Renhets TEKNIK
THE NORDIC JOURNAL OF CONTAMINATION CONTROL AND CLEANROOM TECHNOLOGY NR 2:2022

Welcome to Finland in August

- INVITATION TO R³ NORDIC SYMPOSIUM AND EXHIBITION
- INVITATIONS · NEWS · RELEASER...

Renhets TEKNIK

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r³ nordic

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INNEHÅLL/CONTENT

INBJUDAN TILL HÖSTENS KURSER

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

OMSLAGSBILD / COVER:
FOTO: Naantali Spa - this and pictures in the articel from Naantali

Protokoll Årsmøte med R³ Nordic 2022

1. Åpning av møtet.
Møtet ble åpnet kl. 17:00
2. Valg av ordfører og sekretær.
Lennart Hultberg ble valgt som Ordfører
Geir Valen Pettersen ble valgt som sekretær
3. Innmelding av andre saker i henhold til § 16 og godkjenning av dagsordning
Dagsorden godkjent uten tillegg.
4. Valg av 2 øvrige foreningsmedlemmer for å være stemmeberettiget og til sammen med møteleder justere protokollen fra møtet.
Lene Blicher Olesen
Barbro Reiersøl
5. Møtets lovpålagte kunngjøring
Utlyst i renhetsteknikk og på nettsiden.
Godkjent
6. Opprop og stemmejustering
Om vi behøver å stemme, trekker vi frem stemmelengde.
7. Styrets virksomhetsberettelse
Virksomhetsberettelsen ble godkjent.
Foreningen landet på et overskudd på kr. 110507 sek.
Virksomberettelsen for virksomhetsåret og regnskap for 2021 blir lagt til protokollen (bilag 1 – 4).
8. Hoved revisors berettelse
Hoved revisors berettelse ble godkjent. Bilag 5.
9. Spørsmål om ansvarsfrihet for styret.
Styret ble fraskrevet ansvar det siste året.
10. Bestemmelse av Budget for kommende virksomhets år.
Det ble godkjent. Bilag 6.
11. Bestemmelse av årsavgift for ordinære medlemmer for kommende virksomhets år.
Vi fastholder samme årsavgift.
12. Rapport om fagseksjonene og arbeidsgruppenes virksomhet.
Har ikke kommet noen ytterligere årsplaner fra styrelsen.
13. Valg av styre i henhold til § 8 i vedtektene
Valgnemndens forslag er ikke blitt gjort tilgjengelig tidligere eller på under årsmøtet. Styrevalg er basert på styrets forslag.
Lene Blicher Olesen – valgt for 2 nye år.
Geir Valen Pettersen – valgt for 2 nye år
Lennart Hultberg – valgt som skattmestere for 2 nye år
LAU
Styrelsen velger å nominere.
Norge:
Hong Tanh Thi Nguyen - omvalg
Phong Ngoc Huynh – omvalg
Finland:
Leila Kakko – omvalg for 2 nye år
Jussi Kotomäk – ny person
14. Valg av revisor og vararevisor i henhold til § 8 i vedtektene
Bruker samme revisor som tidligere.
Jonas Høgman – omvalg for 2 nye år.
Anne Perä-Takala – omvalg for 2 nye år.
15. Valg av valgnemnd
Det ble ikke valgt noen valgnemd.
16. Forslag og forhåndsvarslede saker etter § 3
Ingen innkomne forslag og foranmeldte ærend.
17. Avslutning av møtet
17:25

Vedlegg (www.r3nordic.org/member)
1. Resultatrapport vs fg år och budget
2. Balansomslutning
3. Resultatrapport
4. Balansrapport
5. Revisjonsberättelse
6. Budget 2022
7. Styrelsens årsberättelse
8. Dagordning

KALENDER

2022

Aug

29-31 R³ Nordic Symposium 2022
Naantali Spa, Finland

Sep

15 PHSS Annual Conference 2022
Heathrow, UK

26 Sjukhusdagen, Akademiska Sjukhuset,
Uppsala, Sverige

Okt

3 PHSS QP Forum Conference 2022
London, UK

11-12 CTCB-I certifiering, Associate level,
Göteborg

11-13 CTCB-I certifiering, Professional level,
Göteborg

11-13 ICCCS2022, Antalaya, Turkiet

17-18 Grunnkurs RenhetsTeknikk
Olavsgaard Hotel, Norge

? Grundkurs Renhetsteknik
Sverige

Nästa nummer
beräknas utkomma den 29 september

Manusstopp / Annonsbokning:
30 augusti 2022

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

LEDARE

Dear R³ Nordic member

We just had the annual meeting where the board members who were up for re-election all got their seats reconfirmed. This provided consistency and excellent conditions for R³ Nordic as work can continue. Yet there is nothing which is 'business as usual'. We all have a strong commitment to get physical activities up and running again.

SJUKHUSDAGEN 2022

The first event is Sjukhusdagen on June 3rd at Akademiska Sjukhuset in Uppsala, where the theme is 'Ensured cleanliness in the premises of care' (Säkerställd renhet i vårdens lokaler). Sjukhusdagen presents new guides by offering tools to strengthen the role of healthcare professionals in the design of new and existing premises. We are proud that the Swedish LAU has made this guideline in cooperation with LöF (Löf regionernas ömsesidiga försäkringsbolag).

HOSPITAL HVAC DESIGN

Further we have had Jukka Vasara giving a presentation on "Hospital HVAC Design" on an ICCCS webinar on June 8th . This ICCCS event was a joint event between R³ Nordic and the Irish Cleanroom Society (ICS).

R3 NORDIC SYMPOSIUM AND EXHIBITION 2022

The present issue of RenhetsTeknik addresses the Symposium in Naantali to 30th-31st of August 2022. The program committee has made an excellent job with the presentations and there will as usually be an exhibition as well. We hope that many of you will join us there for some inspiring days.

We still hope that more people will consider to contribute further to R³ Nordic; we really need you and don't need to make a huge contribution we will enjoy to get new members onboard and expand the 'family'.

Best wishes for the summer!

LENE BLICHER OLESEN,
CHAIRMAN

ALAN FRIIS
EDITOR

Invitation to the 51st R³Nordic Symposium & exhibition

August 29-31, 2022 Naantali Spa, Finland

THE SYMPOSIUM VENUE

The venue of the 51st R³ Nordic Symposium in Cleanroom Technology & Contamination Control is Naantali Spa (www.naantalispa.fi). Naantali is on the southwest coast 15 km north of Turku with approximate distances of 180 km to Helsinki, 160 km to Tampere and 460 km of Kuopio. International guests can e.g., take the ferry (Viking Line or Tallink Silja) from Stockholm to Turku or the train from Helsinki-Vantaa airport.

SCIENTIFIC PROGRAMME & FEES

The scientific programme, which is arranged by the programme committee (PK22) members, will run in three parallel sessions on both Tuesday and Wednesday. The programme covers general aspects of cleanroom technology (R^3), R^3 news, R^3 applications and applications how to control contamination in pharmaceutical, biotech and food industries as well as in hospitals. These sessions are 1) Pharma (two days) & 2) Hospital (two days) & 3) R^3 News & General (one day i.e., on Tuesday) / Food & Biotech (one day i.e., on Wednesday). All presentations are given in English. The programme with the abstracts are published in this issue of Renhetsteknik (RT) 2:2022. This material will also be available on the R^3-Nordic's website: www.r3nordic.org/symposium-2022 from late May 2022 onwards.

PARTICIPANT

For participant fees and deadlines, please, see the Registration Form available both in this number of RT and online on the symposium-site. For industrial participants there is a GO3PAY2-offer available until end of June 2022. In case you use the offer GO3PAY2, please, give the names of participants in multiple of three. Note, that all participants must either be members or join R^3 Nordic at registration. A non-member pays the registration fee (70 €/non-member) at registration.

EXHIBITOR

In the Exhibition fee one representative's fee is covered. He/she, who is responsible for the stand, has the right to participate in all sessions at the symposium. 1-4 additional representatives can be registered to a reduced fee (700 €/representative to this two-days event + member fee for each non-member) for those companies, which have booked and paid an A, B or C stand. For companies having a D-stand, the additional representatives shall register to normal price. The 2-d offer (to companies with a stand) cannot be split between company representatives based on days. At entrance, the participants get name badges showing which days they attend. Exhibitors, please, contact Gun Wirtanen at guliwi(a)luukku.com to reserve stands and services for the company representatives.

PROGRAMME

Note that the numbers in the brackets after the speakers' names refer to the topic/abstract number on the pages with abstracts.

Monday, August 29, 2022			
8.00-20.00	Exhibitors building their stands		
16:30-18:00	R^3 Olympics		
18.00-20.00	***Get-together Dinner***		
Tuesday, August 30, 2022			
8.00-9.30	***Registration & Coffee***		
9.30-10.00	Opening of the Symposium & Exhibition		
10.00-10.45	Keynote Lecture: Veli-Jukka Anttila (1)		
10.45-11.30	Keynote Lecture: Pirjo Hänninen (2)		
11.30-12.30	***Lunch & Exhibition***		
	PHARMA (BALLROOM)	**HOSPITALS (LOUISE)**	**CLEANROOM NEWS / GENERAL (KAISA)**
12.30-13.00	James L. Drinkwater (4)	Kari Solem Aune (15)	Esa Högel (26)
13.00-13.30	Teijo Paavilainen (5)	Berit Reinmüller (16)	Lene Blicher Olesen (27)
13.30-14.00	Tiina Salo & R. Peltola (6)	Bengt Ljungqvist (17)	Sampo Saari (28)
14.00-15.00	***Coffee & exhibition***		
	PHARMA (BALLROOM)	**HOSPITALS (LOUISE)**	**CLEANROOM NEWS / GENERAL (KAISA)**
15.00-15.30	Cédric Fernandez (7)	Roberto Traversari (18)	Berit Reinmüller (29)
15.30- 16.00	Frans Saurwalt (8)	Bengt Ljungqvist (19)	Aku Karvinen VTT (30)
	Smoothie & exhibition		
16.15- 16.45 16:45- 17.00	Pharma Panel Hospital Panel		
19.00-00.00	***Banquet dinner***		
Wednesday, August 31, 2022			
	PHARMA (BALLROOM)	**HOSPITAL & PHARMACY**	**FOOD & BIOTECH (KAISA)**
8.30-9.00	James L. Drinkwater (9)	Kari Solem Aune (20)	Alan Friis (31)
9.00-9.30	Simone Biel (10)	Frans Saurwalt (21)	Riina Brade (32)
9.30-10.15	***Coffee & exhibition***		
10.15-10.45	Niels-Erik Kongste (11)	Anni Luoto (22)	Gun Wirtanen (33)
10.45-11.15	Alan Sweeney (12)	Kim Hagström (23)	Sanna Tietäväinen (34)
11.15-12.15	***Lunch & exhibition***		
12.15-12.45	Steve Marnach, (13)	Leila Kakko (24)	Allan Zacho (35)
12.45-13.15	Lene Blicher Olesen (14)	Matthew Cokely (25)	Steven Deretz (36)
13.15-14.00	***Smoothie & Exhibition***		
14.00-14.45	Keynote Lecture: Pila Sormunen (3)		
14.45-15.00	**Closing of the Symposium**		

