



Renhets TEKNIK



THE NORDIC JOURNAL OF CONTAMINATION CONTROL AND CLEANROOM TECHNOLOGY

NR 4:2022

Surface Hygiene in Restaurants

- INBJUDAN SYMPOSIUM 2023 DANMARK
- INTERNATIONAL REPORTS
- FÖRETAG & PRODUKTER

RenhetsTeknik utkommer med fyra nummer per år.
Syftet är att tidningen, såväl som föreningen, skall
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r³ nordic

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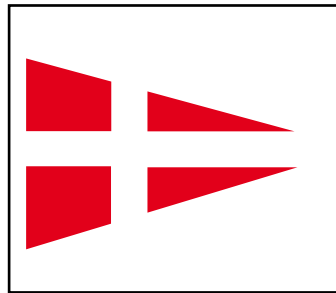
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*For those of you who would like further information in English about the magazine, articles,
advertising or others, please contact the editor Alan Friis; alfr@force.dk*

OMSLAGSBILD / COVER:

FOTO: Industrial kitchen (Ingimage, Stock Photos)



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

Regelbunden tillsyn och service ökar renrummets livslängd, ser till att rätt funktion och kvalitet bibehålls och ger en god driftsekonomi. Våra serviceingenjörer har mångårig erfarenhet av kontrollerade miljöer.

Genom att regelbundet mäta renhetsgrad, utföra kalibrering och funktionskontroll hos olika komponenter som fläktar och filter med mera får vi en ökad driftsäkerhet.

I dag arbetar vi med både avtalskunder som enstaka uppdrag. Självklart har vi kundpassade serviceavtal för nya som befintliga anläggningar.

Efter utfört serviceuppdrag överlämnar vi alltid dokumentation, utbildar användarna och ger tips och råd. Med oss som partner får ni full kontroll över er anläggning. **Välkommen!**

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KALENDER

2023

Mar

- CTCB-I Certifiering
Associate Level 2 dgr
Professional Level 3 dgr
Chalmers, Göteborg

Apr

- 3-5 PDA Annual Meeting,
New Orleans

May

- 23-24 R³ Nordic Annual Symposium
and Exhibition 2023
Marienlyst, Danmark
- 23 Annual Meeting R³ Nordic

Oct

- CTCB-I Certifiering
Associate Level 2 dgr
Professional Level 3 dgr
Chalmers, Göteborg

Nästa nummer
beräknas utkomma den 9 mars

Manusstopp / Annonsbokning:
7 februari

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

Now 2022 soon ends and we have had a almost open year with an activity level approaching the old activity in R³ Nordic We had the possibility to attend the Symposium physical in Naantali and courses and event have in general been In May 2023 we will have the next Symposium, this time in Denmark. At the moment we are working at the details on the program, and you can already find some name of the speakers in this magazine and further information will come as the program evolves Now we just want to wish you a Merry Christmas and a Happy 2023



LENE BLICHER
OLESEN,
ORDFÖRANDE



ALAN FRIIS
REDAKTÖR



Interviews and Surface Sampling Surveys to Improve Surface Hygiene in Restaurants

SANNA TIETÄVÄINEN, JIK KY, ILMAJOKI, FINLAND
GUN WIRTANEN, SEINÄJOKI UNIVERSITY OF APPLIED SCIENCES, SEINÄJOKI, FINLAND

The aims of this study were to update the own-checking guidelines for registered food operators based on the Food Act (297/2021) and the Food Hygiene Decree (318/2021) as well as to guide the food operators in microbial sampling of surface. These instructions for restaurants are based on surface sampling in real working surroundings in 30 restaurants in Ilmajoki and Kurikka (in fall 2021). At the same time as the samplings were performed the operators were instructed in self-monitoring requirements. A total of 268 surface surfaces were taken (Tietäväinen, 2022). The food control is carried out according to the Oiva system, which provides consumers with information on the results of the food control in form of an Oiva report visible both in the restaurant and on the restaurant's homepage (Finnish Food Authority, 2021; 2022).

