Renhets TEKNIK

THE NORDIC JOURNAL OF CONTAMINATION CONTROL AND CLEANROOM TECHNOLOGY NR 1:2020

Welcome to Naantali in May

INVITATION · PROGRAMME · REGISTRATION · EXHIBITION · ABSTRACTS

- ALAN FRIIS NY REDAKTÖR EFTER BERIT REINMÜLLER
- INTERNATIONELLA RAPPORTER · STANDARDISERING · INBJUDNINGAR

RenhetsTEKNIK

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r³ nordic

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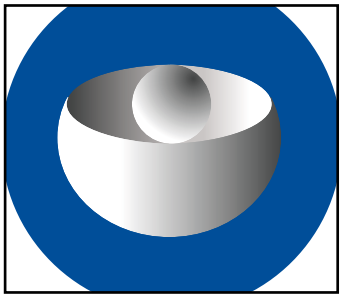
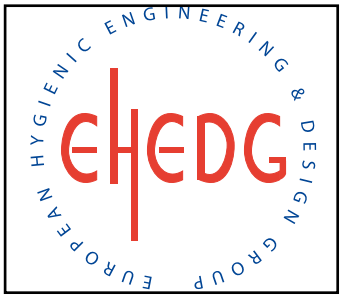
INNEHÅLL





For those of you who would like further information in English about the magazine, articles, advertising or others, please contact the editor (Redaktör).

OMSLAGSBILD / COVER:
FOTO: Naantali Spa, Tampere, Finland (Bild från Naantali Spa bildarkiv)

ORDFÖRANDE HAR ORDET

NU ÄR DET VIKTIGT ATT TVÄTTA HÄNDERNA!

En god handhygien är alltid viktigt, detta kom Ignaz Semmelweis fram till under sitt arbete med barnsängsfeber på första förlossningskliniken i Wien 1847. Av olika anledningar kom hans idéer till större nytta först ett tiotal år senare. Att etablissemanget inte erkände hans upptäckter tidigare, ledde till att tusentals unga mödrar dog i onödan men Semmelweis fick slutligen upprättelse. Detta fall tas ibland upp som exempel på att vetenskapliga framsteg försinkas av de etablerade yrkesmännens tröghet.

CORONAVIRUSET

Dagens medialt stora farosot är Coronavirus. Här är en kort bakgrund om några, sedan tidigare ”kända” Coronavirus:

- Det finns ett stort antal virus som tillhör familjen Corona, flest hos olika djurarter. Endast ett fåtal smittar mellan djur och människor.
- 2003–2004 bröt en epidemi ut av ett nytt Coronavirus som kallas Sars. 8 000 människor smittades och över 750 dog.
- 2012 upptäcktes på arabiska halvön en ny variant av coronavirus som kallas Mers. 2 000 personer drabbades, 700 dog.
- Det nya coronaviruset som kallas n2019-CoV har kopplats till en fiskmarknad i den kinesiska staden Wuhan. Spridning från Kina, Iran och norra Italien är välkänd och våra nordiska länder har också rapporterade fall. Hur stor påverkan den kommer ha på mänsklighet får vi återkomma till i framtiden.

VAD KAN VI GÖRA?

Vi har varje år våra vanliga ”influensa” vilket också ger dödsfall och smittspridning. Så vad kan vi göra? Jo, vara noggranna med att tvätta händerna med varmt vatten och tvål. Känner man sig dålig stanna hemma och kontakta sjukvården hemifrån (minska smittspridning).

Undvik också att ta dig i ansiktet i onödan. Behöver man nysa eller hosta gör en ”renrums nysning/hostning i armveck eller armhåla” - den information ger vi på våra grundkurser.

Den kunskap vår förening förmedlar är både bred och djup. Sprid därför information om vår förening så att vi blir fler medlemmar och vårt nätverk stärks. Till skillnad från mycket annat som sprids via media och sociala närverk, kan vi nog enas om att detta är till positiv gagn för alla.

VAD HÄNDER UNDER 2020?

Planeringen inför årets symposium i Finland pågår. Allt presenteras i denna utgåva. Missa inte detta tillfälle att fylla på kunskapsbanken. Hoppas vi ses i Finland den 25-27 maj!

Årsmötet genomförs i samband med vårt symposium i lokalen Louise. Kom och gör din röst hörd. Vill du delta i styrelse eller landsutskott (LAU) så kontakta vår valberedning.

Grundkurser kommer att arrangeras i Norge och Sverige under hösten. Vidare kommer CTCB kursen att genomföras. Vi anordnar även öppna kurser och företagsspecifika utbildningar.

Är det något ni skulle önska att föreningen tar fram inom utbildningsområdet, så kontakta mig gärna på 0760-399500.

LENNART HULTBERG
ORDFÖRANDE I R³ NORDIC

KALLELSE TILL FÖRENINGENS ÅRSMÖTE

Härmed kallas R³ Nordics medlemmar till föreningens årsmötesförhandlingar måndag 25 maj kl 17.00 på Naantali Spa *(Louise)* i Tammerfors, inför årets Symposium!

Möteshandlingar

kommer att finnas på hemsidan!

Styrelsen för R³ Nordic

KALENDER

2020

Mars

30-1 2020 PDA Annual Meeting
Raleigh, NC, USA

April

1-2 PHSS Aseptic Processing and Contamination Control Syndicate
Marriot Worsley Park, Worsley, UK

2 The Future of Danish and Swedish Life Science, Lund, Sweden

Maj

25-27 51st R3 Nordic Symposium and Exhibition, Naantali, Finland

Jun

9 PHSS Conference; Challenges in Sterile Products Manufacture 2020
Knutsford, Chesire, UK

Sep

12 PHSS Annual Meeting
London, UK

Okt

Grundkurs Renhetsteknik
Akademiska Sjukhuset, Uppsala

6-7 CTCB-I certifiering, Associate level, Göteborg

6-8 CTCB-I certifiering, Professional level, Göteborg

10-17 ISCC'20 Contamination Control Everywhere in our lives,
Antalya, Turkey

19-21 15th Ammual PDA Global Conference on Pharmaceutical Microbiology
Washington, USA

20-22 EHEDG Advanced Course
Tetra Pak, Lund

Nov

Grunnkurs Renhetsteknikk
Olavsgaard Hotel, Skjetten

Nästa nummer
beräknas utkomma före midsommar juni 2020

Manusstopp / Annonsbokning:
25 maj 2020

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

REDAKTÖRENS SPALT

Jeg vil gerne præsentere mig selv som ny redaktør for RenhetsTeknik. Jeg har lidt 'on and off' været med i R3 Nordic gennem de seneste 20 år. Jeg sidder i Styrelsen på 6. år som dansk repræsentant. I mit professionelle virke er jeg leder af Center for Hygiejnisk Design på FORCE Technology, hvor vi som en af hovedaktiviteterne tester og certificerer rengøreligt udstyr efter principper udstukket af European Hygienic Engineering and Design Group (EHEDG). Jeg har min største erfaring inden for design af hygiejniske produktionssystemer til fødevareindustrien, hvilket også dækker internationale standarder og guidelines for hygiejnisk design, renhold af processer og validering heraf. Jeg har gennem karrieren været samlet 25 år på Danmarks Tekniske Universitet, hvor fødevareteknologi og hygiejnisk design har haft stor fokus. Senest har jeg været selvstændig konsulent også med fokus på fødevareproduktion og hygiejnisk design.

Jeg glæder mig til at være redaktør og til at have interaktion med alle jer, som bidrager til, at vi har et levende og relevant RenhetsTeknik til gavn for medlemmerne.

EHEDG

Noget af det jeg personligt vil bidrage med til RenhetsTeknik er, viden om og anvendelse af EHEDG's design principper og certificeringsprogram. Selvom EHEDG traditionelt har haft sit hovedfokus på fødevareindustrien, specielt det at bidrage hygiejnisk design og god rengørelighed af udstyr hertil, så er der meget i de grundlæggende principper, som kan anvendes på tværs af brancher som har fokus på et højt niveau af renhed. EHEDG har mere end 44 guidelines. Hvor en række af de tidlige guidelines har fokus på design af komponenter så har de nyeste har mere fokus på procedurer for designprocesser og validering af CIP-rengøring. EHEDG's certificeringsprogram bygger på specifikationer i guidelines. Certificering af lukket udstyr ser i grundniveauet til anvendelse under CIP, men der kan med yderligere test certificeres til anvendelse i aseptisk produktion.

I DETTE NUMMER

Dette nummer fokuserer på symposiet i Nordendal i Finland til maj, som jo er R3's største begivenhed med fagligt program og sideløbende udstilling. Samtidig med symposiet afholdes årsmødet, som du finder indkaldelse til her i RenhetsTeknik. Som sædvanlig bringer vi også nyt om arrangementer.

TAK TIL MIN FORGÆNGER

Sluttelig vil jeg sige tak til Berit Reinmüller for hendes store og meget engagerede indsats som redaktør for RenhetsTeknik gennem mange år. RenhetsTeknik har haft en høj kvalitet så det bliver svært at udfylde pladsen efter dig.

ALAN FRIIS
REDAKTÖR

Invitation to the 51st R³Nordic Symposium & exhibition

Naantali Spa, Finland, May 25-27, 2020

The 51st R³ Nordic Symposium takes place on 26th-27th of May 2020.The venue of the event is Naantali Spa in the sunshine town Naantali on the south-west coast of Finland.The President of the Republic of Finland stays in the presidential summer residence Kultaranta during the summer and for that reason Naantali can be considered the holiday capital of Finland.We are allowed to use photos from Naantali Spa's image gallery. (www.naantalispa.fi)

PROGRAMME

The Program Committee 2020 (PK20) likes to inform that arrangements of the R³ Symposium 2020 are in good progress. The programme will cover the use and applications of cleanroom technology and contamination control within the pharmaceutical, food and biotech industries and hospitals as well as general knowledge and news in cleanroom technology. Both the scientific and the social programs are under finalization. Most of the session speakers have confirmed their attendance.

Our keynote speakers cover topics on good manufacturing practices and contamination control in cleanroom zones. These topics are in focus in this issue of Renhetsteknik (RT 1:20). Confirmed lectures with speakers are presented in more detail in the updated symposium program. Abstracts are published in this issue of Renhetsteknik. Updated material is also found on the homepage.

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-2020. In case you need accommodation at Naantali Spa and want to take part in the dinner(s), this should be included in the Registration form signed and submitted to guliwi@luukku.com. Registration through the homepage have two possibilities for payment, either by card or through invoicing. The preferred payment should be ticket before submitting the electronic registration.

According to general data protection regulation (GDPR) we are publishing only the names of the participants by country; no further information will be in the participant list. Note also that photos taken at the event will be published in Renhetsteknik and on the R³ Nordic homepage.

EXHIBITION

The annual exhibition is arranged in conjunction with the symposium. Some of the exhibition stands have already been booked, please, see the map. There are still available stands. Please, contact Gun Wirtanen (guliwi@luukku.com), if you are interested in reserving a stand. Please read more on page 10.

SOCIAL ARRANGEMENTS & ACCOMMODATION

All participants are warmly invited to take part in the evening events, a Get-together party on Monday evening and the banquette onTuesday evening (read more on page 11).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 programme committee by end of April 2020.Thereafter PK20 cannot 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 can be found from the website www.r3nordic.org/ symposium-2020.

SPECIAL OFFER "GO 3 PAY FOR 2"

Our early-bird special offer "Go 3 Pay for 2" for industrial delegates is valid until 15th of April 2020. Please, note that prices will raise from 16th of April 2020. The participant fee for persons coming from hospitals, educational institutions etc. is also given and those prices You find in the column "Public & Municipal".

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

PROGRAMME COMMITTEE MEMBERS

Leila Kakko	PK20 Chairperson, General	leila.kakko@tuni.fi
Kari Leonsaari	Pharma & News	kari.leonsaari@santen.com
Inga Mattila	PK20 Secretary & Social events	inga.mattila@vtt.fi
Raimo Pärssinen	Food & Biotech	raimo.parssinen@turkuamk.fi
Miko Stenman	Pharma & Social events	miko.stenman@stennova.com
Jukka Vasara	Hospital & News	jukka.vasara@granlund.fi
Gun Wirtanen	Exhibition & 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 Gun Wirtanen
guliwi@luukku.com

To
obtain discounted prices
please return the filled form at
latest April 8, 2020

Registrate Online
and charge your credit card
The discounted prices Online are available until April 15, 2020 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 April 17, 2020, all fees will be refunded except for a cancellation fee at 250 €.
No refunds will be made after April 18, 2020. 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 26 ☐ May 27 ☐ May 25-26 ☐ May 26-27 ☐ May 25-26-27

REGISTRATION FEES FOR PARTICIPANTS (€)	**Commercial** Before April 15	**Commercial** After April 16	**Public & Municipal** Before April 15	**Public & Municipal** After April 16	**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 non-members you also have to pay the member fees incl. admin. (75 €).