MEMBERS IN PK22

Leila Kakko	PK20 Chairperson, General	leila.kakko@tuni.fi
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Jukka Vasara	Hospital & News	jukka.vasara@granlund.fi
Gun Wirtanen	Exbibition & Food	guliwi@luukku.com / gun.wirtanen@seamk.fi

SYMPOSIUM NAANTALI

Registration Form

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

R³ Nordic Office
info@r3nordic.org

To obtain discounted prices
please return the filled form at
latest on June 20, 2022

Registrate Online
and charge your credit card
The member prices are available Online until **August 26, 2022**, at

www.r3nordic.org

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

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. The room accout is available all June 2022
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 in **June-August 2022**, there will be no **Refunds**.
We neither accept personal nor company cheques!

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

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

CONTACT INFORMATION	***Please print!***	**Only one participant per registration form!**
Family name		First name
Company		
Mailing address		
ZIP code and City		
Country		
Telephone		Mobil phone
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 50 586 96 98 · guliwi@luukku.com

Speakers
are registered through your PK 22 contact

PARTICIPATION

I will participate: ☐ August 30 ☐ August 31 ☐ August 29-30 ☐ Augusti 30-31 ☐ August 29-30-31

REGISTRATION FEES FOR PARTICIPANTS (€)	**Commercial** Price from June 24 onwards	**Public & Municipal** Price from June 24 onwards	**Total EURO**
Registration fee (1) for members, 2 day	**960**	**770**	
Registration fee (1) for members, 1 day	**650**	**500**	
Registration fee for members (GO3PAY2), 2 days	**1920**		
Registration fee (1) for non-members, 2 day	**1080**	**850**	
Registration fee (1) for non-members, 1 day	**730**	**580**	
Registration fee for non-members (GO3PAY2), 2 days	**2160**		

The offer "GO3PAY2" is available to the end of June 2022. In case your register five (5) additional names, please pay the "GO3PAY2"-offer twice. Participants, who are non-members, pay the non-member price or contact the office to add 70 €/non-member.

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

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

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

SOCIAL PROGRAM	**Amount**	**Price from June 24 onwards**	**Total EURO**
Get-together ticket (Monday August 29)		**90**	
Banquet ticket (Tuesday August 30)		**125**	
HOTEL ACCOMONDATION	**Nights**	**Price from June 24 onwards**	**Total EURO**
Naantali Spa, Singel room		**160**	
Naantali Spa, Double room		**180**	

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

GRAND TOTAL **EURO**

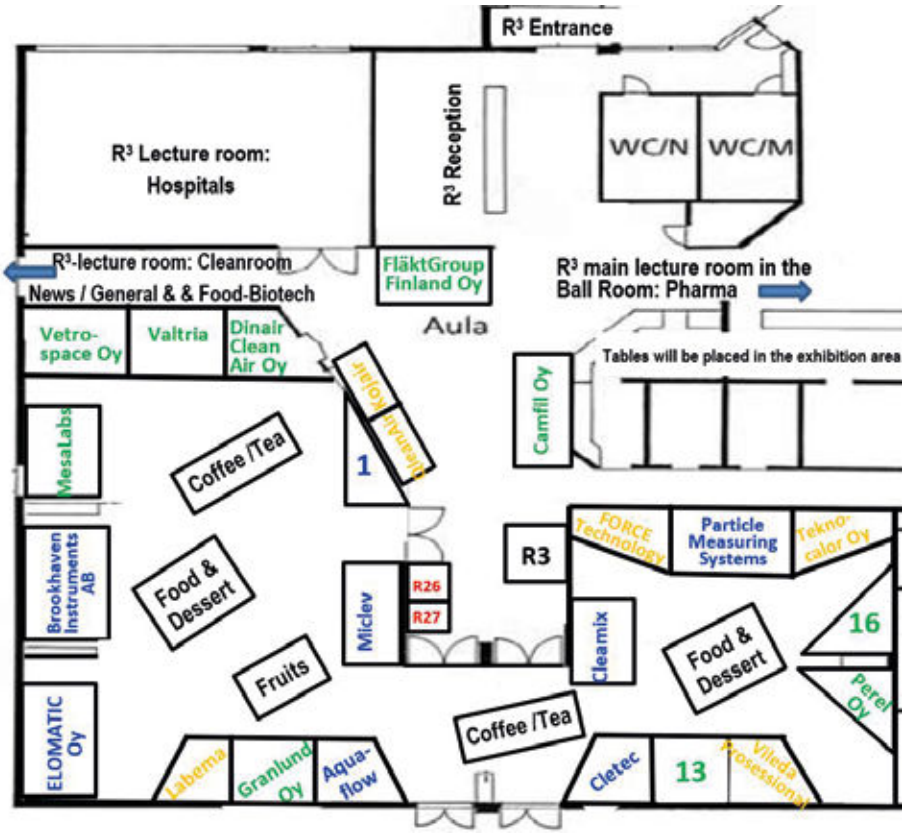
COPY · FILL IN · SIGN · SEND (All payments i Euro)

.....
Signature of authorized signatory

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

EXHIBITION MAP 2022

The exhibition is running both days. In the breaks, the participants can learn about the exhibitors' products / services or just meet with colleagues. There are in total 26 stands in the exhibition area, please see the updated map on the homepage: www.r3nordic.org/symposium-2022. The reservation situation on May 22, 2022 is given on the map below. The following exhibition areas are free to book: 1, 13, 16 & R26-R27 (stands marked with an R are roll-up stands). These areas will be booked based on order of reservations. In case there are new requests unpaid areas can be sold further.



PRICES FOR EXHIBITORS

Stand category:	A	B	C	D
Stand price (€) incl. 1 representative paid 15th of April 2022 and onwards	3100	2550	2100	1600
Ticket(s) for 1-4 additional participant(s) from an exhibitor available until 3rd of August 2022. Note that the invoice must be paid at latest on 22nd of August 2022. Registration (member/non-member) can after this be made through the homepage (see prices below and in the registration form).	+ a 2-d fee: 700 €/representative + 70 €/non-member			Additional participents; normal price
Normal participant fee (€) for members (1 day / 2 days) from an industry/institution from 24th of June -22	650 € / 960 €			
Normal participant fee (€) for non-members (1 day / 2 days) from an industry/institution from 24th of June -22	730 € / 1080 €			
Group-fee (€) for 3 members/company for 2 days; issued 24th of June - 3rd of August 2022 + 70 €/non-member. Note that the invoice must be paid at latest on 22nd of August 2022.	1920 € + (0-3) * 70 €			
NOTE! Early-bird prices are available online until 23rd of June 2022	see RT1:22 or R³Nordic's homepage			
Accommodation in single room; the symposium account is available all June 2022	160 € / person & night			
Accommodation in double room; the symposium account is available all June 2022	180 € / 2 persons & night			
Price (€) for the **Banquett ticket** from 4th of June 2022 onwards as long as tickets are available	125 € / person			
Price (€) for the **Get-together ticket** from 4th of June 2022 onwards as long as tickets are available	90 € / person			

PRESENTATION TOPICS & ABSTRACTS

KEYNOTE PRESENTATIONS

1 Operation room ventilation and risk of postoperative infections

Veli-Jukka Anttila, HUS, Finland

Infections are major complications following surgery. The most common type of infections after operations are surgical site infections (SSI), i.e. wound infections. SSIs cause: harm to the patients, longer stay of patients in hospitals, increased mortality and excessive costs to hospitals, health care system and society. According Centers for Disease Control and Prevention (CDC) recommendations wound infections can be classified in three categories: superficial, deep incisional and deep organ infections.

It has been calculated that SSIs could annually cost the European health care system up to 20 billion euros. It has been estimated, that about every second SSI can be prevented. In medical literature, there are over 30 means, how to lower the risk of SSIs. The role of operation room (OR) ventilation in the prevention of SSIs is not very well known. There are only a limited number of studies focusing on ventilation in OR and on SSIs. In most of these studies, there are also pitfalls and problems in the methodology used. In 2016, the WHO expert group evaluated 29 different measures for prevention of SSIs. Just one point of the above-mentioned addressed OR ventilation i.e. laminar air flow. The recommendation of the WHO expert group was: "Laminar airflow ventilation systems should not be used for patients undergoing total arthroplasty surgery ". This was a conditional recommendation with low or very low evidence. There are many studies of microbial contamination in different OR-ventilation systems. There is, however, a big need of good studies to handle the role of OR-ventilation systems in the prevention of SSIs.

