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New Food Premises for training and research purposes

- MUNSKYDD I NORDEN
- INTERNATIONELL RAPPORT
- KURSER EHEDG & CTCB-I

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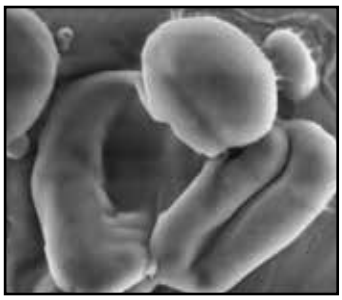


For those of you who would like further information in English about the magazine, articles, advertising or others, please contact the editor Alan Friis; alfr@force.dk

OMSLAGSBILD / COVER:

FOTO: "Potato starch at 60°C" by Merja Kyntäjä, Finland

ORDFÖRANDE HAR ORDET

Kære R³-medlem

Så nærmer tiden for år 2020 sig sin afslutning. Det har jo været et år som nok bød på nogle helt andre ting end det der var forventningerne for de fleste da vi stod for snart et år siden på vej ud af 2019.

Det viste sig at skulle blive et år med fokus, læring og udvikling indenfor netop vores felt. Og selvom anledningen til udviklingen på netop vores område bestemt er alt andet en rar, så må vi sige at vi kunne bidrage med noget godt, nemlig vores viden.

Det resulterede også med at blive et år med fysisk afstand, brug af værnemidler, webmøder og aflysninger af de fysiske møder, kurser og symposiet, alt sammen noget som vi forhåbentlig har til gode, måske ikke i helt samme form som vi kender det fra tidligere, men trods alt meget mere lig hvad vi kender fra tidligere med de fordele der nu en gang er ved at mødes fysisk.

I R³ Nordics bestyrelse arbejder i hvert fald på nogle spændende sager, som vi vender tilbage omkring i det nye år.

Jeg vil benytte denne lejlighed til at ønske alle en glædelig jul og et godt og lykkebringende nytår 2021; et år som vi ser frem til med store forhåbninger.

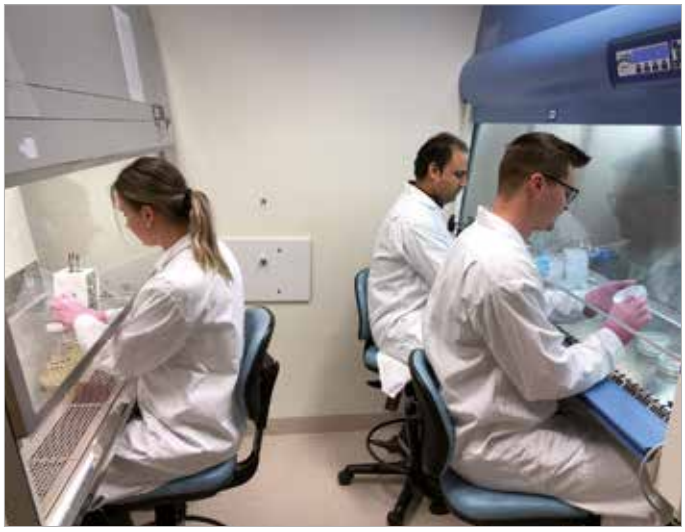
Bedste hilsener

Lene

Lene Blicher Olesen, ordförande

Nå ser vi frem til et nytt godt år 2021!

Renrum i pilotanläggning åt SweTree Technologies!



Ventilator Renrum har fått uppdraget att bygga ett renrum på 100 kvm när **SweTree Technologies AB** tillsammans med **Stora Enso, Sveaskog, Södra** och **Holmen** investerar i en pilotanläggning för framtidens skogsplantor.

SweTree Technologies AB har under flera år utvecklat en teknologi för automatiserad produktion av skogsplantor baserad på somatisk embryogenes. I augusti i år startade Ventilator Renrum projekteringen av det 100 kvm stora renrummet i klass C. Just nu pågår produktion och uppdraget beräknas vara klart strax efter årsskiftet 20/21.