In restaurants, the microbiological compliance of food is ensured by taking care of food preparation, surface cleanliness, sale times, serving times, storage

conditions and storage temperatures (Rahkio et al., 2013; Koskinen et al., 2021). At most, food services are inspected twice a year and at least every three years. Finnish Food Authority recommended sampling frequencies are 4-12 times a year. (Finnish Food Authority, 2021).

Premises and operations must meet the requirements set in food legislation (European Union, 2005; Food Act, 2021; Food Hygiene Decree, 2021; Finnish Food Authority, 2021 & 2022). In the guidelines published e.g., by European Hygienic Engineering and Design Group the operators can find instructions how to apply with the requirements (EHEDG, 2014). The operator is responsible for the self-monitoring, in which samples are taken from surfaces in direct contact with foodstuffs: equipment and vessels used in food preparations, cutting boards and other work-tops, knives, and serving utensils storage etc. (Rahkio et al., 2013).

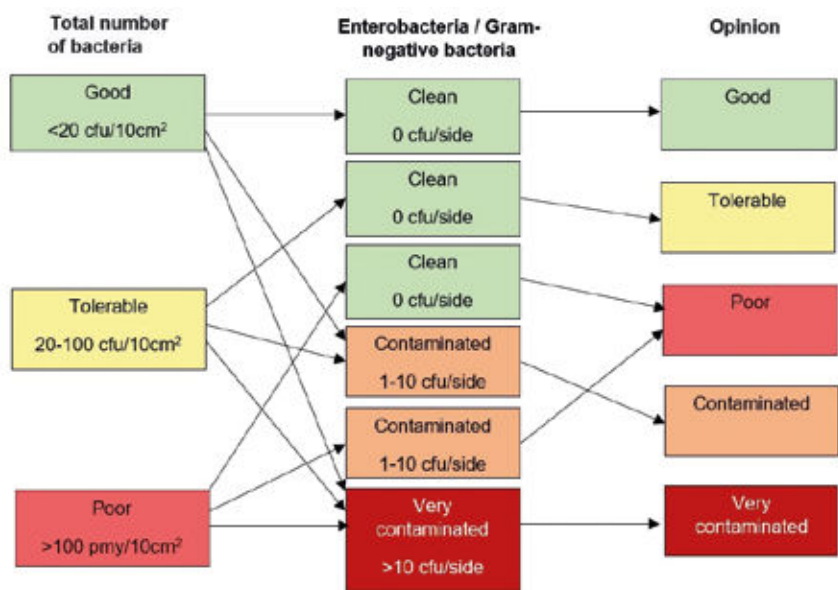


Figure 1. Total aerobic bacterial and enterobacterial counts were used in determining the surface cleanliness in the restaurants.



Figure 2. Overall statement of the microbiological cleanliness of the surfaces in the restaurants is based on the total bacterial and the enterobacterial counts. The presence of enterobacteria on the surfaces lead to classification as either contaminated (1-10 cells) or highly contaminated (> 10 cells).

RESULTS FROM INTERVIEWS AND SURFACE SURVEYS

Based on the interview responses, the restaurant operators showed great importance to surface cleanliness, but according to the study by Tietäväinen, approx. half of restaurants were taking surface cleanliness samples (Tietäväinen, 2022). The level of equipment hygiene and cleanliness of the cleaning closets was good. Storage on the floor is not recommended, because this affects both the material quality and cleaning possibilities. However, the surface cleanliness samples showed that food contact surfaces were cleaner than the indirect food contact surfaces. Food contact surfaces were cleaned several times a day, especially after use. The food contact surfaces in the restaurants were well cleaned, but all restaurants did not expose the surfaces to detergents for a sufficient period. Based on the responses in the interview, there was still room for improvement especially in using disposable gloves and washing hands before putting on disposable gloves. Furthermore, more than half of the restaurants use disposable cleaning cloths. But especially in small restaurants, cleaning cloths were also taken home for washing. At home, it should be noted that these must be washed separately from other laundry. Based on the surface cleanliness samples (Figure 1), the food contact surfaces were cleaner than those surfaces in indirect contact (Figures 2).