2 Current topics in GMP and inspection findings in sterile manufacturing

Pirjo Hänninen, Fimea, Finland

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

3 Pandemic control strategies in smart buildings – individual and shared responsibility

Industry Professor Piia Sormunen, University of Tampere, Finland

The current COVID-19 pandemic has shown the importance of resilience in society and global economics. WHO has presented three C-models, which is an excellent recommendation for improving individual health safety in a built environment. While Swiss cheese model in respiratory virus pandemic defense presents individual and shared responsibilities in pandemics. However, indoor air conditions have had too little role in pandemic response discussion and future prevention actions of pandemics. During the COVID-19 pandemic, more and more evidence has accumulated confirming that airborne transmission plays very important role in the spreading of corona pandemics. Smart buildings will have big role in indoor health safety and mitigation of future pandemics. This paper presents adapted Swiss cheese model for individual and shared responsibilities in smart buildings to improve the health safety of building users.

PHARMA

4: 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, Franz Ziel & Pharmaceutical & Healthcare Sciences Society (PHSS), 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 must balance intrinsic contamination risks that may compromise sterile product quality 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.

5: The main deliverables and tools to provide successful communication in facility projects

Teijo Paavilainen, Bayer Oy, Finland

Engineering is largely communication. Pharmaceutical facility investment projects from concept though planning with detailed design to construction phases all the way to start-up can be complex and challenging task. The success of the project is dependent on several factors, but the success in information exchange is the key. The role of the communication has been emphasized during global pandemic. Efficient communication process combined with relevant deliverables, communication tools and engineering as well as quality reviews safeguard facilities through their lifecycle and ensures proactive compliance with GMP, health authority expectations and industry best practices. The presentation is based on the customers experience and perspective in the large pharmaceutical CAPEX project where project execution model is based on the engineering service contract with external engineering contractor. The presentation shares first-hand experiences of good practices, deliverables as well as lessons learned from helpful project tools like software platform for information exchange.

6: Risk-based approach to GMP – Focus your efforts where it matters

Tiina Salo & Riikka Peltola, ELOMATIC Oy, Finland

In the early 2000s, the FDA published a report titled "Pharmaceutical cGMPs for the 21st Century – a Risk-Based Approach". The purpose of this report was to enhance the regulation of pharmaceutical manufacturing and product quality. Ever since, there has been uncertainty in the pharmaceutical industry regarding "risk analyses", especially as to when, where and how they should be conducted. In the past few years, the European Medicines Agency has also revised most of its GMP guidelines to emphasize the importance of conducting risk analyses, for manufacturers to understand where they should focus their quality-safeguarding efforts. In this presentation, we discuss how the risk-based approach to qualification and validation in pharmaceutical design projects is implemented, present practical examples of different type of projects and discuss the impact of approach to commissioning and validation phases and possible time and cost savings.

7: Biological indicators for sterilization: Why perform a product D-value study?

Cédric Fernandez, MesaLabs, France

D-value studies are needed to know the impact that the properties of the material to be sterilized have on the resistance of microorganisms, and to prove that the biological indicator used to validate the cycle represents an adequate challenge to ensure the required level of sterility assurance (SAL) on the product being sterilized. Topics dealt with in the presentation are standards and references on D-value, parameters affecting microorganism resistance, liquid pharmaceutical D-value studies, custom made Biological Indicators.

8: Design construction and C&Q of a BSL 3 GAPIII facility

Frans Saurwalt, Kropman Contamination Control, the Netherlands

Amongst pharmaceutical projects a project combining GMP with BSL3 and GAP III requirements fall into the most complex category. Combining contamination control with containment ads, a separate approach to the design process that covers all systems involved. Risk analysis and failure mode analysis need to be incorporated and at all stages of the process the systems needs to meet the system requirements as well as form part of the integrated system. Inflow/pressure cascade, fail safe systems, fire suppression, filtration, VHP disinfection, incorporating of decontamination devices as autoclave, VHP-chambers and waste disposal/kill-tanks form a complex system. There is a need to include closed systems, isolators, biosafety cabinets etc. in such a facility. In this case, study the approach and essential challenges and solutions are demonstrated.

9: PHSS initiative in preparation of clarity on GMP guidance notes covering 20 specific GMP topics with MHRA review before publication

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

10: EU GMP Annex 1 – Regulatory baseline of single-use systems for final filtration and filling

Simone Biel, Merck KGaA, Germany

Single-use systems (SUS) are being utilized more frequently in final sterile filtration and filling operation. The benefits of SUS such as quick process changeover or reduced risks of cross-contamination are well acknowledged. However, there are issues regarding SUS standardization of quality information that limits implementation efficiencies. The EU GMP Annex 1 draft addresses the use of SUS in aseptic processing and provides regulatory expectations how to implement and to use single-use assemblies. In this presentation deals with:
1) Annex 1 and "specific risks associated with SUS",
2) Design considerations using SUS for filtration including PUPSIT,
3) Understanding your SUS supplier's quality strategy and
4) Ready to use and sterile – how to keep the integrity?

11: Membrane HEPA filtration to life science: History, present and the future

Niels-Erik Kongste, AAF Europe, Denmark

Membrane HEPA filtration or ePTFE (expanded Poly Tetrafluoro Ethylene) media which is the technically description of the material used in the membrane filter media has been on the market since the mid 1980´s. ePTFE fine fibers was developed by Daikin as part of their chemical division. ePTFE HEPA and especially ULPA (U15-U17) filters were quickly adopted by the semiconductor industry due to the superior mechanical stability and super low outgassing behavior and proven chemical compatibility compared to traditional micro glass HEPA/ULPA filters. Today ePTFE membrane ULPA filters is the industry standard in the most critical process steps in the semiconductor industry.

In the beginning of 2000´s the life science industry started to show industry in ePTFE filters and made several tests in real life environments to check if these filters were in compliance with the standards and especially in relation to the frequent HEPA integrity testing using an oil based aerosol (photometric test methods) which is not used in the microelectronic industry (compatible with Discrete Particle Counters - DPC testing). This presentation deals with the early progress of the fine fiber technology and the development process of manufacturing commercially available membrane HEPA & ULPA filters throughout the 90´s until today.

12: Advances of HEPA filtration in pharmaceutical applications and their new use in day-to-day life post pandemic

Alan Sweeney, Camfil EMEA, Ireland

Air filtration is a physical, biological, or chemical operation that can separate particulate and gaseous contaminants from an air flow by means of passing it through a filter media. This filter media consists of a complex structure designed specifically to provide targeted capture of contaminants of a particular size range or chemical composition. HEPA filters have been around us for more than 70 years. We have most likely breathed or will breathe air filtered by HEPA filters throughout our lives. Everything suggests that HEPA filters will be around for many years to come, helping to improve the air quality of our environment.

As a result of the COVID19 pandemic, HEPA filtration technology has become increasingly popular for treating the air and capturing the airborne SARS-Cov-2 virus. Until recently, this technology has predominantly been used in specialised fields, such as pharmaceutical production clean rooms or hospital operating rooms where exceptional air quality is required. In Pharmaceutical and Hospital facilities HEPA filters are installed in cleanrooms in ceiling housings and many other equipment, such as biosafety cabinets, isolators, sterilization tunnels, aseptic fillers, etc. Other areas of application are nuclear power plants, the food industry, veterinary laboratories, the cosmetics industry, biosafety centres, etc.

Lately, HEPA filters have become more popular due to their use in household vacuum cleaners, car cabin filters, air purifiers. One of the main reasons for the increasing popularity of HEPA filters is due to their use as a consumer product when integrated in an air purifier.

The full paper will outline how HEPA filters work, are certified and their benefit to society. It is my hope that that document will help you to understand HEPA filters a little better, how they work and their great importance for the future. In the presentation, I will amongst other discuss the following issues: “What is a HEPA filter?”, “How does it work?”, “Where is it used?” and “Can it catch viruses?”.

13: GMP Annex 1 – How to validate protective cleanroom garments?

Steve Marnach, DuPont Personal Protection, Belgium

The publication of the new GMP Annex 1 is scheduled for the 2nd semester of 2022 and it will change the requirements on manufacturers of sterile medicine products due to its new approach. It will be expected that all the activities inside the pharmaceutical manufacturing will be governed holistically by the QRM principles and documented in the contamination control strategy (CCS). Since cleanroom garment systems are a critical part of sterile and aseptic manufacturing and the only filter to keep the particles generated by the operators inside the garments to prevent them from contaminating the cleanroom, they should be managed under QRM principles too. In other words, simply relying on experience, visual checks and recommendations from the suppliers will not be enough any longer. This raises the question on how cleanroom garments should be selected and validated under QRM principles to become a part of the CCS. In this paper, an overview a QRM based validation approach for cleanroom garments will be presented and thereafter details, i.e., with their advantages & disadvantages, focusing on the following:

- The particle filtration efficiency & the bacterial filtration efficiency to assess the filtration efficiencies of the materials used to make cleanroom garments
- The Helmke drum test method to assess the particle shedding of cleanroom garments
- The particle shedding of cleanroom garments worn by an operator with the body box test method
- How to assess the sterility of the garments?
- The stability of the performance: how to define the moment when reusable cleanroom garments need to be replaced?
- Assessing the packaging and understanding the contamination risk it may represent

The companies operating cleanroom need to know which scientific test methods are available for validating cleanroom garments and how to interpret the obtained test results. As conclusions it can be stated that cleanroom garment systems are a critical part of the contamination control strategy and process validation. It is therefore important that the companies know how to proactively assess and validate them to meet the latest regulatory requirements as well as the expectations of the GMP auditors.

14: The influence of media, temperature and time on growth of microorganisms from cleanrooms

Lene Blicher Olesen, NIRAS A/S, Denmark

This presentation will give an insight on the parameters that affects the growth of microorganisms. The focus will be on microorganisms found in cleanrooms and the influence on the growth of the microorganisms with focus on growth media, temperature, and time. Further, the presentation will shortly take relevant cleanroom monitoring guidelines into account.

HOSPITAL

15: Is your hospital prepared for the next pandemic?

Kari Solem Aune, COWI, Norway

These two years of pandemic have shown how critical it is to be prepared for unexpected situations. By Stavanger university hospital they wanted to see how prepared the new hospital would be for an upcoming pandemic (or maybe the new normal).