Vi är experter inom renrumsteknologi och erbjuder byggnation, konsultation samt produkter för renrum. Inom labinredning och skyddsventilation är vi ett ledande företag och erbjuder hundratals produkter genom vår digitala produktkatalog på **ventilator.se**

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Ventilator
System för lab och renrum

KALENDER

2021

March

9-11 EHEDG Advanced Course
Force Technology, Copenhagen

May

26-27 R3 Nordic Webinar

October

? CTCB-I Certifiering CLeanroom Tester
Chalmers, Göteborg

2022

May

9-11 R³ Nordic Symposium and Exhibition
Naantali Spa, Finland

Nästa nummer
beräknas utkomma den 12 mars

Manusstopp / Annonsbokning:
11 februari

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

REDAKTÖRENS SPALT

Dear R³-member

The current issue of Renhets Teknik (RT) has two main focus points these being a new facility for training and research for food applications which have been established in Finland and a theme concerning the recommendations concerning use of face masks in public as a means to limit the spread of COVID-19.

This new facility Finish training and research facility for food applications is featured in the main contribution in this issue. The facility offers a unique setup which can be used to study the entire food ecosystem in laboratory scale. Amongst other things the facility applies state of the art hygienic design.

Personal protective equipment has attracted increasing attentions during the COVID-19 pandemic. Faces masks has proven efficient in the health care and hospital sectors but is there an effect when applying them in public? We have been looking at three studies performed in the Nordic countries, extracted key learnings and compared the recommendations issued by the governments of Sweden, Norway, Finland and Denmark. Please note, that it is not the intension the editorial board of RT to draw conclusions or judge what is right and wrong. We have done our best to bring facts forward. In case we have missed something, or over simplified matters please let us know so that we can follow-up in coming issues of RT.

This issue also brings a review paper on applications of dead legs or branches in hygienically designed processing systems.

As usual we have collected relevant news and highlights from international work as well as a information on relevant training courses.

Finally, I would like to wish you all a Merry Christmas and a Happy New Year. We are looking forward to seeing you all in 2021.

ALAN FRIIS
REDAKTÖR

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New Food Premises for Training and Research Purposes

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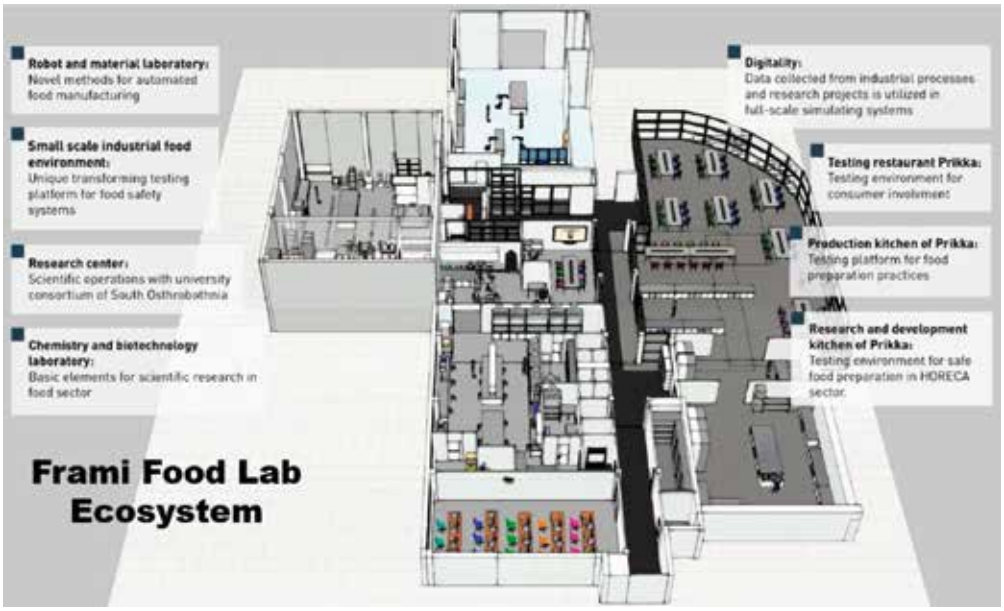
1 INTRODUCTION