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 15**	**Price after April 16**	**Total EURO**
Get-together ticket (Monday May 25)		**65**	**80**	
Banquet ticket (Tuesday May 26)		**100**	**115**	
HOTEL ACCOMONDATION	**Nights**	**Price before April 15**	**Price after April 16**	**Total EURO**
Naantali Spa, Singel room		**138**	**162**	
Naantali Spa, Double room		**158**	**186**	

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.

Programme

MAY 25

07.00-16.30	*Exposet is building the exhibition area*
16.30-20.00	*Exhibitors Set Up / Equip Their Stands*
17.00-18.00	*R³ Nordic Annual Meeting In Louise*
18.30-20.00	*R³ Olympics*
20.00-22.00	*Get-Together Dinner In The Seaview Lounge*

PROGRAMME DAY 1 - TUESDAY MAY 26

08.00-09.30	*Registration, Coffee/Tea & Exhibition*		
09.30-10.00	*Opening of the Symposium & Exhibition*		
10.00-10.30	*Head of Department, Senior Physician Veli-Jukka Anttila, Helsinki University Hospital: Keynote Lecture - Hospital: Operation Room Ventilation and Risk of Postoperative Infections*		
10.30-11.15	*Frans Saurwalt, Kropman: Keynote Lecture: New Developments in Cleanroom Design (ISO 14644-4 rev)*		
11.15-12.30	*Lunch & Exhibition*		
	PHARMA *(BALLROOM)*	**HOSPITALS *(LOUISE)***	**CLEANROOM NEWS / GENERAL *(KAISA)***
12.30-13.00	*James L. Drinkwater, PHSS:* PHSS Initiative in Preparation of Clarity on GMP Guidance	*Aleksanteri Setälä, Helsinki University: Hospital:* Operating Room Ventilation and AC Design Guide	*Camilla Höglund, LED Tailor:* Chemical Free Disinfection Technique
13.00-13.30	*Mervi Saukkosaari, Fimea:* Current Topics in GMP and Inspection Findings in Sterile Manufacturing	*Pedro Gandra, Considero:* Practical Safety Ventilations In Ultraclean Air Operating Rooms	*Francisco Forns-Samso, Granlund Oy:* Digital twins: What is the Value Behind All the Hype?
13.30-14.00	*Steve Marnach, DuPont:* GMP Annex 1 - Selection Criteria of Protective Cleanroom Garments	*Jukka Vasara, Granlund Oy:* Factors Influencing the Cleanliness of Operating Rooms	*Ilpo Kulmala, VTT Oy:* Environmental Contamination and Risk of COVID-19 Transmission at Airports
14.00-15.00	*Coffee & Exhibition*		
	PHARMA *(BALLROOM)*	**HOSPITALS *(LOUISE)***	**CLEANROOM NEWS / GENERAL *(KAISA)***
15.00-15.30	*Timo Kangasmaa, Finnish Red Cross: Blood Service:* Isolator Design and Maintenance	*Kari Solem Aune, COWI AS:* Prefabricated Operating Rooms	*Esa Högel, Valtria Swiss AG:* Layout Based on Plenum integrated Filter Fan Units in Clean Room
15.30-16.00	*Berit Reinmüller, Chalmers:* Microbial Risk Assesment in Safety Cabinets	*Perttu Karjalainen, Granlund:* Operating Room Extraction Systems	*Simone Biel. Merck Life Science:* Single-Use Technology for Aseptic Processing to Meet Requirements
16.00-16.30	*Jochen Wirsching, Vileda Professional:* Microfiber Wiping in Residue Removal in the Context of GMP Annex 1 Revision	*Roberto Traversari, TNO:* Technical Specification Decvelopment - Ventilation in Medical Locations	*Kristina Smith Hansen, Milcor Consulting:* Understanding the Roots to Human Workplace Errors
16.30-17.00	*Smoothie & Exhibition*		
19.00-00.00	*Banquet Dinner*		

PROGRAMME DAY 2 - WEDNESDAY MAY 27

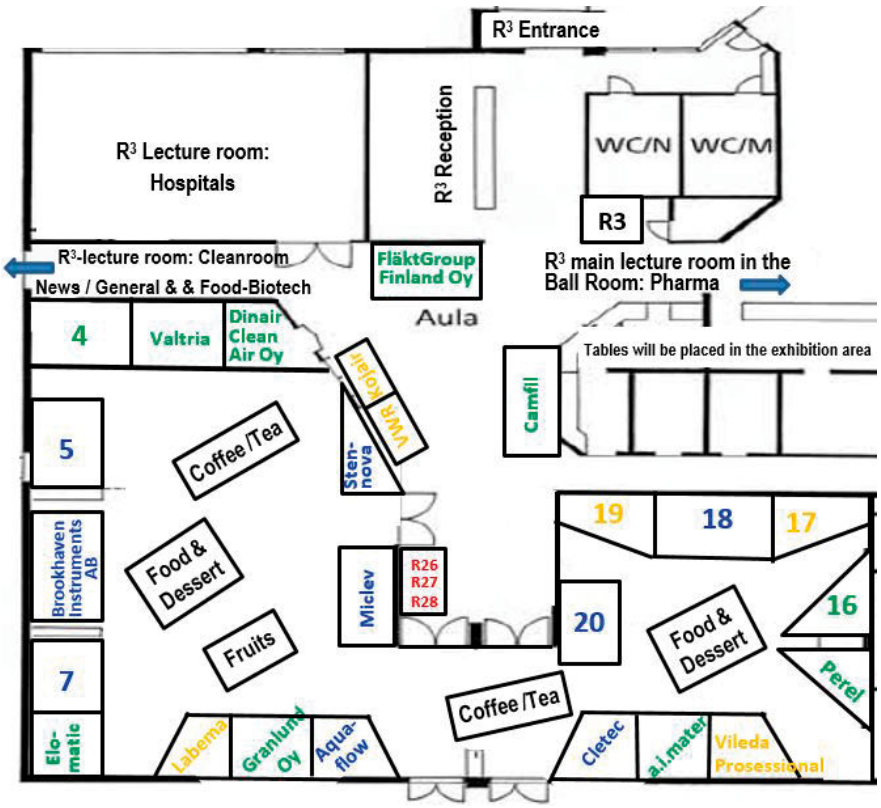
	PHARMA *(BALLROOM)*	**HOSPITALS *(LOUISE)***	**FOOD & BIOTECH *(KAISA)***
08.30-09.00	*James L. Drinkwater, PHSS:* Contamination Control Strategy - Annex 1 Requirement	*Kari Solem Aune, COWI AS:* Sterilization Department	*Steven Deretz, CRDB:* Challenges in Clean Room Projects
09.00-09.30	*Tony Lönnbäck, Elomatic Oy:* Basics of Risk-Based Commissioning, Qualification and Validation	*Frans Saurwalt, Kropman:* Pass through Boxes Design and Performance Testing	*Alan Friis, FORCE Technology & Tech4Bizz:* Hygiene Design as a Support in Planning Controlled Food Premises
09.30-10.15	*Coffee & Exhibition*		
	PHARMA *(BALLROOM)*	**HOSPITALS *(LOUISE)***	**FOOD & BIOTECH *(KAISA)***
10.15-10.45	*Matt Cokely, Ecolab:* Regulatory Requirements and Expectations Including a Review of the New GMP Annex 1	*Hannu Koskela & Petri Kalliomäki, TUAS:* Air Flow Patterns in Hospital Isolation Rooms – CFD Simulations	*Riina Brade, Elomatic Oy & Jim Nyroos, Cadmatic Oy:* Future Food Production Unit - From Designers' Desk to Operational Effiency
10.45-11.15	*Marc Schmidt, AAF - Lufttechnik Gmbh:* Membrane HEPA Filters for Pharmaceutical Applications	*Ismo Grönvall, Halton Oy:* Reducing Nursing Personnel's Exposure by Ventilation	*Gun Wirtanen & Karri Kallio, Seinäjoki University of Applied Scienes:* New Food Premises for Teaching and Development Purposes
11.15-12.15	*Lunch & Exhibition*		
	PHARMA *(BALLROOM)*	**HOSPITAL *(LOUISE)***	**FOOD & BIOTECH *(KAISA)***
12.15-12.45	*Silja Nevalainen, Vaisala Oyj:* Measuring Systems in the Pharmaceutical Area	*Bengt Ljungqvist, Chalmers:* Contamination Risks in Unidirectional Airflow	*Leila Kakko, Tampere University of Applied Sciences:* Contamination Control In Food Premises
12.45-13.15	*Mikko Roininen, Kojair Tech Oy:* Comparison of Cleanroom and Biosafety Levels in Isolaters and Biological Safety Cabinets	*Roberto Traversari, TNO:* Switching Off Air Handling Systems in Operating Theatres to Reduce Energy	*Berit Reinmüller, Chalmers* People as a Contamination Source - Dispersion of Airborne CFU
13.15-14.00	*Smoothie, Exhibition & Certificates of Participation*		
14.00-14.45	*Keynote Lecture: Kristina Smith Hansen, Milcor Consulting: Behavioral Strategies Reducing Human Error*		
14.45-15.00	*Closing of the Symposium*		

Invitation to the 51st R³Nordic Exhibition

EXHIBITION MAP

There are 28 stands in the exhibition area. The A-stands are centrally located either at the entrances or close to the buffet area.The B-stands in the Exhibition Hall have shorter interface area to the public stream than the A-stands. Some of the big B-stands with good public interface are placed in the congress aula. This space is unlocked for hotel guests during evenings and nights. The C-stands are placed both in the Exhibition Hall and in the Aula. The D-stands are unmanned places for a roll-up and a rack for flyers (the rack is not included in the stand fee). On the homepage there is a brochure with exact dimensions of the stands. Please, consult that brochure for exact dimensions of the stands.

The prices for A-C stands until 15th of April varies from 2850 € to 1750 €. This fee includes the participant fee for one representative.



Please contact Gun Wirtanen if you are interested in reserving a stand: guliwi@luukku.com

RESERVATION OF STANDS

The first to contact us will be the first served. Unpaid reservations may be sold further based on requests. Prices are available on the homepage. An updated list of exhibitors is available on www.r3nordic.org/symposium-2020. The following companies have already reserved stands:

1) Stennova Oy
2) Dinair Clean Air Oy
3) Valtria Swiss AG
6) Brookhaven Instruments AB
8) ELOMATIC Oy
9) Labema Oy
10) Granlund Oy
11) Veolia Aquaflow Ltd.
12) Cletec Oy
13) a.i.mater Oy
14) Freudenberg Home and Cleaning Solutions Oy / Vileda Professional
15) Perel Oy
21) Miclev AB
22) VWR International Oy
23) Kojair Tech Oy
24) FläktGroup Finland Oy
25) Camfil Oy

PRICES OF STANDS

The stands in the main exhibtion hall is equipped with two (2) tables (placed as the exhibitor wish) with white table cloth(s), two (2) chairs, electricity for laptop or equal and back wall (white; advertisment on the wall can be added by paying extra to the Exhibition builder Exposet).

In the Aula there is no back walls. Table(s) with table cloth(s), chair(s) and electricity is also available for the stands in the Aula.

The Exhibition builder on behalf of R³ Nordic is Exposet. Exposet is an official supplier of trade fair structures and logistics services. All orders on extra services should be placed (in English or Finnish) by e-mail to Essi Moisio at essi.moisio@exposet.fi.

Invitation to the 51st R³Nordic Banquet

BANQUET ENTERTAINMENT THE VIOLONCELLIST JUSSI MAKKONEN TOGETHER WITH THE PIANIST NAZIG AZEZIAN

Jussi Makkonen began playing the cello at the age of seven in Lieksa. He has attended Master classes taught by Professors Arto Noras, Erkki Rautio and Frans Helmersson. Jussi Makkonen has been a performer both in Finland and abroad. Makkonen has performed the music of Sibelius to hundreds of thousands of listeners in his concerts in Finland, Hong Kong, the Philippines, Indonesia, Vietnam, the United States, Canada, Estonia, Romania, Moldova, Greece, Italy, Denmark, Germany, Czech Republic and Belgium. Now it is Your turn to enjoy music performed by Jussi on a 1757 Henry Jay Cello together with the pianist Nazig Azezian. You find further information: www.jussimakkonen.com & www.youtube.com/user/cellistjussimakkonen.The picture is obtained from Jussi Makkonen's homepage.

Abstracts

KEYNOTES

Operation Room Ventilation and Risk of Postoperative Infections

Veli-Jukka Anttila, Helsinki University Hospital, Finland

Infections are major complications following surgery. The most common type of infections after operations are surgical site infections (SSI), i.e. wound infections. SSIs cause:harm to the patients, longer stay of patients in hospitals, increased mortality and excessive costs to hospitals, health care system and society.

According Centers for Disease Control and Prevention (CDC) recommendations wound infections can be classified in three categories: superficial, deep incisional and deep organ infections.

It has been calculated that SSIs could annually cost the European health care system approx. 1.5-20 billion euros. It has been estimated, that about every second SSI can be prevented. In medical literature, there are over 30 means, how to lower the risk of SSIs. The role of operation room (OR) ventilation in the prevention of SSIs is not very well known. There are only a limited number of studies focusing on ventilation in OR and on SSIs. In most of these studies, there are also pitfalls and problems in the methodology used.

