021. Publicerad: 15 oktober 2021

Fotonräknande datortomograf baserad på kiselteknik

Världens första fotonräknande datortomograf baserad på kiselteknik testas på Karolinska Universitetssjukhuset
Svensk innovativ teknik från Kungliga Tekniska Högskolan testas i en klinisk forskningsmiljö på Bioclinicum, Karolinska Universitetssjukhuset. Bättre bildkvalité och lägre strålningsdos kan förbättra diagnostiken på en rad områden, bland annat för cancer och hjärt- kärlsjukdomar.

Fotonräknande datortomografer kan, till skillnad från vanliga datortomografer, mäta energin för varje röntgenstråle i hela spektrumet av strålning. Det ökar kontrasten i bilden och gör att man kan ta bort det så kallade elektroniska bruset, vilket gör det möjligt att särskilja vävnader på ett bättre sätt och minska strålningsdosen.

Datortomografens detektor som räknar fotonerna är unik och har tagits fram av Mats Danielsson, professor vid KTH. Till skillnad från andra detektorer är den gjord av kisel vilket är det renaste materialet och den bästa lösningen för datortomografer i klinisk miljö.

Staffan Holmin, professor vid Karolinska Institutet och överläkare vid ME Neuroradiologi på Karolinska Universitetssjukhuset, leder den kliniska prövning som ska testa och optimera tekniken.

– Vi genomför nu en pilotstudie och är först i världen med att testa den här tekniken, vilket vi är väldigt stolta över. Det känns bra att vi är utvalda. Den internationella konkurrensen från de bästa universiteten är hård och många var intresserade av att genomföra studien, förklarar Staffan.

Tekniken har ett mycket brett användningsområde där flera olika organsystem kan avbildas. I studien jämförs bilderna från studiedeltagarnas undersökningar med bilder som tagits med vanliga datortomografer. Studien ger även ett större bildmaterial som används till vidare bildbehandlingsoptimering.

- Efter pilotstudien följer fler kliniska prövningar med större antal deltagare och ytterligare optimering av bildkvalitén innan tekniken kan införas i vården, säger Staffan.

Projektet är ett resultat av nära samarbeten mellan hälso- och sjukvården, akademi och näringsliv. Det tvärvetenskapliga centrumet MedTechLabs som finansieras av Region Stockholm, Karolinska Institutet och Kungliga Tekniska Högskolan, har spelat en särskilt viktig roll.

Presstjänsten Karolinska Universitetssjukhuset, oktober 2021
news.cision.com/se/karolinska-universitetssjukhuset

God Jul &

Ny grupp av antibakteriella substanser

Få nya sorters antibiotika har utvecklats under de senaste 50 åren.

Forskare vid Karolinska Institutet, Umeå universitet, och Bonns universitet har identifierat en ny grupp molekyler som har antibakteriell effekt mot många antibiotikaresistenta bakterier. Eftersom molekylernas egenskaper lätt kan förändras kemiskt är förhoppningen att kunna utveckla nya, effektiva antibiotika med få biverkningar. Resultaten har publicerats i den vetenskapliga tidskriften PNAS.

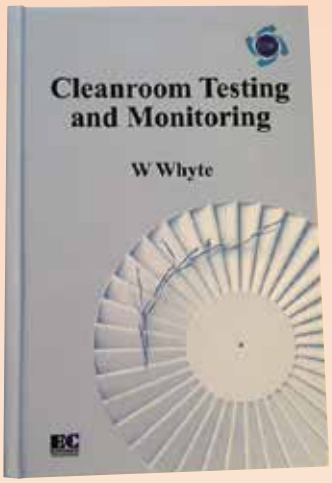
Den ökande antibiotikaresistensen i världen är alarmerande, samtidigt som få nya sorters antibiotika har utvecklats under de senaste 50 åren. Det finns därför ett stort behov av att hitta nya antibakteriella substanser.