Laboratory-based training is the most effective way to learn new science-based methods using experimentally testing of new hypotheses. According to constructive learning, meaningful learning takes place as the learner itself creates new knowledge structures through brainwork. Training in laboratories at university level enables meaningful learning. The learning situation involves the students' personal activity, co-operation, interactivity, purposefulness and self-direction. The laboratory-based training is expensive. Universities around the world have therefore reduced practical training in laboratories. In Finland, training in food technology has also decreased, which can be seen e.g. in reduced training opportunities within meat technology. In Finland, master level food sciences studies can be performed at the University of Helsinki, which has been a unifying force in Finnish food science education. Education in food sciences at bachelor level can be obtained only at the universities in applied sciences in Hämeenlinna and Seinäjoki. Due to traditions, dairy technology has been the focus area in Hämeenlinna and meat technology in Seinäjoki.

Southern Ostrobothnia is considered the food region in Finland. This is the reason why the region has invested in food technology training. At Seinäjoki University of Applied Sciences (SeAMK), School of Food and Agriculture special efforts have therefore been taken to increase practical training systematically in both biotechnology and food technology. The meat pilot plant in Seinäjoki is at the forefront in Finland. Test batches of manufactured products are produced at the meat pilot plant. The students can perform laboratory studies in the Frami Food Lab (FFL), SeAMK's new food premises, where SeAMK with partners enable training in an innovation environment at top level. SeAMK is building up the meat technology teaching in cooperation with the University of Helsinki.



Picture 1. Frami Food Lab Ecosystem includes Analysis, Simulation and Sensory labs and Prikka restaurant with kitchen (Figure: Karri Kallio and Jarmo Alarinta).

Picture 2. Frami Food Lab with some basic equipment (Photos: Gun Wirtanen).

- provide defence against both external and internal hazards,
- ensure correct internal flows of personnel/students and material/equipment with minimized cross-contamination and/or deliberated contamination,
- help to maintain the hygienic conditions during processing, service and cleaning phases and last but not least
- provide students with information about the importance of proper facilities and equipment.

Text box 1. The FFL-facilities were designed based on hygienic design principles.

- construction and layout of premises and workspaces including facilities for personnel hygiene,
- availability of utilities e.g. energy, water and air,
- waste and pest control,
- suitability of equipment including service e.g. cleaning and maintenance,
- warehousing and flows of personnel and material and
- cross-contamination control.

Text box 2. In the EHEDG guideline No. 44 there is information on:

2 BUILDING OF NEW FOOD TRAINING FACILITIES

A built pilot production environment (Picture 1) is the most effective way in technology training, but difficult to implement at large scale, if all food processes must be covered. Furthermore, high costs for raw materials of animal origin, e.g. meat and milk, limit laboratory training. Other limiting factors in FFL are expensive instruments and costs for reagents needed in chemical and microbial analyses. Despite this, the amount of laboratory-based training throughout the food chain must increase in the future, keeping in mind that the unit costs must be decreased. Moreover, new actions together with regional innovation and industrial actors must be sought. (EHEDG, 2014.)

2.1 HYGIENIC PLANT AND EQUIPMENT DESIGN IN THE FFL-FACILITIES

All involved i.e. equipment designers and manufacturers, food processors as well as maintenance and cleaning service producers are never to put food safety at risk. It is a complex task to balance costs, safety regulations and user requirements. If requirements of hygienic design are in conflict with functionality or costs, the safety is to be put first. Furthermore, the hygienic design must be a purchase criterion, when new equipment is bought. With hygienically designed equipment, it is also easier to control critical factors in the food production. In planning, designing and building the FFL-facilities (Picture 2) we used the above-mentioned facts to ensure safe food processing in training and education (Text box 1). (Lelieveld et. al. 2016.)