In 2016 the WHO expert group evaluated 29 different measures for prevention of SSIs. Just one point of the above-mentioned addressed OR ventilation i.e. laminar air flow. The recommendation of the WHO expert group was: "Laminar airflow ventilation systems should not be used for patients undergoing total arthroplasty surgery ". This was a conditional recommendation with low or very low evidence. There are many studies of microbial contamination in different OR-ventilation systems. There is, however, a big need of good studies to handle the role of OR-ventilation systems in the prevention of SSIs.

New Developments in Cleanroom Design (ISO 14644-4 revision)

Frans W. Saurwalt, Kropman, the Netherlands

The current version of ISO 14644-4 dates back to 2001. Within ISO Technical Committee (TC) 209 working group (WG) 4 has been assigned the task to review and update this part of the 14644 and 14698 set of standards.

With the Committee Draft internal ISO balloting of 14644-4 being passed with comments, an overview of the relevant developments and addressed topics of modern cleanroom design will be given and the highlights discussed. This presentation will not present the current content of the revised standard but will give information on the new developments that are considered and discussed. It will also link to the recent ISO 14644-16 on Energy Management as well as parallels to work within CEN TC156 WG18.

Behavioral Strategies that Can Reduce Human Error

Kristina Smith Hansen, MilCor Consulting, Denmark

After understanding the true root cause of human error related incidences, reviewing options on how to reduce the chances of that undesirable behavior is the next step. As demonstrated in the 'AN EXPLANATION TO UNDERSTAND THE ROOT CAUSE OF HUMAN ERRORS IN THE WORKPLACE' presentation, it is imperative to successfully understand phases a employee's mind goes through when making an undesirable behavioral choice. The Stages of Change Model and many other behavioral models and theories are just one of the strategies that can be employed for that. This presentation will explain and then cover a handful of even more behavioral science strategies that have been validated to work in changing behavior within numerous work environments (ranging from schools, public bathrooms, warehouses, hospitals, food facilities, pharma, and more). It must be noted that this presentation will give brief introductions to a handful (not all) strategies of which will be covered: Triggers, Priming, Persuasion principles, Choice Architecture principles and Nudging.

PHARMA

PHSS Initiative in Preparation of Clarity on GMP Guidance Notes Covering 20 Specific GMP Topics with MHRA Review before Publication

James L. Drinkwater, Chairman of Pharmaceutical & Healthcare Sciences Society (PHSS) & Franz Ziel, UK

To provide more applied guidance on environmental control and monitoring the PHSS the PHSS Aseptic processing special interest group are preparing GMP supportive guidance (has a meeting on 7 June 2019 to discuss the guidance initiative of preparation of Clarity on GMP Guidance notes). There was a well-balanced discussion group that included: three ex-MHRA senior GMP inspectors, representation from major pharma industry (GSK, Pfizer Ireland and Belgium, Ely Lilly France & Italy, Filling machine, Barrier technology and environmental monitoring system manufacturers together with academics involved in GMP. All sixteen proposed guidance note were overview reference; presentation on PHSS Initiative Clarity on GMP Guidance notes 2019, with more detailed discussion focused around four guidance notes:

- Clarity on GMP Guidance note no.1 Assurance of sterility in Aseptic manufacturing of contact product contact parts – New and Existing filling lines.
- Clarity on GMP Guidance note no.2 Rationale for Environmental Classification, Qualification, and Monitoring for Aseptic process filling applications with Barrier technology.
- Clarity on GMP Guidance note no.6 Risk assessment in setting EM Sample locations for monitoring during classification, qualification/ process simulations/

Media fills and during routine production operations.

This presentation reviews key concerns of 2019 meetings above notes and current developments and practices in PHSS Guidance.

Current topics in GMP and Inspection Findings in the Area of Sterile Manufacturing

Senior Phamaceutical Inspector Mervi Saukkosaari, Finnish Medicines Agency (FIMEA), Finland

This presentation reviews current inspection trends and last updates to GMP guidelines development status of Good Manufacturing Practices (GMP).

GMP Annex 1: Selection Criteria of Protective Garments for cleanrooms and Controlled Environments

Steve Marnach, DuPont Personal Protection, Luxembourg

The draft revision of GMP Annex 1 from December 2017 has defined special requirements to minimize risks of microbiological, particulate and pyrogenic contamination during the manufacturing of sterile products.

"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."

Cleanroom garments are the only barrier against contamination from people. For the future it will be essential to fully understand the risks to quality cleanroom garment systems can reduce or increase because they form an important part of an holistic contamination control strategy.

Isolator Design and Maintenance

Timo Kangasmaa, Finnish Red Cross Blood Service, Finland

Abstract is not available.

Microbial Risk Assessment with the LR-Method in Safety Cabinets / Class II Benches

Bengt Ljungqvist & Berit Reinmüller, Chalmers University of Technology, Sweden

Microbiological risk assessment with the method for limitation of risks, the LR-Method, is described in this paper. Results from excerpts of case studies in safety cabinets/Class II benches are discussed. The LR-Method, which relies upon visualization of air movements, particle challenge testing, and calculation of a risk factor, presents an effective way for limitation of potential microbial airborne risks.

Residue Removal Instead of Formation: How Microfiber Wiping Contributes to Contamination Control in The Spirit of GMP Annex 1 Revision

Jochen Wirsching, Vileda Professional, Germany

Abstract is not available.

Preparation of a Contamination Control Strategy as an Annex 1 Requirement and Preparation of an Aseptic Containment Strategy if Processing Sterile Toxic or Biologically Hazardous Products.

James L. Drinkwater, Chairman of Pharmaceutical & Healthcare Sciences Society (PHSS) & Franz Ziel, UK

Filling of toxic or biologically hazardous sterile products that cannot be terminally sterilised requires and Aseptic-Containment Strategy (ACS) that fits alongside a Contamination Control Strategy (Annex 1 GMP requirement).

The approach to Aseptic-Containment has to balance intrinsic contamination risks that may compromise sterile product quality/efficacy and patient health with measures that protect process operatives from hazardous product exposure that may put their health at risk.

This presentation reviews following subjects: 1) Overview of Aseptic-Containment strategy and alignment with a Contamination Control Strategy (CCS). Including containment levels, OEB bands and containment 'Pyramid'.2) Examples of Primary and Secondary containment boundaries. & 3) Points to consider in application of Aseptic-Containment through process and support steps including Filling line set-up, Filling operations, line clearance, Cleaning/decontamination, recovery from atypical events; product spills, glass breakage, barrier and barrier glove loss of integrity.

Basics of Risk-Based Commissioning, Qualification and Validation

Tony Lönnbäck, Elomatic Oy, Finland

To understand the very concept of commissioning, qualification and validation (CQV), sometimes collectively referred to as verification, one needs to understand the concept of risk. There is a lot of fuzz surrounding the word "risk" in the pharmaceutical industry. However, the understanding of how risk management should be applied still seems a bit elusive. One problem is that risk is actually very simple. The traditional definitions of risk have just been able to effectively hide this fact.

In this presentation I will drill in behind the smokescreen and extract the data needed for really understanding risk and how it can be applied to control the entire CQV process. When discussing risk, the main perspective should be what kind of consequences it has. This leads us to understanding who the stakeholder is: the quality organization or the manufacturing or technical organization. When we have identified the primary stakeholder, we can select the correct verification path.

We will look behind the complex vocabulary and focus on the essence of verification – all the way from defining user requirements to ensuring that we have achieved a sufficiently documented facility or process and that we are able to keep it in control over time.

Regulatory Requirements and Expectations including a Review of the New GMP Annex 1

Matt Cokely, Ecolab, UK

This presentation will review Annex 1 EU GMP / FDA / PIC/s and USP<1072> requirements and guidance, including a review of the proposed NEW changes to Annex 1. The requirements and best practice for personnel training, documents and records, preparation and use of disinfectants, rotation, cleaning and EM, transfer disinfection and validation will be reviewed.

Membrane HEPA Filters for Pharmaceutical Applications – Properties and Selection Criteria

Marc Schmidt, AAF International, Germany

Strict demands are put on HEPA filters that are installed as terminal filters in cleanrooms, isolators, workbenches etc. or as last filter stage in air handling units being upstream. They must continuously guarantee safe operation while predefined air quality requirements and energy efficiency are optimized. For that the filter media itself is of major importance.

Standard filter media for HEPA filters so far had been fiberglass paper. Being free of boron filter media based on expanded PTFE is used in microelectronics since decades. Based on latest developments in ePTFE membrane technology, such as PAO compatibility, ePTFE based HEPA filters are on their way to replace fiberglass-based filters.

This presentation describes properties and selection criteria for the latest generation of ePTFE membrane HEPA filters. It sets out structure of modern ePTFE membrane media, how air filters with ePTFE membrane media provide significant reduction in energy consumption and risk.

It presents results of several studies on superior stability and durability of PTFE media over traditional fiberglass media. Based on several test regarding mechanical and chemical resistance it is demonstrated that PTFE media offers a significant improvement in reducing media failure risk for a retained filter integrity.

In addition, integration of PTFE HEPA filters and advanced sensor technology in next generation air handling units are discussed.

Measuring Systems in the Pharmaceutical Area

Silja Nevalainen , Vaisala Oyj, Finland

Abstract is not available.

Comparison of Cleanroom and Biosafety Levels in Isolators and Biological Safety Cabinets (BSC)

Mikko Roininen, Kojair Tech Oy, Finland

When regulations provide minimum requirements and guidelines to fulfil safe conditions of work and production, it also leaves possibilities how to build the facilities. The work environment is being subjected to ever higher safety requirements, when handling different hazardous substances including pathogenic microbes. The requirement for aseptic work is strict cleanliness and a critical point is to keep the product free of contamination. In small volume production it is sometimes reasonable to set up a small Grade A zone in a Grade D cleanroom using an isolator. When larger volumes are produced it is better to build an A-grade zone in a B-grade cleanroom with open front biosafety cabinets. Both correct equipment and correct cleanroom grade affect the optimization of the process time and the running costs. The monitoring in the cleanroom and the training of workers also affect the cost structure of the facilities. Where should the line between small- and large-scale production be drawn when the production facilities are optimized? In this presentation, the pros and cons of different setups are compared to enable optimization in the selection strategy.

HOSPITALS

HUS Operating Room Ventilation and Air Conditioning Design Guide

Aleksanteri Setälä, HUS Kiinteistöt Oy, Finland

Currently there is no valid standard for operating room ventilation design in Finland. Because of this, the design solutions of operating rooms have been diverse across different construction projects. However European Committee for Standardization (CEN) is working on a European-wide standard draft "CEN/TC156 WG 18" which focuses on hospital air quality and ventilation design. The standard defines two acceptable cleanliness classes based on operational CFU concentration. The classes are CL-1 (Ultra Clean Air) which is intended for high-risk surgery and CL-2 (Clean Air).

Helsinki University Hospital (HUS) is the biggest health care provider and second largest employer in Finland. It consists of five hospital areas: Helsinki University, Hyvinkää, Lohja, Porvoo and Västra Nyland.

While waiting for the standard HUS has composed a design guide which concentrates specially on operation room ventilation. "Operating Room Ventilation and Air Conditioning Design Guide" is based on the upcoming standard but also enforces/promotes other HUS-applied practices. The purpose of this guide is to ensure that the ventilation of future operating rooms is implemented in a way that has been proven to work and is in accordance with class CL-1. In addition, the goal is to streamline the design process as design practices are defined in the guide and do not need to be reinvented for every project. The guide – as well as the standard – affects not only designer but contractor too as it defines, among other things, all mandatory tests that must be performed before an operating room can be introduced.

Practical Safety Ventilation in Ultraclean Air Operating Rooms

Pedro Gandra, Considero, Sweden

When planning new ultraclean air operating rooms, often the first question is which is the preferred room air distribution system, and which system is the best to meet the requirements of microbiological air cleanliness. Today, in Sweden, the requirement is a target level of 5 CFU/m^3 during the design phase, in order to ensure that the level of≤10 CFU/m^3 during infection prone surgery is maintained. This study is based mainly on the analysis of published

scientific reports and other documentation. The focus is to compare the main principles for room air distribution systems, mixing and displacement principle and to see whether the requirements of microbiological air cleanliness can be fulfilled during ongoing surgery. Three different distribution systems available in Sweden have been compared. The room air distribution systems studied are: Mixing airflow/partly displacement, Unidirectional airflow (UDF) and "Temperature controlled airflow (TAF)" - A specific Swedish room air distribution system.

The result of the comparison shows that in operating rooms for infection prone surgery all three studied room air distribution systems could achieve the target level of 5 CFU/m^3 when the air volume flows are above 2 m^3/s provided that the total microbiological source strength does not exceed 10 CFU/s. The total microbiological source strength depends upon the number of people in the operating room, their chosen surgical clothing system, and their activity level.

Factors Influencing the Cleanliness of Operation Rooms
Jukka Vasara, Granlund Oy, Finland

In Finland, microbial measurements in operating rooms (OR) have been carried out in about 20 hospitals and almost 80 operation rooms. The purpose was to map the microbiological status of current operating rooms to the requirements of a future draft standard CEN/TC156 WG 18.

