Renhets TEKNIK
THE NORDIC JOURNAL OF CONTAMINATION CONTROL AND CLEANROOM TECHNOLOGY NR 4:2019

Unidirectional airflow at different air velocities – evaluation with the LR-method

Ett varmt tack från oss alla till Berit Reinmüller för hennes engagerade och mångåriga arbete som redaktör för RenhetsTeknik

- **INVITATION TO R³ NORDIC 51TH SYMPOSIUM AND EXHIBITION**
- **RAPPORTER FRÅN FORSKNING, UTBILDNING OCH MÖTEN · INBJUDNINGAR**

Renhets TEKNIK

Officiell Publikation för
R³ Nordic, Nordiska R³-föreningen.
Årgång 48, 2019

The Nordic Journal of Contamination Control and Cleanroom Technology.
Official Magazine for R³ Nordic since 1971.

RenhetsTeknik utkommer med fyra nummer per år. Syftet är att tidningen, såväl som föreningen, skall bidra till utveckling och tillgodogörande av R³-tekniken i samhället. Föreningen är ideell och grundades 1969.

UPPLAGA
450 ex

ISSN
1404-806X

Tidningen distribueras gratis till alla medlemmar och medlemsföretag.

r³ nordic

KANSLI/MEDLEMSÄRENDEN
R³ Nordic c/o Ganska
Härjedalsgatan 1, SE-265 40 Åstorp
Tel: +46-(0)40-16 10 80 / Fax: (0)40-16 10 96
info@r3nordic.org
Öppettider: Mån- & Onsdag 08-10

ORDFÖRANDE / ANSV. UTG
Lennart Hultberg
Processhygien & Kontrollerade Miljöer
Medeltidsvägen 11, 265 32 Åstorp
Tel +46 (0)42 583 40 · (0)760 399 500
lennart@processhygien.com

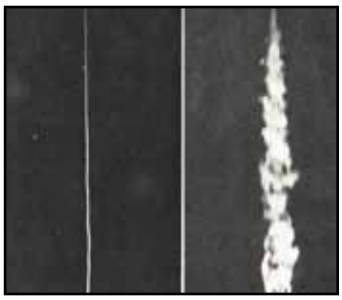
REDAKTÖR
Berit Reinmüller
Chalmers Installationsteknik Göteborg
Mobil: +46(0)70-164 34 11
beritr@chalmers.se

BYRÅPRODUKTION
Anders Jarl Consulting
Ranstavägen 15, 749 61 Örsundsbro
Tel: +46 (0)70 650 82 30 · anders@aj-con.se
www.aj-con.se

TRYCKPRODUKTION
Hylte Tryck AB, Hyltebruk

www.r3nordic.org

INNEHÅLL



For those of you who would like further information in English about the magazine, articles, advertising or others, please contact the editor Berit Reinmüller or the producer Anders Jarl.
Phone numbers and e-mail addresses you will find to the left, at page 2.

OMSLAGSBILD / COVER:
FOTO: Illustration turbulent och laminärt luftflöde av Anders Jarl

ORDFÖRANDE HAR ORDET

Bästa R³-medlem

LENNART HULTBERG
ORDFÖRANDE I R³ NORDIC

Så är det dags igen att tända julens första adventsljus och blicka tillbaka på året som gått.

Under året har vi arrangerat vårt årliga symposium i Stockholm. Eftersom vi hade ett riktigt bra program hade vi dock önskat oss ett större antal deltagare. Det har även arrangerats grundkurser i Norge och Sverige samt CTCB-I-kurs i Göteborg

Mycket händer i vår omvärld. Stora om- och nybyggnationer av sjukhus pågår i våra nordiska länder. Enorma summor pengar investeras i dessa byggnationer och det slår mig emellanåt, om man kunde gjort annorlunda? Det är min övertygelse att man skulle kunna få ut mer av pengarna, som investeras i dessa omfattande projekt. Utmaningen är att våga göra på ett nytt sätt, ta in influenser från andra områden, istället för att snegla på vad som görs inom det egna området. Jag efterlyser mer genomtänkt arbete i tidig kravställning där verksamhet, fastighet och teknisk daglig drift sitter ner och arbetar fram ett bra underlag till beställning. Väl medveten om utmaningarna och murarna som måste rivas, men skall man göra något nytt måste nya strukturer skapas.

R³ Nordic kommer tillsammans med LÖF att kalla till ett uppstartsmöte där tanken är att förutsättningslöst försöka finna nya vägar samt skapa en frågelista att ta ställning till vid byggnation.

Finns intresse att deltaga, så kontakta mig.

SYMPOSIUM I FINLAND –
VAD HÄNDER MER UNDER 2020?

Planeringen inför nästa års symposium i Finland är på gång och framtagning av programmet pågår. Väl mött i Finland till våren!

Grundkurser kommer att arrangeras och vidare kommer en ny CTCB-I-kurs att genomföras. Vi har även börjat sondera läget om en ny sjukhusdag i Sverige till hösten.

Är det något ni skulle önska att föreningen tar fram inom utbildningsområdet så kontakta mig gärna direkt på 0760-399500. Vi kan anordna öppna kurser samt företagsspecifika utbildningar.

Slutligen vill jag på styrelsens vägnar önska er alla en riktigt God Jul och Gott Nytt År.

God Jul och Gott Nytt År

NY REDAKTÖR SÖKES TILL 2020

Efter 13 år som redaktör har Berit Reinmüller meddelat styrelsen att hon vid årsskiftet 19/20 lämnar sitt uppdrag som redaktör. Föreningen tackar Berit för ett utomordentligt väl utfört arbete. Är du intresserad att ta vid efter Berit?

Kontakta ordf Lennart Hultberg på lennart@processhygien.com

KALENDER

2020

Mars

4-6 EHEDG-kurs, Tetra Pak, Lund

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

April

Maj

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

Jun

- PHSS Conference

Sep/okt

- CTCB-I certifiering, Associate and Professional level, Göteborg

Okt

10-17 ISCC'20 Contamination Control Everywhere in our lives, Turkey Information: atwww.iscc2020.com

19-20 Grunnkurs Renhetsteknikk Olavsgaard Hotel, Skjetten, Norge

Nästa nummer
beräknas utkomma den 19 december 2019

Manusstopp / Annonsbokning:
19 november 2019

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

REDAKTÖRENS SPALT

MÅNGA ÅR – TIDEN GÅR FORT

Som redaktör för RenhetsTeknik under 13 år tackar jag för mig och noterar att tiden gått fort. Det har varit synnerligen intressant att få ta del av utveckling och tillämpning inom området Contamination Control/Renhetsteknik. Att få vara en del av pågående kunskapsutbyte, utbildningsaktiviteter och problemlösningar har varit stimulerande. Idag behövs renhetsteknik inom fler områden än tidigare. Den börjar bli en del av vardagen och kanske tas för självklar, men utbildning, förståelse och riskmedvetande är viktigt och här har en ideell förening som R³ Nordic en stor betydelse.

Mitt tack till er alla som medverkat med material och information till tidningen och till er som givit feed back på tidningens innehåll. Ett speciellt tack för gott samarbete till Anders Jarl, produktionsansvarig, och till Lennart Hultberg, ordförande och ansvarig utgivare.

INTERNATIONELLT SAMARBETE/SAMVERKAN

Genom internationella kontakter med såväl ICCCS som PDA och PHSS har artiklar i RenhetsTeknik fått spridning i bl a UK, USA, Ryssland, Italien, Frankrike, Spanien och Brasilien. Det internationella kunskapsutbytet är värdefullt och RenhetsTeknik har i sin tur kunnat publicera artiklar, som publicerats i andra motsvarande tidningar. R³-föreningens medlemmar, som deltar i internationella konferenser och i internationellt standardiseringsarbete, är en del av det kunskapsförmedling och nätverksbyggande som pågår, och som bl a återspeglas i innehållet föreningens symposier.

I DETTA NUMMER

I årets sista tidning finns både rapporter från höstens kurser, om pågående forskning inom operationsrum, en artikel om lufthastighetens betydelse vid UDF och inbjudan till symposiet i Finland och till kurser under 2020.

LYCKA TILL

Jag vill önska R³ Nordic bransch- och medlemstidning RenhetsTeknik och dess nya ledning lycka till med en intressant och betydelsefull arbetsuppgift.

Ett stort varmt tack och en önskan om God Jul och Gott Nytt År

BERIT REINMÜLLER
REDAKTÖR

Unidirectional air-flow at different air velocities - evaluation with the LR-method

BENGT LJUNGQVIST AND BERIT REINMÜLLER,
BUILDING SERVICES ENGINEERING, CHALMERS UNIVERSITY OF TECHNOLOGY, GÖTEBORG, SWEDEN, AND
JOHAN NORDENADLER,
KAROLINSKA UNIVERSITY HOSPITAL, DEVELOPMENT AND INNOVATION, STOCKHOLM, 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 0.3 m/s, while other supply air systems have velocities about 0.4 m/s. The velocity, given by the supplier, is mostly the inlet air velocity just below the filter screen of the unidirectional flow system. The purpose of this paper is to describe contamination risks in unidirectional airflow without obstacles at different air velocities.