Both poor hygienic design and inappropriate Good Manufacturing Practices (GMP) procedures lead to defects on surfaces e.g. visible corrosion, traces of lubricants and dirt accumulation on both food contact and non-contact surfaces. We have followed the hygienic engineering rules given in standards published by international standardisation organisations and in guidelines published by EHEDG, European Hygienic Engineering & Design Group (Text box 2). (EHEDG, 2014.)

2.2 FFL as food production establishment

Validation and verification are both vital parts in the food safety systems. The food produced can despite that many food processes contains heat treatment be post-process contaminated through e.g. surfaces, air or water. Physical, chemical and biological control points (CPs) are to be kept under proper control to ensure the safety in the process. We can obtain validation proof e.g. through mathematical modelling and/or from peer-reviewed scientific literature. In the FFL, we can implement in-house challenge tests and/or shelf life testing in new food processes. When validating a procedure, we can also include worst-case scenarios, data collection from process runs and validation of product run data. The reports will include information on raw material, equipment as well as process and environment facts. The reports will be established in the FFL-procedures. (Lelieveld et al., 2016.)

2.3 Verification procedures

Our aim is to provide evidence that produced products comply with current legislation. The CPs and CCPs in the HACCP plan belong to the verification material. This verification material e.g. reviews of food safety documents and internal audits with testing and confirmation will ensure the quality of process performed in the FFL-facilities (Text box 3). Once verification of the validated facilities and processes is completed, it is important that results are both documented and communicated. Personnel involved is informed about the results to ensure that all clearly understand the food safety issues performed. The students must also understand this process. Furthermore, the food safety program identifies updates needed in new processes. (Brackett et al., 2014.)

2.4 FFL-activities

The FFL is a good framework for both traditional and novel production of meat, dairy, vegetable, cereal and berry products (Bradfors-Knox & Neighbour, 2017). Cleaning of both premises and equipment between different processes is of utmost importance. Processes familiar from the food industry are utilised. The FFL with various equipment systems have been used in RDI projects. Each process is performed as planned with hygiene practices included. In FFL, we have already produced various meat products, sausages, bread, cakes, biscuits, cheeses, ice cream, beer, juice, seitan and vegetable patties. In the PIKI project, the equipment is used to determine protein properties in e.g. various vegetable protein isolates and concentrates, a commercial chicken meat product and a by-product stream of cottage cheese. The project aims to find new product concepts and substrates to be used e.g. as protein additives and enhancers, in modifying textures, in emulsifying, in new products to be used as such or in combined products.

The FFL-pasteurizer has been compiled as a Digital Twin, which allows simulation and testing of various pasteurization process and product parameters. When the pasteurization is run with real equipment, obtained data can be used to correct simulation errors and to improve simulations. The process optimization with various standardized settings can be used in both simulations and comparison to previous results. This system also allows students to do process simulations with information available from the industry. A fascinating study deals with playing music to cheeses during the ripening period. Representatives from various universities and a local dairy providing the cheeses are involved in this project. Music-cheeses have already been ripened and students have participated in the sensory evaluation of these cheeses.

- validation and verification are kept as separate tasks,
  - validation based on scientific proof of possible hazards in the processes,
  - verification based on science-based information to support the validation,
- lessons learnt have and will be used to improve both validation and verification,
- managers will be involved in both tasks.

Text box 3. The "To Do" -list with steps in validation and verification:

Picture 3. Preanalysis and Analysis labs is an entity in which the students perform both chemical and microbial analysis and report results (Photos: Gun Wirtanen).

3 FACILITIES FOR ANALYSING FOOD & FEED

In the Analysis Lab at SeAMK must have as diverse base as possible of tools and equipment to serve different food projects (Picture 3). In the training, we focus on both raw materials and processing methods in food production, because processing affect structure, colour, shelf life, mouth feeling etc. of final products. Variations in both variety and season of raw materials also pose challenges to succeed in the production across the process lines. Various analyses enable fulfilling wishes of both industry and consumers. The students have to know the basics of various analyses. The laboratory analytics in the food industry is commonly based on rapid analysis methods, expensive specific analytics, and services from centralized laboratories. Without background knowledge, it is hard to develop new products based on such information. (Brackett et al., 2014.)