Majoriteten antibiotika som används kliniskt verkar genom att hämma bakteriernas förmåga att bilda sin skyddande cellvägg, vilket gör att bakterierna spricker (lyserar). Det välkända antibiotikumet penicillin hämmar enzymer som bygger upp cellväggen. Nyare antibiotika som daptomycin eller det nyligen upptäckta teixobaktin binder i stället till en speciell molekyl, lipid II, som alla bakterier behöver för att bygga upp cellväggen. Antibiotika som binder till denna byggsten i cellväggen är vanligtvis mycket stora och komplexa molekyler och därför svårare att förbättra med kemiska metoder. De är dessutom vanligen inaktiva mot vissa problematiska bakterier som omges av ett yttre cellmembran, som förhindrar penetration av dessa antibakteriella substanser.

– Lipid II är en mycket attraktiv måltavla för nya antibiotika. Vi har identifierat de första små antibakteriella substanserna som verkar genom att binda till denna fettmolekyl, och i vår studie hittade vi inga resistenta bakteriemutanter vilket är mycket lovande, säger Birgitta Henriques Normark, professor vid institutionen för mikrobiologi, tumör- och cellbiologi, Karolinska Institutet, och en av artikelns tre korresponderande författare.

Karolinska Institutet Nyheter (ki.se)
Foto: Getty Images

Nytt kursmaterial för CTCB-I



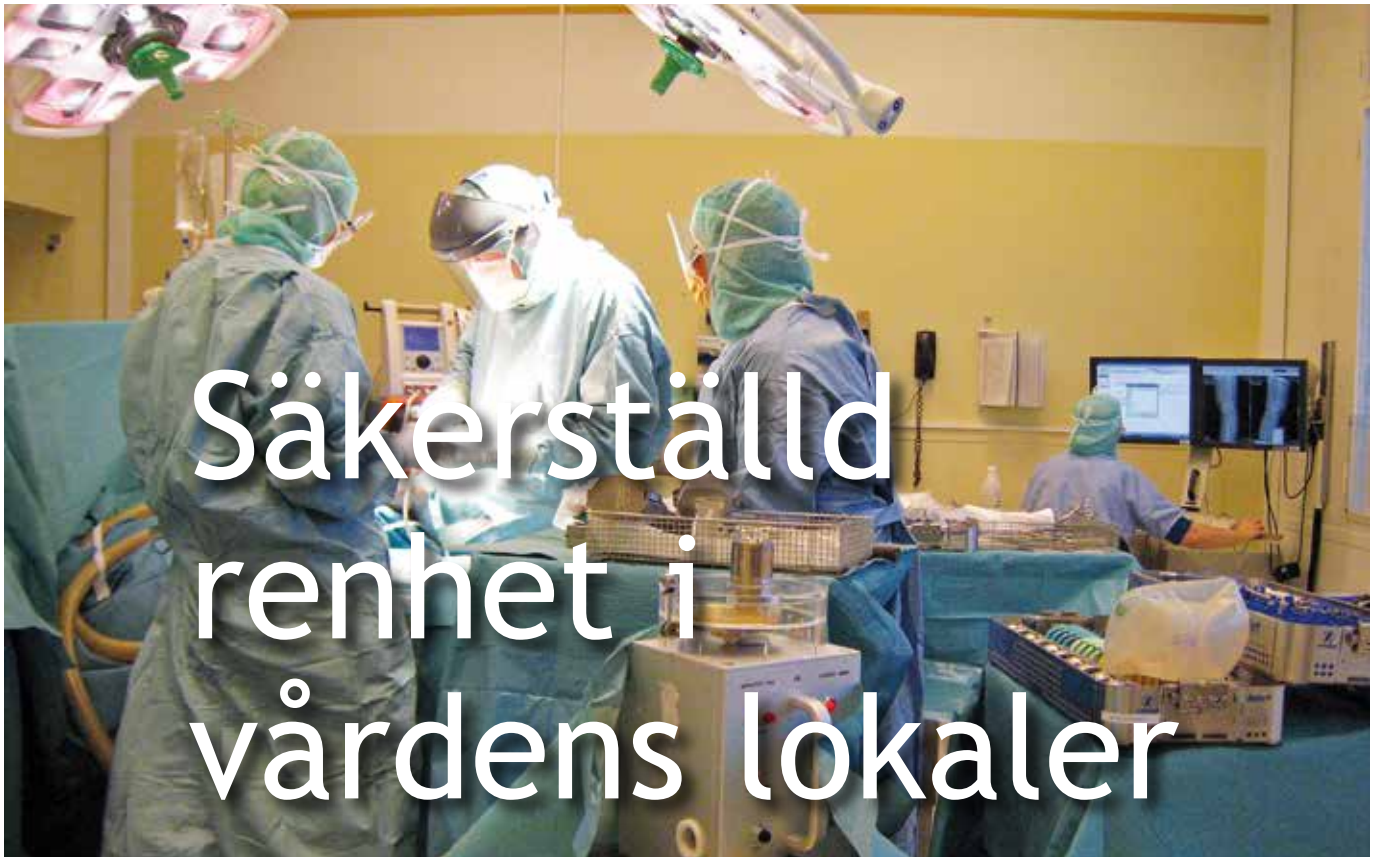
Under november höll CTCB-I sitt årsmöte på nätet med styrelsemedlemmar från de olika organisationerna baserade i UK, Nederländerna, Irland, Turkiet och Norden.