Figure 2 shows that enterobacteria or high levels of other aerobic microbes were found on cutting boards (23%), washed hands (33%) and hand-washed cutters (41%). Furthermore, enterobacteria or high levels of aerobic microbes were commonly detected on indirect surfaces e.g., kitchen handles (38%), worktops (47%) and faucets i.e., taps (59%). In the studied cases, only 23% of the faucet environment were clean. The faucet surroundings were often damp, which support the growth of microbes. Only one fifth of the restaurants had automatic faucets. Checking the cleanliness of the sinks with faucets should be a part of the own checking system. The drying of the surfaces should preferably be carried out with dry, disposable cloths or properly laundered cloths. To improve the hygiene level in the restaurants, site-specific guidance can be provided

to restaurant operators based on the questionnaire responses and the hygiene results.

CONCLUSIONS

Based on the surface sample results and questionnaire responses, restaurant-specific guidance and counseling was provided to improve the hygiene level in the participating restaurants. It must be stated that sensory evaluation is not sufficient for monitoring the cleanliness of surfaces. The restaurant operators must consider: equipment and vessel hygiene, cleanliness of cleaning cloths, keeping surfaces dry, the exposure time of cleaning and disinfecting agents, hand hygiene and proper use of disposal gloves etc. All food contact surfaces should be cleaned several times a day. Furthermore, worn cutting boards must be replaced. Where disposable cleaning cloths are used, they should be used only once. In small sites, where there is only one water point, it is important that the water point is thoroughly washed and disinfected between the various operations. According to the recommendation there should be at least three washing points in a restaurant kitchen i.e., separate washing points for hand washing, rinsing of raw materials and rinsing of vessels and other dishes. Preferably, there should also be a separate washing point for facility cleaning operations. Kitchen hygiene can be improved by cleaning drains before other parts of the floor.

The health inspectors will pay attention to the implementation of both hygiene issues e.g., hand and cloth hygiene and the sanitation procedures during inspections. In the own checking, the restaurant operators sample the surfaces at agreed intervals. The restaurant personnel can themselves take the samples or purchase this service. Note that the responsibility cannot be outsourced. This means that the restaurant owner is obliged to check that agreed samples have been taken and reported according to the plan.



ING IMAGE

LITERATURE

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R³ Nordic Annual Symposium and Exhibition 2023

The program committee invites speakers, participants, and exhibitors to an eventful couple of days on advances in clean rooms and clean technologies.

The program will focus on how to:

- Perform risk assessment (resource efficiency, cover the necessary topics, ...)
- Do proper design (requirements, planning, materials, clean rooms ...)
- Chose effective sanitation & verification regimes
- Implement new technologies and innovations

We would very much like to promote networking therefore we have included the banquet in the conference fee for participants and we also include some free tickets for each exhibitor too.

EARLY BIRD

For the very early bird there is a substantial discount on rooms booked along with sign-up to the symposium.

CONFIRMED SPEAKERS TODAY

GMP – Annex 1 - Annex 15 - Regulatory: *Gordon Farquharson, Conor Murray and Anne-Mette Nielsen Wütekind.*

Contamination prevention – Isolators – Contamination Control Strategy – Microbiology: *Yuanzhong Wang, Berit Reinmüller, Kirsten Jorsal and Maria Høiriis Nielsen.*

HVAC – Energy saving in Cleanrooms: *Ulla Thomsen, Gordon Farquharson, Bengt Ljungqvist and Jukka Vasara*

Risk assessment in practice: *Roland Cocker*

Microbial monitoring acc. to Annex 1: *Sabine Bessieres-Recasens*

Isolator Technology & CCS: *James Drinkwater*

Expectations on Annex 1: *Thomas Vestergaard Petersen*

Standards in Pharma: *Marianne Thorø Vidkjær*

PRICES	The very early bird	Early bird	Normal
Final dates	January 13th 2023	March 10th 2023	May 15th 2023
Symposium including accommodation in single room May 23rd to 24th	950 EUR	1060 EUR	-
Symposium including accommodation in double room May 23rd to 24th	1000 EUR	1000 EUR	-
Symposium for 2 persons accommodation in double room May 23rd to 24th	1810 EUR	1810 EUR	-
Extra participants from exhibitor to symposium with accommodation in single room May 23rd-24th	1450 EUR	1610 EUR	-
Comments		A limited number of rooms will be available	Rooms needs to be booked with the hotel
Symposium without accommodation	810 EUR	885 EUR	960 EUR
Extra participants from exhibitors to symposium without accommodation	500 EUR	550 EUR	600 EUR
Non-members will be charged the membership fee of 70 EUR			