To evaluate contamination risks, the method for limitation of risks, the LR-Method, has been used.

The results show that the convection flows and arm movements from a person standing in the unidirectional airflow system have a great impact on the contamination risks at air velocities below 0.4 m/s and that the air velocity should at least be 0.4 m/s to achieve a good protection efficacy.

INTRODUCTION

The number of airborne bacteria-carrying particles, colony-forming units (CFUs) in operating rooms is considered as an indicator of the risk of infection to the patient undergoing surgery susceptible to infections. An international accepted level of the mean concentration during surgery measured close to the wound is less than 10 CFU/m^3. The main source of microorganisms in an operating room is the personnel and the patient.

Operating rooms for patients undergoing infection-prone surgery often have unidirectional flow (UDF) supply air systems. In the past 25 years, many UDF supply air systems installed in Europe have low air velocity, i.e. equal and below 0.3 m/s. It should be noted that Whyte (1,2) in his review paper in two parts states that the UDF system, to be able to work effectively, shall have a minimum average velocity of 0.38 m/s for partial-walled system (0.3 m/s for a full-walled system) when velocity readings are taken 2 m above the floor and minimum average velocity 0.2 m/s taken 1 m above the floor. This agrees with results presented by Nordenadler (3).

In this paper microbiological risk assessment with the method for limitation of risks (LR-Method) is used for the evaluation of contamination risks in UDF without obstacles at different air velocities at laminar as well as turbulent airflows.

MATERIAL AND METHODS

The LR-Method

The LR-method provides a reliable procedure for assessing potential microbiological risks of airborne contamination in clean zones in a systematic way. The LR-Method is performed in three steps:

1 The first step is to visualize (e.g., by using isotherm smoke technique) the main air movements and identify turbulent regions and critical vortices where contaminants can be dispersed or accumulated in an unpredictable way. The illustrative technique of smoke studies provides a useful technique for visualizing air movements and the dispersal of contaminants. This technique requires that isothermal smoke is released continuously and almost momentum free using a diffuser. The smoke pattern can be recorded by means of still photography and video. Visualizing the air movements improves the understanding of potential risks of airborne contamination.

2 The second step - the challenge test – is to identify potential risk situations. The particle challenge test involves placing the probe of an airborne particle counter in the critical area where during normal operations the process/product is exposed and taking continuous total particle counts (sampling flow 1cft/min) while generating particles in the close surrounding air (e.g., by using Air Current Test Tubes) to a challenge level of more than 300 000 particles equal to and larger than 0.5 μm per cubic foot (approx. 10^7 particles per m^3). These measurements must be carried out during simulated process activity. At least three samples of one minute are sampled at each location or during each process step.

3 The third step is to evaluate the risk situation by calculating the Risk Factor, which is defined as the ratio between the maximum measured particle concentration (number/ft^3) in the critical region and the challenge level in the surrounding air. Due to limited measurement accuracy at high concentrations, a value of 300 000 particles per cubic foot is used as a challenge level in all Risk Factor calculations.

When the Risk Factor is less than 10^{-4} (0.01%) during the challenge test, there are no risks of airborne microbiological contamination during normal operational conditions according to experimental findings from more than 50 studied aseptic production lines. Experiences from the use of the LR-Method have been presented by Ljungqvist et al (4, 5, 6, 7).

Performed tests

The tests have been performed in a special designed clean zone test chamber with a UDF-system of 1.2 m x 1.5 m, where the supply air is HEPA-filtered. The vertical air velocity is adjustable from 0.1 m/s to 0.6 m/s. To stabilize the airflow the test chamber is equipped with partial side walls. Temperature and relative humidity are not controlled but have during the tests been in the range 20-26°C and 25-55% RH, respectively.

Figure 1 shows the principal arrangement of the tests with a person present in the test

chamber. The probe of the particle counter (HiacRoyco 245) is in all tests situated on the table in the test chamber at 60 cm from the test person.

Figure 2 shows the principal arrangement of the particle generation regions in the test chamber.

The particle generation regions A and B were situated at floor level at the outer edges of the clean zone and the particle challenge was performed without a test person in the clean zone of the test chamber. The particle challenge in particle generation region C was performed below the table without a test person in the clean zone. In particle generation region D the particle challenge was performed in the clean zone in front of a cleanroom dressed test person, who was standing still, or calmly moved his arms in standardized cycles, moving the arms forwards and back, see Figure 3 (8).

The supply air filter screen creates a low turbulence airflow, which in practical situations should often be called laminar. By using a turbulence generating grid placed just below the filter screen a turbulent airflow should be achieved.

The turbulence generating grid was made of tubes with a diameter of 20 mm and the tubes were situated at a distance of 55 mm. A Reynolds Number of about 400 and 660 was achieved at velocities of 0.3 m/s - 0.5 m/s, respectively at normal room temperature. According to photographs presented by Schlichting (9), it is to be expected that a change to turbulent flow principally consisting of interfering Karman vortex streets will occur at a Reynolds Number of approximately 100. This gives that in the described tests with the turbulence generating grid that turbulent flow is well established and is in the following called flow with high degree of turbulence.

The velocity measurements were performed 0.2 m below the filter screen according to ISO 14644-3 (10), which gives that the readings were taken about 2 m above the floor.

For velocities between 0.3 - 0.5 m/s measurements have been performed in the test chamber with the LR-method of flows with low degree of turbulence (almost laminar) as well as with flows with high degree of turbulence. Figure 4 shows these two types of flow visualized with aid of smoke.

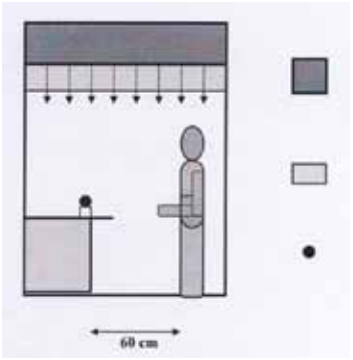


Figure 1
Principal arrangement of the tests in the chamber, section view.

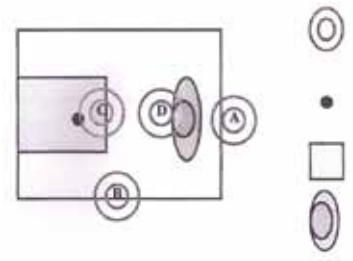


Figure 2
Principal arrangement of the particle generation regions in the test chamber, plan view.

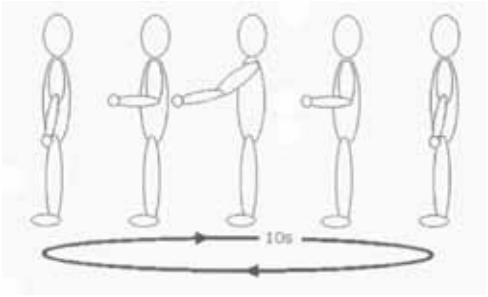


Figure 3.
Standardized cycle of arm movements, time 10 seconds. (from Sipilä (8)).

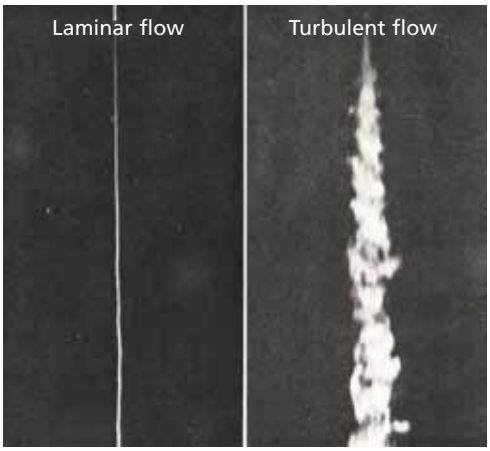


Figure 4
Dispersion of smoke in laminar and turbulent parallel flow.

Note:
The value of Reynolds Number is an indicator of the degree of turbulence in the parallel flow.

RESULTS

Results from the measurements with the LR-method at UDF with low and high degree of turbulence at different air velocities are shown in Table 1 and Table 2.

The results in Table 1 and Table 2 show, independently of the turbulence degree of the UDF, that the air velocity should exceed 0.4 m/s to achieve a good protection efficacy, i.e. a Risk Factor less than 10^{-4}.

Indicative measurements have also been performed at air velocities of 0.25 m/s, 0.35 m/s and 0.45 m/s. The values for the air velocity 0.25 m/s are for particle generation regions A, B, and C in the same range as the values given for the velocity 0.3 m/s, while the values in particle region D (person present) become higher than those given for the velo-

Table 1
Measured particle levels (max. values) during the challenge tests and calculation of the Risk Factor at UDF with low degree of turbulence.