Utveckling och uppdatering av certifieringskurserna och av kursen Cleanroom Technology diskuterades. Bill Whyte, en av initiativtagare till CTCB, presenterade sin bok ”Cleanroom Testing and Monitoring” pulicerad av Euromed Communications. Boken kommer att ersätta kursmaterialet i de internationella certifieringskurserna. Copyright för boken överlämnades av författaren till CTCB-I, som tacksamt accepterade det generösa erbjudandet.

Boken kan beställas via Lars Ekberg, CIT, på mail ctcb-gothenburg@cit.chalmers.se
Mobil +46 (0)703 15 11 55

Companies and members who want to participate with a release, must send this well in advance of script stop to editor Alan Früs.

Gott Nytt 2022



Säkerställd renhet i vårdens lokaler

AV LENNART HULTBERG, PROJEKTLEDARE

Skriften **”Projekteringsprocess för att uppnå optimal lokalfunktion med avseende på renhet”** ligger nu färdigt för att tryckas. Dokumentet, ägs av R³ Nordic och LÖF.

En presentation och diskussion kring arbetets tillämpning kommer att ske vid R³ Nordics sjukhusdag i Uppsala den 2 februari.

TVÅ HUVUDMÅL

Arbetet har haft två huvudmål; Dels att förtydliga och stärka begreppet ”renhet”, partikulär och mikrobiologisk, vid projektering av vårdlokaler och dess tekniska försörjningssystem, dels att säkerställa vårdverksamhets krav och behov. Vårdverksamhetens representanter ska finnas med i hela projektprocessen, från programskrivning, projektering till drift och förvaltning. Kontroll av att projektets formulerade krav och ambitioner uppfylls sker genom risk- och konsekvensbedömningar under under projektprocessens alla steg. I dokumentet ges exempel på hur riskbedömning kan utformas och nyttjas för ett operationsrum.

FÖRUTSÄTTNINGAR OCH METODIK

En grundförutsättning för vårdarkitektur och teknikutformning är att nivåer på renhet tydliggörs. Detta gäller för vårdenhetens samtliga lokaler, där nivån varier från exempelvis allmänna utrymmen till rum med krav på kontrollerad renhet som operationsrum och sterilcentraler. Metodiken kan tillämpas från specialistsjukhus till vårdcentraler. Grundläggande är därvid att förväntade flöden; patient-, personal-, material- och utrustningsflöden, redovisas och att detta är baserat på hur verksamheten är planerat att bedrivas. Underlag för ventilationsteknisk utformning och behov av sektionering blir därmed tydliggjord och möjlighet att nyttja samordning med brandskydds- och säkerhetsutformning.