----- EXHIBITION -----

Exhibition booths are available in the following sizes and numbers.
The exhibition area is located right outside the main lecture hall.

For booking of exhibition space please contact:

Alan Friis alfr@forcetechnology.com

Registration will be available through the webpage:

www.r3nordic.org

PRICES

Size	No of booths	Footprint m2	Included participants	Price EURO
XS (roll-up)	4	-	0	200
S	7	3 - 4	1	1300
M	5	4,5 - 5,5	1	1700
L	5	6 - 7	2	2500
XL	3	8 - 9	2	3000

----- ORGANISING COMMITTEE -----

NIRAS: Lene Blicher Olsen and Jan Mottlau

FORCE Technology: Alan Friis and Annette Baltzer Larsen

CTCB-I certifiering 2022

TEXT & BILD: LARS EKBERG

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

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

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

Under dag tre genomfördes de praktiska proven. Denna gång var totalt sex examinatorer engagerade i detta moment: Lars Ekberg och Stefan Aronsson från CIT Energy Management, Lars Jansson, MyAir, Daniel Laggarr och Johan Ahnfeldt, båda från Brookhaven, samt Erik Ristorp från Labkontroll Väst.

När de praktiska proven avslutats samlades lärarna och examinatorerna för att gemensamt gå igenom och sammanfatta resultaten av samtliga kontrollmoment under ledning av Lars Ekberg. Vid tillfället i oktober certifierades nio personer på nivån Professional och tre personer på nivån Associate. Dessutom gjorde en person ett omprov vid ett extra tillfälle i november och certifierades då som professional. De certifierade personerna presenteras på sid 12.

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



Bild 1. Erik Ristorp och Stefan Aronsson övervakar ett praktiskt prov.



Bild 3. En kandidat testar ett HEPA-filter med fotometer.

Nya kurstillfällen för certifiering i Göteborg planeras till våren och hösten 2023. Detaljer om detta publiceras efter hand i kommande utgåvningar av RenhetsTeknik, på hemsidan www.r3nordic.com samt på www.safetyventilation.com. Eventuellt planerade kurstillfällen i de andra medverkande länderna kan du läsa om här: <http://www.ctcb-i.net/courses.php>.

Tänk på att antalet deltagare på Professional Level är begränsat, varför du som ska förnya ditt certifikat efter fem år bör anmäla ditt intresse så snart som möjligt till Lars Ekberg på mail - se nedan. För Associate Level är antalet inte lika begränsat.

lars.ekberg@chalmersindustrierteknik.se



Bild 2. Victoria Edenhofer (CIT Energy Management) och Johan Ahnfeldt (Brookhaven).

**ASSOCIATE
LEVEL**



Lassi Laine
Halton



Ivan Stridh
Olaf Johansens efff



Antti Silvennoinen
Bravida

**RECERTIFICATE
PROFESSIONAL
LEVEL**



Veli Koskinen
Halton

**PROFESSIONAL
LEVEL**



Jan Christian Halvorsen
Olaf Johansens Efff



Zurab Gogoladze
Aversi Rational Ltd



Torbjörn Anstenruud
Niras



Ronny Ekman
MyAir



Adam Karlsson
Vita Verita



Robert Haugen
Labkontroll Väst



Jerry Nilsson
Labkontroll Väst



Dick Westlund
Caverion



Bård Steen
Olaf Johansens Efff



Report

The 25th edition of the ISCC International Symposium on Contamination Control was realized with a great success in Antalya by Cleanroom Technologies Society of Turkey, between 11-13th October 2022,

All attendees and Sponsors of ISCC 2022 enjoyed Turkish culture and hospitality in the beautiful city of Antalya and all contamination professionals and experts shared their knowledge and experiences with the delegates who came from the different member countries of ICCCS.