The work was performed through a huge risk assessment, which included the staff from all departments in the hospital – from the ambulance hall, emergency unit, infection, and intensive care units and all the way throughout the hospital. Key elements discussed were:

- How to divide into separate loops for infected/not infected patients
- How to handle the spread of infected patients into the hospital units
- How to prepare for cohort isolation in different units
- How to prepare the ventilation systems
- How to prepare the clinical routines
- Cost impact of the items above

This presentation will give an overview of how the work was conducted, to show how such issues can be dealt with.

16: People as a contamination source in cleanrooms

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

Results are presented from studies performed in a test chamber on cleanroom garments used, laundered, and sterilized (autoclaved 20 minutes at 121 °C), 50, 60, and 70 times, and garments used, laundered, and sterilized with a prolonged autoclave cycle 50 times. The garments are used in aseptic production of sterile drugs (Grade B). The source strength is described as the mean value of the number per second of airborne particles and aerobic CFU, respectively, emitted from one person dressed in the clothing system to be evaluated.

Results are compared to previous presented values of human source strengths in cleanrooms. Furthermore, results of the source strength values of the studied cleanroom garments in the test chamber have been used to calculate theoretical expected mean value concentrations of airborne aerobic CFU and particles (≥0.5µm) in cleanrooms with different number of people present, and at different airflows (m^3/s.). The calculations assume turbulent mixing of air in the cleanroom. It can be noted that the theoretical calculated mean value concentrations of airborne aerobic CFU often are below the detection level of traditional measuring equipment.

17: Protective efficacy of surgical clothing systems and additional clothing components concerning airborne CFUs

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

The number of airborne bacteria-carrying particles, colony-forming units (CFUs) in the operating room is considered as an indicator of the risk of infection to the patient undergoing infection prone surgery. To reduce surgical site infections, it is desirable to keep the bacteria-carrying particles at a low number in the operating room air, especially during orthopedic prosthetic surgery.

The main source of airborne bacteria-carrying particles is the people staff, and patient. It is important that the surgical team and all other people in the operating room wear functional clothing systems. Here, results from measurements studies of the protective efficacy are compared, i.e., source strengths of a clothing system with different additional clothing components. The studies were performed during ongoing surgery. Results show that the use of disposable hood or textile hood and the use of knee-length textile boots have considerable influence of the source strength, i.e., microbial air cleanliness in the operating room during ongoing surgery.

18: Humidification in healthcare facilities

Robert Traversari, Marcel Loomans[1], Karin Kompatscher, Emelieke Huisman[2], Helianthe Kort[2,3] & Wim Maassen[3], TNO, Delft, the Netherlands, [1]Eindhoven University of Technology, the Netherlands, [2]University of Applied Science, the Netherlands & [3]Royal Haskoning DHV, the Netherlands

Humidification is not a common procedure in many buildings in the Netherlands. An important exception are buildings that are used for healthcare, especially hospitals. There, e.g. in operating theatres, relative humidity (RH) generally is controlled stringently at levels around 50%. From an energy point-of-view humidification is an energy-intensive activity.

Currently, more than 10% of the total energy used in buildings for healthcare is spent on humidification. The basis for an RH of around 50% is however, unclear. Therefore, we pursued a scoping review to find evidence for specific RH thresholds in such facilities. In addition, an inventory was made of the current practice in the Netherlands. In the literature review, references were selected based on keywords. Guidelines and current practice were analyzed by referring to existing (inter)national guidelines and standards, and by contacting experts from Dutch hospitals through a survey and semi-structured interviews. The literature review was grouped into four topics: 1) microbes including viruses, 2) medical devices, 3) human physiology and 4) perception. No scientific evidence was found for the currently generally applied RH set-point of approx 50%. Some studies suggest a minimum RH of 30% but the evidence is weak. A lack of research that addresses more long-term exposure (a couple of days) and includes frail subjects, is noted. Following current practice related to humidification, it was found that RH requirements are strictly followed in all hospitals consulted, some only focusing on the hot zones, but in many cases extended to the whole hospital. For humidification, steam is mostly applied due to hygienic reasons. Alternatives are available but nearly not considered yet. The conclusion, therefore, is that there is no solid evidence to support the RH-setpoints as currently applied in the Netherlands. It is merely a code of practice.

19: Risk assessment in unidirectional airflow at different air velocities

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

Operating rooms for patients undergoing infection prone surgery often have unidirectional air flow (UDAF) supply air systems. Many UDAF systems installed in Europe have low air velocities i.e., equal to or below 0.3m/s, while other UDAF supply air systems have velocities about 0.4m/s. The velocities, declared by the supplier, is mostly the velocity measured 150 to 300mm below the filter screen. The purpose of this presentation is to describe microbial airborne contamination risks at different air velocities in UDAF systems without blocking obstacles, such as monitors, lamps, etc.

To evaluate contamination risks, the method for Limitation of Risks, the LR-Method is used. The LR-Method, which relies upon visualization of air movements, particle challenge testing, and calculation of a risk factor, presents a fast and reliable way for evaluating microbial safety and detection of potential airborne microbial risks.

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

20: Planning of a sterilization department

Kari Solem Aune, COWI, Norway

The sterilization department in a hospital is more or less the same as a factory producing sterile goods. This means, we need to understand the sterilizing process 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.

21: Design considerations for ATMP facilities

Frans Saurwalt, Kropman Contamination Control, the Netherlands

Advanced Therapeutic Medical Products (ATMP) form an increasing part of the pharmaceutical market. The Eudralex Vol 4 ATMP-guideline deals with their specific requirements. As diverse, as they are they generally require a flexible and modular approach. Furthermore, logistics on product, materials and in process quality control pose requirements on routing and layout. This is particularly of importance when autologous products are processed. Developing from manual lab procedures the expected developments to more closed and automated systems require adaptable designs. Based on recent projects and considering the contamination control strategy aspects, design concepts and solutions will be presented including layout concepts, flow/pressure cascades including GMP and containment.

22: Ventilation solutions for healthcare patient rooms to control respiratory infections

Anni Luoto, Granlund Oy, Finland

During the Covid-19 pandemic, more attention has been paid to healthy indoor conditions and safety, as air is the main route of transmission of the Sars-Cov-2 virus. The airborne spread of the virus highlights the importance of a ventilation strategy, as well as the development of new ventilation solutions. Current studies have shown that sufficient ventilation reduces potential exposure to the virus. The aim of the study is to optimize the location of ventilation terminals in a typical hospital emergency reception room.

The study compares different computational fluid simulation models implemented in the room, where the location of the exhaust air device has been changed in different cases. The research methods of the work are computational fluid simulation (CFD), literature research and comparison of ventilation solutions with the using Choosing by Advantages method (CBA).

23: Ventilation solutions enhancing Health Care Worker's safety in isolation rooms

Kim Hagström & Ismo Grönvall, Halton OY, Finland

According to recent studies, there is a high risk for HCWs to be exposed to microbes exhaled by patients especially, while they are conducting their work close to patient. Current ventilation solutions that are used in Isolation rooms are not designed to address this challenge. With high airflows rates that are used in isolation rooms, ventilation airflow can reduce the average microbial concentrations in the room, but they are not able to affect the Health Care Worker's (HCW's) exposure to patients' outbreath close to patients. These may lead to substantially higher exposure levels compared to general room air conditions.

The performance requirements for isolation rooms have been considered from 1st principles in standardisation work at CEN TC156 WG18. The defined verification requirements for ventilation systems aim to account both for general and local exposure risks. Also, sustainable operation must be considered when room is used for other patients without isolation need.

A new dynamic protective flow ventilation approach has been developed for isolation rooms allowing different operation modes for isolated and normal patient needs. Its performance has been verified according to principles emphasized in CEN working draft including also thermal comfort.

24: Surface hygiene in hospital environment

Leila Kakko, Tampere University of Applied Sciences, Finland

The cleanliness and clean surfaces in hospital environment must be self-evident, but sampling of surface hygiene has more relevant during the COVID-19 pandemic. Surfaces are always contaminated with dirt, dust, microbes, and condensed matter. Therefore, cleaning has a long history. The criteria for what we want to obtain by cleaning differ. The level can be acceptable perception both visual and tactile, hygienic and health concerns, and prevention of surface degradation. To keep clean is to reduce any pathway ultimately transporting mass into the surface layer. There are only two methods for removing dust and dirt that has been introduced into the indoor environment: ventilation and cleaning. The current COVID-19 situation challenges and highlights the importance of hygiene and cleaning expertise and skills in all operation environments. In Tampere we collect surface and air samples from the hospital environment, e.g., from the premises of the units that treat COVID-19 patients and from other facilities of the hospital. The samples were analyzed in the Virology Laboratory at the University of Tampere. In the presentation I will show some of the results.

25: Cleaning and disinfection: Regulatory requirements and expectations including GMP Annex 1 draft

Matthew Cokely, Ecolab, UK

Cleaning and disinfection processes are often undervalued. This presentation reviews the regulatory requirements and 'best practice' recommendations for cleaning and disinfection of controlled manufacturing areas. The pertinent regulations are considered.

The regulatory guidance relating to cleaning and disinfection in the draft EudraLex Vol.4 Annex 1, version 12 (v.12) issued in February 2020 and potentially the final version is examined. This presentation gives a summary of the history of these publications and revisions to date, and discusses the relevance of the revision to the international state members of PIC/s.

Finally, the presentation considers the regulations specifically relating to cleaning, disinfection, documentation and records, cleaning equipment, in-house preparation of detergents and disinfectants, residues, validation, rotation, transfer disinfection, validation, and training of cleanroom personnel. Recommendations for best practice are provided.

CLEANROOM NEWS/GENERAL

26: Through process optimization to reduce production time, energy, and costs

Esa Högel, Valtria Swiss AG, Switzerland & Valtria Finland Oy, Finland

Thinking of the warming of the Earth's atmosphere, we all have a responsibility, starting with each of us, companies, and states, because the air is common to us. A good example of this is how all these benefits can be achieved by optimizing production stages by shortening production time and reducing energy use, i.e. energy costs. An example new production plant of the Ecoflac-Plus infusion bottles® at B. Braun, those responsible - among many other criteria - have demanded a time optimization of the process, a short implementation phase and a significant reduction in operating costs for the drying of the bottles between the sterilization autoclave and the bottle labeling.