3.1 Physical analysis

The raw materials significantly affect the properties of the final products. Therefore, the students learn how to measure particle size, size distribution, dry matter, water activity (aw), water binding capacity, temperature, colour, specific gravity, viscosity, texture hardness/softness, adhesion etc. These can be analysed for both the raw materials and the food products. Important information about the product safety is provided by monitoring temperatures with holding times during heat treatments. (Fellows, 2017). Furthermore, cereal can be analysed using e.g. Brabender's farino-, extenso- and/or amylographs as well as determining the falling number of the cereals (Kent & Evers, 1994).

When we in the food product development want to evaluate the organoleptic product properties e.g. chewing more thoroughly, we have determined the structure with TA-XT2 Texture Analyser (Rosenthal, 2015). In the Analysis Lab the structure properties have been used to determine products' physical properties and in improving the preservation of food product. The students have also thoroughly studied various food structure phenomenon e.g. tenderness of meat, crust formation in bread and potato ripeness (Kilcast, 2010).

The organoleptic quality and shelf life of mushrooms, salads and meat have been measured with the colorimeter, which is available in the Analysis Lab. These observations are based on colour changes. In colour measurements, the goal is to convert for human eye visible colours into numeric values. Thus, small changes in colour can accurately be observed and changed into information about various products in students' work-based projects or project-based theses (Kilcast, 2010).

3.2 Chemical analysis

The food chain studies include exercises in which chemical properties and quality of different raw materials and food products are analysed quantitatively. Titrimetric analyses are commonly used to quantitatively determine vitamin, mineral, and salt contents as well as levels of various acid e.g. acetic acid and lactic acid. These methods are both accurate and reproducible. In the Analysis Lab, we have also tools and equipment to determine the protein content using both the spectrophotometric method and the Kjeldahl method (Self, 2005). In the Kjeldahl method the total protein, i.e. the crude protein, content in a product is achieved by multiplying the total nitrogen content of the sample with the conversion factor. In the spectrophotometric method the properties of a substance are determined by means of UV-Vis radiation. Spectrophotometry can be used to monitor e.g. the quality of food, the levels of additives, the protein content and some minerals. In addition, students determine the fat content in products using various extraction methods e.g. the Mojonnier method (Deibel & Deibel, 2016). The extraction is a chemical separation method based on solubility properties of different compounds.

Acidity is measured using a pH meter. The acidity affects the quality, appearance, shelf life and taste of foods. The chemistry studies in food quality may also include conductivity measurements, especially of water-soluble foods. The conductivity in an aqueous solution depends on the amount of dissolved ionic substances of salts,

acids and bases. We can also produce various synthetic substances e.g. esters used as fragrances and flavours in small scale. These syntheses are based on reactions at certain conditions in which the starting agents are reacting forming new substances. These products can be purified through distillation or extraction. (Damodaran & Parkin, 2017.)

The bachelor students are introduced how to use the HPLC equipment and in their intermediate studies they use it in analysing acids and sugars in food products (Guillarme & Veuthey, 2011). Now, when the resources are increased in both project and exchange studies, conscientious students can deepen their knowledge in the method. In student works, it has been used to study e.g. the effect of different processing methods on the amount of benzoic acid in lingonberry juice and an entirely new method to determine value compounds of side streams in the food industry. The uHPLC, which enables very accurate analyses, has been used in co-operation projects with University of Turku to study the influence of various processes on amino acid compositions of e.g. fungi and potatoes. (Damodaran & Parkin, 2017.)