THEME

The theme of ISCC'22 was "Contamination Control Is In Every Aspect of Our Lives" While talking over the importance of contamination control in different industries such as; pharmaceutical, health, defence, aviation, electronics, biosafety, semiconductor and automotive, all attendees had the opportunity to review together great many technologies that support and make our lives easier even when we are not aware. The symposium also hosted ISO TC 209 delegates from 23 member countries, developing ISO 14644 standards, who provided first hand information regarding the future of the standards. The annual ICCCS COD meetings was also held at the venue of ISCC 2022 .

During these 'full' days of ISCC 2022, global brands and important figures in the sector were introduced to the international delegates and a very rich Symposium Program including different panels, training groups, special presentations, technical trips and sessions created a very successful atmosphere and a perfect network for cleanroom professionals.

32 SESSIONS

The sessions were held in two lecture halls within the Symposium Program. The main topics were as follows :

- Cleanroom Design,
- Standards & Regulations
- Recent Developments
- Hospitals & OT
- Cleaning & Sterilization
- HVAC & Control
- Standards & Regulations Applications
- Aerospace & Semicon
- Surface Contamination
- Design & Organic Contamination
- Biocontamination
- Fill & Finish Tech

TEXT AND PHOTOS:
TANER YEDIKARDAŞLAR



Having started this journey with the "Education, Communication, Sharing" motto, the Cleanroom Technologies Society of Turkey meticulously hosted the event to make this experience unique for all guests.

"50 Years, 50 Articles" and "50 Young Professionals" programs were successfully organized during ISCC 2022 Symposium.

On the other hand, as part of ISCC 2022 a technical trip for observing the applications on site, was realised with a group of 50 attendees. The visited facility NovaMed GmbH produces Blood Sets and other medical consumables used in dialysis machines.

International Confederation of Contamination Control Societies (ICCCS) held cleanroom symposium and meetings at the beginning of October in Antalya, Turkey. The event was held at the Titanic Golf hotel, which provided a wonderful setting for the Symposium's lectures, exhibition and other meetings.

ICCCS is an international community for national society on cleanrooms and contamination control. From each country only

one society can be a member and represent their country. At the moment there are 19 members. R³ Nordic represents four countries (Denmark, Norway, Sweden and Finland).

ICCCS members organise an international symposium every two years.

ICCCS stimulates the development and exchange of cleanroom technology and contamination control courses and provides international accreditation to courses of members that fulfil the IEC guidelines.

ICCCS has an liaison with the TC209, the Technical Committee of cleanroom standard International meetings of ICCCS, IEC and TC209 are aligned yearly.

The week was full of events, because in addition to the symposium, the Technical Committee ISO/TC209 meeting, ICCCS Technical Committee Meeting and ICCCS Council of Delegates Meeting were also held in the same week.

JUKKA VASARA, GRANLUND



PDA har publicerat flera Technical Reports under hösten. Se PDAs hemsida om du är intresserad.

PDA Annual Meeting 2023, April 3-5, hålls i New Orleans

Journal of Pharmaceutical & Parenteral sciences, Volume 76, Issue 5 innehåller bl a: Microbial Contamination in Water Systems by *Fritz Röder and Tim Sandle*

Accepted articles November 2022

- Multisite Qualification of an Automated Incubator and Colony Counter for Environmental and Bioburden Applications in Pharmaceutical Microbiology by

Hans Joachim Anders, Daniel Mannle, William Carpenter, Wolfgang Eder, Ivana Heckel, Tobias Gotzen, Corinne Oechslin, Cedric Joosen, Maria Eugenia, Giribets Parra, Jason Rose, Vaishali Shah and David L Jones

- Flexible loading pattern approach in overkill steam sterilization based on the physical properties of steam and thermodynamics of sterilization by *Anan Ben-David*



Every year PHSS nominate the most read article for both Peer Review and Opinion, we believe this is quite an achievement.

