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A Comprehensive Comparison of Hydrogen Peroxide-Based Technologies and terminology

- RAPPORT R³ NORDIC SYMPOSIUM & EXHIBITION 2023
- RAPPORT CTCB-I MAY 2023
- NYHETER OM FÖRETAG & PRODUKTER

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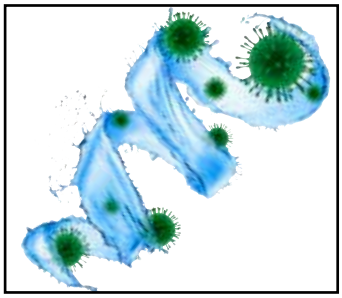

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KALENDER

2023

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Okt

3-4 CTCB-I certifiering, Associate level, Göteborg

3-5 CTCB-I certifiering, Professional level, Göteborg

16-17 Grunnkurs Renhetsteknikk Olavgaard, Norge

Nov

11 PHSS QP Conference 2023 The Glen Yr Afon House Hotel UK

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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 have just concluded an excellent R³ Symposium and exhibition at Marienlyst Strandholet in Elsingore, Denmark. It has been a high priority to get the symposium back in Denmark after 7 years absence. We are content that was well visited event. Next year we going to Norway, and we are looking forwards to that.

The R³ Nordic board is pleased to announce that we have got activity again in a working group on standards and guidelines and that the first topic there is guidance on hospital ventilation systems. We hope that more are to come. If you have ideas, please send us an email and share your thoughts.

We are pleased to have papers back in Renhets Teknik and we do invite you to submit your findings and insights to us for publishing in the future.

In this issue you will find link to a questionnaire concerning the future of Renhets Teknik. Shall we continue as a printed journal or shift to digital format, please participate through the QR code.

Please go to our website, www.r3nordic.org, to read the minutes from our Annual Meeting 2023.

Best wishes for the summer

ALAN FRIIS
REDAKTÖR

LENE BLICHER OLESEN,
ORDFÖRANDE

Food safety of cobots

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There is very little information on food safety of collaborative robots i.e., cobots available in the literature. Organic substances e.g., raw materials from the processes can be transferred with the cobots. These organic residues in structures increase the risk of organic cross-contamination and growth of pathogens. This will act as food safety threats in the food process. Hopefully, this project on food safety of cobots, which is financed by the research fund of Töysä Savings Bank, will act as an impulse for further research on food safety of cobots to be used in high hygiene areas.

The aim was to obtain information about the food safety of cobots. The structure of cobots were analysed. The cleanability of materials used in cobots was also analysed by comparing the plastic material in joint covers with stainless steel. In the first part of the work photographs were used to analyse the structures. The tests used in this work were protein and allergen tests as well as petrifilm AC to obtain the total bacterial count. The material choices, irregularities in surfaces and wiring of parts can cause significant food safety risks. Improved design of both structures and surfaces are needed when developing equipment, e.g., cobots, to be used in high hygiene areas in the food industry.

1. INTRODUCTION

1.1 General information about cobots

The technologies in safe, green, and sustainable food processing should be built on the integration of hyperflexible robotics including machine learning, machine vision, hyperspectral imaging, sensors and artificial intelligence. Today robots are mainly used in packaging, but hygienically designed cobots with new sensor technology creates new opportunities. There is very few research reported about cobots in the food industry (International Federation of Robotics, 2022a). Tölli (2019) has written about the history and the standards of cobots and Koukkari (2016) has examined cobots in heavier applications. Traditional industrial robots are fenced so that persons cannot get close to the robot for safety reasons (International Federation of Robotics, 2020).

The fourth industrial revolution (Industry 4.0) was implemented in the beginning of 2000, when many new technologies based on AI and robotics had developed, so that they could be used in practice. It is to be stated that Industry 4.0 with further development has enabled new opportunities for employees in their work in the food process (Sang-Soon & Sangoh, 2022). One of the first definitions of the fifth revolution (Industry 5.0) was employed in late 2015. Then the focus was on industrial sustainability. Later definitions of Industry 5.0 comprehend customization of the manufacturing processes through collaboration between AI and humans.

The food safety as a part of the fourth industrial revolution must be built on hygienically designed robots and cobots. Furthermore, industry 5.0 will be about the possibility to efficiently make technologies, e.g., robotics, work for the humans in a safe way (Ball, 2022). Romanov et al. (2022) stated that the design of the food safety in robot applications is important. These cobots can lower the contamination risk of food when compared to food treated manually, when the cobots are designed hygienically. Today, a collaborative robot usually has a six-jointed arm that can turn a tool at the end of the arm to any angle within the cobot's operating radius. Strengths of cobots are accuracy and tirelessness, but the cobot is not able to work in problem-solving situations. It is not flexible like a human. Thus, the cobots are not intended to totally replace humans. The cobots can be used in reducing repetitive jobs, which exhaust the personnel (Robots Done Right. (n.d.); Lempiäinen, 2022). Tasks between the cobot and the workers are being swapped. Cobots are usually given heavy, repetitive and non-ergonomic tasks. In this case, the cobot works independently. When necessary, it reacts to contact, for example by dodging or stopping.

Globally, the number of industrial robots is growing rapidly (International Federation of Robotics, 2022a). In Finland, the growth of robots is slower compared to the rest of the western world. In the food industry, the number of robots is small compared to other industries. In 2021, 532 robots were installed in the industry in Finland (Lempiäinen, 2022). It is to be stated that the number of industrial robots in cleanrooms is low. From food industry perspective, traditional industrial robots are used much less than in electronics and automotive industries, where they are used in e.g., handling, welding and assembly tasks (International Federation of Robotics, 2022a).

The machine learning is a method with which the system enables classification of data or images into comprehensive, practical information (Koukkari, 2016). Machine learning and data analytics can be used to improve productivity in the food supply. Traditional machine vision technology with AI can be used in quality control of organic materials and of irregular shapes (Young, 2020; Sang-Soon & Sangoh, 2022). Previous studies related to machine learning in the food industry have been related to tomato ripeness, strawberry maturity, meat freshness as well as quality changes in both pork and fish (Sang-Soon & Sangoh, 2022). Despite improved food safety standards, foodborne disease outbreaks remain at a rather high level both in Europe and in the United States of America (EFSA & ECDC, 2022; CDC, 2023).

Workers in a factory sorting food by hand, could be assisted by cobots equipped with machine vision and other improved sensors. There are both pros and cons in using cobots in the food industry. The pros are e.g., diminishing the impact of workers' hand hygiene. The cons can be e.g., the surface hygiene of cobots if they are not maintained and cleaned properly. Hygienically designed cobots can improve product quality efficiently and may also manage labour gaps, which could persist in the future. The use of robots can help controlling cross-contamination in food processing plants (Newton, 2021). It can be stated that some food processing sectors can benefit from niche robots

automated for specific tasks. As an example, a stainless steel cheese maintenance system with stringent hygiene standards has been installed in the Leupolz Emmental dairy in Germany. In this system, a six-axis Stäubli TX200L HE industrial robot was chosen for moving cheeses. This robot is in contact with the cheese. Therefore, it must comply with the stringent hygiene requirements. The Stäubli robot is designed to operate in challenging food industry conditions. The dairy personnel stated that contamination buildup of condensate and lubricants via the axes' joints could not be avoided. This challenge had to be solved, because the Stäubli robot arm is toughing the unwrapped cheeses. The dairy chose to use a robot arm with encapsulated joint points. Thus, the robot is designed to protect food from both lubricants and condensate (International Federation of Robotics, 2022b).