The mission of this kind of drying tunnels is reducing the drying time spend in between the autoclave and labelling system. During sterilization process, the autoclave in flooded with pressurized water, which creates a problem in labelling, as it will not be possible to stick the labels on the humid bottles. To achieve a complete drying process, airflow is created and directed to the exterior surfaces of the bottles, absorbing the water and humidity of the products. The air involved in the process is treated inside the AHU. The air is insufflated and recirculated in the interior of the tunnel, removing the water and the humidity, and cooling the product. Water is drained through the inclined trays and pipeline system.

27: Re-qualification of cleanrooms

Lene Blicher Olesen, NIRAS A/S, Denmark

This presentation will give an insight on the re-qualification of cleanrooms. The focus, of this presentation, will be on the relevant test methods, equipment, and guidelines, which are expected to be basis for re-qualification of cleanrooms in a GMP environment.

28: Respiratory aerosol particle emissions and control in the clean room environment

Sampo Saari, Anna Tuhkuri Matvejeff, Enni Sanmark*, Lotta-Maria Oksanen*, Topi Rönkkö**, Jani Hakala#, Aimo Taipale# & Ahmed Geneid*, Tampere University of Applied Sciences, Finland, *HUS, Helsinki University Hospital, Finland; **Tampere University, Finland & #VTT Technical Research Centre of Finland, Finland*

The current COVID-19 pandemic has highlighted the importance of understanding better the rapid aerosol transmission of pathogens. In this study, the emission mechanisms, and dynamics of aerosol particle emissions from respiratory tract are presented based on the recent studies. A new developed portable measurement system for respiratory particle emission experiments and some preliminary results are presented. The measurement system enables the investigations of absolute and time-resolved exhaled aerosol emission rates with controlled drying and dilution processes of generated droplets. Absolute aerosol emission rates are important parameters when modeling and assessing the transmission of viral aerosols and the infection risk in indoor environments. With this measurement system we can study aerosol particles generation rate in real time over a wide particle size range. The results will help us gain new insights on aerosol transmission events, especially on the differences between common spreaders and potential super-spreaders. The study also presents the efficiency of some potential aerosol control measures in the clean room environment.

29: Microbial risk assessment in safety cabinets/Class II benches with the LR-method

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

Microbiological risk assessment of airborne contaminants in safety benches/class II with the method for limitation of risks, the LR-Method, is described. Results from excerpts of case studies in safety cabinets/class II benches are discussed. The influence of heat sources, movements around the safety cabinet, and monitoring are discussed. The LR-Method, which relies upon visualization of air movements, particle challenge testing, and calculation of a risk factor, presents a fast and reliable way for evaluating microbial safety and detection of potential airborne microbial risks to the product. In e.g., safety cabinets it can be used for tracing dispersion routes of airborne contamination and for the evaluation of single steps of the process. When developing SOPs for aseptic processes and the training of operators, the LR-Method has proven to be very useful.

30: Preparing for the next pandemic - simulation-based solutions

Aku Karvinen, VTT Technical Research Centre of Finland, Finland

At the beginning of 2020, frightening news began to emerge around the world. The unknown threat caused a lot of pneumonia and other several illnesses. Soon it turned out that the cause was the coronavirus closely related to 2002-2003 SARS (Severe Acute Respiratory Syndrome) virus. New virus was later named SARS-CoV-2 (SARS Corona Virus 2) and the disease was named COVID-19 (Corona VIrus Disease 19). At first, it was thought that the virus would not be transmitted from human to human, but when this turned out to be the case, it was time for urgent measures. Different methods to prevent the spread of the disease were applied, including full lockdowns. At first, it was thought that the virus was transmitted mainly through droplets and fomites. The research community started soon, however, to speculate whether the virus can also be transmitted by small particles floating in the air called aerosol particles. When this transmission route turned out to be important, perhaps even dominant, it was time to start look for, research, and develop the methods to prevent aerosol transmission.

This paper explains how to use simulations to study methods to prevent the aerosol transmission of diseases. The main simulation tool used is computational fluid dynamics (CFD), which allows the movement of individual aerosol particles to be predicted and visualized in different situations, such as in different ventilation strategies. The simulation also enables the assessment of the effectiveness and development of various methods of preventing transport, such as air purifiers and UV lights. In addition to simulating the transport of aerosol particles, the method also enables the study of transmission via droplets and surfaces. The method has also been used to illustrate for the public how the virus spreads, facilitating, among other things, daily decision-making on which facilities are safe and when the use of a respirator is necessary. In addition to COVID-19 situation, the methods developed will be used to prepare for the next pandemic.

FOOD & BIOTECH

31: The hygiene factor as an improved description of the hygienic quality of food contact surfaces

Alan Früs, Annette Baltzer Larsen, Nicole Ciacotich and Thomas Fich Pedersen, FORCE Technology, Denmark

Research articles and studies in literature have highlighted that the intrinsic surface characteristics of a food contact product has a great impact on the cleanability of the surrounding materials and foodstuff. However, a clear correlation between surface topography and cleanability has not yet been scientifically proven and established. With this aim, we have developed a hygiene factor based on the surface roughness profile and correlated it to practical hygiene testing.

The current guidelines and rules of thumb are based on the characterization of surface roughness given by the Ra value, which is often measured only in one direction across the surface, traditionally moving a physical pickup across the surface. This characterization of the surface characteristics by only one value is a major simplification, and it is evident by simply observing a typical surface topography. Therefore, the hygiene factor we have developed also includes the number of peaks on the surface, giving a more adequate description of its topography. Moreover, the entire measurement is carried out by using an optical 3D microscope, thus avoiding physical contact with the surface. The hygiene factor is defined as the inverse product of Ra (the geometric mean distance from the mean line of roughness profile) and Rpd (the peak density i.e., the number of peaks per cm of the roughness profile).

The validity of the hygiene factor has been evaluated and verified with both stainless steel and plastic plates. The tested stainless-steel surfaces had different finishing (grinding, polishing, bead blasting and ViwaTeq®), and the tested plastic surfaces were obtained by injection moulding using mould with different surface roughness. The overall goal is to provide the industry a tool for the characterization of materials in terms of hygienic quality by using 3D optical microscopy and the calculated hygiene factor. In addition, the hygiene factor can have high practical relevance for industry, e.g., in case of comparing the hygienic between new surfaces and surfaces in use.

32: How do you prepare for future sustainability challenges in food unit investment planning and technology choices?

Riina Brade, ELOMATIC Oy, Finland

Food manufacturing is Europe's largest industry and under unprecedented pressure for change. In the sustainability crisis, consumption, population growth and sustainable food production are the biggest of our longer-term challenges. In addition, during the pandemic, it has become clear how important the food industry is in maintaining a stable and functioning society and ensuring security of food supply both in Finland and globally. Companies now need crisis resilience and innovation. Under the change is the division of labor between different actors, the ownership of raw materials and commodities and, in general, the ways in which companies generate income. The prerequisite for success is smooth cooperation with stakeholders in the food sector, research and development and project planning. The investment planning emphasizes adequate technical functionality studies in the initial stages, as well as profitability and sustainability reviews, utilizing agile design tools. With 3D modeling software with visual modeling, the desired change or expansion can be tested efficiently and proactively. The virtual model also allows you to test the functionality of your equipment or production line and even furniture investment and usability on a real scale. Those who take advantage of new value chains and the opportunities brought by the digitalization platforms will continue to thrive, and overall they will continue to invest in resource-efficient efficiency and productivity programs. There is also a need for the ability to develop, scale and, where necessary, adapt existing technology to suit new types of processes, as well as carbon-neutral energy solutions.

33: Importance of correct materials and structures in hygienic food facilities

Gun Wirtanen & Jenni Peltomaa, Seinäjoki University of Applied Sciences, Finland

The aim of this work was to prepare guidelines for the hygienic design of a food production facility in Finnish language. The legislation broadly defines what a food facility should look like. The purpose of this work is to elaborate the details of critical items in food hygiene. Both the equipment and the production facility must be designed, manufactured, constructed, and installed in accordance with hygienic design principles. The hygiene principles in the food factory are to:
1) protect the activities in the factory from both external and internal hazards,
2) manage the internal flows (people, products, packaging, air, and waste),
3) prevent cross-contamination and
4) maintain hygienic conditions through choice of structures and materials (appropriate foundations, steel structures, materials used on walls, ceilings and floors).

These principles are there also to ensure compliance with customer requirements. The above-mentioned facts ensure that both the food facilities and the food equipment can be cleaned and disinfected properly.

34: A study on surface hygiene in restaurants

Sanna Tietäväinen & Gun Wirtanen, JIK ky, Finland & *Seinäjoki University of Applied Sciences, Finland*

The aims of this thesis were:
1) to update the own-checking guidelines for registered food operators based on the amendments in the Food Act (297/2021) and the Food Hygiene Decree (318/2021),
2) to guide the food operators in surface cleanliness sampling (in accordance with the new recommendations) and
3) to harmonize the control of the surface cleanliness. In the thesis, the restaurants' hygiene measures were investigated based on a survey and the cleanliness level based on surface sampling.

Food contact surfaces are well cleaned in the restaurants. Based on surface cleanliness samples, food contact surfaces were also cleaner than the indirect surfaces were. According to the performed survey, most restaurants clean the door handles daily. Half of the responding restaurant operators neither disinfect their cleaning tools nor wash the floor drains before washing the floors as it is recommended. Based on the answers, improvements in the hygiene of used disposable gloves are needed. The hands must be washed before putting on and when changing the protective gloves.

These results showed the importance of the cleaning cloths and their cleanliness, the exposure time of the disinfectants used and the use of clean cloths or paper towels in drying the surfaces. Enterobacteriaceae were found on chopping boards, kitchen handles, worktops, taps, and sink rims. Based on the hygiene results and the questionnaire responses, site-specific guidance and counseling can be provided to restaurant operators to improve the hygiene level in the restaurants.