Velocity m/s	Region	Challenge	Number of particles ≥0.5µm/ft³	Risk Factor
0.3	A	Without person – with particle challenge	8 839	$2.9 \bullet 10^{-2}$
0.3	B	Without person – with particle challenge	3 625	$1.2 \bullet 10^{-2}$
0.3	C	Without person – with particle challenge	18 469	$6.2 \bullet 10^{-2}$
0.3	D	Person still – without particle challenge	<10	-
0.3	D	Arm movements – without particle challenge	1 138	-
0.3	D	Person still – with particle challenge	>100 000	$>3 \bullet 10^{-1}$
0.3	D	Arm movements – with particle challenge	>100 000	$>3 \bullet 10^{-1}$
0.4	A	Without person – with particle challenge	0	$<10^{-4}$
0.4	B	Without person – with particle challenge	0	$<10^{-4}$
0.4	C	Without person – with particle challenge	0	$<10^{-4}$
0.4	D	Person still – without particle challenge	<10	-
0.4	D	Arm movements – without particle challenge	41	-
0.4	D	Person still – with particle challenge	<10	$<10^{-4}$
0.4	D	Arm movements – with particle challenge	1 623	$5.4 \bullet 10^{-3}$
0.5	A	Without person – with particle challenge	0	$<10^{-4}$
0.5	B	Without person – with particle challenge	0	$<10^{-4}$
0.5	C	Without person – with particle challenge	0	$<10^{-4}$
0.5	D	Person still – without particle challenge	0	-
0.5	D	Arm movements – without particle challenge	0	-
0.5	D	Person still – with particle challenge	0	$<10^{-4}$
0.5	D	Arm movements – with particle challenge	0	$<10^{-4}$

city 0.3 m/s.

The values for the air velocity 0.35 m/s are in a level between the values for the velocities 0.3 and 0.4 m/s. The values for the velocity 0.45 m/s are close to the values for the velocity 0.5 m/s.

The results show clearly that the convection flows from the test person and arm movements have a great impact on the particle dispersion at air velocities below 0.4 m/s.

DISCUSSION AND CONCLUSION

When the test person is within the UDF region the results show, when the air velocity is 0.3 m/s or less, that the airflow pattern occurs in a disordered manner in the region around the table and the test person. However, when the air velocity exceeds 0.4

Velocity m/s	Region	Challenge	Number of particles ≥0.5µm/ft³	Risk Factor
0.3	A	Without person – with particle challenge	73	$2.4 \bullet 10^{-4}$
0.3	B	Without person – with particle challenge	7 006	$2.3 \bullet 10^{-2}$
0.3	C	Without person – with particle challenge	18 394	$6.1 \bullet 10^{-2}$
0.3	D	Person still – without particle challenge	130	-
0.3	D	Arm movements – without particle challenge	1 296	-
0.3	D	Person still – with particle challenge	83 224	$2.8 \bullet 10^{-1}$
0.3	D	Arm movements – with particle challenge	>100 000	$>3 \bullet 10^{-1}$
0.4	A	Without person – with particle challenge	<10	$<10^{-4}$
0.4	B	Without person – with particle challenge	0	$<10^{-4}$
0.4	C	Without person – with particle challenge	392	$1.3 \bullet 10^{-3}$
0.4	D	Person still – without particle challenge	<10	-
0.4	D	Arm movements – without particle challenge	<10	-
0.4	D	Person still – with particle challenge	<10	$<10^{-4}$
0.4	D	Arm movements – with particle challenge	167	$5.6 \bullet 10^{-4}$
0.5	A	Without person – with particle challenge	0	$<10^{-4}$
0.5	B	Without person – with particle challenge	0	$<10^{-4}$
0.5	C	Without person – with particle challenge	0	$<10^{-4}$
0.5	D	Person still – without particle challenge	0	-
0.5	D	Arm movements – without particle challenge	0	-
0.5	D	Person still – with particle challenge	0	$<10^{-4}$
0.5	D	Arm movements – with particle challenge	0	$<10^{-4}$

Table 2
Measured particle levels (max. values) during the challenge tests and calculation of the Risk Factor at UDF with high degree of turbulence.

m/s, the airflow pattern more closely resembles undisturbed airflow, and the sweeping action seems to be significantly improved.

UDF vertical downwards airflow has been used for decades in industrial cleanrooms as well as in many ultraclean air operating rooms worldwide. If the main concern in an operating room is to achieve an almost bacteria-free environment by the sweeping action of the air in a region around the operating table during ongoing surgery, a UDF-based room air distribution system with an inlet velocity about 0.4m/s is needed. This is in agreement with results presented by Whyte (1,2), Nordenadler (3), Gandra (11) and Whyte and Lytsy (12).

While most UDF-based room air distribution systems for operating rooms, such as those which have been installed in Europe in the last 25 years, have air velocities below 0.3m/s, the air movements during ongoing surgery just above the operating table become partly turbulent mixing.

For operating rooms with UDF systems with air velocities below 0.3 m/s, one can assume that the dilution principle starts to become valid in the operating zone during ongoing surgery. In such cases the number of people in the operating room and chosen clothing system should be taken into consideration when the microbial air cleanliness is of importance.

REFERENCES

1 Whyte, W., The effect of mechanical ventilation and clothing on airborne microbes and wound sepsis in hospital operating rooms, Part 1, Clean Air and Containment Review, 2015, Issue 22, 4-11.

2 Whyte, W., The effect of mechanical ventilation and clothing on airborne microbes and wound sepsis in hospital operating rooms, Part 2, Clean Air and Containment Review, 2015, Issue 23, 4-12.

3 Nordenadler, J., Some observations on safety ventilation in operating rooms, PhD-thesis, Bulletin No 74, Building Services Engineering, KTH, Stockholm, Sweden, 2010 (in Swedish).

4 Ljungqvist, B., Reinmüller, B., Hazard Analysis of Airborne Contamination in Clean Rooms – Application of a Method for Limitation of Risks, PDA Journal of Pharmaceutical Science and Technology, 1995, 49, No 5, pp 239-243.

5 Ljungqvist, B., Reinmüller, B., Risk assessment with the LR-Method, European Journal of Parenteral Sciences, 2002, 7, No 4, pp 105-109.

6 Ljungqvist, B., Reinmüller, B., Maier, C., Roth, A-C., Assessing contamination control of the pre-sterilised container tub transfers into an aseptic manufacturing filling isolator via a de-bagging/no-touch-transfer process step, European Journal of Parenteral &Pharmaceutical Sciences, 2016, 21, No 3, pp 90-100.

7 Ljungqvist, B., Reinmüller, B., Microbial risk assessment with the LR-method in safety cabinets/Class II benches, European Journal of Parenteral and Pharmaceutical Sciences, 2018, 23, No 2, pp 54-59.

8 Sipilä, D., Some observations on air movements and particle dispersion in unidirectional air flow with application to operating rooms, MSc-thesis, Building Services Engineering, KTH, Stockholm, Sweden, 2006 (in Swedish).

9 Schlichting, H., Boundary-Layer Theory, Mc Graw-Hill Book Company, New York, 1979.

10 ISO 14644-3, (2005), Cleanrooms and associated controlled environments - Part 3, Test Methods, International Organization of Standardization, Geneva, 2005.

11 Gandra, P., Practical Safety Ventilation in Ultraclean Air Operating Rooms, Licentiate-thesis, Building Services Engineering, Chalmers University of Technology, Göteborg, Sweden, 2018.