1.2 General information about equipment requirements

The general framework for food safety is given in the Regulations (EC) 178/2002 (about the general principles and requirements of the food law, the European Food Safety Authority and procedures in matters of food safety), (EC) 852/2004 (on the hygiene of foodstuffs), (EU) 10/2011 (on plastic materials), (EU) 1169/2011 (on substances causing allergies or intolerances) and (EU) 382/2021 (on the food safety culture). In addition, rules on materials and articles intended to come into contact with food are given in the regulation (EC) 1935/2004 and furthermore also in the regulation on good manufacturing practice for these materials (EC) 2023/2006. Design requirements for food equipment are given in the Directive 2006/42/EC. The European food legislation consists of both horizontal and vertical measures. Remember to check that the regulation is in force i.e., that you follow a consolidated version of the regulation. (Lelieveld et al., 2014; Wirtanen 2002)

The standard of hygiene in food processing, EN 1672-2:2020 is also giving proper advice. Furthermore, European Hygienic Engineering & Design Group (EHEDG) has published more than fifty guidelines, which provides practical suggestions how food production facilities, process lines, and equipment should be designed, so that they are cleanable and can be maintained properly. In these guidelines, there are examples how to combat hygienic risks and find acceptable solutions. Detailed information on hygienic design of both closed and open equipment can be found in several of the EHEDG Guidelines. Common hygiene requirements for equipment used in preparing and processing food and feed state that the food safety must be in focus. The equipment functionality and the hygienic design principles can be inconsistent. Generally, compromises can be found. In case no compromises are found the functionality must be sacrificed, because non-hygienic equipment will contaminate the food processed. In the standard EN 1672-2:2020 there are principles, which can commonly be applied to food and feed processing equipment. Hygienic and/or aseptic systems comprise individual components, equipment, measuring and management systems and automation in food and feed production.

The choice of surface materials is important in designing and building process lines and equipment for food and feed production. The process lines and equipment must be easy to clean and maintain. Thus, the surfaces must be smooth and in good condition i.e., without crevices, cracks, comers and dead ends. Note, that joints, screws, bolts, nuts, threads and also gaskets are vulnerable spots for accumulation of biofilm. Nearly all commonly used materials in food processing support biofilm formation. Most of the adherent bacterial cells have been found in the grain boundaries of stainless steel and thus the surface structure of stainless steel is very important in avoiding build-up of biofilms in the equipment. Stainless steel is the most used material in food processing equipment, because it can be treated using e.g., mechanical grinding, lapping, electrolytical polishing or mechanical polishing to improve the surface smoothness. Experiments carried out with pathogens and spoilage microbes on elastomers and rubbers, which are used e.g., in gaskets, have shown that the cleanability of surfaces is important. These rubber and elastomer surfaces are prone to microbial growth that some of the microbes even decomposed rubber as energy sources för growth. The smoother a surface is and the younger a biofilm is the easier it is to eliminate the microbial colonies from the process equipment and the process lines (Woodling & Moraru 2006; Burkert et al., 2013; Park & Kang, 2017; Ciacotich et al., 2022).

2 METHODS

2.1 Two cobots

The focus in the two theses was on studying two different cobots (Haapala, 2023; Korkiamäki & Samppala, 2023). The chosen, studied cobots were available for teaching and training purposes in the SeAMK laboratories: UR5 by Universal Robots and GoFa by Asea Brown Boveri.

2.2 Structure analysis

The structure of the above mentioned cobots were photographed and analysed accurately. The aim of structure analysis was to find places, which can be challenges to food safety according i.e., crevices, comers and dead ends (Directive 2006/42/EC; Annex I).

2.3 Cleanability of plastic joint covers compared to stainless steel surfaces

The cleanability of surface materials is important for food hygiene. The cleanability of plastic joint covers were compared to stainless steel (AISI 304) surfaces. The experiments were performed in triplicate. The tests formed were:

1) petrifilm for aerobic counts,
2) protein test and
3) milk allergen test.

The order of the testing was: first microbial testing and thereafter chemical testing on proteins left on the surfaces. The surfaces to be tested were soiled with a creamy cheese sauce, which had been left at room temperature overnight before soiling. The soil was dried on the test surfaces, whereafter they were cleaned. The soiling of the test surfaces were performed both once and several times before the cleaning. The cleaning procedure:

1) 15 min soaking in warm water +
2) rinsing +
3) soaking for 15 min in foamed detergent +
4) rinsing +
5) drying +
6) testing.

Samples were taken before and after washing.

3 RESULTS

3.1 Structure analysis

There are plenty of risky spots on the cobot arms (Pictures 1a & 1b). The photographing shows that growth of microbes can be a big problem in screw joints, in gaps and crevices, and on uneven surfaces (Pictures 2a & 2b). Furthermore, the wiring must be developed. The biggest risks are wide gaps and screw connections.

Cleaning of cobots are difficult to perform, especially when the Ingress Protection (IP) rating is low. The IP rating of the cobot shows the protection towards cleaning exercises. The IP rating consist of two digits, the first shows the protection from solids and the second the protection from moisture. Both investigated cobots had an IP of 54, which means that they are protected against dust and water splashes from all directions. The controller of the cobot and possible add-ons have lower IP-ratings. Those values varies between IP 20-40 (Smiley, 2020).

In food safety, the most important cobot part is the grippers, which touch the food product. Thus, the food safety is of utmost importance and the equipment should be cleaned properly. When the IP rating is 65, it means that the equipment is dust proof. This type of equipment stands immersion in water for very short periods but not what is requested in a cleaning procedure. In case the IP rating is 66 the equipment is protected against powerful water jets. Thus, the IP rating for an equipment to be cleaned should be either 67, which means that it stands water treatment for 15 – 90 min, or 68, which means that it is watertight under pressure (Smiley, 2020). There are plenty of grippers on the markets.

3.2 Soiling of plastic joint covers and stainless steel surfaces

The plastic joint cover material seemed to repel water during cleaning and thus these surfaces were a bit greasy after the cleaning when compared to the stainless steel surfaces, which were cleaned normally. Testing based on protein tests is rapid and appropriate i.e., it gives information on the cleanliness rapidly. Petrifilm AC is easy to use and microbial results on surfaces are obtained after an incubation of 1-3 days. However, the incubation in the microbial tests means that the results are obtained too late to prevent contaminated food products to reach the market. The drying of accumulated soil on the surface impaired the cleaning results. The longer the dirt remains on the surface the worse was the result (Table 1). Repetitive soiling for several days without cleaning weakened the obtained cleaning results considerably. The microbial results (Table 1) show that the cobots must be cleaned every day it has been in-use and are in touch with unpacked food products. The stainless steel surfaces were cleaned more successfully than the plastic joint covers. This type of or similar

results can be used in choosing/investigating both materials in cobots and cleaning agents on cobots.

4 CONCLUSIONS

Information about equipment surfaces and structures can be found in both the machinery directive 2006/42/EC and the EN-standard 1672-2:2020. The photographing showed the cobot structure, which are problematic in terms of food safety. The shape of some parts e.g., the joints and the covers, and a low waterproof rating of the cobots make cleaning challenging. This has been discussed both in the theory and the practical parts. Screws, connections and end points of the arm are usually the most difficult shapes to clean. Photographing as well as microbial and chemical analysing of the structures have been used in the documentation.

The wiring can also hamper the cleaning. When installing additional parts, the cord has to be pulled along the arm of the cobot. The tool's watertightness must be considered because it is lower in some cobots. By installing safety-enhancing features under the shell already at manufacturing, food safety is promoted.