3.3 Microbial analysis

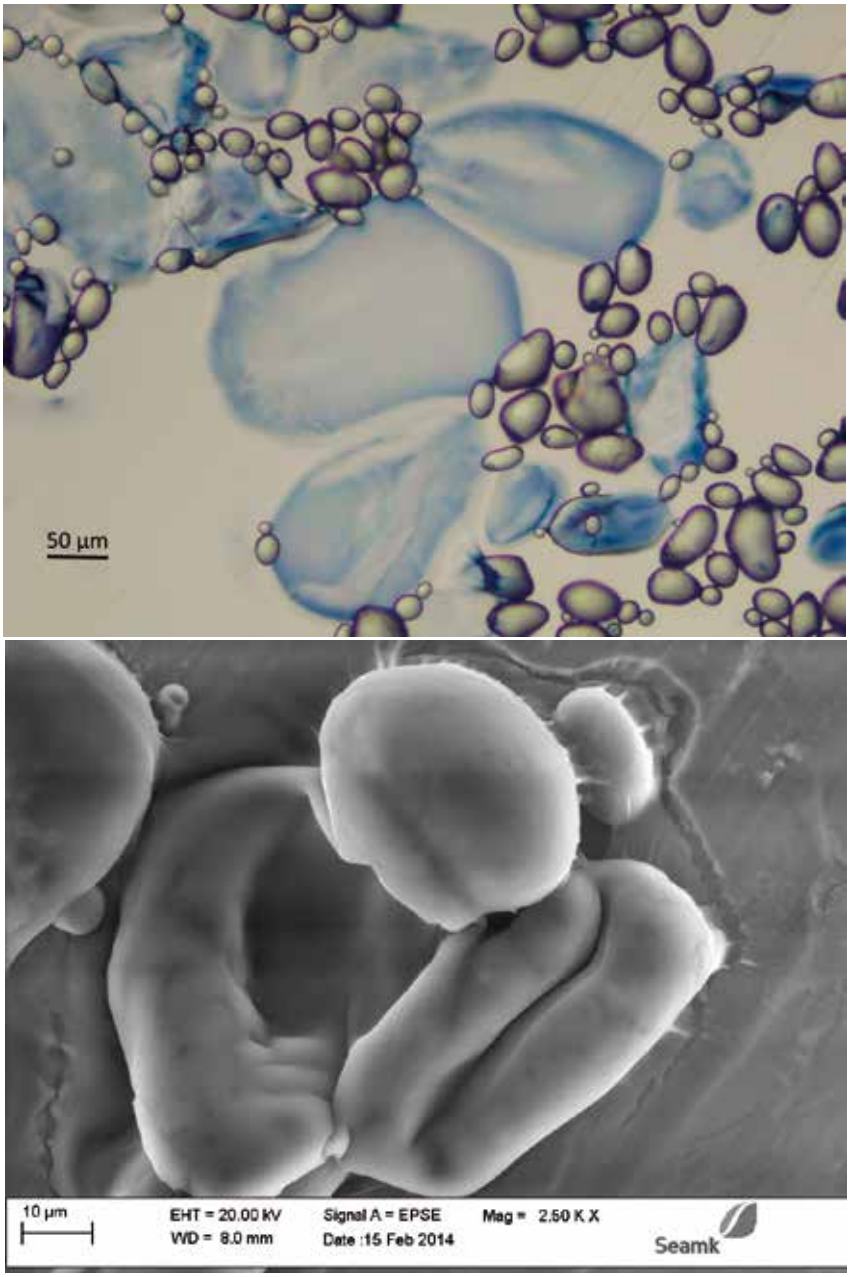
The Analysis Lab facilities are also utilised for studies in microbiology. These activities are divided into basics of microbiology, growth conditions e.g. in culturing and fermentation, surface hygiene and personal hygiene. Rapid methods are used e.g. in monitoring surface cleanliness. Microbes have been grown under both aerobic and anaerobic conditions. Both wanted and unwanted microbes in biotech and food environments are identified based on growth factors and biochemical reactions (Adams et al., 2016).

Results are obtained through colony counting and with different microscopic techniques, i.e. light, stereo, electron and microscopy, as well as using spectroscopy. For example, lactic acid bacterial strains have stepwise been inoculated from slant surface through culturing in a 4-position BiostatQ fermenter into experiments in larger fermentation vessels (Najafpour, 2007). Growth of microbes in different nutrients under various environmental circumstances have also been studied in more detail using a Bioscreen C instrument with space for 2 x 100 growth curves at a time (Russell, 2005). Various microbial research topics have been carried out in theses and project works in the Analysis Lab.