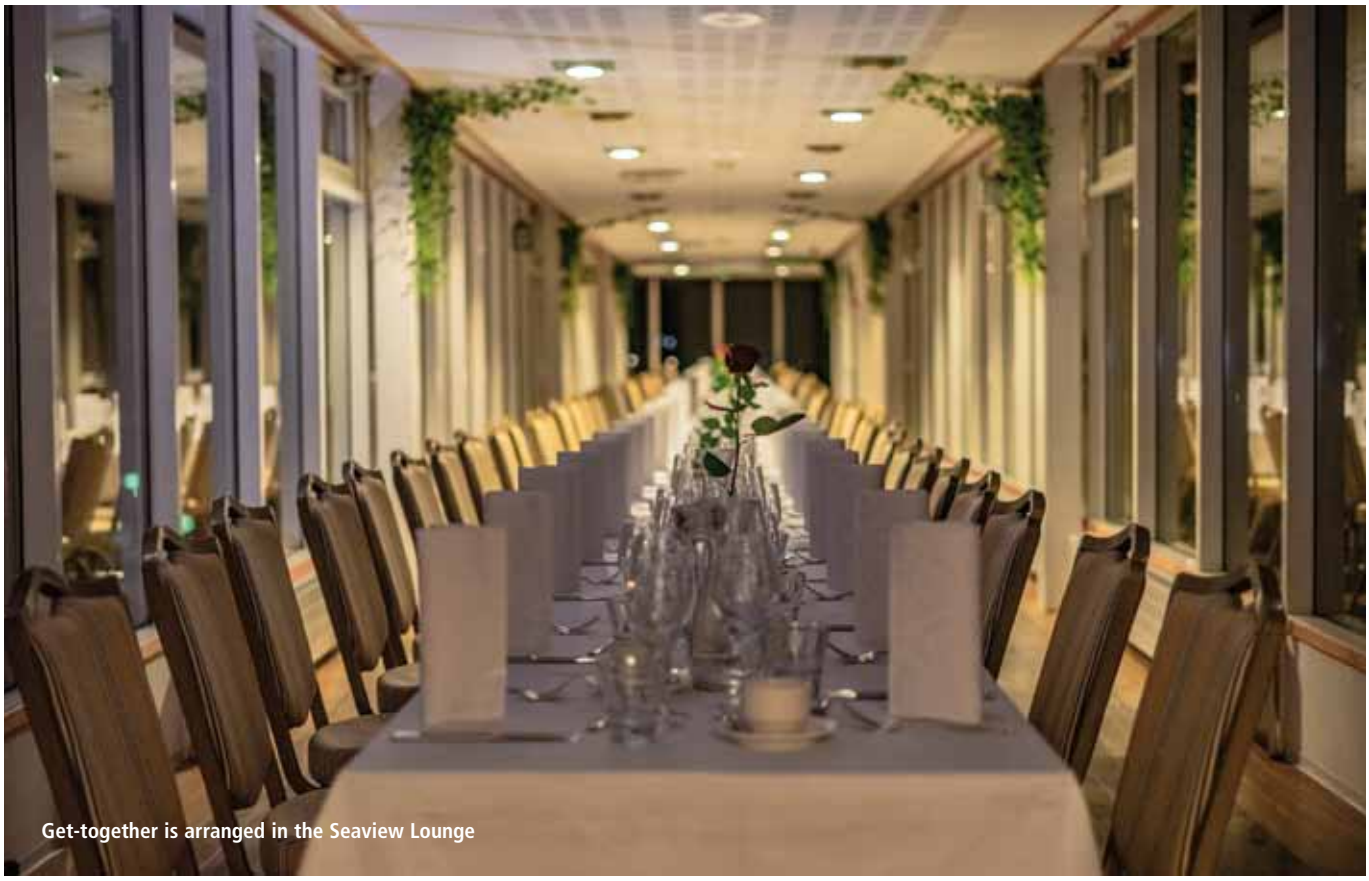
12 Whyte, W., and Lytsy, B., Ultraclean air systems and the claim that laminar airflow systems fail to prevent deep infections after total joint arthoplasty, Journal of Hospital Infection, 103, (2019), e9-e15.

NAANTALI

Invitation to the 51st R³ Nordic Symposium and Exhibition at Naantali Spa, Finland, on 25th - 27th of May 2020

www.naantalispa.fi

PHOTO: NAANTALI SPA IMAGE GALLERY



Get-together is arranged in the Seaview Lounge

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)

The Aula

PROGRAMME

The Program Committee 2020 (PK20) likes to inform that arrangements of the R^3 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 will be in focus in the first issue of Renhetsteknik next years (RT 1:20). Confirmed lectures with speakers are presented in more detail in the updated symposium program. Abstracts are published both in this issue and in the 1st issue 2020 of Renhetsteknik. Updated material will be found on the homepage from December 2019 onwards until the event.

PARTICIPATION

For registration to the 51st R^3 Nordic 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 R^3 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 16.

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 on Tuesday evening. 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 R^3 Symposium is waiting for you;
come and enjoy the event!
Welcome to Naantali – Nådendal!

PHOTO: NAANTALI SPA IMAGE GALLERY

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. For contact, please look at page 13.

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
+358 405 525 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 avaiable 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 TBN*		
10.30-11.15	*Frans Saurwalt, Kropman: Keynote Lecture on new developments in cleanroom design*		
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 the Area of Sterile Manufacturing	*Pedro Gandra, Considero:* Practical Safety Ventilations In Ultraclean Air Operating Rooms	*Francisco Forns-Samso, Granlund:* Digital twins: What is the value behind all the hype?
13.30-14.00	*TBA* TBN	*Jukka Vasara, Granlund:* Factors Influencing the Cleanliness of Operation Rooms	*Berit Reinmuller, Chalmers:* Microbial Risk Assessment in Safety Cabinets
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, Kowi:* Prefabricated Operating Rooms	*TBA* TBN
15.30-16.00	*TBA* TBN	*Perttu Karjalainen, Granlund:* Operating Room Extraction Systems *Kari*	*Marko Ettermann, R8tech:* TBN
16.00-16.30	*Smoothie & Exhibition*		
16.30-17.15	*Panel Discussion*		
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:* Preparation of a Contamination Control Strategy as an Annex 1 Requirement	*Kari Solem Aune, Kowi:* Sterilization Department Topics Would Be Acceptable	*Jukka Hurme, Merck Life:* Single Use Systems, Design Considerations And Mitigation of Cross Contamination Control Risks
09.00-09.30	*TBA* TBN	*Frans Saurwalt, Kropman:* Pass through Boxes Design and Performance Testing	*Steven Deretz, CRDB:* Challenges in Clean Room Projects
09.30-10.15	*Coffee & Exhibition*		
	PHARMA ***(BALLROOM)***	**HOSPITALS** ***(LOUISE)***	**FOOD & BIOTECH** ***(KAISA)***
10.15-10.45	*NN, Ecolab:* Regulatory Requirements and Expectations Including a Review of the New GMP Annex 1	*Koskela, Kalliomäki, TUAS:* Air Flow Patterns in Hospital Isolation Rooms – CFD Simulations	*Gun Wirtanen, SeAMK:* New Food Analysing and Processing Premises
10.45-11.15	*Steve Marnach, DuPont:* GMP Annex 1 – Selection Criteria of Protective Garments for Cleanrooms	*Kim Hagström, Halton:* Air Conditioning Solutions in Isolation Rooms	*Riina Brade, Elomatics:* TBN
11.15-12.15	*Lunch & Exhibition*		
	PHARMA ***(BALLROOM)***		
12.15-12.45	*NN, Vaisala:* Measuring Systems in the Pharmaceutical Area	**HOSPITAL** ***(LOUISE)*** *Bengt Ljungqvist, Chalmers:* Contamination Risks in Unidirectional Airflow	**FOOD & BIOTECH** ***(KAISA)*** *Leila Kakko, TAMK:* Contamination Control In Food Premises
12.45-13.15	*TBA* TBN	*TBA* TBN	*TBA* TBN
13.15-14.00	*Smoothie, Exhibition & Certificates of Participation*		
14.00-14.45	*Keynote Lecture: TBA*		
14.45-15.00	*Closing of the Symposium*		

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.

RESERVATION OF STANDS

The first to contact us will be the first served. Reservations made by end of 2019 will be invoiced in early-January 2020 with a due time of 28 days i.e. first deadlines for payments are thus in late-January 2020. Unpaid reservations may be sold further based on requests. Prices are available on the home-page. An updated list of exhibitors will be available on www.r3nordic.org/symposium-2020 from January 2020 onwards. The following companies have already reserved stands: Camfil Oy, Dinair Clean Air Oy, FläktGroup Finland Oy, Freudenberg Home and Cleaning Solutions Oy / Vileda Professional, Granlund Oy, Labema Oy, Miclev AB, Particle Measuring Systems and Stennova Oy.

PRICES OF STANDS

In total there are 28 stands at 3.6 - 8 m^2 to the price of 1 750 to 2 850 €, when ordered by latest April 15, 2020. The stand fee includes the participant fee for one representative. Please contact Gun Wirtanen for further information.

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

ABSTRACTS

KEYNOTES

New Developments in Cleanroom Design (ISO 14644-4 rev.)

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.

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, Department Manager, Finnish Medicines Agency (FIMEA), Finland

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

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.

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

NN, Ecolab

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.

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

Steve Marnach, DuPont Personal Protection

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.

HOSPITAL

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 what 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.

Prefabricated operating rooms

Kari Solem Aune, Kowi, 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?

Contamination risks evaluated with the LR-Method in unidirectional airflow at different air velocities

Bengt Ljungqvist & Berit Reinmüller, Chalmers University of Technology, Sweden, 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 0.3 m/s, while other supply air systems have velocities about 0.4 m/s. The purpose of this paper is to describe contamination risks in unidirectional airflow without obstacles at different air velocities.

Sterilization Department Topics would be Acceptable

Kari Solem Aune, Kowi, 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.

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

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.