PHSS congratulates both authors for their fantastic contributions this year:

George Sykes Memorial Award Winner 2022
T Eaton, K Capper, A Nash, S Drinkwater,

J Bright, AstraZeneca: Recovery of Microbial Contamination with Settle Plates Exposed in a Unidirectional Airflow

John Sharp Memorial Award Winner 2022

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



In the issue EJPPS Volume 27 Issue 3:

Peer Review Papers

- Identification of Bacterial Isolates Recovered from the Surface of Cleanroom Operators Garments following Wear by *Dr Laurie M. Smith, Dr Christina Lowes, Dr Noëlle H. O’Driscoll, Prof Andrew J. Lamb*
- LAL Non-Endotoxin Reactivity - Surprisingly Non-specific by *Kevin Williams, bioMerieux*

Opinion Papers

- Anaerobes and the cleanroom operator association: Is there a case for anaerobic environmental monitoring by *Tim Sandle*

- A3P/AFI Survey on Sampling & Testing Practices for In-Process Pre-Filtration Bioburden for Sterile Products: Presentation of the Results & Critical Discussion *Par Isabelle Hoenen, Lilly France S.A.S*
Key contributors: *Thierry Bonnevey, Di Morris and Radhakrishna Tirumalai*

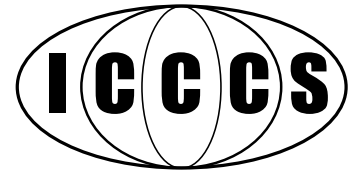
Editorial

- Guest Editorial: Due Diligence
- PHSS News

The 26th edition of the International Symposium on Contamination Control - ISCC will be held between 15 and 18 of October 2024 in Milan, organized by the Italian Society of Contamination Control - ASCCA.

For the preparation of this event, some information is essential for the organizing society. This why we kindly ask you to complete the survey below, one for the society representative and one for the members.

The survey could be accessed by link below directly or by QR code.



- Main features in CACR Issue 48, 2022:
- Filter leak testing with an LSAPC 4, *W. Whyte*
 - How AstraZeneca optimised Vapor Phase
 - Hydrogen Peroxide gassing cycle development with Enzyme Indicators, *Stephen Dawson, Miriam Guest*
 - Unknown knows: Bringing it home – The final stages of a project 14, *Andrew Watson*

- Regulatory reflections EU GMP and Annex 1: The new version 1A paper prepared by Cherwell Laboratories Ltd
- A new challenge for quality experts – the Data Quality Concept, *Maurizio Della Pietra*
- News and Events/Training courses/ and Life-lines on peace

Clean Air and
Containment Review

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CACR

Welcome to CACR48. Apologies for the delayed publication due to temporary indisposition now resolved. This issue contains several articles that should be of interest. Bill Whyte and CTCB-I have very kindly given permission to publish another extract from Bill's recent book, Cleanroom Testing and Monitoring, this time the Annex on filter leak testing with an LSAPC (light scattering airborne particle counter). Hopefully the clear and detailed explanations will encourage readers to buy the book. Enzyme indicators (EIs), on account of their instant response as compared with biological indicators (BIs), will surely have a place in the validation of biodecontamination processes and the paper from Stephen Dawson and Miriam Guest of AstraZeneca describes how EIs were used at AstraZeneca to optimize gassing cycle development. Andrew Watson, in the next of his unknown knows series, examines the ingredients that ensure a successful conclusion to a project. It might sound obvious, but these include access to cleanroom experience and genuine expertise from conception to conclusion. Cherwell Laboratories have very kindly allowed us to reproduce their take on the 2022 EU GMP Annex 1. Speaking for myself, I was delighted to see that the authors of the new Annex 1 have defined and adopted the term 'first air' to describe desirable airflow arrangements for aseptic work. This term is not popular in all circles and does not feature in cleanroom standards, but it has always appealed to me. In unidirectional airflow systems it helps to define the placement of work zones and operators in relation to the filtered air supply, and in non-unidirectional airflow systems it helps to determine the positioning of filtered air supply points and air extract points in relation to the work. On a visit to Malaysia many years ago I heard 'first air' referred to as 'Virgin Air'! Finally, Particle Measuring Systems have very kindly allowed me to publish their White Paper on the Data Quality Concept.