The results were surprisingly good considering that some operating theaters are more than 10 years old. However, some OR remain CL2 or Clean Air class. The results cannot directly be explained by air distribution or supply airflow in the OR. The study aims to determine the effect of various factors on the microbiological cleanliness of operating rooms.

According to a forthcoming draft standard, one of the significant factors influencing the design of the OR airflow is the staff's clothing system. Its purpose is to filter out the amount of microbes released into the air from human skin. Most of the operating room microbes are derived from human skin. In December 2019, Finland carried out the first microbial filtration measurement of washable operating room clothing. The results showed the usefulness of the measurement and provide a good starting point for further development of operations. The presentation also provides analysis of the background to the results.

Prefabricated Operating Rooms
Kari Solem Aune, COWI AS, Norway

When applying for a new operating room, the customer should consider whether to construct it on site or apply for a prefabricated one. This decision will have huge influence on the further process and should be done in a very early stage. When decided, the decision needs to be developed, and the wanted interfaces must be recognized and described.

The number of possible suppliers for prefabricated operating rooms is increasing, and each one of them comes from different sectors. Some of them have their main experience from the building elements (walls, doors etc) or ventilation/technique area, others from the medical equipment and even from the AV-perspective. All those have their strengths and weaknesses and may be combined in different ways.

In this session we will highlight the project process, some common interfaces and how to deal with them in your project. What should be decided – and when? What are the benefits and disadvantages be choosing the one solution instead of the other?

Operating Room Extraction Systems
Perttu Karjalainen, Granlund Oy, Finland

Surgical staff may be exposed different chemicals and contaminants as anesthetic gases and diathermy plumes in their daily work. Studies have shown that long-term exposure to anesthetic gases can cause infertility and exposure to diathermy plume is compared to passive smoking. These contaminants are extracted through both the ventilation system in the operating room and also the local exhaust ventilation.

This research examined affection of these contaminants to demand of ventilation by mass balance calculations. Results of these calculations were compared to ventilation requirements and instructions of new TC156/WG18 "Ventilation for hospitals" -standard. The results showed that in theory diathermy plumes can be removed efficiently through ventilation. The ventilation system should be equipped with gas filtration to efficiently remove anesthetics from the indoor air. It would be more efficient to capture gases with local exhaust ventilation.

Surgical staff was interviewed as part of study. Most of staff had been exposed to anesthetics or diathermy plumes in their daily. This has caused for example headache and irritation in respiratory tract. In summary, there is not much evidence of long-term effects of exposure to these contaminants. These contaminants are still considered problematic in terms of worker comfort.

Development of a Technical Specification for Ventilation in Medical Locations
Roberto Traversari, TNO, the Netherlands

The scope of this new technical specification (TS) developed in CEN Technical Committee 156 on ventilation in medical locations. It is applicable in healthcare premises and medical centres, where clinical and health-related services are provided, including specific risk areas. The individual member states will decide on national level, whether or not to adopt and publish it on national level (e.g. SS-CEN / TS), refer to parts of it as a national standard and/or add specific requirements if needed.

This TS is intended for project managers, designers, construction and commissioning engineers, estates managers and operations/facilities managers and provides defined levels of air quality/cleanliness and comfort for these areas. It addresses the requirements for ventilation systems. It specifies the design, installation, operation, verification process, maintenance and reverification of the ventilation systems. It describes the following issues related to the ventilation system: a) protection of patients, staff and visitors against harmful agents; b) reducing the growth of microorganisms; c) air quality and d) control of the airflow.

An important part of the TS is the organization of design, construction and operation. The approach must be structured and based on a user requirement specification, functional design, and detailed design as well as on installation verification, operational verification and performance verification. During the operational phase the maintenance process, documentation and reverification are important aspects. It focuses on general medical location and on operating suits and isolation rooms.

Two cleanliness levels are defined for the operating rooms. These cleanliness levels are in principle independent of the ventilation principle used. Both ventilation principles (diluting mixing and unidirectional airflow) can be used for these cleanliness levels. However, for the different cleanliness levels other test methods are applicable. For the performance verification, microbiological test may be used.

The TS deals only with airborne isolation for isolation rooms. Based on this, the airflow direction and pressure differences are of less importance in the new TS. The requirements of isolation rooms are now more based on the recovery time in the room and airlock. The following types of isolations are included in the TS: source isolation, protective isolation and combined isolation. The draft TS will be ready for format vote in the beginning of 2021. It will be discussed in more detail in the presentation.

Sterilization Department

Kari Solem Aune, COWI AS, Norway

The sterilization department in a hospital is more or less a factory for producing sterile goods. This means, we need to understand the sterilizing process in order to design and construct the right solution for each hospital.

There are no common guidelines on European level yet, but based on the Swedish requirements and Norwegian experience we want to share our best practice. This session will focus on the sterilizing process as a basis for the demands, the project process and how to design and construct suitable rooms and ventilation system for this purpose.

Pass through Boxes Design and Performance Testing

Frans W. Saurwalt, Kropman, the Netherlands

Wherever cleanrooms are used, items need to be transferred into and out of the processing rooms. Although common in pharmaceutical facilities, especial autologous ATMP facilities do require extensive application of pass through boxes to provide transfer without the need for personal access. The design of pass through boxes can vary widely relative to the application. The EU GMP Annex 1 revision states it does not recommend not active ventilated pass through boxes. Various forms of active, combined and passive ventilated types can be evaluated. As contamination control performance aspects are considered: flow/pressure cascade, order of magnitude of the cleanliness transition from less clean to cleaner or clean to less clean. For typical GMP / ATMP cleanroom situations various design studies, proof of concept tests and qualification tests of in actual projects are presented.

Hospital Isolation Room Air Flow Patterns: CFD Simulations

Hannu Koskela & Petri Kalliomäki, Turku University of Applied Sciences, Finland*

Patients with airborne infectious diseases are placed to airborne infectious isolation rooms (AIIRs) in Hospitals. Hospital staff and visitors can be exposed to the airborne pathogens released by the patients when working/visiting in AIIRs. Staff and visitors protect themselves against airborne pathogens with personal protective equipment (PPE), like gloves, masks etc. However, PPEs might not always provide complete protection against airborne contaminants and hence supplementary cover is needed. Direct exposure to the patient released pathogens can be reduced by controlling the airflow pattern with air distribution or local ventilation solutions.

In this study, computational fluid dynamics (CFD) methods were used to study air flow patterns and HCW exposure to the patient exhaled air in an isolation room setup. CFD simulations are widely used in ventilation research and provides an efficient tool for characterizing the local airflow patterns and effectiveness of the ventilation solutions. Three different air distribution methods were investigated in this study: mixing, zonal and displacement ventilation. Unsteady RANS (URANS) was used as a computational method. In the simulations, HCW was standing next to a patient bed and the patient was lying on the bed. The patient and the HCW were breathing out through nostrils with a normal breathing cycle. The simulations were compared against experiments carried out in a full-scale isolation room model.

URANS predicted realistic flow patterns when compared to experimental smoke visualizations. Also, the HCW's exposure was relatively well estimated by the URANS method. Zonal mixing ventilation seemed to work most effectively in reducing HCW exposure. On the other hand, air velocities close to bed area were notable with the zonal ventilation and hence it might cause draught and thermal discomfort in long term usage.

Reducing Nursing Personnel's Exposure By Ventilation

Ismo Grönvall & Kim Hagström, Halton Oy, Finland

Amount of sick leave days among nurses is in relatively high level compared to many other occupations. One of the risk factors for nurses at work are respiratory infections. According to recent studies there is a high risk for nurses to be exposed to microbes exhaled by patients especially, while they are conducting their work close to patient.

Current ventilation solutions that are used in patient environments are not designed to address this challenge. At best they are able to dilute the microbial concentrations in the room, but they are not able to effect on nurse's exposure to patients' outbreath close to patients. In the presentation new type of ventilation solutions will be presented which can be utilized in patient environments to reduce nurse's exposure and infection risk.

Contamination Risks Evaluated with the LR-Method in Unidirectional Airflow at Different Air Velocities

Bengt Ljungqvist & Berit Reinmüller, Chalmers University of Technology, Sweden and Johan Nordenadler, Karolinska University Hospital, Sweden

Operating rooms for patients undergoing infection prone surgery often have unidirectional flow supply air systems. Many systems installed in Europe have low air velocities, i.e. equal and below 0.3m/s, while other supply air systems have velocities about 0.4m/s. The purpose of this paper is to describe contamination risks in unidirectional airflow without obstacles at different air velocities.

Switching Off Air Handling Systems in Operating Theaters to Reduce Energy

Roberto Traversari, TNO, the Netherlands

Switching off air handling systems in operating theaters during periods of prolonged inactivity, e.g, nights, weekends, can produce a substantial reduction of energy expenditure. However, little evidence is available regarding the effect of switching off the air handling system during periods of prolonged inactivity on the air quality in operating theaters during operational periods. The aim of this study is to determine the amount of time needed after restarting the ventilation system to return to a stable situation, with air quality at least equal to the situation before switching off the system.

The results are based on measurements were performed in three operating theaters, all of them equipped with a unidirectional downflow (UDF) system. Measurements with 9 particle counters simultaneously (particle counts of emitted particles with a particle size ≥0.5 µm) were taken during the start-up of the ventilation system to determine when prespecified degrees of protection were achieved. Temperature readings were also taken to determine when a stable temperature difference between the periphery and the protected area was reached, signifying achievement of a stable condition.

The results of this study show that after starting up the system, the protected area achieved the required degrees of protection within 20 min (95% upper confidence limit). A stable temperature difference was achieved within 23 min (95% upper confidence limit). Both findings lie well within the period of 25 min normally required for preparations before the start of surgical procedures. The conclusions of this study are that switching off the ventilation system during prolonged inactivity (during the night and weekend) has no negative effect on the air quality in UDF operating theaters during normal operational hours. Switching off the system during the night and weekend can result in energy saving, up to 70% of energy consumption (ventilation, cooling, heating, and humidification) compared with systems that function on full capacity continuously, and therefore costs saving. Compared with systems with night set back (reduction to 20% of the normal ventilation flow rate) it is estimated that a reduction of 14% of the energy consumption is feasible by switching off the system completely. However, in practice there shall always be a small amount of ventilation to deal with the with the internal load of the medical equipment in the operating theater, emission of building materials and cleaning agents and other odors.

CLEANROOM NEWS / GENERAL

New, Chemical Free and Automatic Disinfection Technique - Enhancing the Antimicrobial Effect of Blue Light

Camilla Höglund, LED Tailor, Finland

The antimicrobial effect of blue light has recently attracted a lot of attention as a new technique for disinfection of surfaces and air. Antibiotic and chemical resistance among microbes has been recognized as a global threat, encouraging the search for new methods to eliminate HAIs (Healthcare associated infections).

A 12-month study conducted by a Medical Center in the US, has showed a 73% reduction in SSIs (surgical site infections) in one operating room during the following year after an automated blue light disinfection system was installed. This is the first long-term clinical study showing actual reduction in SSIs as a result of adding blue light photon disinfection to the disinfection procedures in the operating room.

Studies have shown blue light to be effective in inactivating a wide range of microbes; Gram-positive and Gram-negative bacteria, moulds and yeast. Blue light can penetrate biofilm and inactivates microbes regardless of their antibiotic resistance profile.

A photocatalytic coating can be applied to environmental surfaces to enhance the antimicrobic effect of blue light. In addition, the photocatalytic coating inactivates viruses, spores and VOCs effectively. A TiO2-based photocatalytic coating activated by low intensity blue light (0,7 mW/cm2) has been shown to drastically enhance the inactivation of Staphylococcus aureus on a table surface.

Blue light offers a chemical free, continuous disinfection of the air and surfaces. It is a modern technology, safe for humans and surfaces, and worth to consider as a complement to the existing disinfection systems.

Digital Twins: What is the Value Behind All the Hype?

Francisco Forns-Samso, Granlund Oy, Finland

The Digital Twin concept is an emerging trend in the built environment. Essentially meaning the coupling of the physical system with its digital representation. The idea is that the digital information duplicates the information embedded in the physical systems and it is linked throughout its lifecycle. Digital twins are essentially used for simulation, monitoring, analytics and reporting. In practice, it is still unclear how digital twins create tangible value in the industry considering the complexity and diversity of buildings. It is logical to think that a building might have several digital twins that serve a specific function or purpose. The aim of the presentation is to show the untapped the benefits of digital twins beyond the hype with real case examples. In this presentation, we will show:

1) how digital twins can enable integration of existing and new information for improved analysis and visualization,

2) how we can reuse existing information for supporting different use cases and
3) how the integration of information enables the creation of new information to better understand the building behavior and improve decision-making process.

Environmental Contamination and Risk of COVID-19 Transmission at Airports

Ilpo Kulmala, VTT Oy, Finland

Transportation plays an important role in the spread of infectious diseases. Global air travel around the world facilitates the quick and uncontrollable spread of person-to-person transmissible pathogens around the world. As was the case for SARS in 2002/03 and influenza A(H1N1)pdm09 in early 2009, and the COVID-19 now, air travel will be the key to the spreading of such pathogens internationally.