Två examensarbeten som berör OP-rum

Operating Theatres: Study of Unidirectional Flow Ventilation Conditions for microbiological air cleanliness during advanced surgeries

By Alessandro Nava, Chalmers, Master Thesis ACEX30-19-18

Handledare har varit professor Jan Gustén, Chalmers och professor Cesare Maria Joppolo, Politecnico di Milano

Design of heating, ventilation, and air conditioning (HVAC) for an operating room is aimed at preventing the risk of infection during surgical operations while maintaining an adequate comfort condition for the patient and the surgical staff.

One of the key elements to ensure the OT (operating theatre) cleanliness is the control of microbiological contaminants in the room through the ventilation system, medical equipment and staff routine. Generally, in OT two types of ventilation systems are adopted: turbulent system, which mixes all the air volume of the operating room following the dilution principle concept; and the unidirectional airflow (UDF) ventilation system, which concentrates all the airflow over the sterile zone. The idea of UDF system is to sweep away the dirtiness present in the sterile zone and to avoid disturbances or entrainment of contaminated particles from external dirty zone. The aim of this Master Thesis is to study more in details UDF ventilation systems by means of UFP (Ultrafine Particles) and CFU (Colony Forming Unit) concentration measurements performed during different types of advanced real surgeries in two different hospitals in Sweden.

The common hospital type of technical gowning available inside the OT are: the single use type with high performances and the ordinary scrub suit, more comfortable but less performing in the particle retention from the staff. Therefore, there are two main types of protection for the diffusion of airborne particles: technical clothing system and the air ventilation technology. The deployment of low performance technical clothing allows a more direct testing of the UDF capacity to keep the surgery table area clean. Furthermore, the current standards do not make a clear distinction between the air distribution systems used and their cleaning capacity over the surgery table. According to the standards, sterile area protection mostly depends upon the technical gowning quality, and the use of less performing technical clothing leaves the ventilation system as key determinant of contamination control. The airborne samples collected during the surgeries data collection allowed new scenarios in this field, also due to the small number of available studies and data in the literature. The experimental values measured have shown the UDF´s capacity to ensure ahigh degree of cleanliness on the surroundings of the surgery table. Despite the use of less performing technical clothing, the UDF ventilation system can keep the surgical area safe throughout all the surgery routine. Furthermore, the work defines an outlook over the specific positions required for the optimal measurement campaign. Moreover, the amount of measurements allows an understanding of the weak points of the UDF ventilation system in combination with medical procedures, especially during the medical staffs shift changes.

Air Contamination Control in Operating theatres - Microbiological Contaminants during orthopedic Surgeries – An Experimental Study

By IlariaBeccio, Chalmers, Master Thesis ACEX30-18-3

Handledare har varit professor Jan Gustén, Installationsteknik, Arkitektur och samhällsbyggnadsteknik.

Surgical site infections in operating theatres (OTs) are a real problem during implants in orthopaedic surgeries. Patients are exposed to higher risks than other types of surgeries.

In order to understand the air cleanliness level in operating theatres during those types of surgeries, a parallel measurement of Colony Forming Units (CFUs) and Ultrafine particles (UPs) has been carried out during real ongoing surgeries. OTs with upward displacement ventilation was monitored during 30 surgeries.

Viable airborne particle monitoring has been performed via air sampling close to the patient´s wound while ultrafine particles were monitored close to one of the exhausts grills, in order to have a mean value of the total non-viable contamination inside OT. In addition, other important parameters which may influence OT activities and contamination have been monitored and recorded. In particular, the number of OT´s personnel and the type of movements within the OTs were taken into account as well as the frequency of door opening, staff changes and surgical routines. Data have bee logged and divided into the different surgical phases of an operation in order to separately evaluate the contamination contribution of each phase.

The clothing system adopted has also been taken into consideration, as well as the health and infection level condition of the patient before and after surgery.

After twenty-five surgeries the research results highlighted which parts of the surgery have more impact from an aircontamination point of view. The possibility to follow when the operations gave the opportunity to evaluate how the X-ray time and the clothing system influence significantly the amount of colony forming units nearby the wound. Other three surgeries in another OT, with the same ventilation principle were followed. This was carried out to understand if the air flow pattern and a bigger size of the room would influence the presence of viable airborne contaminants inside the room.

The study highlighted how the OT ventilation system adopted in this study do not reach the cleanliness required for orthopaedic back surgery in which the infection percentage is very high.

Två doktorsarbeten som berör renhet i operationsrum

Den 23 oktober disputerade **Catinka Ullmann** på Chalmers Tekniska Högskola, Installationsteknik, Institutionen Arkitektur och samhällsbyggnadsteknik med arbetet ”Some aspects on Contamination Control in Hospitals – Observations and Measurements”

Opponent var professor Guangyu Cao, Department of Energy and Process Engineering, Norwegian University of Science and Technology, Trondheim. Betygskommitteen bestod av docent Ann Tammelin, Överläkare, Hälso- och sjukvårdsförvaltningen/Stockholm, professor Dr. Horst Weißieker, professor of Project Management Business Research Center Energy and Health Care, Sachverständigenbüro für Reinraumtechnik, Deautchland, professor Peter Fröst, instutionen för Arkitektur och samhällsbyggnadsteknik, Chalmers, samt Prof emeritus Kai Ödeen, KTH, Stockholm.

Huvudhandledare har varit docent Berit Reinmüller, biträdande handledare prof. Bengt Ljungqvist och examinator prof. Jan Gustén.

Catinka redovisade sitt arbete inför ca 50 åhörare. Opponenten och betygsnämnden ställde sina frågor och disputationen avslutades med frågor från åhörarna.

Abstrakt återges på sidan 22

Den 27 november disputerade **Cong Wang** på KTH, Hållbara byggnader, Skolan för arkitektur och samhällsbyggnad med arbetet ”Ventilation Performance in Operating Rooms – A Numerical Assessment”.

Opponent var professor Anna Bogdan, Warsaw University of Technology. Betygskommitteen bestod av professor Margareta Björklund -Sänkiaho, Åbo Akademi, docent Mattias Celin, Högskolan i Gävle och docent Ardehir Hanifi, KTH. Handledare har varit professor Sture Holmberg och docent Sasan Sadrizadeh, Hållbara byggnader.

Catinka tillsammans med med opponent, delar av betygsnämnden, handledare samt eximinator.

Ett 20-tal åhörare samlades i KTHs kollegiesal för att ta del av Congs redovisning, opponentens och betygsnämndens frågeställningar. Åhörarna bidrog med ett flertal intressanta frågor.

Abstrakt återges på sidan 23

Cong Wang med opponent, betygsnämnd, handledare, ordförande och de flesta av deltagarna.

ABSTRACT

Some aspects on Contamination Control in Hospitals – OBESERVATIONS AND MEASUREMENTS

CATINKA ULLMANN

The thesis describes an engineering approach to airborne contamination risks in different environments of Swedish hospitals and the purpose is to increase the understanding and awareness of these risks.

Autoclaves are common process equipment in sterile supply centers. During unloading of autoclaves, temperature differences cause entrainment of room air into the autoclave chamber with its sterile packages, and contamination risks occur. To increase the understanding of air movements through the autoclave opening, measurements and CFD simulations have been performed. Results show that UDF-unit with HEPA-filter close to the opening of the autoclave reduces the risk of contamination.

Functional clothing systems reduce the number of airborne bacteria-carrying particles from the staff in the operating room. Measurements show that the microbial source strength varies among clothing systems. The number of people present, their activity level, and type of clothing systems affect the microbiological air cleanliness during ongoing surgery. Furthermore, studies indicate that higher microbial concentrations often occur on the outer surface of the clothing system when the surgical staff visits uncontrolled environments outside the surgical departments.

Measurements of the cleanliness level have been performed in operating rooms classified as tissue and cells establishments for bone tissue to compare the results with the requirements given in the Tissue and Cells Directives of the European Union (EUTCD). The results show that the requirements are not always fulfilled. Common deficiencies in maintenance of e.g., HEPA filters are reported.

A theoretical study describes the influence of door-openings to the microbial air cleanliness of ultraclean air operating rooms for infection prone surgery. The results explain why door openings sometimes increase the level of airborne bacteria-carrying particles in the operating rooms. Temperature differences increase the air volume flows through the door openings and differences in concentration levels increase the contamination risks.

A comparison is presented between airborne cleanliness requirements for pharmaceutical manufacturing (EU GMP Annex 1) and recommendations for ultraclean air operating rooms and differences are discussed.

ABSTRACT

Ventilation Performance in Operating Rooms:

A NUMERICAL ASSESSMENT

Surgical site infections (SSIs) remain one of the most challenging postoperative complications of healthcare and threaten the lives of millions of patients each year. Current evidence has shown a positive relationship between the airborne concentration of bacteria-carryingparticles (BCPs) in the operating room (OR) and the rate of infections.