Based on the obtained results, the cleaning of stainless steel surfaces was more successful than that of the plastic joint covers. In the tests taken after cleaning, the results of the joint covers showed much weaker results than those of the stainless steel surfaces. From the results, it can be concluded that the dried, accumulated dirt on the surface weakened the cleaning results. The stainless steel surfaces were much easier to clean than the plastic joint covers. Furthermore, the material of the joint covers seemed to repel some water during cleaning. Thus, the surface seemed a bit greasy after washing compared to the stainless steel surfaces, which seemed normally clean. In determining the equipment hygiene, the use of rapid tests was suitable in this work. Using protein and allergen tests gave a good assessment of the cleanliness of the materials. Quick, chemical measurements show possible dirt residues left on the surfaces. It is to be noticed that microbial methods take more time due to culturing and colony formation.

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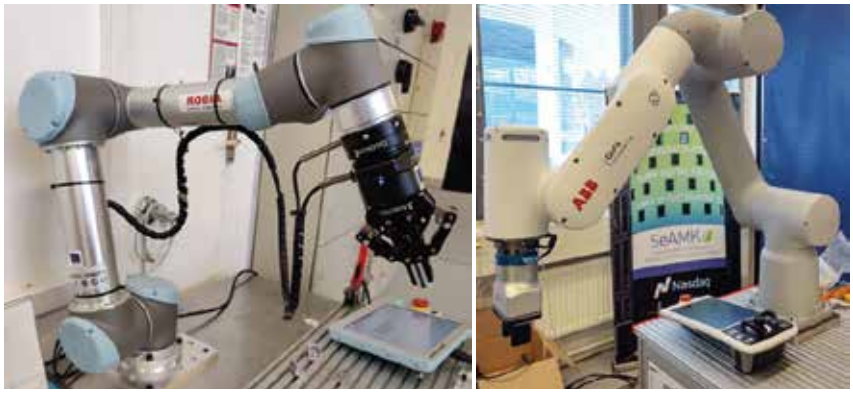
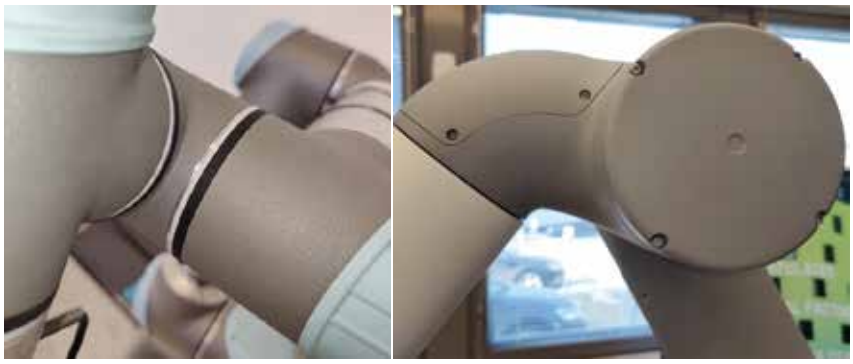


Picture 1.
Six-jointed cobot arm: left) UR5 and right) GoFa
(Photos: Samppala, 2023).



Picture 2.
Hygienically week points on the cobot arms:
left) UR5 and right) GoFa
(Photos: Samppala, 2023).

Test series with replicates	Results before cleaning (cfu/100 cm²)		Results after cleaning (cfu/100 cm²)	
	Plastic joint cover	Stainless steel	Plastic joint cover	Stainless steel
Reference surface	< 1	< 1	Not performed	Not performed
	< 1	< 1	Not performed	Not performed
	< 1	< 1	Not performed	Not performed
Soiled once	TNTC	TNTC	22	1
	TNTC	TNTC	34	3
	TNTC	TNTC	41	2
Soiled several times	TNTC	TNTC	12	8
	TNTC	TNTC	46	27
	TNTC	TNTC	121	58

Table 1.
Culturing results of both plastic joint covers and stainless steel

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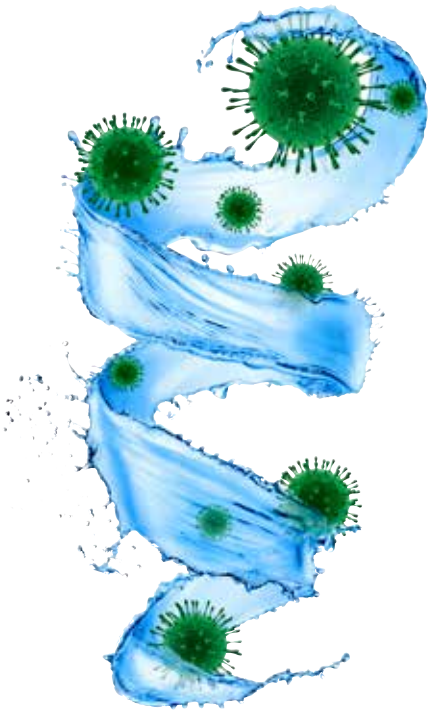
A Comprehensive Comparison of Hydrogen Peroxide-Based Technologies and terminology

Effective decontamination of clinical environments is crucial for minimizing the risk of contamination and infections. Hydrogen peroxide-based technologies have emerged as promising alternatives to traditional chemical disinfectants, offering broad-spectrum antimicrobial activity and good material compatibility. However, often all the different technologies are used interconnected, mixing the terms up. This article provides an in-depth comparison of four hydrogen peroxide-based decontamination technologies that are marketed for various areas: vaporous hydrogen peroxide (vH_2O_2), hydrogen peroxide misting, hydrogen peroxide ionization, and aerosolized hydrogen peroxide while also clearing the differences between the terminology.

BILD Ingimage, Stock Photos



VAPOROUS HYDROGEN PEROXIDE

Vaporous hydrogen peroxide (vH_2O_2) is a widely recognized decontamination technology that generates vapor by heating aqueous solution of hydrogen peroxide. vH_2O_2 is known for its high microbicidal efficacy, killing a wide range of microorganisms, including bacteria, viruses, and spores. Log reduction values of 6 or higher are commonly reported for vH_2O_2, indicating a high level of microbial inactivation (1–6).

Material compatibility is a crucial factor to consider when evaluating decontamination technologies, as they can potentially cause damage to surfaces or equipment. Fortunately, vH_2O_2 has been demonstrated to have excellent material compatibility, with minimal impact on sensitive materials such as metals, plastics, and electronics (7). However, it's worth noting that some studies have reported minor discoloration or corrosion, particularly in the presence of high concentrations of hydrogen peroxide or extended exposure times (8,9).

Despite its remarkable microbicidal efficacy and material compatibility, vH_2O_2 does have some limitations. The technology requires specialized equipment, and the decontamination process can be time-consuming. Additionally, the decontamination efficacy of vH_2O_2 may be affected by environmental factors such as porous materials, temperature, and the presence of organic material (1,2).

One notable advantage of vH_2O_2 technology is its extensive research history, spanning several decades, which has consistently proven its high efficiency in various environments. There are numerous research articles that extensively cover the efficacy of the vH_2O_2 method, and comparison studies have consistently shown vH2O2 systems to be more efficient than other hydrogen peroxide-based methods, highlighting its advantage over others (6–9).

In summary, vH_2O_2 offers excellent microbicidal efficacy and material compatibility but may be limited by its time requirements, and environmental factors like porous surfaces, and organic materials. However, its proven effectiveness through extensive research makes it a compelling choice for decontamination applications, showcasing vH_2O_2 as a reliable and efficient method for microbial inactivation.

HYDROGEN PEROXIDE MISTING

Hydrogen peroxide misting is a decontamination technology that generates a fine mist (droplet size of 1-10 µm) of hydrogen peroxide, which is dispersed throughout the target area. It is important to note that this is a droplet of aqueous hydrogen peroxide. The mist is known to be effective against various microorganisms, including bacteria, viruses, and spores when misted directly (10,11).

Log reduction values for hydrogen peroxide misting typically range from 3 to 5, although lower values have been reported especially against Mycobacteria (10). Microbicidal efficacy can be influenced by factors such as mist concentration, particle size, and exposure time especially when compared to vH_2O_2 methods (12,13).