35: Contamination control - Make cleanroom cleaning reusable and minimize waste

Allan Zacho, Freudenberg Home and Cleaning Solutions, Denmark

Cleanroom cleaning utensils are worldwide mostly disposable. This is part of the large amount of waste produced by Pharmaceutical and other cleanroom industries. Vileda Professional are focusing together with dedicated and validated cleanroom laundries around the world, to change this by offering reusable cleaning and disinfection systems and same time trying to convince the industry to use less water and chemicals.

Vileda Professional have since 1989 been working with microfiber cleaning textiles and since 2003 introduced microfiber reusable cleaning systems for Pharma companies. A constant developing and designing "intelligence" textiles and methods which can both minimize the use of liquid and chemicals and same time re-use mops and wipes again and again, even inside Sterile environments.

Our Key brand MicronSwep™ is already worldwide accepted by majority of the top 50 Pharma companies and is helping these companies to reduce their carbon footprint.

By using the unique "Pre-dosing" method, we ensure maximum efficacy of our cleaning tools and with clear evidence we can remove both particles and even down to virus size microorganisms – which are proven by the German Institutes BMA and Dr. Brill + Partner GmbH.

The complete cleaning/disinfection system contains both Microfiber wipes, Mops and Above the Floor Tools. This system is giving the user an Ergonomic system to work with and same time minimize the time used to clean the cleanrooms – and finally minimizing biofilm and residues to comply with the Annex1 which are soon to come.

We look forward presenting the methods, products and answer any kind of questions that might come up. Vileda Professional got active partnership with dedicated cleanroom laundry partners all over Europe.

36: The new era of the cleanroom wall systems

Steven Deretz, CRDB, Belgium

The room is called a cleanroom when it is airtight and easily cleanable. Cleanrooms are traditionally made from plaster walls, monobloc panels or a kind of cassette system. All of these three systems got their advantages and disadvantages. Plaster walls are fragile and produce a lot of dust during assembling. Second, monobloc panels. They are modular; however, space between the panels is not easily accessible unless the request is specified during the design process. Lastly, the cassette system that has been found practical; however, they are relatively expensive, and they have many joints on the wall surfaces. Moreover, some additional points to make a cleanroom system more practical has been recognized. For example, from a maintenance perspective, easily dismountable wall surfaces to offer access between the walls would provide agile entry for wiring and pipes. Furthermore, from an installation point of view, faster assembling of the room building process would offer several advantages. There are two types of systems on the market to answer the demand: a fully metallic system with smaller `cassettes´ and the newest system, with full plates, hung on the metal studs. The advantage of the prior one is that there are much fewer joints than in the traditional cassette system. Importantly, providing higher cleanliness with less cleaning and maintenance cost-efficiently.

Minnesord Åke Möller

R³-entusiasten tekn lic Åke L Möller har avlidit i en ålder av 89 år. Efter studentexamen bedrev Åke studier i kemi på KTH, där han blev tekn lic 1963 på en avhandling om mikrobiologisk provtagning av luft med impaktionsinstrument. Efter anställningar på bl a AB Kabi i Strängnäs, Sockerbolaget i Arlöv och Statens bakteriologiska lab i Stockholm startade Åke egen konsultverksamhet med företaget Cogito Consult AB.

År 1966 var Åke med och startade en kommitté för Renlighetsteknik och Rena Rum (R³), som blev en nordisk förening 1969 med namnet Nordiska Föreningen för Renhetsteknik och Rena Rum, ofta kallad Nordiska R³-föreningen. Idag är namnet R³ Nordic. Vidare tog Åke, för R³-föreningens räkning, en mycket aktiv del i att bygga upp en internationell konfederation av liknande nationella föreningar, vilket 1972 ledde till bildandet av ICCCS (International Contamination Control Societies) där han var R³-föreningens representant fram till sin pensionering.

Åke var föreningens tredje styrelseordförande under åren 1976-82, vilket utgör den maximala mandatperioden på sex år. Han drev föreningens kansli tillsammans med hustrun Eva under åren 1977-91.

I samband med att Åke blev föreningens ordförande 1976 tog han över ansvaret för medlemstidskriften R³-Info i A5-format, vilken år 1986 blev en tidning i A4-format som hette Nordisk Tidskrift för Renlighetsteknik, för vilken han var redaktör fram till 1994. Därefter ändrade föreningstidningen namn till RenhetsTeknik, vilket gäller fram till idag.

År 1993 utsågs Åke till hedersmedlem i Nordiska R³-föreningen.

Det bör även nämnas att Åke tillsammans med Eva under många år var mycket aktiva som funktionärer under föreningens årliga symposier. Åke var även initiativtagare till att mer varaktigt bygga upp föreningens kursverksamhet.

Avslutningsvis bör påtalas att Åke deltog aktivt i det internationella standardiseringsarbetet inom R³-områden, där han var SIS representant (Head of Swedish delegation) i såväl ISO som CEN kommittéer.

Vi som har arbetat tillsammans med Åke i olika R³-frågor minns honom som en kunnig, pådrivande och entusiastisk person med hängivet engagemang.

R³-vännerna Bengt Ljungqvist & Berit Reinmüller

In Memorial

Dr Åke L Möller passed away in March this year, at an age of 89 years. He was internationally recognized as an R³ Nordic contact person. He was one of the founder members of R³ Nordic in 1969 as well as of ICCCS in 1972.

Dr Möller was the chairman of the R³ Nordic board between the years 1976 – 1982 and the Executive R³-manager between 1982-91. Furthermore, he was the Editor of the R³ Nordic Journal between the years 1976-94. Finally, it could be mentioned that he was an enthusiastic R³ Nordic member always eager to discuss contamination control issues.

PDA Journal of Pharmaceutical Science and Technology 2022; Volume 76, Issue 2, March/April finns på PDAs hemsida

- Ny PDA Technical Report No. 13 Revised 2022 (TR 13) Fundamentals of an Environmental Monitoring Program
- I samband med PDA Annual Meeting utdelades flera utmärkelser, mottagarna presenteras i kommande PDA Letters
- Each year, the PDA Letter editors and the Editorial Committee identify top articles published that year and select the one that best encapsulates PDA's mission of connecting People, Science and Regulation®. The award was given to Stephan Krause, PhD, Adele Chambers, Ryan Courtney, Darrin Cowley, and Anthony Mire-Sluis, AstraZeneca at the Awards Ceremony, at the PDA Annual Meeting 2022. The 2021 honor was awarded to the article: The Modern Quality Professional Development Tool, Part 1: Developing a Capability Matrix for Product Quality Leaders, Part 2: The Case Studies, and Part 3: Using the Scoring System

EJPPS Volume 27 Issue 5, March 2022

Peer Review Papers

- A review on analytical methods of cilnidipine and its combinations, by *Pranali Mishra, Ankit Mishra, Parul D Mehta*
- Formal methods of selecting monitoring locations and control levels,

The article has been published in the book Cleanroom Testing and Monitoring. It was originally written by *Dr Whyte*, with the assistance of *Tim Eaton* and *Joe Geesey*, for publication in the EJJPS, but owing to the demands of publishing it was redirected to become an annex in the book. However, the subject of the annex is considered to be of interest to readers of the EJPPS and is reproduced here. It was also considered useful to alert readers who are concerned with the testing and monitoring of cleanrooms about the publication of the book.

- Recovery of Microbial Contamination with Settle Plates Exposed in a Unidirectional Airflow Workstation for 4 Hours, by *T Eaton, K Capper, A Nash, S Drinkwater, J Bright*

Opinion Papers

- Walk on the wild side: The application of environmental isolates in microbiological testing by *Tim Sandle*

Editorial

- Guest Editorial: Contamination Control Strategy in the QC Microbiology Laboratory by *Tammy Hassel* & *Lina Celis Bautista*

PHSS News

- Book Review - Cleanroom Testing and Monitoring - *W Whyte*

Regulatory Update by *Malcolm Holmes*

- January 2022, February 2022 and
- March 2022

Clean Air and Containment Review (CACR) Issue 47 2022 Number One, ISSN 2042-3268, that in addition to John Neiger's editorial, Pearls of wisdom, and Life lines contains the following

- Multiple users in a Biosafety Cabinet Cleanroom Testing and Monitoring by *Kara F. Held* and *Robert Thibeault*. This paper is reprinted with the kind permission of The Baker Company and is one of a series of white papers under the heading of 'Baker BSC Myth Busters
- Cleanroom Testing and Monitoring, Chapter 8: Filter installation leak testing by the photometer method, by *W Whyte*
- Comparison of radiation methods for the sterilisation of cleanroom items, by T*im Sandle*
- News, Events, and Training Courses

Printed with permission of CACR

Organised every two years, the International Symposium of Contamination Control (ISCC 2022) will be hosted by the Cleanroom Technologies Society of Turkey on 11-13 October 2022 in Titanic Deluxe Golf Belek-Antalya. It will bring industry professionals together to learn the research and developments on contamination control and its applications. The theme of the symposium is "Contamination Control Is In Every Aspect of Our Lives"

The symposium, which is organized in cooperation with the Cleanroom Technologies Society of Turkey, the International Confederation of Contamination Control Societies (ICCCS) and Akdeniz Tanıtım, is giving its attendees the opportunity to get the information about the future of the ISO 14644 standards first-hand with the developers of the said standards, ISO TC 209 delegates from 23 member countries, attending. This event also happens to be the first time ICCCS COD meetings and board meetings take place in Turkey.

Utmärkelse till Lars Ekberg

In April 2022, Lars Ekberg (CIT Energy Management & Chalmers) received REHVA Professional Award from the hand of REHVA vice-president professor Ivo Martinac, KTH.
Lars says that he straightened his back when he heard the motivation:
"In recognition of his outstanding academic achievements and for his contributions to improve energy efficiency and the indoor environment of buildings".

The challenges in this field are many and they are great. One key to success lies within collaboration. Collaboration across various academic disciplines, and collaboration between academia, industry and society.

Now even roofs can be cleaned from the ground

The launch of the water-fed pole has made it possible to clean most windows from the ground. And if a building is particularly high, then an abseil, scaffold or cradle system might be required. But what about the humble roof? Is it simply supposed to stay dirty? Not any longer, says Ionic Systems' managing director Reuben Reynolds.
"We launched our new Roof Wand at Interclean this week," he said. "It makes the roof cleaning task a whole lot easier. And we've had a lot of interest from shopping centres which often have angled roof canopies."