The OR ventilation is crucial for mitigating the dispersion of airborne bacterial contaminants and thus controlling the risk of SSIs. A variety of ventilation schemes have been developed for OR use. Each has pros and cons and may be better suited than another for operations under certain conditions.

The proper functioning of OR ventilation is also affected by external and internal disruptions. By applying Computational Fluid Dynamics (CFD), the present study investigates the airflow and contaminant distribution in ORs under different conditions. The airflow distribution is of critical importance in removing or diluting airborne contaminants. The conventional mixing ventilation is not able to reliably create an ultraclean environment. The usage of mixing ventilation in infection-prone surgery should be limited, especially when a large surgical team is involved.

Laminar airflow (LAF) ventilation demands a sufficient airflow rate to achieve desired performance. Temperature-controlled airflow (TAF) ventilation represents an effective ventilation scheme that can serve as an energy efficient alternative to LAF.

Door openings have a detrimental impact on the microbiological cleanliness of the OR. The temperature in the OR and adjacent space should be well controlled to minimize the interzonal contaminant transfer. Temporarily reducing the OR exhaust flow during door operation forms a directional airflow towards the adjacent space, which is found to be an effectivesolution to ensure the isolation.

Surgical lamps serve as physical obstructions in the airflow path and significantly deteriorate the performance of LAF ventilation. It is highly recommended to improve the shape and design of the lamps in the LAF ventilation.

TAF is found to be less sensitive to the presence of surgical lamps in the airflow path. The buoyancy-driven airflow used by TAF is more capable of circumventing obstacles than the inertia-driven flow used by LAF. Thermal plumes developed from the surgical equipment in the OR have the potential to distort the buoyancy-driven airflow in TAF

The thesis conducts a comprehensive literature review of important topics in OR ventilation.The present study enhances the understanding of the strengths and limitations of different ventilation schemes and increases the knowledge of the design and usage of OR ventilation.

CONG WANG

Rapport Grunnkurs Norge

TEXT BARBRO REIERSØL

Grunnkurs i R[3]-teknikk ble arrangert av medlemmene i LAU-Norge. Kurset ble holdt på Olavsgaard hotell 14-15 oktober 2019. Grunnkurset består av emnene man trenger for grunnopplæring innen renromsteknologi. Kurset ble fulltegnet med 52 deltagere fra hele landet, i hovedsak fra sykehusapotek og industri.

Årets kurs er modernisert i forhold til kurset som ble holdt i 25 år på Tjøme. Det er også harmonisert i forhold til grunnkurs som holdes i Sverige. Kurset ble arrangert med tre nye forelesere som er oppdatert innenfor hver sine fagfelt.

Foreleserne var:

Barbro Reiersøl, AET: renrom, forurensere, renhold, klær
Kari Solem Aune, COWI: Ventilasjon, benker, standarder, planlegging av renrom
Kjersti Aulie: GE Healthcare: Mikrobiologi og mikrobiologiske metoder på renrom.

Dette bidro til to lærerike dager innenfor renromsteknologi. Deltagere var fornøyde og ga veldig gode tilbakemeldinger om innholdet av kurset, servering fra hotellet og underholdning under middagen som arrangeres av programkomite.

Nytt kurs planlegges i 19-20 oktober 2020 på Olavsgaard hotell og er begrenset til 50 deltagere. Detaljer om kurset vil komme på det nye året.

52 deltagere på kurset og Arrangementskomiteen

Rapport Grundkurs Sverige

TEXT LENNART HULTBERG

Den svenska grundkursen avhölls i Uppsala på Hubben den 14-15 nov. På Hubben sitter bland annat vårdhygien för Akademiska sjukhuset.

15 deltagare från framförallt sjukhusområdet deltog. Så årets inriktning blev mer åt det hållet vad det gäller frågeställningar och erfarenhetsutbyte.

Hygienöverläkare Birgitta Lytzy hade på ett föredömligt sätt hjälpt till att ordna lokal till oss och deltog själv i utbildningen. Kursen hade många intressanta frågeställningar som ställdes och genomgicks. Det kom direkt en fråga om vi inte kunde anordna en kurs till i Uppsala nästa år. Vilket vi givetvis skall uppfylla. Återkommer med datum.

Deltagarna var jättenöjda med kursen och frågade undertecknad om jag inte kunde skriva en lärobok i ämnet. Denna fråga får jag ta hem och fundera på. Vi får se om någon skrivklåda kan infinna sig. Kurslärare var Lennart Hultberg, tillika ordförande i R[3] Nordic.

ISO TC 209 möttes i USA

TEXT OCH BILD:
LENE BLICHER OLESEN

14th & 15th November 2019, the 31st ISO TC209 meeting was held in Rosemont, Illinois, USA. 14 countries were represented by their delegates to the meeting.

The meeting was opened by roll call of delegates followed by adoption of the agenda and final approval of the last years TC209 meeting, which was held I Haag.

ISO have revised their Code of Conduct, which were distributed to the participants. The main scope with the ISO Code of Conduct is to ensure uniform work frames throughout ISO committees and working groups (WG). Creating and ensuring an environment with focus on respect, ethicality and consensus are key areas in the Code of Conduct, which is reasonable as people from all over the world participates and should feel comfortable by participating in the ISO work.

On the meeting all active and dormant working groups under TC209 are discussed. In TC 209 WG 4 (ISO 14644-4) WG 8 (ISO 14644-8, -9 & -10), WG 11(ISO 14644-18) and WG 14 (ISO 14644-17) were active and WG 2 (ISO 14698-1 & -2), WG5 (ISO 14644-5) and WG 7 (ISO 14644-7) were dormant working groups. During the meeting it was decided to reactivate WG 5, evaluate on the need for reactivation WG 7 on the next ISO TC 209 meeting, which also might be the case for WG 2, due to the new standard of EN 17141 and the coming vote on ISO 14698-1 &-2

Furthermore the status in WG3, were the revision of ISO 14644-3 has taken place, were discussed. The last part of the revision process has been challenging. On the meeting it seems that the last puzzle pieces were placed, and the finish touches to the work can be done.

The day 1 of the meeting ended her. The evening was spent small talking at the dinner, kindly hosted by the US delegation.

Next day the meeting started by looking at liaisons to TC 209. A new suggestion had been made to make a liaison to the CEN TC332 in which EN 12649 placed, which gives quite good meaning as there are many areas which are of interest in both groups.

Hereafter it was time for making resolutions, 9 in total were formulated. The resolutions are made to reflect the decisions taken during discussions in the TC 209 meeting. The voting procedure takes place were 1 member country participating have 1 vote. All 9 resolution were approved with no negative votes. This is a success as ISO appreciates decisions taken in consensus

Before closing of the meeting, the expectations for the next years meeting were discussed. Next years meeting is decided to be in Turkey, in conjunction with the ICCCS conference.

CTCB-I certifiering 2019

TEXT OCH BILD:
LARS EKBERG

I mitten av september hölls CTCB-I:s certifieringskurs i Norden för mätspecialister och inköpare/granskare/utvärderare av mättjänster för renrum. Certifieringen, som hölls på Chalmers, genomfördes på två nivåer i enligthet med CTCB-I:s internationella riktlinjer.

Ett certifikat på **Associate Level** visar att man förstått teorin bakom renrumsmätningar och kan bedöma och förstå dokumentation från sådana mätningar. Ett certifikat på **Professional Level** intygar att man dessutom behärskar mättekniken och självständigt kan genomföra kontroller. I år kom deltagarna från Danmark, Norge, Gambia och Sverige. Birgitta Lytsy från Akademiska Sjukhuset i Uppsala samt Kai-Uwe Riedel från Läkemedelsverket deltog som observatörer.

Under dag 1 hölls en genomgång av det utsända kursmaterialet av Berit Reinmüller, Bengt Ljungqvist och Lars Ekberg, varvid deltagarna gavs möjlighet att ställa frågor kring kursmaterial samt diskutera mätteknik, mätutrustning och mätproblem. Det skriftliga provet dag 2 med 60 frågor på kursavsnitten, genomfördes under kontroll av Bengt och Berit. I försökshallen hade Håkan Larsson, Installationsteknik, tillsammans med Lars Jansson, MyAir, förberett allt inför eftermiddagens demonstration - där såväl mätutrustning som mätteknik belystes.

LÄRARKOLLEGIET

Under dag 3 genomfördes de praktiska proven, som bedömdes av de praktiska lärarna, alla själva certifierade på Professional Level. Lärare var Johan Ahnfeldt och Daniel Laggar från Brookhaven Instruments AB, Stockholm, Nils-Johan Björklund, CRC Clean Room Control, Uppsala, Mari-Liis Maripuu, Lars Ekberg och Stefan Aronsson från CIT Energy Management, Göteborg samt Lars Jansson, MyAir, Linköping.

Efter dagens avslutade praktiska prov samlades lärarna för att gemensamt bedöma resultat från teoretiska och praktiska prov under ledning av Lars Ekberg.