Material compatibility with hydrogen peroxide misting is generally good, as the fine mist particles are less likely to cause damage to surfaces or equipment (11). However, there are reports of material degradation, particularly with sensitive materials such as electronics, if exposed to high concentrations of hydrogen peroxide or extended exposure times (14).

Hydrogen peroxide misting is relatively easy to implement and does not require specialized equipment or training. However, the efficacy of hydrogen peroxide misting can be limited by environmental factors, such as airflow, room configuration, and the presence of organic material (10,12,15). In addition, it may take longer to achieve desired log reduction values compared to other hydrogen peroxide-based technologies.

In short, hydrogen peroxide misting offers a relatively rapid and cost-effective decontamination method with some microbicidal efficacy and material compatibility. However, its efficacy may be limited by environmental factors and challenges in accessing hard-to-reach areas and when faced with organic load.

HYDROGEN PEROXIDE IONIZATION

While hydrogen peroxide ionization (iHP) is a promising decontamination technology, it currently lacks the extensive research history and proven efficacy vH_2O_2. Although iHP has demonstrated microbicidal activity against bacteria, viruses, and spores, its log reduction values are typically lower than those reported

for vH_2O_2, with ranges from 3 to 6, compared to the log reduction values of vH_2O_2 technology (16,17).

One of the main concerns with iHP technology is the limited amount of research and data available on its efficacy. While some studies have reported positive results, the overall body of research is relatively small compared to that of other decontamination technologies like vH_2O_2 (18). This lack of extensive research data makes it challenging to draw definitive conclusions about iHP's effectiveness and reliability, particularly when considering its adoption in critical healthcare environments.

iHP has excellent material compatibility, posing minimal risk to surfaces and equipment, including sensitive materials like electronics in low concentrations as long as condensation does not occur (18,19).

Despite its advantages, there are some limitations to iHP. The technology requires specialized equipment and can be costly to implement. Moreover, limited research has been conducted on the impact of environmental factors on iHP efficacy, and more studies are needed to fully understand its performance under various conditions (18).

In summary, iHP offers good microbicidal efficacy and material compatibility. However, limited research data, challenges in evaluating efficacy, lack of standardization, and cost considerations are all factors that warrant further investigation.

AEROSOLIZED HYDROGEN PEROXIDE

Aerosolized hydrogen peroxide is a decontamination technology that generates a fine aerosol of hydrogen peroxide, which is dispersed throughout the target area (droplet size of 0.5 to 10 µm). The aerosol has been shown to be effective against various microorganisms, including bacteria, viruses and spores (20). Log reduction values for aerosolized hydrogen peroxide typically range from 3 to 6, although lower values have also been reported (21).

Material compatibility with aerosolized hydrogen peroxide is generally good, with minimal impact on sensitive materials such as metals, plastics, and electronics in low concentrations (18,19). However, studies have reported problems with porous materials and soft furnishings, raising concerns about its compatibility with certain surfaces (22).

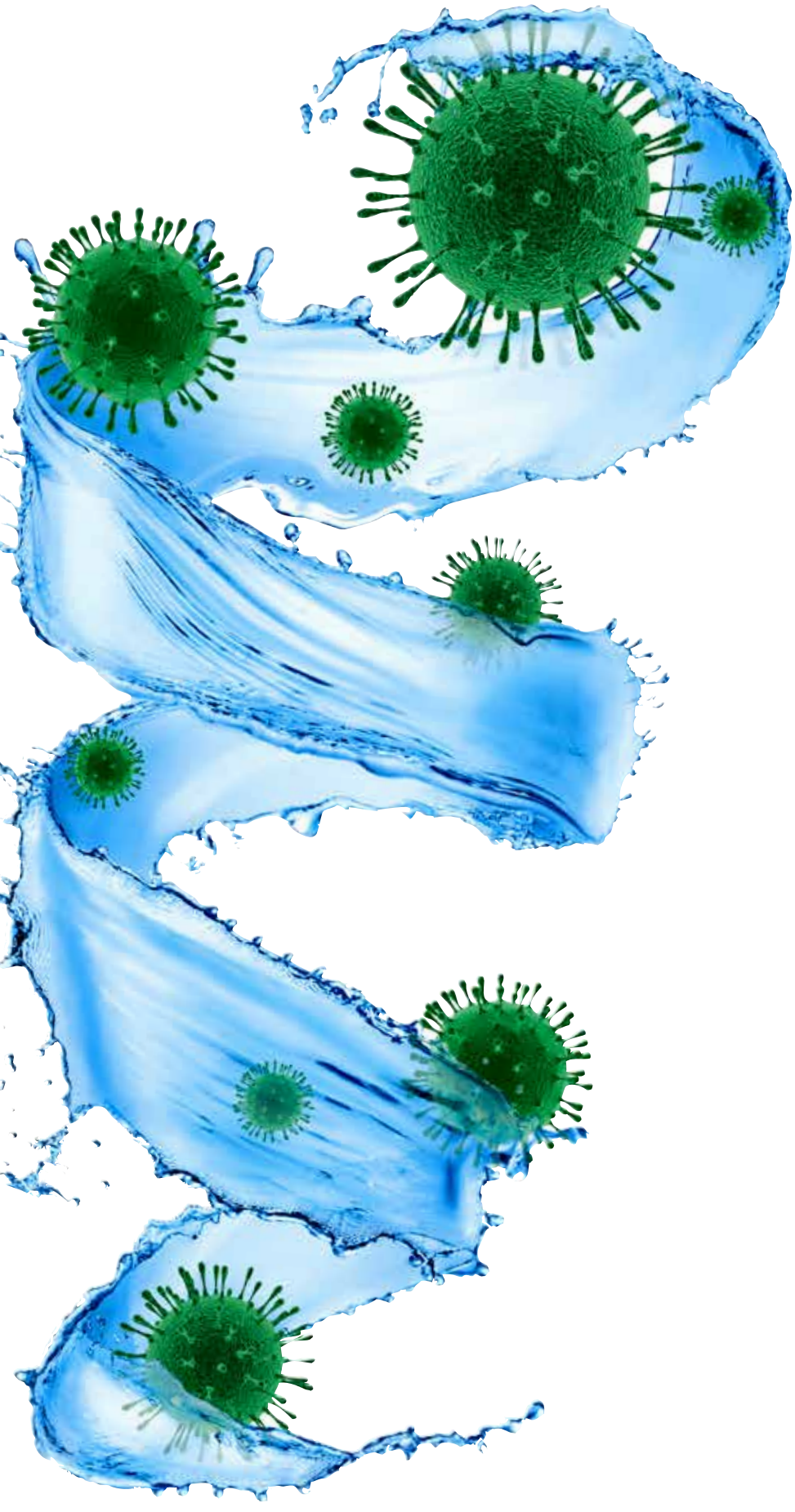
Like any decontamination method, aerosolized hydrogen peroxide has its limitations. The technology requires specialized equipment, which can be costly, and the process can be time-consuming, especially for large spaces or complex geometries. Additionally, the efficacy of aerosolized hydrogen peroxide may be affected by environmental factors such as humidity, temperature, and the presence of organic material (22). It is important to optimize the process to overcome these limitations for aerosolized hydrogen peroxide to be an effective decontamination method.

In summary, aerosolized hydrogen peroxide is a decontamination technology that has shown promise in inactivating microorganisms. However, it also has limitations such as specialized equipment requirements, potential impact on certain materials, and potential efficacy variations based on environmental factors. Further research is needed to fully understand its efficacy and limitations, and to compare it with other decontamination methods such as vH_2O_2 with proven efficacy. Current research on the aHP is still lacking, so extra care and validation are required when utilizing aHP systems.