The Roof Wand was actually devised on the back of another Ionic innovation. "We came up with a soft-washing system for removing moss, lichen and other organic growth from conservatories and facades," said Reynolds. "But we then discovered that people were climbing on to roofs and using it there.

The patent-protected product consists of 10 poles - three telescopic ones and seven quick-release carbon fibre poles - giving a total possible length of 20m."

Further informations at http://www.europeancleaningjournal.com/magazine

FDA Updates Guidance on Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production

The U.S. Food and Drug Administration (FDA) has published a new version (Revision 1) of its Guidance for Industry on Out-of-Specification (OOS) Results. The original version of the document was published almost 16 years ago, in October 2006.

Self-cleaning spacecraft surfaces to combat microbes

NEWS BRIEF"@IEST, MAY 2022

Astronauts live and work in orbit along with teeming populations of microorganisms, which could present a serious threat to health – and even the structural integrity of spacecraft. To help combat such invisible stowaways, an ESA-led project is developing microbe-killing coatings suitable for use within spacecraft cabins.
Crewmen on the International Space Station are not alone. A microbial survey of surfaces within the orbital outpostfound dozens of different bacteria and fungi species, including harmful pathogens such as Staphylococcus aureus – known to cause skin and respiratory infections as well as food poisoning. These microbial populations could even make spacecraft sick, not just astronauts. Bacteria and fungi produce 'biofilms' – akin to the plaque on your teeth – that can in turn tarnish and eat away at metal and glass as well as plastic and rubber.
This problem proved acute in the latter days of the ISS's predecessor, the Mir space station, where microbial colonies were observed growing on parts of spacesuits, cable insulation and even the seals of windows. The IIT team has begun work on titanium oxide, also known as 'titania', used for example in self-cleaning glass down here on Earth, as well as in hygienic surfaces. When titanium oxide is exposed to ultraviolet light, it breaks down water vapour in the air into 'free oxygen radicals', which eat away whatever is on the surface, including bacterial membranes.
"Bacteria gets inactivated by the oxidative stress generated by these radicals," says Mirko Prato of IIT. "This is an advantage because all the microorganisms are affected without exception, so there is no chance that we increase bacterial resistance in the same way as some antibacterial materials."
The choice of titanium oxide was guided by previous research into antimicrobial coatings for hospitals. The team are probing method to 'dope' the compound; tweaking its recipe to increase its sensitivity to the visible portion of the light spectrum.

For further information - https://www.esa.int/Enabling_Support/Space_Engineering_

Framtidens Hälso- och sjukvård

Från region Stockholms pressnytt Nyhet - Forskning och innovation - Maj 2022

Efter ett beslut i regionstyrelsen avsätts 10 miljoner kronor för att stärka det innovationsfrämjande arbetet inom Region Stockholm år 2022. Ett programkontor för Life Science inrättas som kommer att ledas av en programkoordinator, Martin Tegnér. Han är idag ansvarig för arbetet med utvecklad krisberedskap från pandemin.
- Det känns fantastiskt kul att få vara en del av framtidens hälso- och sjukvård där Life Science spelar en viktig roll i forskningen för att rädda liv och bota sjukdomar som idag är obotliga. Detta är en otroligt viktig satsning inte bara för stockholmarna utan för alla svenskar, säger Martin Tegnér.
Det nya kontoret ska initialt fokusera på Life Science för att sedan utökas och hantera samtliga fyra inriktningsområden för smart specialisering:
- Life Science, vård och hälsa
- IKT, informations- och kommunikationsteknik och digitalisering
- Industriell omställning genom hållbar produktion
- Klimat- och miljösatsningar för hållbar stadsutveckling

New report!

Ensured cleanliness in the premises of care: Design process to achieve optimal local function regarding purity

The needs and routines of care activities shall form the basis for the design of care facilities. This paper focuses on the process of designing care facilities so that adequate particular and microbiological purity is reached.

The conditions of care are described and collected in room function programs, compilation of the different levels of purity of the care department, expected person and material flows and the need for sectioning. A model for risk assessment is presented. This can be applied for each step of the project process and ensure that formulated purity requirements are met.

As stated in this document, extensive cooperation between several different parties is required in to achieve the purity requirements of the business. The basis of this cooperation is that the business describes early in the process what kind of activities will be conducted on the premises.

This description then forms the basis for how premises are designed and equipped, and what control systems then exist to know that the correct level of purity is reached and maintained.

The report has been drafted by a working group consisting of Lennart Hultberg, Catinka Ullman and Jan Gustén. Pelle Gustafson, LöF, and Lennart Hultberg, R[3] Nordic, have been project managers for the work.

PURPOSE

The document provides guidance and describes the business-related functional requirements that need to be considered regarding microbiological and particulate purity with the aim of

A. provide a basis for increased collaboration in the different stages of the project process between the functional requirements of operations and the design of care premises and technical systems, to create a more optimal final solution, including both function and economy
B. create conditions for, and maintain, the level of purity of premises during ongoing operations by highlighting the importance of considering requirements for operation and maintenance early in the project process
C. provide a basis for a description of business–related documentation in the design process and to ensure that the design process includes a secure function, and that responsibility and action strategy are clarified in the operational stage.

THE PROJECT PROCESS FOR CARE FACILITIES

The process is described in the following paragraphs:

- Description project process
- Requirement specification and design review
- Risk assessment

This provides a structured approach to defining requirements and checking that they have been met during the design process.

EXTRACT FROM THE DESCRIPTION PROCESS (CHAPTER 4.1 OF THE REPORT)

Care facilities are designed based on both business-specific and building technical requirements. It is of great importance that all parties work together as far as possible to create the most optimal final solution possible regarding the purity requirements required by the intended activity. This collaboration also provides an economic added value to the project. Room-specific requirements shall be quantified, documented and verified during the different parts of the project process. Requirements shall be documented and defined, with the advantage of a tender specification, which shall also include current operating and maintenance conditions. These must therefore be identified and highlighted already at the program stage.

Responsibilities between the actors of the project process and the representatives of the business must be established at an early stage, to ensure clear forms of cooperation and directives for the implementation of the requirements and needs of the business, as well as to ensure function and medical safety. Investigation and determination of the requirements and needs of operations is also a process that runs parallel to the main project, see Figure at page 30.

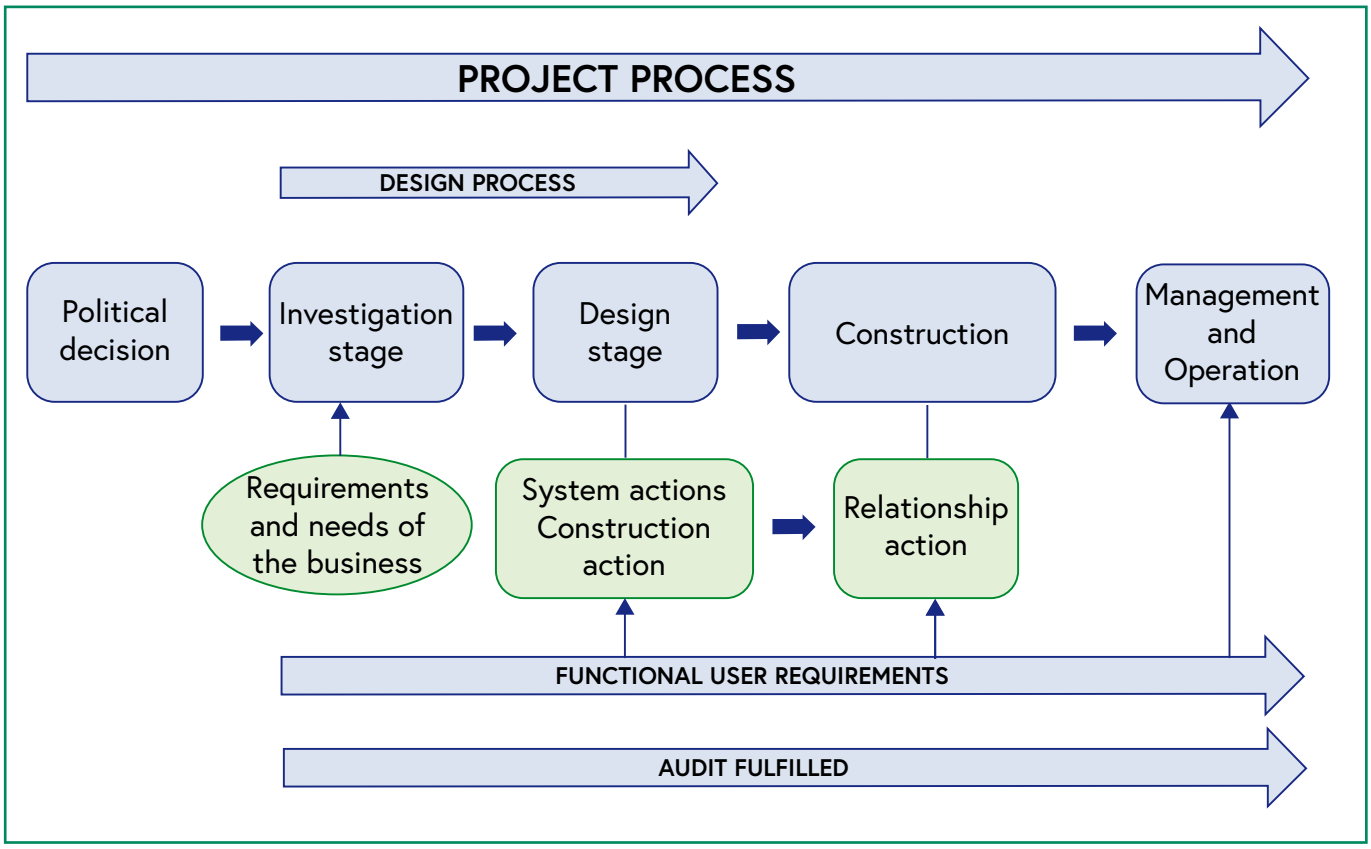


Fig 4.2
The user's requirements and review of the requirements' fulfillment lie as a parallel process along the project process.