Ett stort tack till alla lärare och företag som stöder CTCB-I certifieringen genom att medverka på plats under kursdagarna, genom att skänka filter och genom att låna ut mätutrustning till de praktiska proven.

Nästa tillfälle för certifiering i Göteborg planeras till september/oktober 2020. Exakta datum publiceras i kommande nummer av RenhetsTeknik, på hemsidan samt på safety-ventilation.com.

Uppdaterad information om detta finns på www.ctcb-i.net/courses.php.

Tänk på att antalet deltagare på Professional Level för närvarande är maximerat till 12 deltagare, varför du som ska förnya ditt certifikat efter fem år bör anmäla ditt intresse så snart som möjligt till Lars Ekberg, lars.ekberg@cit.chalmers.se. För Associate Level är inte antalet lika begränsat.

PROFESSIONALS


Edvin Andersson
Labkontroll Sverige AB
Sverige


Emil Andersson
Labkontroll Sverige AB
Sverige


Ismaila A Jallow
Ecomed Scientific Ltd
Gambia


Ola Stenbäck
MyAir Test and
Validation AB, Sverige


Ivar Fjellfindal
Caverion Norge AS
Norge


Thomas Schultz
Ventilationspartner
Danmark


Arild Eggen
Bryn Byggklim A/S
Norge


Jan Karlsson
Vita Verita AB


Johan Byberger
Vita Verita AB
Sverige


Morten Jakobsen
Bryn Byggklima A/S
Norge


Stefan Hoffren
Vita Verita AB
Sverige


Thorgrim Ullereng
Bryn Byggklima A/S
Norge


Tor Arne Johansen
Caverion
Norge


Rudy Vogelpoel
CRC Cleanroom Control

ASSOCIATE


Christian Berg Hansen
Ventek Air ApS
Danmark


Dan Seidegård
Galderma Uppsala
Sverige


Elin Wallin
Vita Verita AB
Sverige


Knud Lyngsie
Ventek Air ApS
Danmark


Nils Ledermann
Camfil Norge A/S
Norge


Robert Löfgren
Bengt Dahlgren Syd AB
Sverige


Thorkild Pedersen
Ventek Air ApS
Danmark


Birgitta Lytsy
Akademiska Sjukhuset
OBSERVER


Kai-Uwe Riedel
Läkemedelsverket
OBSERVER

PDA Europe Conference

TEXT OCH BILD
BERIT REINMÜLLER

20-25 oktober arrangerade PDA Europe en konferens ”2019 Universe of Pre-filled Syringes and Injection Device” på Svenska Mässan och Congress Center Gothia Tower i Göteborg. Mathias Romacker, Pfizer, och Thomas Schoenknecht, LONZA delade på ordförandeskapet under konferensen. Över 1000 personer deltog, varav ca 50 från Norden. Konferensen hade ett omfattande vetenskapligt program med många talare och en stor utställning. Deltagarna gavs också tillfälle till net-working i det sociala programmet med välkomstparty på Universeum, och Chat and Dance på Teatergatan. Konferensen och utställningen följdes av workshops under två dagar där följande ämnen diskuterades All about Pre-filled Syringe Systems, Extraction and Leachables, Container Closure Integrity Testing, Measuring Quality Culture Maturity och Test Methods for Pre-filled Syringe Systems.

ICCCS 2019 i USA

TEXT OCH BILD
LENE BLICHER OLESEN

The ICCCS 2019 meeting take place every year. Every second year the meeting is held together with the ICCCS conference, next year in 2020 in Turkey.

The ICCCS meeting was an effective one day meeting with participation of 18 member countries. Presentations were given by the respective board members chairman's report, secretary's report, financial report (accounting, audit & budget), educational committee, technical committee and finally on communication & the lounge of a new homepage.

Furthermore strategy and business plan were presented and discussed. This year there were election on one executive board member. Da Qian Wang was elected to this. Two countries had applied for membership, Poland and North Macedonia, and both countries were approved and welcomed as member in ICCCS.

At the end of the meeting resolution seven resolutions were formulated; they were all approved unanimously.

PHSS Conference

LENE BLICHER OLESEN EJPPS BOARD MEMBER &
CHAIR DANISH CLEANROOM GROUP AT DANISH STANDARDS

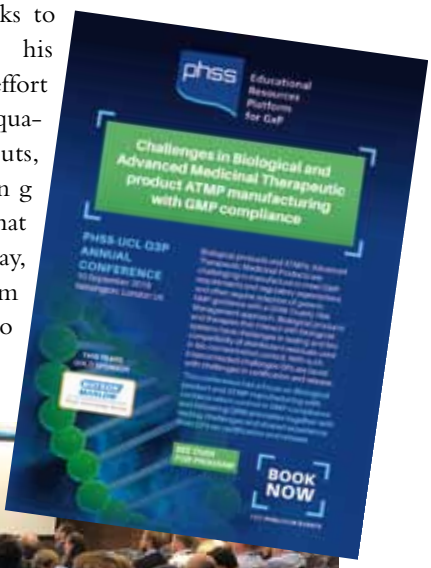
September 10, 2019, the Pharmaceutical & Healthcare Sciences Society (PHSS) held their annual conference in London.

The main topic for this year's conference was the Challenges in Biological and Advanced Therapeutic Medicinal Products. Several interesting presentations were given, covering different views and aspects within the field.

Another and very helpful initiative from PHSS, is the project on bringing clarity on GMP topics by preparing GMP Guidance notes. These GMP Guideline notes, can be seen as a kind of guidance how to overcome the "gap" sometimes seen between the written GMP Guidelines & standards, and the regulatory expectations. The topics and the status of the guidelines were given as the last presentation of the day by James Drinkwater.

PHSS has a long history in collaborating with other organisations, including R[3] Nordic, which was also highlighted on the conference.

On the conference James Drinkwater handed over the PHSS chair position to Jenny Tranter. This shift has been long planed and James will still play an important and active role in all the activities in PHSS. A big thanks to James for his enormous effort and always qualified inputs, bringing PHSS to what it is today, and a warm welcome to Jenni.



SIS samverkansdag om MDR/IVDR

Med anledning av bl a att nya lagar har införts av EU maj 2020 anordnades en samverkansdag av SIS den 21 november i Stockholm. Samverkansdagen inleddes med ett gemensamt möte med deltagare från de tekniska kommittéerna TK 333 Operationstextilier, TK 349 Rengöring, desinfektion och sterilisering och TK 527 Renhet i operationsrum. Under mötet diskuterades och informerades om den nya handboken SIS/TR 57 för grundläggande rekommendationer för lagerhållning, hantering och transport av sterila medicintekniska produkter inom hälso-och sjukvård, mm, den pågående revisionen av TS 39 Mikrobiologisk renhet i operationsrum – Förebyggande av luftburen smitta – Vägledning och grundläggande krav, och den kommande vägledningen för EN 13795 Operationskläder och draperingsmaterial -Krav och testmetoder.

Behovet av att bevaka internationella standarder i CEN/TC 2216 kring kemisk och antiseptisk desinfektion tydliggjordes.

Efter en gemensam lunch inleddes eftermiddagen med föreläsare och grupparbeten kring MDR, (medical device regulations) och IVDR (in vitro diagnostic medical device regulations).

CIT 35 år

Chalmers Industriteknik (CIT) firade sitt 35 års jubileum den 25 november I Göteborg med föreläsningar och en utställning där många pågående projekt presenterades. CIT är en länk mellan forskning och företag. Deltagarna välkomnades av Golaleh Ebrahimpur, CEO på CIT, och Chalmers rektor Stefan Bengtsson, som betonade vikten av samverkan mellan Chalmers, CIT och industrin, varefter en panel diskuterade pågående projekt, framtiden och hållbar utveckling. Efter lunch blev det mingel och presentation av några av CIT:s projekt med närvarande experter.

Clean Hospitals

Källa: European Cleaning Journal

Clean Hospitals är ett nytt nätverk för ett internationellt samarbete med målet att förbättra hygienen i sjukhusmiljön och därmed patientsäkerheten. EuropeanCleaning Journal har pratat med professor Didier Pittet, som leder initiativet Clean Hospital. Han är läkare, sjukhusepidemiolog och chef för programmet för infektionskontroll vid WHO vid universitetet i Geneve, Schweiz.

Tidigare ledde professor Pittet WHOs kampanj för rena händer som räddar liv och WHOs globala handhygiendag den 5 maj. Nu leder han ett nytt initiativ som fått namnet Clean Hospitals. Det är ett nätverk av relevanta aktörer som har bildat ett samarbete för att förbättra hygienen på sjukhus och därmed patientsäkerheten.Han lyfter fram flera skäl för satsningen. Bland annat att man använder fel produkter och t ex desinficerar golvytor där inga patienter vistas vilket är onödigt och dessutom dyrt.