3.4 Microscopical techniques

Knowledge of food structures and interactions between structural elements in food can be examined with both light and electron microscopes. It is useful to combine information from both types of microscopes to understand various behaviours.

The bachelor's students have used the light microscope technique to identify microbes based on e.g. Gram and spore staining as well as yeast staining. They have also determined the cell density of both bacteria and yeasts using counting chambers during fermentation processes. The microbes or food examined can be stained to improve interpretation and visualization of images. Staining techniques have also been used to detect changes in food structures (Picture 4).



Picture 4. Potato starch at 60°C: photos of iodine stained starch in light microscopy (upper) and in elecrone microscopy (lower). Photos: Merja Kyntäjä.

The advantage of light microscopy is the images' colour perceptibility (Heertje, 2014).

The scanning electron microscope at SeAMK is a Variable Pressure - Environmental Scanning Electron Microscope (VP-ESEM). The advantage of this method is that the samples do not need to be coated, thus the microbial or organic food samples examined remain in natural form and are not damaged. Structural changes due to processing, changes in the raw materials and localization of microbes growing in the samples can be observed using this technique. (Groves & Parker, 2013.).

There are image analysis programs, which can be used in analysing the microscopic images. The most widely used software programme is ImageJ, which is an open source solution. The microscope and camera manufacturers have their own software programmes. The software programme can be used in automatizing the image analysis. Approaches based on software programmes enable efficient processing of data from large numbers of images e.g. from timeline series. New samples can also be subjected to exactly the same analysis as the previous ones. Thus, the reproducibility rises to a new level. Furthermore, the clarity of the images can be improved. Thus, images can be interpreted easier, when information from the colour measurements and grayscale SEM images are combined (Rueden et al., 2017).

3.5 Sensory analysis

Due to the place of the Sensory Lab, it is easy to attract passing students, personnel and visitors to take part in sensory tests. There can be eight evaluators at a time. The white walls on the white table guarantee the product reviewers their own place and peace during the evaluation. A test panel of experts can also be trained for special analysis. In the research, products can be evaluated by combining the organoleptic evaluation with chemical, physical and microbial analyses including information from microscopy and imaging techniques. This type of comprehensive evaluation can be used in preservation research and for new products developed. (Kilcast, 2010.) Our international students can take part in developing products for the international market. In 2019, there were 554 international students at SeAMK.

4 FUTURE NEEDS

Development in the food sector, and in particular in technology, is strong. For these reasons, the FFL facilities will continuously be developed towards future needs. One of the most important areas for future development is the deepening of international co-operation in small-scale pilot and teaching activities. SeAMK aims strongly to be on the cutting edge of development and to work with industrial stakeholders, thus we can act as a credible partner in the business community. As a school educating food processors, we are responsible to implement validated activities complying with verified food safety. Furthermore, we are actively developing both our training syllabus and work commissioned to meet future needs. Due to the rising vegetarian, vegan and flexitarian booms, more equipment suitable for preparing vegetarian and vegan food will be acquired in the future. These will be at the top on the investment list. The renovated facilities will provide a good framework for operations for the coming decade. The equipment base will actively be renewed in cooperation with the business community, research institutes and other trainers.

5 SUMMARY

The Frami Food Lab project started based on needs to have new food laboratory facilities at Seinäjoki University of Applied Sciences (SeAMK) and to make the education in food more work oriented. The enterprises in Southern Ostrobothnia need the facilities as a showcase of food expertise i.e. the premises boost the visibility of the food sector. We have considered both training and research aspects, when designing the facilities. In use, these premises will provide opportunities for the students to develop their skills in food processing including attractive and demanding business ideas. The food laboratory entity will be used in project studies in co-operation with food and biotech companies. We designed the controlled food-processing laboratory to enable application in food establishments approved by the food authorities. The facilities are divided into various departments for e.g. the reception of raw materials, the pre-processing facility, the changing area with barriers e.g. washing and disinfection of hands, use of face masks and changing of clothes as well as shoes before the staff enters the food processing area. All analysis will be carried out in the Analysis Lab. The accessibility and the possibility to arrange

training in both chemistry and microbiology in the same facilities were also very important. This enables us to use the facilities more efficiently. It also supports the training in both food processing and biotechnology. These new facilities with hardware and state-of-the-art design create a framework for various activities. Some activities will also be placed in the Sensory Lab.