CONCLUSION

To summarize it all, hydrogen peroxide-based technologies offer a diverse range of options for cleanroom decontamination each presenting its unique advantages and limitations. When considering the specific needs and priorities of these environments, it is crucial to carefully evaluate the microbicidal efficacy, material compatibility, and potential limitations associated with each technology.

CDC (Centers for Disease Control and Prevention) and HICPAC (Healthcare Infection Control Practices Advisory Committee) do not recommend disinfectant fogging in 2003 Guidelines for Environmental Infection Control in Health-Care Facilities and the 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities (23). Also, most of the chemicals used



in these applications are not EPA-registered. This same is true for ECHA registration, where you are required to have PT2 or PT4 registered product for it to be used as a biocide. vH_2O_2 applications comply by this legislation, but for other products the PT rating must be verified before usage.

vH_2O_2 stands out as a reliable choice, providing excellent microbicidal efficacy and material compatibility, though its cost, time requirements, and sensitivity to environmental factors must be considered. Hydrogen peroxide misting offers decent efficacy to vH_2O_2 but with risk for reduced material compatibility and requires precise control of environmental conditions. Hydrogen peroxide ionization delivers rapid decontamination and material compatibility, but its microbicidal efficacy may be lower compared to other technologies and requires further investigation. Finally, aerosolized hydrogen peroxide presents a cost-effective alternative with promising efficacy, but its potential impact on equipment and material compatibility needs additional research.

Cleanrooms should assess their unique requirements and limitations when choosing a decontamination technology, taking into consideration factors such as room configuration, material compatibility, and the presence of organic material. Collaborative research and comparative studies are essential to further optimize the performance and application of these technologies in real-world settings. Based on the current knowledge and research, vH_2O_2 technologies seem to be the most reliable choice for efficient and validated decontamination, though other technologies may be better suited to specific situations or budgets. Ultimately, informed decision-making and continuous improvement of these technologies will help ensure optimal product quality, safety, and regulatory compliance in cleanroom environments.

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Standardiseringsarbetet

Textilhandboken revideras

Textilhandbokens revidering ska göra vården mer cirkulär. Rätt krav på produkter och material genom hela användningskedjan underlättar inte bara vid upphandling, utan stärker även processens hållbarhet samt skapar en bättre arbetsmiljö, patient- och personalsäkerhet.

Standarder inom området utvecklas av kommittén för sjukvårdstextilier, TK332, som utöver Textilhandboken främst arbetar med nationella standarder och tillskärningsmönster för patient- och personalkläder, vårdbäddens produkter och brandegenskaper för madrasser.

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Revideringen av SIS-TR 11 ”Textilhandboken”, som beskriver tvätt och hantering av textilier inom vården, är ett omfattande arbete som påbörjats inom kommittén för sjukvårdstextilier, SIS/TK 332, under våren.

Det är viktigt att få med ny kunskap om tvättprocesser, materialutveckling och återbruk av uttjänta kläder. Är du nyfiken och känner att du vill bidra med din expertis inom tvättprocesser, kemikalier, väv, återbruk och återvinning, vill vi att du tar kontakt med oss!
Kommittén för Sjukvårdstextilier
https://www.sis.se/tk332
Kommittén för Operationstextilier
www.sis.se/tk333

Work in progress

”Nordic Guideline for Hospital Ventilation” under the R^3 umbrella. Kim Hagström, Finland, leads the group with participants from all Nordic countries; Jukka Vasara, Kari Solem Aune, Flemming Malcho, Jan Mottlau, Lars Jansson, Bengt Ljungqvist och Berit Reinmüller.

ISO/DTR 14644-21 Cleanrooms and associated controlled environments – Part 21 Airborne particle sampling techniques - Röstning pågår under sommaren.

ISO/FDIS 13408-1 Aseptic processing of health care products – Part1: General requirements, Ed 3 godkändes i juni av 19 nationer.

TK108 Renhetsteknik bevakar arbetet i ISO/TC209 Cleanroom and associated controlled environments, WG 2 Biocontamination, som bl a innebär en ISO anpassning av EN 17141 2020 Cleanroom and associated environment Biocontamination control.

TK 333 Operationstextilier
Översättning till svenska av EN13795:1 Operationskläder och draperingsmaterial - Krav och testmetoder Del 1 Draperingsmaterial och operationsrockar och :EN 13795:2 2 Operationskläder och draperingsmaterial - Krav och testmetoder Del 2 Specialarbetsdräkter skickas under sommaren ut på remiss. Ett annex om miljöaspekter har lagts till i varje del.

Sjukvårdstextilier – SIS TS 137
Vägledning till SS-EN 13795 gällande operationsrock, draperingsmaterial och specialarbetsdräkt i flergångsutförande går ut på remiss under sommaren.

TK 527 Renhet i operationsrum
arbetar vidare med revidering av TS 39:2015 och hoppas kunna presentera den nya versionen under hösten.

Rapport Temadag Annex 1 Gardemoen Norge

TEXT & BILD BARBRO REIERSØL

I forbindelse med utgivelsen av nye Annex 1, valgte det norske LAU (Landets Arbeids Utvalg) i R3 å holde en temadag om emnet.

Temadagen «Temadag /kurs i Annex 1» ble holdt 13. mars 2023 på Quality Airport Hotel Gardermoen som ligger på Jessheim. Det var 67 deltagere og for de som ønsket overnatting, kunne det bestilles ved påmelding.

Dagen startet med en historisk gjennomgang av R3 Nordic og det norske LAU fra starten og frem til i dag, som ble holdt av Geir Valen Pettersen (NMS). Videre fortsatte programmet med temaet

«Nye Annex 1 – en oversikt», holdt av Kristian L. Forsberg (COWI), hvor de ulike kapitlene ble gjennomgått. Kari Solem Aune (COWI) og Kristian L. Forsberg (COWI) foreleste om tema «Lokaler og Utstyr» og «Miljømonitorering».

Vi hadde besøk av representanter fra Ecolab, Jane Forbes og Juha Harju som foreleste om «Rengjøring og Desinfisering».

Temaet «Contamination Control Strategi (CSS)» ble holdt av Bjarne Hagen (GE Healthcare) og videre foreleste Kari Solem Aune om «Praktisk eksempel på GAP-analyse».

Dagen ble avsluttet med spørsmål og svar fra salen.

Deltagerne kom jevnlig med spørsmål og pausene gav deltagere tid til gode samtaler på tvers av industrier og fagmiljøer.

Evaluering og tilbakemeldingene fra kurset var veldig bra.


















The R³ Nordic Symposium and Exhibition

was held on the 23rd and 24th of May. The event had more than 35 speakers distributed over two parallel sessions as well as a few plenaries. The focus was on topics like regulatory trends, risk assessment, cleaning and disinfection, contamination control and guidelines. The 125 participants really had a lot to choose from also the possibility to visit the exhibition with more than 20 exhibitors and could enjoy the nice weather and social events like a visit to Hamlets Kronborg Castle and the banquet.
The organisers would like to thank everyone who was part of making the event great. The participants, the speakers and the exhibitors.

CTCB-I certifiering 2023

RAPPORT VICTORIA EDENHOFER

Erik Ristorp och Stefan Aronsson övervakar ett praktiskt prov.

Infälld bild: Test av ett HEPA-filter med fotometer

I början av maj 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, Sverige och Kuba.

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 Victoria Edenhofer.

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

Under dag tre genomfördes de praktiska proven. Denna gång var totalt fem examinatorer engagerade i detta moment: Lars Ekberg, Chalmers samt Stefan Aronsson och Peter Filipsson från CIT Renergy, Lars Jansson, MyAir 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 maj certifierades fem personer på nivån Professional och tre personer på nivån Associate. De certifierade personerna presenteras på nästa sida.