The current knowledge suggests that COVID-19 spreads from person to person by the same mechanism as other common cold or influenza viruses—that is by droplet or airborne transmission during sneezing or coughing, or by direct or indirect contact transmission with secretions of people who are infected.

In the recent PANDHUB FP7 project, the presence of respiratory viruses in the passenger environment of a major airport was investigated in order to identify risk points. We collected surface and air samples weekly at three different time points during the peak period of seasonal influenza. Surface sample swabs and air samples were tested using real-time PCR for influenza A and B viruses, respiratory syncytial virus, adenovirus, rhinovirus as well as coronaviruses.

Pathogen viral nucleic acids were detected on different surfaces indicating respiratory viral surface contamination at multiple sites associated with high touch rates, and suggests a potential risk in the identified airport sites. Of the surfaces tested, plastic security screening trays appeared to pose the highest potential risk, and handling these is almost inevitable for all embarking passengers. Other high risk sites were key-pads, children's playground, handrails. In one air sample adenovirus was also found. The results are useful in identifying hot spots or places or sites, where the risk of disease transmission is at least temporarily elevated, and in guiding measures to minimize transmission.

Layout Based on Plenum Integrated Filter Fan Units in Clean Rooms

Esa Högel, Valtria Swiss AG, Switzerland

Until now, by clean room air conditioning has mainly been used in the past circulating air machines with filter terminals or pressurized plenum, Circulation Air units with Filter-Outlets and pressurized Plenum. However, Filter Fan Units began to be used in microelectronics in the second half of the 80s and in the pharmaceutical industry from the late 1990s.

Central Europe, America and Asia have been repeating history for the first time in large display manufacturing plants and electronics with a new clean room air conditioning solution, followed by the pharmaceutical industry recently on the continents mentioned above. This new clean air conditioning option is called Plenum Integrated Filter Fan (PIFF), which is not yet known in Finland or Scandinavia.

The PIFF solution is a compact standalone air recirculation and contained plenum system. The PIFF unit recirculates the return air directly from the cleanroom. Additional fresh air/make-up air can be connect-ed directly to each PIFF unit, as well as any exhaust air. In addition, convection air cooling can be added to each PIFF unit.

At the end of this lecture will be seen a visualization video of PIFF the air recirculation in clean room as well some information about installations by pharmaceutical industry. In practice, the results obtained with the PIFF method have shown that there is no risk of cross contamination, where the PIFF solution has been welcomed by users in the pharmaceutical industry.

Important benefits to the user have been achieved. The presentation will present this in more detail.

Single-Use Technology for Aseptic Processing – Design and Quality Considerations to Meet Regulatory Requirements

Simone Biel, Process Solutions Merck Life Science, Germany

The implementation of single-use (SU) technology in aseptic processing is steadily increasing to meet the stringent requirements for the final filtration and filling step. SU assemblies are pre-configured, pre-sterilized, and ready-to-use to provide benefits like quick process change-over and reduced risk of cross-contamination. As the process conditions highly depend on i.e. the drug product, batch size, equipment, and environment, a case-by-case SU assembly design needs to be developed to fit for purpose. The presentation will consider best design considerations for filtration and filling process and how to meet regulatory requirements related to SUS integrity, filter pre-use post sterilization integrity test (PUPSIT), particle load, and toxicological assessment.

An Explanation to Understand the Root Cause of Human Errors in the Workplace

Kristina Smith Hansen, MilCor Consulting, Denmark

Working within health care, life sciences, and food manufacturing disciplines, it goes without saying how imperative it is to maintain high standards of compliance. Mere mistakes resulting from poor personnel handling are just not acceptable!

Human error related discrepancies have been shown to be the true root cause of devastating occurrences, such as: Poor data integrity findings, hospital associated infections (HAI), outbreaks of food-borne illnesses (FBI), 483s and warning letters from the Food & Drug Administration (FDA), destructive change management, just to name a few.

Yet, changing an undesirable behaviors such as these have shown to be far more intricate than just inserting the 'better knowledge = better practices' principle.

It is imperative to first understand why a human behaves a certain way before addressing it. In this presentation, there will be an explanation on human error in the workplace, what a person's mind goes through when having to influence before you attempt to fix that error.

The model used is one created by the presenter, called the B4UNUDGETHEM™ Method. This method breaks down each construct: Informative, Motivational, and Situational Environments. For it is these pillars that must be broken down, dissected, and understood before moving on to add aides or processes (incl. Behavioral Strategies to be discussed in another presentation) in an attempt to reduce human error.

FOOD & BIOTECH

Challenges in Clean Room Projects

Steven Deretz, CRDB, Belgium

Abstract is not available.

Hygienic Design as a Support in Planning Controlled Food Premises

Alan Friis, FORCE Technology & TECH4BIZZ, Denmark

Food Safety is non-negotiable in food production, however hygienic design provides more benefits to the end-user such as improved product quality, reduced environmental impact and improved process-efficiency due to reduced maintenance costs and optimal cleaning processes. In many ways hygienic design specifications capture key essential aspects also beyond food safety, which if not monitored and managed properly during planning, design, installation and commissioning may hamper the ability of a process plant / line to provide the intended high-end food products.

The transfer of responsibilities and ownership between the project supplier and the end-user is not supported by EU Laws. The Machinery Directive and supporting standards addresses design of modules and machinery but not the integration of these into process lines. Particularly the lack of assurance of the integrity and safety of foodstuffs produced using supplied entities may lead to unintended errors that will be costly to rectify.

HACCP is applied to entities where process and products are known and food-operators typically have personnel that are qualified in HACCP-management, whereas for their suppliers, assessment of the hygiene-risk of their designs mainly concerns generic systems with broader intended use-range. Furthermore, tools to integrate proper risk assessment into the process of building and assessing necessary compromises made during the project lifetime are scares.

European Hygienic Engineering and Design Group (EHEDG) has guidelines that provides an idealized procedure, that can form the basis of an engineering- and design-manual. It applies to all phases of the lifecycle of any entity and process intended for use in hygienic food-handling and -production.

The procedure which is based on the V-model (a common tool in process line projects) includes, qualification- and validation-activities undertaken throughout the design- and commercialization-phases of a project. To be efficient the oversight should be carried out in close partnership between supplier and end-user, and with joint sign-off to criteria pre-defined in a user/stakeholder-specification, to minimize the risk of failure.

Future Food Production Unit – From Designers' Desk to Operational Efficiency in Rapidly Changing Consumer Demands

Rüna Brade, Elomatic Oy, Finland & Jim Nyroos, Cadmatic Oy, Finland

The outlook for the food processing and handling industry is positive and sector growth is expected to accelerate in the near future. McKinsey (2018) estimated that the growth rate from 2016-21 will raise with 5 percent annually. Domestic food companies also intend to increase their investments, where rationalization investments play a major role. This means investing not only in efficiency projects but also in environmental and safety development.

The focus areas of research strategy for the food industry 2018-2025 by the Finnish Food and Drink Industries' Federation also guides the engineering companies in their strategy process related to industrial investments services. The challenge of food manufacturers to continually match their products to changing consumer demands requires lean design methods and tools although traditionally plant investments projects are not considered especially agile. The 3D-plant design software with visual modelling can effectively and proactively test a desired change or extension. You can also utilize a virtual model to test the functionality of your equipment or production line and even furniture investments and usability on a real scale. Circular economy targets e.g. in waste and side streams processing and not forgetting digitalization, will request new collaborations and new value chains. We production and plant designers are also ready for operational efficiency studies that cut costs, increase uptime & energy efficiency. As a result, new traceability technologies (e.g. block chain), intelligent inventory management systems and IoT solutions are emerging that will change the service model and distribution chain of food sector in the future.

New Food Premises for Teaching and Development Purposes

Gun Wirtanen & Karri Kallio, Seinäjoki University of Applied Sciences, Finland

The Frami Food Lab project started based on needs to have new food laboratory premises at Seinäjoki University of Applied Sciences (SeAMK) and to make the education in food more work-oriented. Both teaching and research aspects were considered, when designing the premises. The food enterprises in Southern Ostrobothnia need the premises as a showcase boosting the visibility of the food sector with food expertise activities. The premises together with the process hardware create a framework for the students to improve their skills in food processing and biotechnology and to develop attractive and demanding food business ideas. The possibility to arrange teaching in both chemistry and microbiology in the same premises is very important, which enables more efficient use of the premises. Good, holistic implementation of activities serves both agrology, food processing and hospitality management students and stakeholders in performing food and biotech activities.

We designed the controlled food processing premises to enable the acceptance as approved food establishment by the food aut-

horities. The lock at the entrance to the food premises is a space with various barriers i.e. hand washing as well as changing of clothes, headgear, shoes and gloves. The premises are, furthermore, divided into various zones e.g. zones for raw material reception, pre-processing, processing and packaging. Activities will also be performed in the simulation and the sensory laboratories as well as in the restaurant. Some of the laboratory equipment e.g. mills used in grinding grains affect how the area is kept clean and free from dust. The ovens and stoves produce heat. This also put pressure on the air conditioning system, because the area should be kept free from condensate. The ventilation was by far the biggest challenge, because the system had to be built into an existing building. We used two different systems. The one implemented in fume hoods and chemical storage was based on stainless steel ductwork and the other covering the rest of the food premises was based on normal air conditioning. The mills had to be placed in a small, closed room. The ovens and stoves will be used at certain periods based on timing of processes.

Contamination Control in Food Premises

Leila Kakko, Tampere University of Applied Sciences, Finland

In the food premises, cleanliness and clean surfaces must be self-evident. Surfaces contaminate always with various kind of dirt, dust, microorganisms and condensed matter. In–house control is mandatory for all the food premises and it means that the operator must identify and list all critical points in food handling and they must organise their regular control. In-house control helps to maintain the safety of manufactured and sold products. The in-house control plan includes etc. incoming goods control, information on incoming and outgoing products, control of production and storage conditions, health care, hygiene training, waste disposal plan and cleaning schedules.

Planning in-house control should start with the identification of hygiene risks in the premises and it includes all the products and activities. Using method called Hazard Analysis Critical Control Points (HACCP) the risks are easier to achieve.

In the process, all those work stages, in which a health hazard is possible, must be carefully monitored. Most important is to focus on the critical control points and choosing the right monitoring measurements.

The plan of monitoring methods and the critical limits for control points and corrective measures within the acceptable limits needs to be included in-house control plan as well as the ways to secure and record those methods. Some monitoring systems can be continuous but the records must be observed periodically.

In surface hygiene, several different methods in measurements can be used depending on the premises.

People as a Contamination Source – Dispersion of Airborne CFU

Berit Reinmüller, Chalmers, Sweden

The number of airborne bacteria-carrying particles in a cleanroom or a controlled environment is considered an indicator of the risk of contamination to the process or product. When the supply is HEPA-filtered, the main source of airborne microorganisms should only be people. The filtration efficacy of the fabric in clothing systems plays an important role. The design of the clothing system also affects the number of particles emitted from people to the air of the working environment. In cleanrooms and controlled environments, the selection of clothing systems for the personnel is an important issue.

Today clothing and clothing systems for cleanrooms and associated controlled rooms are firstly tested regarding material properties, such as particle generation, particle filtration, resistance to wear and comfort. At Chalmers University of Technology, a modified dispersal chamber or "body-box" has been used to study and evaluate the protective efficacy of clothing systems in use. From measured concentration levels of aerobic CFU during standardized cycles of movements, the source strengths (number of CFU dispersed per second and person) of clothing systems have been calculated.

The source strength, the level of activity, and the air volume flow will give a first approximation of expected CFU levels during activity in cleanrooms or controlled environments, where people are the main source of microbial contamination.

PDA Journal of Pharmaceutical Science and Technology January 2020

Senaste utgivning av PDA Journal innehåller bl a en artikel "Quality Risk Management – A Role - Based Competency Model" av Ghada Haddad and Anne Greene, ett mycket aktuellt ämne.

James P. Agalloco bidrar med "A Tale of Two Sterilizers", där skillnaden mellan sterilisering av produkt och s k utensilie laster diskuteras. PDA Letter uppdateras varje vecka på PDA:s hemsida. PDA förbereder sitt 75 års-jubileum och tar gärna emot bilder och minnen från föreningens historia.

The European Medicines Agency (EMA)

Founded in 1995, the European Medicines Agency (EMA) has worked across the European Union (EU) and globally to protect public and animal health by assessing medicines to rigorous scientific standards and by providing partners and stakeholders with independent, science-based information on medicines.

EMA's success is based on cooperation within the European medicines regulatory network – a unique partnership between the European Commission, the medicines regulatory authorities in the European Economic Area countries, and EMA. Working together has encouraged the exchange of knowledge, ideas and best practices, in order to ensure the highest standards in medicines regulation.

On 20 November 2017, European Union (EU) Member States decided to relocate the European Medicines Agency (EMA) to Amsterdam, the Netherlands, as a result of the United Kingdom's (UK) withdrawal from the EU. The Agency immediately began working with the Dutch authorities to prepare for the move and take up its operations in Amsterdam by 30 March 2019. After 24 years, the European Medicines Agency (EMA) closed the doors of its London offices on 1 March 2019.