I hope you enjoy this issue and find it useful!

John Neiger



john neiger

Kärchers städrobot KIRA

CETReport this content November 2022

Kärcher lanserade nylige rengöringsroboten KIRA B 50, en helt autonom kombiskurmaskin.

Nu har MTR inlett tester av roboten i Stockholms tunnelbana.

KIRA B 50 är säkerhetscertifierad för allmänna utrymmen enligt CSA_22.2 nr 336-17 och IEC 63327 och identifierar okända hinder och människor på ett tillförlitligt sätt. Roboten är enkel att installera och använda utan behov av expertkunskaper. Maskinen har en stor högupplöst pekskärm för intuitiv kontroll av alla enhetsfunktioner med ett grafiskt användargränssnitt och tydliga instruktioner.



CRC Medical Stipendier

CRC Medical delar årligen ut stipendium på 10 000 kr till studenter eller personal från vårdens verksamhet eller bygginstitution för engagemang i vårdhygieniska frågor, baserat på studier, forskningsarbeten eller liknade.

- Roligt att få vara med och uppmärksamma ert förbättringsarbete för minskad risk för vårdrelaterade skador, sade Anders Rehn, CRC, som delade ut stipendierna.

Årets stipendium delades ut i samband med WHO:s Handhygiendag den 5 maj 2022 till Kerstin Lennmark, Martin Rundström och Yvonne Tunfjord.

Vectura tecknar hyresavtal med Atlas Antibodies

November 2022, News – Forskaren i Hagastaden

Fastighetsbolaget Vectura har tecknat hyresavtal med det svenska biomedicinska företaget Atlas Antibodies. Uthyringen om 1700 kvm blir bolagets nya huvudkontor med framtidens arbets- och labbmiljöer i Forskaren på Hagaplan 1.

Atlas Antibodies är en ledande global utvecklare av antikroppar för biomedicinsk forskning. Under andra kvartalet 2024 blir bolaget en del av Forskaren och kommer bidra till Vecturas vision om en plats för innovativa samarbeten.



Utvecklar topikala beredningar

Life Science Sweden. Foto Zelmic.

David Sagna är vd för Zelmic och en av talarna på årets upplaga av Pharma Outsourcing. När Zelmic grundades 2002 tog företaget fram egna produkter, men på senare år har det fokuserat på att hjälpa kunder med utveckling av topikala och transdermala farmaceutiska formuleringar. Strategin är att bygga upp projekten, hitta metoderna och tillverkningsätten och se till att projekten blir skalbara.

Bolaget har nyligen byggt en GMP-anläggning i Lund för klinisk tillverkning. Anläggningen är en viktig pusselbit för bolagets utveckling men öppnar också upp för nya affärsmöjligheter – eftersom företaget kan släppa tiderna att komma in i klinisk fas.



Microbiological Monitoring in cleanrooms and clean areas

Tolv deltagare från skilda delar av Sverige deltog i "Microbiological Monitoring in cleanrooms and clean areas" med praktisk bakgrund och teori, praktiska övningar och skriftligt prov. Kursen hölls på CIT Management och i Installationstekniks lab på Chalmers. Lärare var Berit Reinmüller och Bengt Ljungqvist.



Boule erhåller CE-märke

Boule Medical AB har nått ytterligare en viktig milstolpe i sitt förebyggande och noggranna arbete med att möta de nya och ökade regulatoriska kraven inom in vitro-diagnostik. Boule har erhållit CE-märke enligt IVDR klass B för två av sina produktlinjer, Medonic M32 och Swelab Alfa Plus.