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 tillhandahålla mätutrustning till de praktiska proven.

Nästa kurstillfälle för certifiering i Göteborg kommer att hållas den 3–5 oktober 2023, se annons i slutet. Eventuellt planerade kurstillfällen i de andra medverkande länderna kan du läsa om här: https://ctcb-i.net/calendar/.

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 Victoria Edenhofer victoria.edenhofer@chalmersindustriteknik.se. För Associate Level är antalet inte lika begränsat.

PROFESSIONAL LEVEL

CLEANROOM TESTING AT PROFESSIONAL LEVEL:

Glenn Johansson, GK Norge AS

Kenneth Hansen, LMteknik ApS

Knut-Olav Bjørgum, Camfil Norge AS

Otto Reyes Pino, Aica Laboratories, Cuba

Paul-André Tilrem, GK Norge AS

ASSOCIATE LEVEL

CLEANROOM TESTING AT ASSOCIATE LEVEL:

Knut-Olav Bjørgum, Camfil Norge AS

Otto Reyes Pino, Aica Laboratories, Cuba

Paul-André Tilrem, GK Norge AS

International Symposium on Contamination Control and Cleanroom Technology

Every two years, a member society of the ICCCS (International Confederation of Contamination Control Societies) organizes the International Symposium on Contamination Control and Cleanroom Technology.

The 26th edition of the ISCC Contamination Control Symposium will be held in Milan, by the Italian Society of Contamination Control-ASCCA.

The ISCC2024 will bring together leading technology providers, end users of the different areas of use of contamination control, academic scientists, and international regulators to network, share insights and provide an outlook on the evolving landscape and future of cleanroom technology and side applications.

The 26th symposium theme is "connecting the dots... of contamination control" highlighting the link of different technologies and applications interconnecting various aspects of Contamination Control. The aim is to provide quality, robustness and reliability of the different processes in any area of utilization such as biotech, pharmaceutical, healthcare, aerospace, electronics, semiconductor, automotive and last but not least the preservation of the artistic heritage.

Integrating such different knowledge and skills is the key of innovation. Hence, the Symposium will provide an interdisciplinary program for all stakeholders of the contamination control chain creating an interactive scenario to exchange ideas, strengthen existing research networks and build new ones. The symposium agenda will showcase recent innovations and trends, and directly discuss practical challenges and solutions, from a technical, logistical, and regulatory standpoint.

We Welcome All Contamination Professionals and Experts To Share Their Knowledge and Meet Colleagues Between 14 And 17 Of October 2024 In Milan!

More on PDA's History - PDA History Book

The History of PDA: 65 Years of Connecting People, Science and Regulation.
This 232-page book details the explosive growth in PDA activities in the 15 years since the Golden Anniversary. Chapters cover the people who make PDA what it is, the scientific activities of the organization, the membership's influence on regulation, PDA's manufacturing training facility, international growth, and conferences. Nearly 200 photos and graphics are included. Two 50th Anniversary booklets produced in 1996 are included as appendices.
I PDAs bookshop finns 87 Technical Reports, flera rapporter som Surveys, and Points to consider, allt tillgängligt via PDAs hemsida.
I Journal of Pharmaceutical &Parenteral Sciences, January-February 2023; Volume 77, Issue 1 presenterar sig PDAs nya ordförande Glenn E. Wright. Tidningen innehåller som vanligt flera intressanta artiklar.

EJPPS Volume 28 Issue 1:

Peer Review Papers

- Recovery of Naturally Occurring Human Borne Microbial Contamination with Settle Plates Exposed to a Unidirectional Airflow Workstation for 4 Hours by T Eaton, K Capper, A Jones, C Barnett and J Bright
- Formation and Evaluation of Controlled Release Bromfenac Sodium Ocular Insert by Swathy Govindaswamy*, Rampriya R, Saffrin Fatima S, Siranjeevi A, Ramachandran V, Sudharsan M.
- Combined novel approach to enhance the solubility and Intestinal absorption: A recent review by Dr. Bhavna A. Patel, Mr. Ambuj Dubey*, Dr. Shraddha J. Parmarz

Opinion Papers

- Workforce Training for Pharmaceutical Manufacturing Operators By Tyler DeWitt PhD, Quality Executive Partners, Inc

Editorial

- Guest Editorial: The Fallacy of Sterile Gowns by Russell E. Madsen
- PHSS News by Jenni Tranter, PHSS Chair

Regulatory Update by Malcolm Holmes

- January 2023
- February 2023
- March 2023

CACR49

CACR49 is now out with articles on airborne particle counting with an LSAPC (from Bill Whyte's book Cleanroom Testing and Monitoring), Particle deposition, environmental monitoring in Advanced Therapeutic Medicinal Products (ATMP) facilities, control of viruses in cleanrooms, the turbulent history of VPHP bio-decontamination, the upcoming ISO TR 14644-21 'Airborne particle sampling techniques' and a book review of Bill Whyte's latest book.

CACR is a member benefit for R³ Nordic members."

Caverion förvärvar verksamheten i CRC i Sverige

Caverion övertagit verksamheten i det svenska företaget CRC Clean Room Control AB, en avancerad aktör inom renrum med service och tillsyn inom läkemedelsindustrin.
CRC grundades 1997 och har som huvudsaklig uppgift att bedriva specialiserade mättjänster för renrum och verkar i dag med fem specialister. I slutet av 2022 omsatte bolaget cirka 1 miljon EUR.

Förvärvet breddar Caverions kunskaper inom mätning, validering och eftermarknad för avancerade renrum där Caverion redan har djup kompetens.
Båda företagens kunder gagnas av utvecklingen. Ytterligare kompetens inom renrumslösningar adderas till Caverions verksamhet Cleanroom, samtidigt som antalet specialister utökar vår förmåga, framför allt i Mellansverige, att stötta gamla och nya kunder.

”För oss på CRC blir detta ett naturligt steg framåt och en spännande utveckling. Våra kunskaper kommer att berika Caverions etablerade utbud. Tillsammans blir vi mycket starkare. Våra kunder får fortsatt professionella leveranser och våra medarbetare kommer till en stabil, utvecklande verksamhet”, säger Nils-Johan Björklund, CEO CRC Clean Room Control AB.

Caverion har under lång tid haft ett brett erbjudande inom både byggande av renrum, mätverksamhet samt eftermarknad där det för många kunder är avgörande med en kompetent partner.

”Förvärvet stärker vår satsning inom smarta, hållbara, digitala tjänster där spetskompetens är avgörande. Vi ser stora möjligheter att skala upp den erfarenhet CRC byggt upp under många års tid. Synergierna med vår befintliga mätverksamhet skapar redundans inom ett alltmer krävande område där rätt tillsyn är avgörande. Förvärvet stärker därmed ytterligare vår satsning inom läkemedelsindustrin”, säger Uno Lundberg, vd Caverion Sverige AB.

Parterna är överens om att inte uppge köpeskillingen.

Getinge förvärvar High Purity New England, Inc.

Göteborg den 31 maj 2023

Getinge ingår ett avtal om att förvärva 100 % av aktierna i High Purity New England, Inc., ett ledande amerikanskt företag inom det snabbväxande området för engångsprodukter inom biofarmaceutisk utveckling och produktion.

“Förvärvet är ytterligare en del av Getinges Life Science strategi för att expandera vår närvaro inom biofarmasegmentet”, säger Eric Honroth, President Life Science Getinge. “High Purity New England (HPNE) har under de senaste åren framgångsrikt försett industrin med unika engångsprodukter. Vi är glada över att gå samman med HPNE för att förse våra kunder med omfattande och innovativa lösningar för bioprocessapplikationer.”