EMA's 25th anniversary. Since the Agency's creation on 26 January 1995, the environment in which EMA operates has undergone fundamental scientific, technological, legislative and social changes. But its mission has remained: bringing the best experts from around the EU together to create an efficient and robust system for the evaluation and supervision of human and veterinary medicines that serves citizens throughout the EU.

"25 years is a significant milestone for EMA. Together with our partners and stakeholders from national authorities, EU institutions and civil society we harmonised and improved medicines' evaluation, stimulated innovation, improved safety monitoring and management, fostered transparency and dialogue, built relationships with international partners, and helped to make medicines accessible to those who need them", said Guido Rasi, EMA's Executive Director. "As we look to the future, we will continue to build on these strong foundations to deliver high-quality work for the benefit of public and animal health".

Today, seven EMA scientific committees and more than 30 working parties provide scientific expertise for the regulation of medicines by drawing on a pool of several thousand European scientific experts from the network.

From 4 March 2019, the official address of the Agency is that of its permanent building in Amsterdam Zuidas

EU flags are up in EMA's new building in Amsterdam.

EMA's staff gathered 3rd February to raise the EU flags in the lobby of its new and final building in Amsterdam.

"A year ago, we lowered the flags in our London offices with a heavy heart. With this flag-raising ceremony in our new Amsterdam home, we can now close the chapter of our relocation, look to the future and finally refocus fully on our public-health mission," said Guido Rasi, EMA's Executive Director..

"Moving EMA to Amsterdam has been a challenging endeavour; I would like to thank our staff members for their commitment and remarkable resilience; the Dutch authorities for their support; and the Dutch people for their warm welcome," said Guido Rasi.

The flag-raising ceremony was also an occasion for EMA to celebrate its 25th anniversary and reflect on the success the Agency has achieved, since its creation on 26 January 1995, in bringing the best experts from around the EU together to create an efficient and robust system for the evaluation and supervision of human and veterinary medicines that serves citizens throughout the EU.

Annex 1

Manufacture of sterile products Version 12 är nu publicerad för kommentarer under 3 månader räknat från 20 februari. PHSS kommer att sammanställa kommentarer från intressenter och har redan skickat ut en blankett för kommentarer till sina intressegrupper.

European Journal of Pharmaceutical and Parenteral Sciences (EJPPS)

EJPPS ges nu ut i digitalt format (se www.ejpps.online. Där finns att läsa om:

Pharmaceutical Cleanroom Classification using ISO 14644-1 and the EU GGMP, Annex 1 Part 1 och 2 av *T. Eaton, AstraZeneca, Macclesfield, UK*

Part 1 - Testing rationale: Cleanroom classification is an essential part of the qualification activities in pharmaceutical cleanrooms that confirm the effectiveness of the cleanroom's airborne contamination control system. A review of the classification requirements and principles associated with ISO 14644-1:2015 and the 2008 version of Annex 1 of the EU GGMP is contained in this first article, and a suitable classification test method derived for aseptic manufacturing. A second article will consider the application of the method by means of practical examples.

Part 2 - Practical application: Classification of cleanrooms and clean zones associated with the manufacture of medicinal products has been assessed in two articles. The first article discussed the classification requirements and principles associated with ISO 14644-1and Annex 1 of the EU GGMP, and a suitable classification test method for aseptic manufacturing was derived. This second article considers the practical application of the method for the classification of a pharmaceutical cleanroom, and isolator located within it.

Issue 40 av CACR innehåller följande artiklar (Läs på föreningens medlemssida):

Clean Air and Containment Review

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Standards for pharmaceutical isolators - an overview, *Tim Coles*

Abstract: Pharmaceutical isolators have wide application in critical processes such as aseptic filling and genetic engineering, and yet they are not covered by any specific UK, or international standard. At present, users have to rely on standards essentially written around cleanrooms, which are a very different contamination control system. There is also one standard which is a sub-section of an aseptic processing standard. This paper highlights areas where these existing standards are perhaps deficient.

The sense and otherwise of ISO 16890 - Air filters for general ventilation, *Alexander Fedotov and Oleg Provolovich*

Abstract: At the end of 2016, the ISO 16890 series of standards replaced EN 779 standard on filters for general ventilation. EN 779 is well-known, well accepted and widely used for the specification of pre-filters for cleanrooms and other controlled environments. It was declared that ISO 16890 gives a better picture of indoor air quality than EN 779 in terms of particle contamination. But is this really so?

There are two areas of application for air filters for general ventilation that differ from each other in principle:

- to protect humans
- to help achieve the necessary air cleanliness levels by serving as pre-filters in certain technologies and processes.

The first purpose has been known for centuries but the second came from industrial progress and the appearance of cleanrooms and other controlled environments. This article discusses this and other issues concerning ISO 16890.

EN 1822 and EN ISO 29463, *Chris Hews*

A step towards a globally unified standard.

Source strength, *Andrew Watson*

Abstract: This article is the first of a series that identifies gaps that still exist between practice and meaningful verification in the design, operation and testing of cleanrooms. The topic for this article is source strength and the article assesses the validity of published source strength data as well as source strength data derived from body box testing for the purpose of calculating airflow rates in cleanrooms.

Decontaminating and decommissioning a biological containment facility, *John Yuill*

Abstract: This article is aimed at giving a greater understanding of the requirements of decontaminating and decommissioning equipment and facilities that have been contaminated with products that could adversely affect the health and wellbeing of the decontamination operatives involved in its safe removal. The article also discusses the effects on the environment and other staff along the safe disposal routes of the resultant wastes produced.

Observing airflows in cleanrooms, *Bill Whyte*

CEN TC156 WG18 Ventilation in hospitals Møte i Madrid

TEXT O BILD:
KARI SOLEM AUNE, COWI AS

I desember 2019 ble det votert over et nytt forslag til arbeidsdokument (Work Item Proposal) for å etablere dette som en Teknisk spesifikasjon (TS) i stedet for en europeisk standard. Samtidig skiftet det tittel fra "Ventilation in hospitals" til "Ventilation in medical locations". Denne voteringen ble positiv, det vil si at forslag om å lage en TS er akseptert. Dette er et stort gjennombrudd for arbeidet, selv om det ikke ble flertall for å lage en standard. En teknisk spesifikasjon vil si at alle land som ikke har en egen standard på området kan velge å ta den inn som en nasjonal standard likevel, og legge til noen spesifikke krav i egne nasjonale anneks. For de nordiske landene vil dette bety at vi kan få et felles rammeverk å forholde oss til. Og kanskje kan de nasjonale anneksene samkjøres i de nordiske landene?

Tidsplanen for å ferdigstille dette dokumentet er ganske stram. Utkastet til ferdig dokument må foreligge til sommeren 2020 for å kunne gå gjennom den offisielle saksgangen før årsskiftet 2020/21.

Det aller meste er nå avklart, men det gjenstår noe arbeid med å definere ulike kategorier for renhet og beskyttelse for ulike rom. Det ble satt ned en egen gruppe for å gå nøye gjennom dette.

Neste – og forhåpentligvis siste – møte i arbeidsgruppa er i mai 2020, og etter det håper vi å kunne melde om et gjennomarbeidet og ferdigtygd dokument. Følg med!

Annex 1 Version 12

The European Commission (EC) have started a targeted consultation process on 20 February 2020 for commenting on Annex 1 version 12. The consultation period is 3 months.

Targeting is in the context of targeting comments around specific clauses of version 12 that are either significantly changed from the initial draft shared in the public consultation with revision as a result of comments received or concerns were expressed from the industry during the public stakeholder consultation.

Targeting is also the process of streaming comments through representative Stakeholders groups that are acknowledged by the EC as 'Interested parties' mainly formed of industry Not –for –Profit societies/ associations of which the PHSS are included and invited to participate in the commenting process. Across the commenting groups there is a cooperation initiative with a view, where possible, to harmonize comments or understand where non-alignment is present with a chance to align or agree to disagree but with knowledge that is the case before submission of comments.

The PHSS have included Kari Leonsaari on "PHSS Annex 1 focus group" to link R³ Nordic with the PHSS as an recognised commenting platform. PHSS will send an Annex 1 commenting form soon to Kari, in order to start to collate comments from R³ Nordic members. Send your relevant comments ASAP to Kari! (kari.leonsaari@santen.com).

TC 209 WG14

TC209 WG 14 / DIS 14644-17 "Particle deposition rate application" har ett inplanerat möte i Köpenhamn i början av mars. Värd för mötet är AlfaNordic där företaget utöver arbetsgruppens möte ns experter kan delta och ge sina synpunkterdessutom arrangerar en öppen sektion där industrins experter kan ge sin syn på standarden som utarbetas.

TEXT:
LENE BLICHER OLESEN

How Camfil can help in reducing the risk of infectious virus in the indoor air using high efficiency air filtration

A research team comprising scientists from the United States, Canada and Spain reveals that more than 800 million viruses fall on every square metre of the planetary boundary layer (the lowest part of the atmosphere) every day – the equivalent of 12 viruses for every person in the UK, 25 viruses per person in Canada. The risk of getting an infection through virus is high as unlike bacteria rain cannot wash them away.

A potentially devastating new disease has infected thousands of people since it was discovered in Wuhan, China in December last year. Chinese cities have been placed in lockdown in a bid to control the spread of the virus. This latest strain of the disease is particularly threatening because it causes pneumonia but will not respond to antibiotics. However, coronavirus (COVID-19) is by no means the only threat to human health.

This, of course, begs an important question – **what can you do to protect yourself** from these infections (not to mention other biological contaminants that pose health risks for building occupants such as smoke, mite, bacteria, house dust and pollen)?

Unlike with many other risks, we have no choice about breathing. But while most of us don't have the power to make the air cleaner, there are some things individuals can do to reduce the effect of these infectious particulates in the air.

HEPA filters can reduce the impact of the virus from the air

HEPA filters have been proven over decades across a wide range of healthcare facilities and life sciences applications, controlling the spread of airborne particles and organisms such as viruses and bacteria.

Indeed, many professional engineering organisations recommend HEPA (high-efficiency particulate air) filters in hospitals, infection control clinics and other healthcare facilities to eliminate microbes and other dangerous particles.

True high-efficiency particulate air (HEPA) filters most commonly are rated by test methods that begin with a minimum capture efficiency. The efficiency of HEPA filters is measured at MPPS (most penetrating particle size) that means this is the lowest efficiency of the filter. For smaller or larger particles that filter will perform even better. MPPS is typically between 0,1-0,25 micrometer in size. Bacteria and viruses are often smaller than that but typically attach themselves to larger particles. It's also important to understand HEPA filters do not actively kill living organisms. They capture and hold them within the matrix of the filter.

High efficiency air filters can be installed in HVAC systems, filtering out biological pollutants and particulate matter carried by the airstream, preventing them from entering or recirculating back into the room. As unfiltered air flows through the HVAC unit's ductwork, the air filter captures and holds the airborne pollutants.

For further risk mitigation of airborne pathogens, it is recommended to upgrade or install the highest possible efficiency HEPA filtration (H13 or higher) in the existing ventilation system. This will improve your chances to avail an extra layer of protection against airborne pathogens.

What kind of solutions you need to reduce the risk of virus in the air?

Virus containment at health care facilities and biosafety labs is very much about control measures and precautions for airborne exposure. Measures include ventilation, pressure differentials, exhaust ventilation, air filtration and cleaning, ultraviolet and germicidal irradiation (UVGI) and even temperature and humidity control.

Air filtration solutions depend on the category of the risk when in application. High density areas with most affected surroundings such as laboratories, containment units, quarantined zones need much higher level of protection compare to low risk exposure surroundings or controlled areas like homes or small business space. High risk application needs air containment and filtration equipment of HEPA Class H13 or higher along with use of special personnel equipment and clothing, as well as a segregated air supply, among other precautions.

Consider using air cleaners for fast and easy retrofit in case of sub-standard ventilation system for improvement in air filtration. It is also a way to rapidly boost the air quality of an already good functioning system when there is an increased risk that demands even better protection.

For crucial high-risk applications such as quarantined zones and laboratories Camfil provides compelling containment equipment. However, an air cleaner is recommended for use where the risk of airborne contamination is elevated. Both containment units and air cleaners cannot be installed anywhere as they are specific to the risk and nature of the surroundings, but an air cleaner can never replace a full containment set where there is a need. On the other hand, low risk applications can consider using EPA filters or ePM1 80% or higher category of air filtration.

"There are more than 60 biosafety laboratories classified as Level 4 (highest risk) by international commission in the world. Camfil has already delivered containment solutions for many of them in China, France, Switzerland, Germany and the U.S.A" - Anders Sundvik, Vice President Research & Development, Camfil

See the graphic below created by Camfil experts to understand air filtration and containment requirements on basis of its application.

In order to educate and create awareness about role of air filtration and containment of airborne infections in order to reduce the risk indoors, Camfil has created a series of education based infographics that provides value-based insights in order to combat the virus in the air. Please find them here.

Camfil's clean air solutions helps to reduce the potential spread of diseases through the air handling systems of biosafety labs and hospitals.