Dokumentet ger ett förtydligande av begreppen renhet och renhetsteknik och hur renhetsnivåer i olika rum kan beskrivas. Vidare beskrivs projektprocessens olika delar; från programarbete till drift och förvaltning, med fokus på säkerställd renhet. Detta innefattar att åtgärdsstrategi och ansvarsförhållande klarläggs redan under programarbetet. Det är viktigt att betona att dokumentet inte redovisar färdiga tekniklösningar utan istället presenterar ett underlag för att stärka vårdens roll i utformning av nya och befintliga lokaler. En vägledning och konkret stöd ges i den bilaga ”Vägledning och frågeställningar för säkerställd renhet i vårdlokaler” som kompletterar huvuddokumentet.

R³ NORDIC INBJUDER TILL

Sjukhusdagen

2 februari 2022
Uppsala

Säkertställd renhet i Vårdens lokaler

”LÖF, Regionernas Ömsesidiga Försäkringsbolag, har som ett av sina viktiga uppdrag att arbeta för ökad patientsäkerhet. Detta sker bland annat genom att presentera olika expertdokument.

I samverkan med R³ Nordic, presenteras nu skriften ”Krav att beakta i projektprocessen för att uppnå optimal lokalfunktion med avseende på renhet”. Denna lägger fokus på renhet, mikrobiologisk, visuell och partikulär, i vårdens lokaler. Detta ska ske i projektprocessens alla skeden; från utrednings- och programarbeten, under projekteringsprocessens olika delar, under byggnation samt under driftskedets olika faser.

Arbetet syftar till att verksamhetens behov och rutiner får ett genomslag i utformningen av lokaler och tekniska försörjningssystem. Detta sker genom att stärka en aktiv medverkan från verksamheten i utrednings- och programarbete. Detta tydliggörs genom att redovisa arbetsmetodik, förväntade person- och materielflöden och definiera erforderliga renhetsnivåer.

En metod för riskbedömning presenteras och exempel på tillämpning exemplifieras. Denna ska kunna användas i projektprocessens alla skeden. Resultatet, förändrade förutsättningar och eventuella avvikelser och konsekvenser ska redovisas för verksamhetens representanter. Riskbedömningen blir således ett verktyg för att säkerställa att uppställda krav uppfylles.

Projektledare för arbetet har varit Lennart Hultberg.”

Prof Jan Gustén, Chalmers Tekniska Högskola

Anmälan på mail till Lennart Hultberg
lennart@processhygien.com

R³ NORDIC INBJUDER TILL

Grundkurs i renhetsteknik

Flyttad till 2022?
Prel Uppsala

PREL PROGRAM DAG 1:

09.00-11.00	Kontaminanter och partikelmätning
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

PREL 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 7.850,- (R³-medlem 7.200,-)

Inkluderar kursmaterial, diplom, lunch, kaffe fm och em.
Information om kursen lämnas av Lennart Hultberg
Telefon +46 (0)760 399 500/ lennart@processhygien.com

Kursansvarig:
Lennart Hultberg, R³ Nordic

Anmälan
www.r3nordic.org

Anmälan till alla våra kurser ska vara skriftliga och är bindande. Avbokning ska ske skriftligen och inkomma minst en månad före kursstart för att kursavgiften, minus avdrag med 500 kr, ska 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. R³ 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.