IVDR är EU:s nya vägledande förordning som specificerar säkerhets-, integritets- och kvalitetskraven för alla medicintekniska produkter som utför en in vitro-diagnostisk funktion. Övergången från IVDD till IVDR inkluderar ett nytt riskbaserat klassificerings-system som rangordnar från klass A (lägst risk) till klass D (högst risk). Klass A produkter är baserat på självcertifiering. Klass B kräver en komplett genomgång av ett så kallat anmält organ (Notified Body).

Boules instrument tillhör klass B, för vilka IVDR träder i kraft den 26 maj 2027. Genom att ta kvalitetsarbetet ett steg längre har två av bolagets produktlinjer, Medonic M32 och Swelab Alfa Plus, certifierats redan under hösten 2022. Utvärderingen och certifieringen inför de kommande högre kraven genomfördes av BSI Group.



Nitrogen dioxide for sterilisation of protein-filled polymer-based syringes

By Hannah Balfour (European Pharmaceutical Review)

Nitrogen dioxide (NO₂) gas found not to ingress and cause protein degradation when sterilising polymer-based prefilled syringes (P-PFSs), according to study. Researchers have shown that nitrogen dioxide (NO₂) gas sterilisation may be the most appropriate choice for the sterilisation of intravitreal injections (IVIs) packaged in polymer-based prefilled syringes (P-PFSs). In their work, the team compared the ingress of gas and the resulting physical and chemical degradation to a model protein in formulation, when sterilising with NO₂, ethylene oxide (EO) and vaporized hydrogen peroxide (VHP).

IVIs of biological drugs are critical for the treatment of visual diseases and are one of the most commonly performed intraocular procedures worldwide. Despite this, IVIs can sometimes cause severe adverse events, including infections, with silicone oils used as lubricants in most syringes thought to play a role. In addition to immune reactions, silicone oil has also been shown to contribute to the formation of protein aggregates and particles during long-term storage.

To overcome this issue in biologic IVIs packaged in prefilled syringes (PFSs), silicone oil-free polymer-based prefilled syringes (P-PFSs) have been developed.



Vaisala celebrates 10-years of Martian measurements

Gathering a decade of accurate measurement data is a major feat in itself, but to do so on a robot travelling around the surface of an inhospitable planet 140 million miles away is almost unbelievable. But that is exactly what has happened; NASA's Mars Science Laboratory (MSL) 'Curiosity' landed on the planet Mars in August 2012. Since then, the Curiosity rover has continuously collected environmental measurement data that has delighted scientists around the world.

Some of the rover's mechanical parts are showing signs of wear due to the very challenging environmental conditions on Mars, but the measurement sensors are still going strong, delivering unique data and dramatically surpassing the initial two-year mission objective. Among the most important measurements are humidity and pressure – parameters that are measured by sensors supplied by the Finnish Meteorological Institute (FMI), using measurement technologies from Vaisala.

Mars is dusty and cold, with a very thin atmosphere. The average temperature is about -63 °C, but daytime surface temperature highs of +35 °C have been recorded. From a research perspective Mars offers an opportunity to better understand the ways in which Earth has evolved and how it may change in the future.

The Curiosity rover is mobile, which means that it is acting as a weather station in multiple locations. In addition, NASA's latest Mars rover, Perseverance, is also now travelling across the surface of Mars, taking measurements also with similar Vaisala technologies. Operating about 2,000 km apart, the two rovers are laying the foundations for an atmospheric observation network, which is needed to better understand and predict the Martian weather.

The Vaisala measurement technologies deployed on Curiosity and Perseverance are essentially the same as those that are in everyday use in almost every industry on Earth, although Vaisala made a slight modification to the pressure sensor in order to accommodate the very low ranges that are experienced on Mars.

More information for the media:

Miia Lahti, Communications Manager, Vaisala, +358 50 555 4420, comms@vaisala.com or Ari-Matti Harri, Head of Space Observation & Research, Finnish Meteorological Institute (FMI), +358 2 9539 4632, ari-matti.harri@fmi.fi

R³ NORDIC, CTCB-I OCH CHALMERS INVITE TO

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Planering pågår för våren och hösten 2023

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 2023

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@chalmersindustrietechnik.se /+46 (0)703 15 11 55

The number of seats is limited. Apply no later than February 15, 2023.



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