It is of great importance to establish the requirements that are critical for each process step, in order to obtain a correct basis for further design and construction. Businesses should have an active role in the entire project process to ensure that correct functional requirements are implemented in the project process and in the right steps. This can be done by subjecting each process step to a risk assessment, so that it can be ensured that correct functional requirements have been formulated and implemented in the project.

SUMMARY

This document intends to serve as a support in the design work and with the aim of implementing requirements for cleanliness in care facilities as early as possible in the process. The document should provide guidance and ensure that questions raised are answered during the design work. The support is primarily aimed at activities to provide information and basis for the requirements that they need to define and take a position on for the final function of the premises to be as optimal as possible. Clarifying the needs of operations also provides the conditions for the design of the technical systems of care buildings.

The requirement specification focuses on requirements for premises with a controlled level of purity. The requirement formulation shows, together with the description of person and material flows, the conditions for maintaining purity during ongoing operations. The need for additional sectioning and documentation for technical supply and monitoring systems is clarified.

To ensure that requirements in the requirements specification have been incorporated into the design documentation, and that premises thus receive appropriate design and design, solutions can be risk assessed to verify formulated requirements. Risk assessment, which is presented in the main document, must ensure that the conditions and formulated requirements for purity of healthcare activities can be achieved. It also provides a basis for assessing selected technology solutions.

Extracts of the report has been translated into English for presentation in Renhets Teknik. The full report in Swedish can be downloaded from the R^3 Nordic homepage.

R³ NORDIC INBJUDER TILL

Sjukhusdagen

26 september 2022 kl 08.00 - 16.00
Akademiska sjukhuset Uppsala, Rosénsalen (Ing 95/96)

Säkertställd renhet i Vårdens lokaler

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

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

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

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

Projektledare för arbetet har varit Lennart Hultberg.”

Prof Jan Gustén, Chalmers Tekniska Högskola

Anmälan på mail till Lennart Hultberg lennart@processhygien.com

Anmälan till alla våra kurser ska vara skriftliga och är bindande. Avbokning ska ske skriftligen och inkomma minst en månad före kursstart för att kursavgiften, minus avdrag med 500 kr, ska återbetalas. Vid avbokning senare, minst 14 arbetsdagar före kursstart, återbetalas halva kursavgiften. Vid avbokning senare än 14 arbetsdagar före kursstart sker ingen återbetalning. Ersättare kan registreras fram till och med första kursdagen. R³ Nordic förbehåller sig rätten att ändra kursinnehåll och föreläsare utan att meddela deltagare eller att ställa in kursen. Föreningen ansvarar inte för merkostnader i samband med kursens inställelse. Vid inställelse återbetalas kursavgiften i sin helhet.

R³ NORDIC, CTCB-I OCH CHALMERS INVITE TO

Cleanroom Testing & Certification

11-13 Oktober 2022

Installationsteknik, Chalmers, Göteborg

The course material is intended for self-study prior to attending the lectures.
The content of the course material, written in English, forms the basis for the lectures.
The course material will be delivered after payment of a registration fee, at latest one month before the start of the course.
Candidates can apply for either of two levels of certification; Professional or Associate. As proof of the certification, a diploma will be issued to each participant who completes the course and passes the examination.

ASSOCIATE LEVEL

For people who are either familiar with some aspects of cleanroom testing, and wish to gain knowledge about the subject (purchasers and evaluators of clean room testing), or have been working less than two years as a cleanroom tester, but wish to use the certification course as a basis of training and working towards professional status. If you apply for the associate course, and have suitable qualifications, you will be required to:

- study the self-study course material that will be sent to you, attend a lecture course, and then pass a written examination on cleanroom testing
- attend a demonstration exercise on practical aspects of cleanroom testing.

PROFESSIONAL LEVEL

For people whose profession is cleanroom testing, and who routinely carries out all aspects of cleanroom testing. At the time of their exam they should have a minimum of two years' experience. If you apply for, and have suitable qualifications, you will be required to:

- study the self-study course material that will be sent to you, attend a lecture course, and then pass a written examination on cleanroom testing
- Complete a particle counting exercise.
- pass a practical exam by showing a high level of competence in (a) filter integrity testing and (b) measuring air velocities and volumes and write adequate reports

  Note that certificates on Professional Level are valid for five years. Recertification is required to maintain certification on Professional Level beyond five years.

COURSE FEES 2022

CTCB Associate Level - 2 days in Gothenburg
Included: Course material, lecture notes, written exam, practical demonstration and lunch both days.
Registration fee: SEK 3 950
Course and exam fee: SEK 12 000

CTCB Professional Level - 3 days in Gothenburg
Included: Course material, lecture notes, written and practical exams and lunch day 1 and 2.
Registration fee: SEK 3 950
Course and exam fee: SEK 15 000

Exam Re-sit and Upgrading from Associate to Professional Level - 1 day in Gothenburg
Candidates who do not pass a practical exam (filter leak testing and/or air velocity) can "re-sit" the exam within one year. Candidates who wish to upgrade their certificate from associate to professional level can complement with the practical exam within one year.
Registration fee: SEK 2 950
Practical exams fee: SEK 3 500 *(per exam)*

Recertification CTCB Professional Level - 3 days in Gothenburg
Included: Course material, lecture notes, practical demonstration, written and practical exams.
Registration fee: SEK 3 950
Course and exam fee: SEK 12 500

Note 1: 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 2: VAT will be added to all prices given above.

Note 3: Any costs required for accommodation are the responsibility of the candidate.

Further information is available at www.safetyventilation.com
Questions and application form: Lars Ekberg,
lars.ekberg@chalmersindustriteknik.se /+46 (0)703 15 11 55

The number of seats is limited. ***Apply no later than August 15, 2022.***

R³ NORDIC LAU NORGE INBJUDER TILL

Grunnkurs i renhetsteknikk

17-18 Oktober 2022
Olavsgaard Hotel

BEGRENSET DELTAGERE

PREL PROGRAM - Dag 1

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

PREL PROGRAM - Dag 2

08.30-10.30	Mennesket i det rene rom, arbeidsteknikk og påkledning (BR)
10.45-11.30	Mikrobiologi i renrom (KA): Nyheder vedr Annex 1
11.30-12.15	Lunsj
12.15-13.00	Mikrobiologiske testmetoder (KA)
13.00-13.20	Kaffepause
13.20-14.45	Klær, vask og rengjøring (BR)
14.45-15.30	Case - gruppeoppgave
16.00	Avslutning, kursevaluering, deltakerbevis

Kursavgift
NOK 8 730 (R³-medlem 8 080)
Inkl kaffe, te, frukt, lunsj, felles middag mandag kveld.
Påmeldingsfrist: 16.09.2022
Meld deg inn i R³ Nordic via hjemmesider:
r3nordic.org/shop/medlemskap/ansok-om-medlemskap/
Påmelding
mail til r3nordic.no@gmail.com eller
kontakt Barbro Reiersøl på mobil 95 13 19 45.
Overnatting på Olavsgaard hotel (Hvamstubben 11, 2013 Skjetten, Norge)
Ordnes ved å kontakte hotellet direkte. Husk å oppgi at du deltar på dette kurset.
Overnattingsprisen pr. natt er kr 1195,- Dette er ikke inkludert i kursprisen.
Tlf. til hotellet: +47 63 84 77 00 / booking@olavsgaard.no

Arrangør: Norske LAU R³ Nordic
Barbro Reiersøl, AET AS,
Hong Thanh Thi Ngyen, IFE, Kjeller
Phuong Huynh, Sykehusapoteket i Drammen og
Geir Valen Pettersen, Norsk medisinsk syklotronsenter AS

R³ NORDIC INBJUDER TILL

Grundkurs i renhetsteknik

Hösten 2022
Prel Uppsala

PREL PROGRAM DAG 1:

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

PREL PROGRAM DAG 2:

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

Kursavgift SEK 7.850,- (R³-medlem 7.200,-)
Inkluderar kursmaterial, diplom, lunch, kaffe fm och em.
Information om kursen lämnas av Lennart Hultberg
Telefon +46 (0)760 399 500/ lennart@processhygien.com

Kursansvarig:
Lennart Hultberg, R³ Nordic

Anmälan
www.r3nordic.org

Anmälan till alla våra kurser ska vara skriftliga och är bindande. Avbokning ska ske skriftligen och inkomma minst en månad före kursstart för att kursavgiften, minus avdrag med 500 kr, ska återbetalas. Vid avbokning senare, minst 14 arbetsdagar före kursstart, återbetalas halva kursavgiften. Vid avbokning senare än 14 arbetsdagar före kursstart sker ingen återbetalning. Ersättare kan registreras fram till och med första kursdagen. R³ Nordic förbehåller sig rätten att ändra kursinnehåll och föreläsare utan att meddela deltagare eller att ställa in kursen. Föreningen ansvarar inte för merkostnader i samband med kursens inställelse. Vid inställelse återbetalas kursavgiften i sin helhet.

MARKNADSGUIDE

FÖRETAGS- & BRANSCHREGISTER ÖVER STÖDJANDE MEDLEMMAR I R³ NORDIC

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

FÖRBRUKNINGSMATERIAL FÖRPACKNING PROCESS

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

INSTRUMENT ÖVERVAKNING VALIDERING KALIBRERING

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

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

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

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

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

MIKROBIOLOGI STERILISTERING

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

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

NINOLAB, AB (SE)
Inkubatorer, värmeskåp, class100 sterilasatorer. Autoklaver - diskmaskiner. Niklas Nordin.
Tel 08-59096200 / info@ninolab.se

KONSULTER PROJEKTERING

CIT ENERGY MANAGEMENT AB (SE)
Teknisk utveckling, validering, funktionskontroll inom luftrenhet, klimat och energi. 0762-345818
mari-liis.maripuu@chalmersindustriteknik.se

CRC CLEAN ROOM CONTROL AB (SE)
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