Standarder för sjukhusstädning skiljer sig mellan olika länder och det behövs en global vision för rengöring och underhåll, säger han till ECJ. Ett första forum för sjukhusstädning hölls under Interclean Amsterdam 2018. Därefter har en grupp experter och tillverkare från städsektorn satt ihop en strategi med fem grundstenar: ytor, luft, vatten, avfallshantering och sterilisering.

– Med tanke på hur mycket vi investerar i sjukhus och iskyddet mot bakterier och virus är miljö och hygien oerhört viktigt. Ingen vill hamna på sjukhus i en miljö där man inte är säker, konstaterar Didier Pittet.Han säger också att hittills har inte många forskare varit involverade i städområdet. Satsningen på Clean Hospitals gör att vi kan ändra på det och optimera sjukhusmiljön.

På sjukhus idag ligger fokus på budget, säger han. Vi ser fortfarande fall med sjukdomsutbrott men där ledningen inte vill öka städkostnaden. Utmaningen för modern medicin är att sjukhus inte leds av experter på sjukvård utan av administratörer. Deras prioritet är att sänka kostnaderna.

Enligt hans uppfattning tar sjukhusledningar bara hänsyn till kostnaden för städning trots att kostnaderna för sjukhusinfektioner är långt högre. Men det hamnar på en annan budget och den kopplingen görs inte.Didier Pittet betonar också vikten av att investera mer i utbildning av städare som måste vara medvetna om vilket ansvar de har för omvårdnaden av patienter. De måste ha rätta kunskaper för olika delar av sjukhuset. Han menar att alla sjukhus står inför samma utmaningar. Målet är att genom forskning, utbildning och information ta fram världsomspännande riktlinjer. Den officiella starten för Clean Hospitals skedde i samband med International Conference on Prevention and Infection Control (ICPIC) i september detta år.

Kontakperson på Clean Hospitals är marianne.kemmer@cleanhospitals.com

For Life-utställning

En fotografisk For Life-utställning där Malin Fezehai visar ögonblicksbilder ur vardagen från världens alla hörn. Hygien- och hälsoföretaget Essity är kunskapspartner till utställningen och för dem är utställningen en visuell resa som speglar hur människor världen över lever sina liv utifrån värdeorden engagemang, omsorg, mod och samarbete.

Människans starka bindning till sina händer som relationsskapande märks tydligt i språket. Vi kallar att engagera sig att ”ta tag i saker”, att bry sig om en annan är att ”ta hand om”, medan när någon har mod att visa ansvar tar de ”hand om saken” och när vi i samarbete lyckats skapa en överenskommelse så ”tar vi i hand” på det. På bara en dag kommer våra händer i kontakt med mängder av föremål och platser, liksom oss själva och andra människor. Evolutionärt är det också de som har förmåga att samverka som bäst överlevt, de som lyckas skapa samhörighet och sammanhang vilket ger den viktiga känslan av meningsfullhet.

”Power of Hands hyllar ett av människans viktigaste verktyg. Om vi använder händerna på rätt sätt kan vi stärka och hjälpa varandra, vi kan rädda liv. Men händer är också en källa till spridning av infektioner om de inte hålls rena. Essity sprider kunskap om vikten av god handhygien som kan förhindra infektioner. Vi vill att varje besökare av utställningen blir en ambassadör för god handhygien. Genom samarbeten når vi fler människor. Ju fler vi är desto mer kan vi förebygga spridning av infektioner och öka välbefinnandet i världen”, säger Joséphine Edwall Björklund, kommunikationsdirektör på Essity.

Orena händer är en av huvudanledningarna till spridning av några av världens mest smittbara sjukdomar och utvecklingen av multiresistenta bakterier. Otto Cars, senior professor i infektionssjukdomar vid Uppsala universitet, är en av experterna i FN:s samverkansgrupp om antimikrobiell resistens och grundade 2005 Organisationen ReAct - Action on Antibiotic Resistance. I utställningen bidrar han med sina reflektioner kring den livsavgörande frågan om multiresistens som Power of Hands bidrar till att lyfta upp och sätta fokus på.

”Vi behöver starkare globala samarbeten för forskning och utveckling av nya läkemedel – som tas fram på ett hållbart sätt och som når ut till alla som behöver dem. I annat fall kommer miljontals människor dö i infektionssjukdomar – sjukdomar som vi vant oss vid att snabbt kunna bota med hjälp av antibiotika. Resistenta bakterier ger redan ett ökande antal dödsfall i blodförgiftning (sepsis) och om vi inte kan vända trenden finns risk att sårinfektioner och lunginflammation åter blir dödliga. Alla måste bidra till att minska onödig antibiotikaanvändning vid till exempel vanliga förkylningar. Tillgång till rent vatten och hygien måste öka världen över – så att infektionerna och behovet av antibiotika minskar”, säger Otto Cars.

Succé för Clean & Facility

Text och bild: Boel Jönsson | Tipsa redaktionen

Första gången mässan landade i Örebro, på Conventum Arena, strömmade besökarna till under båda dagarna. Antalet blev långt över förväntan och utställarna, 48 stycken, var väldigt nöjda. Här fanns allt – från de små viktiga detaljerna till de stora investeringarna; både väl utprovade produkter till nyheter.

På ett torg i mitten av utställningslokalen fanns möjlighet att prova på en rad olika städmaskiner. Det blanka, vita golvet på mässan har väl aldrig varit så välpolerat.

Alla Drop-in seminarierna under båda dagarna fick intresserade åhörare. Det handlade om karriärmöjligheter, Kommunikation över gränser, Att städa ger bra träning, Status och attityder och om att våga ta betalt för sina tjänster.

Till Örebro kommer Clean & Facility-mässan gärna tillbaka. Men först slår mässan upp portarna i Stockholm den 7 och 8 oktober 2020, om ett år alltså.

Guidelines for preventing surgical site infections

Ny artikel i Journal of Hospital Infection

Ultraclean air system and the claim that laminar airflow systems fail to prevent deep infections after total joint arthroplasty by W. Whyte, University of Glasgow, UK, B. Lytsy, Uppsala University Hospital (Akademiska Sjukhuset), Sweden.

The World Health Organization published guidelines in 2016 for preventing surgical site infections. The guidelines contained a conditional recommendation that laminar airflow (LAF) ventilation systems should not be used to reduce the risk of infection after total joint arthroplasty (TJA). This recommendation was largely based on a systematic review and meta-analysis of information from hospital infection surveillance registries. The recommendation contradicts information published in earlier major studies carried out by Charnley and the UK Medical Research Council (MRC).

The first aim of this article is to revisit and explain the MRC study, and reply to the criticism of it. The second aim is to suggest reasons why some recent studies have failed to demonstrate that ultraclean air (UCA) systems reduce deep joint infection after TJA. It demonstrates that if a UCA system establishes average airborne concentrations of microbe-carrying particles (MPC) <10/m^3, and preferably <1/m^3, then deep joint infection after TJA will be lower than in conventionally ventilated operating theatres

R³ NORDIC INVITES TO

EHEDG advanced course in Hygienic Engineering & Contamination Control

4th - 6th of March 2020

Tetra Pak, 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 January 30, 2020.
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 to guliwi(at) 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 Friis, Ferdinand Schwabe and Gun Wirtanen.

Programme

Wednesday 4th of March

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

Thursday 5th of March

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

Friday 6th of March

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 CERTIFIERING

CTCB certifiering av Cleanroom Testers

SEPTEMBER/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 instruments and their characteristics. The requirements on adequate documentation will be discussed.
- Possibility to **Hands-on**. Associate candidates only. Work two an two on installed filter leakage test and air velocity and volume flow measurements with comments from teachers.

Third Day Practical Exam:
Professional candidates only

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

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

ANMÄL DIG REDAN IDAG TILL LARS EKBERG

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

CTCB Professional Level - 3 days
Registration : SEK 3 950 · Course and exam: SEK 13 500
Lecture course. Practical training. Written and practical exams.

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

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

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

Moms tillkommer på samtliga angivna priser.

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

Information also available at www.safetyventilation.com

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 proj, tillverkning, leverans, montering och validering.
070-6188052 · tomas.horman@caverion.se

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

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

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

VENTILATION FILTER

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

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

BERENDSEN

Autoclave Service

Validated & Documented Sterilising

For the consistent decontamination of your cleanroom products, thereby freeing up resources so you can focus on your core business.

GARMENTS • MOPS • CLEANING EQUIPMENT • GOGGLES

Berendsen Textil Service A/S
Holbæk, Danmark
59 43 22 22
59432222@berendsen.dk
www.berendsen.dk

Berendsen Textil Service AB
Nyköping, Sverige
0155-20 96 00
kundservice.nykoping@berendsen.se
www.berendsen.se

Berendsen Tekstil Service AS
Oppaker, Norge
22 88 48 00
info@berendsen.no
www.berendsen.no