MARKNADSGUIDE

FÖRETAGS- & BRANSCHREGISTER ÖVER STÖDJANDE MEDLEMMAR I R³ NORDIC

DK DANMARK +45 FIN FINLAND +358 NO NORGE +47 SE SVERIGE +46

FÖRBRUKNINGSMATERIAL FÖRPACKNING PROCESS

AET ARBEIDSMILJØ OG ENERGITEKNIKK AS (NO)
Ing.firma, prosjektering, produkter for renrom.
Tel 23 06 73 30 / info@aet.no

INREM AB (SE)
Pincetter, kläder, torkdukar, svabbar, handskar, klibbmattor, renrumspapper, skor, stolar mm
Tel 08-59080720 / info@inrem.se

INSTRUMENT ÖVERVAKNING VALIDERING KALIBRERING

MY AIR AB (SE)
Kontroll och validering för att minimera luftburen smitta och säkerställa processer
Tel 072-503 84 59 / lars.jansson@myair.se

NINOLAB, AB (SE)
Partikelräknare, automatisk övervakning. Bänkar. LAF-tak, luftduschar. Niklas Nordin.
Tel 08-59096200 / info@ninolab.se

PARTICLE MEASURING SYSTEMS (DK)
Partikelräknare, sensorer och system.
Lars Peter Kristensen, Tel: 25 21 82 88
lpkristensen@pmeasuring.com

PSIDAC (SE)
Gain control and safer healthcare environments - CPS 6000 Monitor System
Björn Österlund / www.psidac.com

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. Niklas Nordin.
Tel 08-59096200 / info@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

COWI AB (SE)
Teknikutveckling, miljöteknik och projektledning
Torbjörn Lång / trla@cowi.com

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

VENTILATOR RENRUM, INDUSTRI AB (SE)
Renrum, säkerhets- och sterilbänkar. Lufttak. Projekt ventilation, entreprenader, utrustning.
Tel 070-9711454 / bjarne.osterberg@ventilator.se

RENRUM OP-RUM LAF INREDNING BÄNKAR TAK

AET ARBEIDSMILJØ OG ENERGITEKNIKK (NO)
Ing.firma, prosjektering, produkter for renrom.
Tel 23 06 73 30 / info@aet.no

CRC MEDICAL AB (SE)
Kundunika renluftslösningar för miljöer med mycket höga krav i sjukhus och sterilcentraler
070-389 63 22 / anders.rehn@crcmed.com

CAVERION SVERIGE AB (SE)
Clean-Plus®: nyckelfärdigt renrum inkl proj, tillverkning, leverans, montering och validering.
070-6188052 / henrik.fredlund@caverion.se

MENARDI FILTERS EUROPE A/S (DK)
Renrum. OP-tak.
Tel (070) 521 2565
anders.lofgren@menardifilters.com

NINOLAB AB (SE)
Renrum, säkerhets- och sterilbänkar. LAF-tak (ScanLaf), Thermo Partikelräknare (MetONE)
Tel 08-59096200 / info@ninolab.se

INREM AB (SE)
LAF-enheter, moduler, säkerhetsbänkar etc
Tel 08-59080720 / info@inrem.se

VENTILATOR RENRUM, INDUSTRI AB (SE)
Renrum, säkerhets- och sterilbänkar. Lufttak. Proj ventilation, entreprenader, utrustning.
Tel 070-9711454 / bjarne.osterberg@ventilator.se

RENGÖRING STÄDNING

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

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

RENRUMSKLÄDER TEXTILIER TVÄTTNING

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

BERENDSEN TEXTIL SERVICE AB (ELIS) (SE)
Renrumstvätteri. Renrumskläder.
Tel 020-740116 / goran.nilsson@elis.com

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

VENTILATOR RENRUM, INDUSTRI AB (SE)
Renrum, säkerhets- och sterilbänkar. Lufttak. Proj ventilation, entreprenader, utrustning.
Tel 070-9711454 / bjarne.osterberg@ventilator.se

VENTILATION FILTER

CAMFIL SVENSKA AB (SE)
Renluftslösningar. HEPA-, ULPA och gasfilter. Till- och frånluftsdon. www.camfil.se
Tel 08-6030800 / lotta.rosenqvist@camfil.se

INREM AB (SE)
Filter för renrum
Tel 08-59080720 / info@inrem.se

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