HPNE erbjuder egenutvecklade och distribuerade produkter som täcker allt från läkemedelsframtagning och bearbetning, till förpackning och slutbehandling. HPNE:s produkter hjälper ledande biofarmaceutiska och biotekniska aktörer i produktionen av monoklonala antikroppar, vacciner, cell- och genterapier samt andra betydande terapier av nästa generation. Företaget, som grundades 2002, är privatägt och har cirka 150 anställda, med huvudkontor i Smithfield, USA.

”Vi är mycket glada över att bli en del av Getingefamiljen. I över 20 år har High Purity New England levererat förstklassiga produkter och lösningar till den biofarmaceutiska industrin. När vi nu går vidare in i de kommande 20 åren, är jag glad att veta att HPNE kommer att fortsätta att göra det möjligt för våra kunder att effektivisera och förnya sina bioprocesser ihop med Getinge. Tillsammans kommer vi att åstadkomma stora saker,” säger Mark A. Sitcoske, grundare och VD för High Purity New England

Kontakta: Anna Appelqvist,+46 (0)10 335 5906
anna.appelqvist@getinge.com

Kundpartner blir en del av Northclean

KUNDPARTNER.SE/NYHETER

Genom partnerskapet etablerar sig Northclean i sydvästra delen av Sverige och stärker sitt erbjudande mot privata företagskunder. Förvärvet går helt i linje med Northcleans strategi om att förvärva ledande kvalitetsbolag inom lokalvård och närliggande tjänster i Sverige och Norden.

Kundpartner behåller sitt väletablerade varumärke och sin starka lokala förankring efter förvärvet. Peter Rehnström och Roy Lindqvist, VD respektive vice VD i Kundpartner, fortsätter även som stora ägare i Kundpartner, och kommer fortsätta vara med och driva bolaget framåt tillsammans med Northclean.

Peter Rehnström, VD och medgrundare på Kundpartner, säger: ”När vi funderade på att ta in en partner var det viktigt för oss att det fina vi har i Kundpartner – starkt varumärke, nära kundrelationer och fantastiska medarbetare – ska behållas precis som tidigare, medan vi skulle få bättre möjligheter för fler affärer. Partnerskapet med Northclean är precis vad vi letade efter och vi är oerhört glada att vi blir en del Northclean och får möjligheten att fortsätta utveckla Kundpartner som en del av gruppen.”

Vinnovas uppdrag att etablera nytt Innovationskluster

Det nya nationella innovationsklustret hamnar i Mölndal. Goco Health Innovation City blir platsen för ett nationell innovationskluster för avancerade terapier. Näringslivet och staten delar på kostnaderna för projektet, som är tänkt att leda till nya behandlingar mot folksjukdomar som cancer och diabetes.

Det var i mars som Vinnova fick regeringens uppdrag att etablera det nya klustret.

New laboratory for the advanced medicines of the future will strengthen Sweden's position in global research

One of Sweden's largest and most important ventures in medicine and life science is soon to commence - the building of a brand new center for accelerating Advanced Therapy Medicinal Products (ATMP) to treat diseases that until now could not be cured.
GoCo Health Innovation City will establish a laboratory for international research at the forefront of the pharmaceutical industry.

"GoCo Lab gives us the conditions to attract the world's best researchers and talents. It strengthens Sweden as a research nation and enables us to take a leading role in development in the life science area," says Marcus Wallenberg, chairman of Patricia Industries.

There is a global race around Advanced Therapy Medicinal Products (ATMP), medicines and methods based on the body's own cells, tissues or genes. These advanced medicines provide groundbreaking possibilities for the treatment of diseases and injuries, for example Alzheimer's, leukemia and other genetically inherited diseases. Relevant advanced laboratories have long been in short supply in Sweden. The establishment of GoCo Lab provides a large and necessary increase in capacity and infrastructure to create the medicines of the future.

"State-of-the-art lab infrastructure is an extremely important asset for GoCo Health Innovation City as a life science cluster, where the lab will be crucial for health innovations", says Jacob Torell, CEO of Next Step Group and one of the initiators of GoCo Health Innovation City.

Close interaction between business and academia has been one of the keys to success since the start of GoCo Health Innovation City.

The importance of correct lubrication

May 2023

Contamination events in pharmaceutical manufacturing can be extremely costly. One such area that introduces potential contamination risk if not managed effectively, is the use of bearing lubrication in equipment.
- There's more pressure than ever on pharmaceutical companies to meet production demand. Chris Johnson is the Managing Director at bearing lubrication specialist SMB Bearings. He explains the importance of careful lubricant selection to manage contamination risks and boost drug output.
- Drug shortages pose a significant threat to public health. As the global population ages and access to drugs increases, pharmaceutical companies face growing pressure to meet the production demands needed to provide critical care to patients. While it may seem like the obvious solution is to simply ramp up production, the manufacturing realities are more complex.

Despite evolving manufacturing techniques, safety and the control of contaminants remains of the utmost importance. One such area that introduces potential contamination risk if not managed effectively, is the use of bearing lubrication in equipment.

Effective bearing lubricant selection in pharmaceutical settings starts by considering the application of the machine. Equipment used in the production of pharmaceuticals, such as tablet packaging machines or peeler centrifuges, generally use very little lubrication or no lubrication at all. This is because contact between active pharmaceutical ingredients and products such as lubricants cannot take place.

Food grade lubricants are used for the lubrication of machinery in the pharmaceutical industry and are purpose-designed to help minimise risks. Lubricants are classified by NSF into several food-grade categories H1 and H2. H1 lubricants are food-grade lubricants used in food-processing environments where there is the possibility of incidental food contact. However, for equipment that is not situated in the production zone and does not have any direct contact with production machinery, the product or packaging — H2 lubricants will suffice.

Novo Nordisk invest in an API Production facility

Bagsværd, Denmark, 12 June 2023

Novo Nordisk will invest 15.9 billion DKK to expand an existing Active Pharmaceutical Ingredient (API) production facility in Denmark for the future portfolio within serious chronic diseases.
The investment in Hillerød, Denmark will create additional production capacity and increase Novo Nordisk's ability to meet future market demands and be a key enabler for Novo Nordisk to develop its future clinical late-phase product portfolio.
"This investment will ensure the continuous development of our late-phase pipeline into deliveries of important medicines for treatments to patients worldwide," said Henrik Wulff, executive vice president of Product Supply, Quality & IT.

The new facility – approx 65,000m^2 – will be designed as a multi-product facility with maximum flexibility to accommodate new processes and displaying state-of-the-art technology and working environment.

Construction is underway and the facility is expected to start producing API by early 2029. This project is expected to create 340 new jobs when construction is completed, and the facility is fully equipped.

Contacts for further information
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abmo@novonordisk.com

Tidigare okänd antibiotika-resistens utbredd bland bakterier på Göteborgs universitet

gu.se juni 2023

Gener som gör bakterier resistenta mot antibiotika är mycket mer utbredda i vår omgivning än man tidigare känt till. En ny studie från Chalmers och Göteborgs universitet visar att resistensgener finns hos bakterier i nästan alla miljöer, och riskerar att spridas och förvärra problemet med bakterieinfektioner som inte kan behandlas med antibiotika.

De gener som gör bakterier resistenta har studerats under lång tid, men studierna har traditionellt fokuserat på att identifiera och kartlägga de resistensgener som redan är vanligt förekommande i sjukdomsalstrande bakterier. I den nya studien från Chalmers och Göteborgs universitet har forskarna i stället analyserat stora mängder DNA-sekvenser från bakterier för att kartlägga nya former av resistensgener, och för att få en förståelse för hur vanligt förekommande dessa är. De har spårat generna i tusentals olika bakterieprover från olika miljöer, som i och på människor, i jorden och från reningsverk. Totalt analyserade studien 630 miljarder DNA-sekvenser.