For more information about our range of HEPA, EPA and ULPA filters, visit www.camfil.com and reach the experts.

Uppdaterad strategi för arbetet mot antibiotikaresistens i Sverige

Regeringen har beslutat om en uppdaterad strategi för arbetet mot antibiotikaresistens. Strategin bibehåller den övergripande målsättningen att bevara möjligheten till effektiv behandling av bakteriella infektioner hos människa och djur, och kommer att gälla till och med 2023.

– *Regeringen prioriterar antibiotikaresistensfrågan högt. Förmågan att kunna förebygga och behandla infektionssjukdomar är absolut central för hälso- och sjukvården, och även om vi i Sverige står starka internationellt sett riskerar även vi att inom de närmaste åren nå kritiska nivåer av antibiotikaresistens*, säger socialminister Lena Hallengren.

Strategin för arbetet mot antibiotikaresistens ska ligga till grund för Sveriges arbete med att bromsa uppkomst och spridning av antibiotikaresistens, samt att förebygga och hantera dess konsekvenser. Det svenska arbetet mot antibiotikaresistens nationellt, inom EU och internationellt ska vara långsiktigt och hållbart samt utgå från effektiva insatser inom alla relevanta områden.

Uppdateringen är gjord i linje med hur förutsättningarna för arbetet mot antibiotikaresistens har förändrats under de senaste åren i Sverige, inom EU samt globalt. Den tar fasta på utvecklingen som skett på flera områden, särskilt i och med det ökade engagemanget inom FN-systemet.

– *Sverige ska fortsatt visa ledarskap i det internationella arbetet, i linje med vår politik för global utveckling inom ramen för Agenda 2030 och arbetet inom EU,* säger socialminister Lena Hallengren.

– *Den svenska djurproduktionen kännetecknas av ett starkt djurskydd och en god djurvälfärd. Vi har stark samverkan mellan staten, näringen och forskningen och har bland annat visat att det går att minska användningen av antibiotika rejält i djurhållningen med bibehållen produktion. Det gör oss till en viktig förebild i omvärlden,* säger landsbygdsminister Jennie Nilsson.

Delar av regeringens politik bygger på januariavtalet, en sakpolitisk överenskommelse som har slutits mellan Socialdemokraterna, Centerpartiet, Liberalerna och Miljöpartiet de gröna.

Kontakt Jasmina Sofic, pressekreterare hos socialminister Lena Hallengren
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CEPI forskar kring vaccin mot coronaviruset

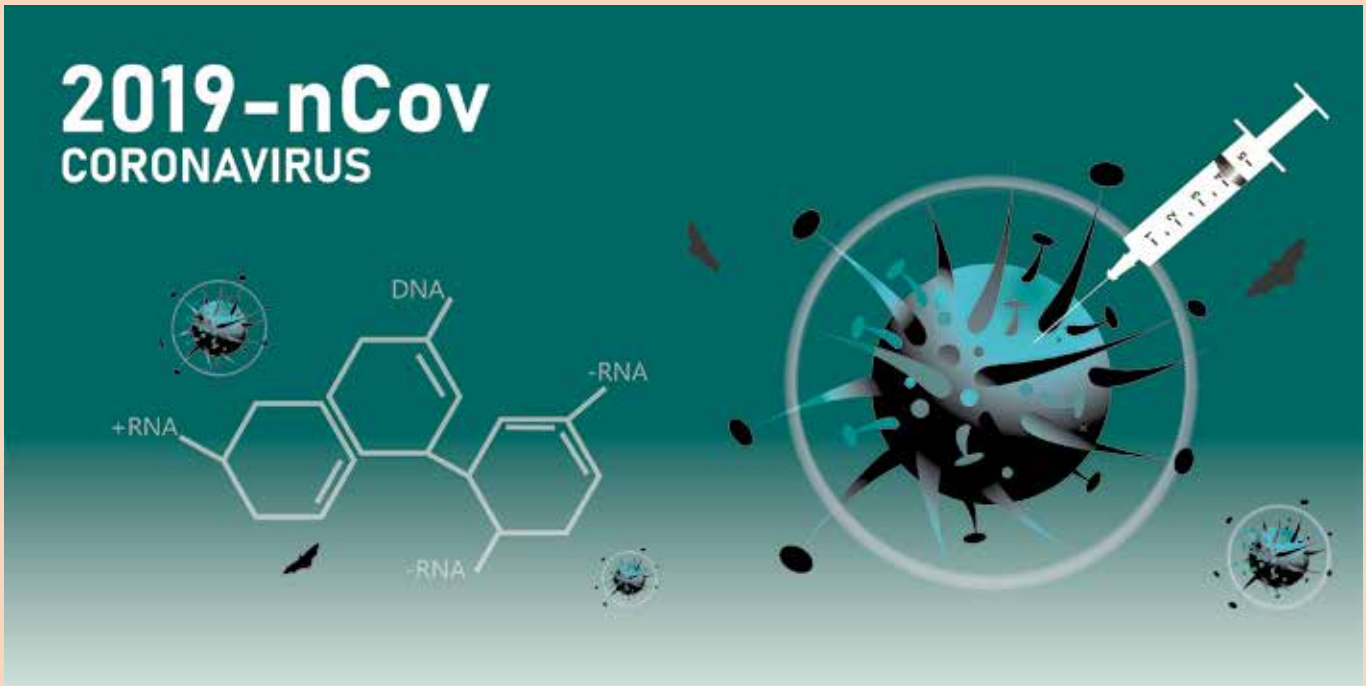
Utdrag ur publikation Vetenskapsradion · Annika.Ostman@sverigesradio.se

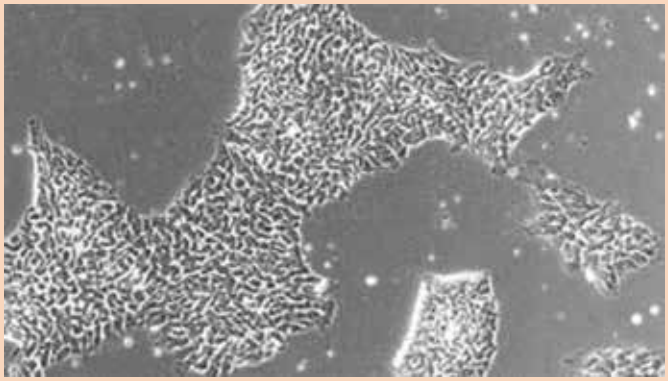
Forskare försöker nu skapa ett prototypvaccin mot den nya versionen av coronavirus i Kina.
– *Vårt hopp är att vi kan ha ett vaccin som kan skalas upp i slutet av året*, säger Frederik Kristensen som jobbar i ledningen för nätverket Coalition for Epidemic Preparedness Innovations, CEPI.
Nätverket med forskare kom till efter utbrottet med ebola i Västafrika 2013-2015. CEPI finansieras av flera länder, som Norge, Tyskland, Japan och Indien, samt Bill och Melinda Gates stiftelse.
– *De som är specialister på epidemiologi och modellering säger att på grund av Kinas våldsamma storlek och antal människor, så kan toppen antagligen nås efter sommaren,* säger Frederik Kristensen på CEPI.

Om man tittar på ett coronavirus ovanifrån i mikroskop, kan det se ut som en liten prinsesskrona. Forskarna tror sig veta vilken av de här spetsarna i kronan, alltså ett ytprotein, som binder till andra celler i människokroppen, och skapar lungsjukdom.
Om forskarna med sina professionella kunskaper har gissat rätt skulle det proteinet kunna injiceras i människor, och på så vis skapa ett immunsvar. Den nya tekniken innebär att forskarna skapar ett vaccin via ytprotein, ett protein som kallas budbärar-RNA.

Sedan tidigare jobbar CEPI med att ta fram ett vaccin mot MERS, en annan typ av coronavirus. Det är inte kartlagt hur likartade de båda virusen är.
Ali Mirazimi, adjungerad professor i virologi på Karolinska institutet och på Statens Veterinärmedicinska anstalt, SVA, säger till Vetenskapsradion att: *problemet är att ingen än så länge vet hur immunförsvaret reagerar på det här proteinet, och därmed hur bra skydd som kan ges.*

Frederik Kristensen håller med om att det är osäkert om det nya vaccinet kommer att fungera:
– *Det är ett högriskprojekt på så vis att det är en hög risk att man inte lyckas.*
Även om det skulle fungera återstår många steg innan ett vaccin kan vara på plats, med säkerhetstester och att testa om det verkligen kan ge skydd mot den nya versionen av coronavirus.





Satsning på biobank med stamceller i Lund

Vetenskapsradion · vet@sverigesradio.se · Foto: Johan Jakobsson.

Diabetescentrum och Stamcellscentrum vid Lunds universitet satsar på att bygga upp världens största biobank med stamceller.
Många lider av diabetes, alzheimer och hjärt-och kärlsjukdomar. Målet är bland annat att biobanken med stamceller från både friska personer och patienter, ska bidra till en ökad förståelse för olika folksjukdomar uppkommer.

Biobanken ska bestå av 100 stamcellslinjer och forskare från hela världen kommer kunna ansöka om att ta del av den.
– Arbetet med att bygga upp biobanken har redan startat. Vi hoppas att vara klara med hela arbetet inom 3 till 4 år, säger Johan Jakobsson, professor i neurovetenskap på Stamcellscentrum vid Lunds universitet.

Projektet VisBac på KTH

KTH-forskare använder VR (Virtual Reality) för att göra bakterier synliga i luften.
– Vi visualiserar inomhusluftens partikelrörelser och föroreningar i operationssalar genom så kallade superdatorsimuleringar, berättar Parastoo Sadeghian, medarbetare i VisBac-projektet på KTH.

Forskarna har visualiserat bakterierörelserna i luften med hjälp av VR och AR (Augmented Reality), och ett gränssnitt som översätter komplicerad simuleringsdata till lättförståeliga animationer. Med hjälp av VR-glasögon kan nu läkare och vårdpersonal få en bättre bild av vad som händer i luften under pågående operation
VisBac-projektets forskningsledare, Christophe Duwig, tillägger:
– De senaste årens ökning av bakteriell resistens mot antibiotika gör att den här sortens teknikanvändning är extra viktig framöver. Resistenta bakterier betraktas som ett globalt hot, och i framtiden kan enkla kirurgiska ingrepp bli livshotande om vi inte kommer tillrätta med problemen.

För mer information kontakta Katarina Ahlfort. Foto: VisBac

Första spadtaget för ett nytt, modernt renrumstvätteri i Nyköping!

Efter att Elis förvärvade Berendsen i september 2017 har renrumsverksamheterna från de båda bolagen gått samman under ett nybildat varumärke – Elis Cleanroom.
Under 2021 kommer ett nytt renrumstvätteri ska stå klart i Nyköping och i dagarna togs det första spadtaget. Under 2020 sker själva byggnationen samt installation av utrustningen och under det första kvartalet 2021 ligger fokus på certifieringar och valideringar.
Den nya anläggningen kommer att kunna stoltsera med en större yta – nästan 2 400 m^2, på vilken man kan styra flödet på ett helt annat sätt än i dag. Med ökad effektivitet skapas främst en möjlighet till ännu bättre kontroll och dokumentering av processer än vad som kan utföras i dag. Likaså är det en enorm investering när det gäller arbetsmiljön för de 35 anställda som idag arbetar på anläggningen.

För ytterligare information om kontakta Egle Hammering
+45 2373 8639 eller via mail egle.hammering@elis.com

Nytt från SIS

Agneta Gunillason efterträder Sarah Sim som projektledare för ett antal tekniska kommittéer:

TK 108 Renhetsteknik
TK 333 Förbrukningsmaterial inom vården
TK 340 Implantat och biologisk säkerhet
TK 527 Renhet i operationsrum
TK 572 Kvalitet i särskilt boende och hemtjänst.

Hyresgäster inte nöjda med miljötvätt

Den 10 februari 2020 | Av Boel Jönsson | Tipsa redaktionen

Hyresgäster hos Varbergs Bostad har felanmält de nya tvättmaskinerna som tvättar i kallt vatten utan tvättmedel. Nu har Folkhälsomyndigheten fått frågan på sitt bord.
I december kopplade Varbergs Bostad in ett filtersystem med avjoniserat vatten till fyra tvättmaskiner (Diro-systemet) på bostadsområdet Havstruten; kostnad 186 000 kronor, exklusive moms.

De flesta tvättprogrammen sker i kallt vatten utan tvättmedel och ska vara ett mer miljövänligt alternativ. Tekniken har dock fått stark kritik från forskare.
– Jag har faktiskt gjort en felanmälan till Varbergs Bostad, eftersom det inte fungerar. Sedan har jag anmält det till Hyresgästföreningen, säger Therese Carlsson till Hallands nyheter. Hon har testat tvättmaskinerna vid två tillfällen och inte tyckt att tvätten blivit ren.
– Det positiva är väl att det ska vara bra för miljön. Jag antar det är därför man satt in dem. Men jag vill helst ha ren tvätt.

Totalt har fyra personer kontaktat Hyresgästföreningen om den nya tvättekniken på bostadsområdet Havstruten, enligt tidningen. Sven Olof Andersson i kommittén för kvarterets gårdsråd har även kontaktat miljö- och hälsoskyddsförvaltningen om maskinerna. Han bryr sig egentligen mindre om att fläckarna inte försvinner utan är orolig för bakteriespridning och smittspridning, säger han till Hallands nyheter.

Miljö- och hälsoskyddsförvaltningen har i sin tur kontaktat Folkhälsomyndigheten för att få reda på deras eventuella uppfattning om tvättmetoden.

Varbergs Bostads marknadschef Dzejna Seta medverkade på ett informationsmöte med ett 20-tal hyresgäster förra veckan:
– Det fanns en missuppfattning kring hur systemet fungerar och genom mötet hade vi chans att svara på det. Det fanns personer där som nu kände att de blev mer positiva och ville prova maskinerna, säger hon till tidningen.

Jordnötsallergi spåras till magen

Vetenskapsradion · stefan.nordberg@sverigesradio.se

För många av oss är jordnöten en god baljväxt att äta utan komplikationer. Men för andra kan den leda till livsfarliga allergiska reaktioner. Men var i kroppen tillverkas de antikroppar som leder till en allergisk reaktion?

Nu har forskare i en amerikansk studie försökt komma närmare ett svar.
19 personer med jordnötsallergi har deltagit i studien och hos dessa fann forskarna en extra stor ansamling av ett speciellt protein, en antikropp kallad immunoglobulin E, i mag-tarmkanalen. Och det är en antikropp som är kopplat till just allergiska reaktioner.

Enligt forskarna tyder mycket på att immunoglobelin E, hos dessa personer, bildas av att vissa celler i magen går över från att producera ofarliga antikroppar, till just immunoglobulin E. Men fortfarande är det svårt att exakt förklara varför kroppen gör detta, berättar Caroline Nilsson, överläkare och docent på Karolinska institutet.
– Det finns många olika teorier. Vi vet att vi har mer allergier nu än för 50 år sedan. Men exakt varför är svårt att svara på, säger hon.

Bjarne Österberg ny enhetschef för Ventilator Renrum

Bjarne Österberg har tillträtt som ny enhetschef för Ventilator Renrum. Bjarne har mer än 20 års av erfarenhet av tät- och kvalitetskontroll genom mätning- och kvalitetstest för industrin. Han tar också med sig gedigen erfarenhet kring projektledning samt försäljning och distribution - på både en nationell som internationell marknad. Bjarne tillträdde som enhetschef januari 2020 och tillför ytterligare kompetens och erfarenhet till ett starkt kunskapsbärande Ventilator Renrum

Ventilator Renrum är en av tre enheter inom Ventilator som i sin tur ingår i företagskoncernen Energivärden med ca 150 anställda och en omsättning på ca 350 Mkr 2019. Enheten Ventilator Renrum startade 2003 och blev snabbt ett av Sveriges mest kunskapsledande företag när det gäller helhetslösningar för kontrollerade miljöer.

Under 2018 utvecklades Ventilator Renrum ytterligare genom tillkomsten av affärsområdet Laboratorieinredning & skyddsutrustning.
Det nya affärsområdet har fått en flygande start och erbjuder helhetslösningar i form av produkter och tjänster till sjukvårds- och forskningsenheter samt skolor mfl. I affärsområdet ingår också försäljning av laboratorieutrustning som säkerhetsbänkar, klimatskåp, och klimatrum mfl.

I dag är Ventilator Renrum ett rikstäckande företag, specialiserade på renhetsteknik och kontrollerade miljöer. Deras erfarenhet och kompetens spänner över samtliga renhetsklasser, principer och standarder som gäller inom branscher som sjukvård, biotech-, elektronik-, läkemedel- och livsmedelsindustrin.

R³ NORDIC INVITES TO

EHEDG Advanced Course in Hygienic Engineering & Contamination Control

20th - 22th of October 2020

Tetra Pak, Ruben Rausings gata, Lund, Sweden

AIM

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

PARTICIPANTS

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

CONTENT

The course is given in English from a practical point of view. The theoretical fundamentals of the different subjects are given in a concise way, continuously relating these to practice through pictures or examples. Design guidelines are dealt with in terms of the basic properties experimental evidence. The course gives you tools to solve hygienic problems within your own organization.

The course is interactive due to training in small groups. On the last course day, there will be an Exam (course material allowed). EHEDG certificate will be mailed to approved participants attending the full course.

REGISTRATION

The course fee is 1950 €/participants. Company members get 10% reduction on the fee. The fee comprises course material, course certificate (posted to approved participants attending the whole course), coffee/tea, lunches and dinners mentioned in the programme.

The prices are excl. VAT.

REGISTRATIONS AT LATEST ON SEPTEMBER 18.

Please, contact Gun Wirtanen for further information and/or registration by e-mail guliwi@luukku.com. At registration, we need:

1) Name of participant
2) Company
3) Contact address (incl. e-mail)
4) Invoicing address (incl. e-mail)
5) Information on e.g. food allergies, diets.

CANCELLATION POLICY

Cancellations must be sent in writing by mail to Gun Wirtanen at guliwi@luukku.com. Participation in this training course can be cancelled free-of-charge at latest five weeks prior to the event except for an administration fee of 100 €.

Cancellations thereafter, we will charge 50 % of the participation fee. We charge the full participation fee for late cancellations made two weeks before the event start or thereafter (a colleague can take a paid course place at late cancellations).

THE COURSE TRAINERS ARE

Alan Fris, Ferdinand Schwabe and Gun Wirtanen.

Tuesday 20th of October

08.45 – 09.15	Registration with Coffee/Tea and Presentation
09.15 – 09.45	Introduction to Hygienic Design - Motivation
09.45 –11.15	Legal requirements
11.15 – 12.00	Lunch
12.00 – 13.15	Hygienic design criteria
13.15 – 13.30	Coffee/Tea -break
13.30 – 15.00	Hazards in hygienic processing
15.00 – 15.15	Coffee/Tea -break
15.15 – 16.30	Construction materials
16.30 – 17.00	Video - Verification of hygienic design & EHEDG test methods and certification
17.00 – 17.45	Welding stainless steel
18.30 – 21.00	Dinner

Wednesday 21st of October

08.30 – 10.00	Static seals and couplings
10.00 – 10.15	Coffee/Tea -break
10.15 – 11.30	Cleaning & Disinfection
11.30 – 12.15	Lunch
12.15 – 13.30	Valves & Pumps
13.30 – 14.15	Demo on process flows / traceability system
14.15 – 14.30	Coffee/Tea –break
14.30 – 16.30	Equipment exercises with coffee/tea available
16.30 – 17.00	Lubricants
17.30 – 20.00	Dinner

Thursday 22th of October

08.30 – 10.15	Building and process layout
10.15 – 10.30	Coffee/Tea -break
10.30 – 11.30	Installation & maintenance
11.30 – 12.15	Lunch
12.15 – 13.30	EHEDG Advanced Course exam (1 h)
13.30 – 13.45	Coffee/Tea -break
13.45 – 14.45	Group work (4-6 participants/group) on design pictures
14.45 – 15.30	Presentation of EHEDG
15.30 – 15.45	Exam results

R³ NORDIC, CTCB-I OCH CHALMERS INBJUDER TILL

CTCB-I Certifiering Cleanroom Testers

6-8 Oktober 2020

Installationsteknik, CHalmers, Göteborg

KURSMATERIALET FÖR ”CLEANROOM TESTING CERTIFICATION” ÄR PÅ ENGELSKA OCH SKICKAS EFTER INBETALD REGISTRERINGSAVGIFT TILLSAMMAN MED QUESTION/ANSWERS-HÄFTE TILL KURSDELTAGAREN FÖR SJÄLVSTUDIER, SENAST EN MÅNAD FÖRE KURSSTART. EFTER GODKÄNT RESULTAT ERHÅLLS ETT CERTIFIKAT. OBS. CERTIFIKAT PÅ PROFESSIONAL LEVEL ÄR GILTIGA I ENDAST 5 ÅR.

First Day Lecture Course:
Associate and Professional candidates

- Lecture course revising the course notes
- Tutorial revision

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

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

Third Day Practical Exam:
Professional candidates only

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

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

Information also available at www.safetyventilation.com

Latest Application date September 6, 2020

CTCB Associate Level - 2 days, October 6-7
Registration: SEK 3 950 · Course and exam: SEK 11 250
Lecture course. Written exam. Practical training and hands-on.

CTCB Professional Level - 3 days, October 6-8
Registration : SEK 3 950 · Course and exam: SEK 14 500
Lecture course. Practical training. Written and practical exams.

Exam Re-sit and Upgrading (Assoc to Prof) October 7-8
Candidates can re-sit their or upgrade their exams within a year.
Registration: SEK 2 950.
Practical exams will be SEK 3 500 per exam.

CTCB Prof Level Recertifikation - 3 days, October 6-8
Registration: SEK 3 950 · Course and exam: SEK 12 500
Lecture course. Pracital training. Written and practical exams.
Note: Candidates who are not already members of R³ Nordic or another ICCCS affiliated society will also be charged the cost of one year’s individual membership - currently SEK 650,- in R³ Nordic.
Note: Any costs required for accommodation are the responsibility of the candidate.
Moms tillkommer på samtliga angivna priser.

Questions and application form: +46 (0)703 15 11 55
Lars Ekberg, e-post: ctcb-gothenburg@cit.chalmers.se

R³ NORDIC LAU NORGE INBJUDER TILL

Grunnkurs i renhetsteknikk

Prel November 2020
Skjetten, Norge

BEGRENSET 35 DELTAGERE

PREL PROGRAM - 14. oktober 2019

09.00-09.30	Registrering
09.30-10.00	Åpning, introduksjon. Presentasjon.
10.00-10.45	Standarder i renrom (KS)
10.45-11.30	Ventilasjon og luftbevegelse (KS)
11.30-12.30	Lunsj
12.30-13.30	Ventilasjon og luftbevegelse fort. (KS)
13.30-13.45	Kaffepause
13.45-14.30	Konstruksjon av renrom. Kvalifisering av renrom (KS)
14.30-15.30	Ulike type benker. Testing av ulike type benker (KS)
15.30-15.45	Kaffepause
15.45-17.00	Kontaminasjonsbegrepet. Levende og døde partikler (BR)

PREL PROGRAM - 15. oktober 2019

08.30-10.30	Mennesket i det rene rom, arbeidsteknikk og påkledning (BR)
10.45-11.30	Mikrobiologi i renrom (KA)
11.30-12.15	Lunsj
12.15-13.00	Mikrobiologiske testmetoder (KA)
13.00-13.20	Kaffepause
13.20-14.45	Klær, vask og rengjøring (BR)
14.45-15.30	Case - gruppeoppgave
16.00	Avslutning, kursevaluering, deltakerbevis

Kursavgift
NOK 6 950 (R³-medlem 6 300)
Inkl kaffe, te, frukt, lunsj, felles middag mandag kveld.

Meld deg inn i R³ Nordic via hjemmesider:
r3nordic.org/shop/medlemskap/ansok-om-medlemskap/

Påmelding
mail til r3nordic.no@gmail.com eller
kontakt Barbro Reiersøl på mobil 95 13 19 45.

Overnatting på Olavsgaard hotel
Ordnes ved å kontakte hotellet direkte. Husk å oppgi at du deltar på dette kurset. Dette er ikke inkludert i kursprisen. Tlf. til hotellet: +47 63 84 77 00

Arrangør: Norske LAU R³ Nordic
Eli Bjørnson, Serviceproduksjon, Barbro Reiersøl, AET AS,
Phuong Huynh, Sykehusapoteket i Drammen og
Geir Valen Pettersen, Norsk medisinsk syklotronsenter AS

R³ NORDIC INBJUDER TILL

Grundkurs i renhetsteknik

Prel Oktober 2020
Uppsala, Sverige

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 5.850,- (R³-medlem 5.200,-)

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

FÖRBRUKNING FÖRPACKNING PROCESS

AET ARBEIDSMILJØ OG ENERGITEKNIKK (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 ÖVERVAK VALID KALIB

BROOKHAVEN INSTRUMENTS AB (SE)
Partikelräknare, sensorer och system.
Tel 0768-581000 / www.brookhaven.se

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. Christian Jansson
Tel 08-59096200 / cja@ninolab.se

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

MIKROBIOLOGI STERILISTERING

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

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

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

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

KONSULTER PROJEKTERING

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

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

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

PB-TEKNIK AB (SE)
Projekterar rör, luft, styr för renrum, prod.lokaler och laboratorier.
Tel 08-56485952 / tl@pbt.se

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

RENRUM BÄNKAR INREDNING PROD

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 projektering, leverans, montering och validering.
073-0755210 · cleanroom@caverion.com

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

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

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

RENGÖRING STÄDNING

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

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

RENRUMSKLÄDER TEXTIL TVÄTTNING

BERENDSEN (PART OF ELIS) (SE)
Uthyrning och tvätt av textilier
www.berendsen.se
Tel 020-74 01 01 / info@berendsen.se

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

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

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

VENTILATION FILTER

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