? Datan kräver mycket bearbetning innan man kan hämta information ur den. Vi har använt metodiken metagenomik, som gör det möjligt att analysera enorma mängder data, säger Juan Inda Díaz, doktorand på Institutionen för matematiska vetenskaper och artikelns försteförfattare.

Studien visade att de nya resistensgenerna mot antibiotika finns hos bakterier i nästan alla miljöer. Detta innefattar även våra mikrobiom – generna hos de bakterier som finns i och på människor – och, mer alarmerande, även sjukdomsalstrande bakterier, vilket kan leda till ännu fler svårbehandlade infektioner. Forskarna såg att resistensgener hos bakterier som lever på och i människor och miljön var tio gånger fler än de som hittills varit kända. Och av de resistensgener som fanns hos bakterier i människans mikrobiom var 75 procent inte alls kända sedan tidigare.

Forskarna betonar behovet av ytterligare kunskap om problemet med antibiotikaresistens.

– Före studien fanns ingen kunskap alls om dessa nya resistensgeners förekomst. Antibiotikaresistens är ett komplicerat problem, och vår studie visar att vi behöver fördjupa förståelsen för hur bakterier utvecklar resistens och vilka resistensgener som kan utgöra ett hot i framtiden, säger Erik Kristiansson.

– Vi har identifierat nya resistensgener i många miljöer där de hittills har varit oupptäckta. Dessa gener kan utgöra ett tidigare förbisett hot mot mänsklig hälsa, säger Erik Kristiansson, professor vid Institutionen för matematiska vetenskaper.

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

By Hannah Balfour
(European Pharmaceutical Review)

Nitrogen dioxide (NO_2) 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 (NO_2) 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 ingression of gas and the resulting physical and chemical degradation to a model protein in formulation, when sterilising with NO_2, 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.

MICLEV

Miclev launches a new brand identity

Introducing Miclev's new corporate identity, centered around the concept of cells. These building blocks perfectly symbolize our unwavering commitment to growing together with our customers and partners. We are happy to share this exciting new chapter with you.

Operationsavdelningen i Piteå sjukhus Stipendiater och Pristagare av Halton Health Academy Prize 2022

Motivering till priset:
För ett aktivt arbete med att ständigt leta förbättringar för att kunna ge varje patient bästa förutsättning för att förhindra och minska risken för postoperativa (protes) infektioner.

”För att minska risken för att patienterna ska få protesinfektioner har vi granskat hela vårdkedjan. Ett fokusområde i operationsavdelningens enhetsplan är patientsäkerhetsarbetet med att minska infektioner och ha en 100% följsamhet till hygienrutiner för all personal.

Men att arbeta med hygien och följsamhet till rutiner är ett dynamiskt arbete som aldrig kan stanna av utan hela tiden måste hållas levande. Det kräver fortlöpande utbildning och diskussioner med focus på förbättringsmöjligheter.

-Vi på Halton health gratulerar Operationsavdelningen i Piteå och ser fram emot nya ansökningar till vårt Stipendium 2023.

European Riverside Establishes European Contamination Control Group for Cleanrooms

News Release March, 2023 - www.riversidecompany.com

The Riverside Company, a global private investor focused on the smaller end of the middle market, has signed a definitive agreement to acquire Dastex Reinraumzubehör GmbH & Co (Dastex), a leading specialized independently owned cleanroom garment & consumables distributor in Europe. In parallel, Riverside signed a definitive agreement to acquire Vita Verita, a leading player in the Swedish market, as a first add-on to the platform. Closing of the deals is subject to customary approvals by the competent regulatory authorities.

Founded in 1979 in Germany, Dastex has grown to become a market leading provider of both third-party brand and proprietary garments and consumables for cleanrooms in Germany, Austria and Switzerland with a strong foothold in the Benelux and a growing pan-European presence. The company has grown rapidly in recent years, driven by its unique technical know-how and R&D capabilities, comprehensive product assortment and excellent customer service, meeting strong demand from the pharmaceutical and semiconductor industries.

Vita Verita was founded in Sweden in 1983. The company offers both own-brand and third-party products including disposable garments, gloves and wipes, as well as qualified verification and validation services.

Damien Gaudin, Partner at Riverside Europe who led the deals, commented: *“By acquiring Dastex and Vita Verita, we combine two cleanroom consumables specialists in Europe, providing mission-critical products and services and forming the nucleus to our pan-European buy-and-build strategy. This creates a unique platform perfectly positioned to continue growing organically and via acquisitions. We are excited to team-up with the strong management teams at Dastex and Vita Verita with the aim to build the European leader in contamination control for cleanrooms, offering best-in-class products as well as value-add technical and regulatory services supported by an ambitious ESG strategy.”*

Dastex and Vita Verita serve the resilient and growing cleanroom industry, helping customers in pharmaceutical, life sciences and other high-tech industries to meet ever stricter quality and regulatory standards. The acquisition of Dastex and Vita Verita will create a leader in contamination control to the benefit of its customers, facilitating further growth of the sector in Europe.”

Carsten Moschner, CEO of Dastex, commented: “The management team and I are excited to join forces with Vita Verita and Riverside to open the next chapter in the company’s history. I truly believe Riverside is the ideal partner to support our ambitious growth plans and that the addition of Vita Verita’s commercial platform and value-add service offering in Sweden is a critical step in our journey to become one of Europe’s preeminent providers of contamination control products and services. We look forward to further expanding our business across the continent and continuing to serve our customer base with an even broader full-service offering. I would like to thank all employees, colleagues, suppliers and customers for their support and trust.”

Anders Kumbrant, CEO, and Magnus Kumbrant, COO of Vita Verita, added:
“We are delighted to partner with Dastex and Riverside to further realize our ambitions and vision for the company. We are particularly thrilled by the prospect of teaming up with Dastex, one of Europe’s leading players well known for their outstanding expertise and professionalism. We would like to thank Anna-Lena Weiss and the whole team at Vita Verita, our customers, suppliers, and the team at Riverside for their trust and support.”

R³ NORDIC, CTCB-I OCH CHALMERS INVITE TO

Cleanroom Testing & Certification

3-5 oktober 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 4 500
Course and exam fee: SEK 13 800

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 4 500
Course and exam fee: SEK 17 200

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 3 400
Practical exams fee: SEK 4 000 *(per exam)*

Recertification CTCB Professional Level - 3 days in Gothenburg
Included: Course material, lecture notes, practical demonstration, written and practical exams.
Registration fee: SEK 4 500
Course and exam fee: SEK 14 300

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: Victoria Edenhofer
victoria.edenhofer@chalmersindustriteknik.se /+46 (0)70 440 64 68
Course examinator: Lars Ekberg
lars.ekberg@chalmersindustriteknik.se /+46 (0)70 315 11 55

Note: The number of seats is limited.

R³ NORDIC LAU NORGE INBJUDER TILL

Grunnkurs i renhetsteknikk

16-17 Oktober 2023

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: 17.09.2022
Meld deg inn i R³ Nordic via hjemmesider: www.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

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

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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)
Kvalificering & kontroll av renrum, LAF, säk.bänkar och skyddsvent. Mikrobiologiska tester. Rökstudier.
018-246460 / info@cr-control.se

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

RENRUM OP-RUM LAF INREDNING BÄNKAR TAK

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

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

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

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

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

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

RENGÖRING STÄDNING

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

PIMA AB, SERVICEFÖRETAGE (SE)
Bemanning - Entreprenad - Konsultation
www.pima.se
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BERENDSEN TEXTIL SERVICE AB (ELIS) (SE)
Renrumstvätteri. Renrumskläder.
Tel 020-740116 / goran.nilsson@elis.com

NINOLAB AB (SE)
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