The ventilation system in the food facilities was by far the biggest structural challenge in building it into the already existing facilities. Two separate ventilation solutions are used. One was implemented with rails and is used in the fume cupboards and chemical storage. A system based on traditional ventilation is used in the rest of the FFL area. This area will serve training in a holistic way and provide researchers with a very good opportunity to carry out various types of research. Students studying agrology, food processing, biotechnology and hospitality management will all use the facilities. Some of the equipment used e.g. in grinding grains affects how the area is kept clean and free from dust. Then we also have ovens and stoves causing heat that affect the air conditioning. The area should be kept free of condense droplets. Due to this, the mills are place in a small, closed room and ovens are used at certain periods based on timing for the various processes. With a good implementation, the area serves both students and other stakeholders in performing RDI activities.

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The 51st R³Nordic Symposium & exhibition has been postponed to

May 9-11, 2022 at Naantali Spa, Finland

Invitation to the R³Nordic Webinar May 26-27, 2021

THE PROGRAMME IS AVAILABLE IN RT 1:21
PK 21-22 INVITES YOU TO SEND IN ABSTRACTS TO THE PK CHAIRPERSON BY 5TH OF OCT 2021

The 51st R³ Nordic Symposium takes place on 10th-11th of May 2022. The venue of the event is Naantali Spa in the sunshine town Naantali on the south-west coast of Finland. The President of the Republic of Finland stays in the presidential summer residence Kultaranta during the summer and for that reason Naantali is considered the holiday capital of Finland.

We are allowed to use photos from Naantali Spa's image gallery. (www.naantalispa.fi)

Detailed information about the webinar will be presented in the next issue of RenhetsTeknik.

SYMPOSIUM-WEBINAR PROGRAMME

The Program Committee 2021-22 (PK21-22) likes to inform You that the arrangements of the next R³ Symposium & Exhitition has been postponed a second time due to the coronavirus pandemic. The new dates are 9th-11th of May 2022. The venue will still be Naantali Spa (Naantali, Finland).

Many presentation in the programme, which was finalized just before we postponed the Symposium in March 2020, will be given as presentation in a Symposium-webinar consisting of two halfdays on 26th-27th of May 2021. These presentations will cover the use and applications of cleanroom technology and contamination control in pharmaceutical, food and biotech industries and hospitals.

We have been in contact with the speakers to find out who will have the possibility to give their presentations in the spring Symposium-webinar. This programme will be available in RT1:21 and already in January 2021 on the R³Nordic homepage www.r3nordic.org.

PARTICIPATION IN THE WEBINAR

Registration to the Symposiumwebinar will be arranged on-line on www.r3nordic.org. We will favour credit card payment, which means that you will not have to pay other additional costs than the membership fee. In case you have missed to pay this fee or you are not yet a member it will be added to the invoiced fee.

The webinarfee (without membership) is: 175 € / 2 half-days and 95 € / 1 half-day.

The presentations will be available as pdf-files on the homepage after the webinar for those, who has paid the participation fee. According to general data protection regulation (GDPR) we are publishing only the names of the participants by country; no further information will available.

THE 51ST SYMPOSIUM & EXHIBITION

A draft of the renewed symposium programmed will be published in RenhetsTeknik in autumn 2021. Abstracts available at publishing time are included in RT4:21.

In case You are working with cleanroom technology and contamination control in hospitals and pharmaceutical, food and biotech industries, we urge You to send in an abstract to the Chairperson Leila Kakko at leila.kakko@tuni.fi.

The deadline for abstract submission is 5th of October 2021. The members in the Programme Committee will approve abstracts suiting the programme. There are also invited speakers in the programme. Further information on the symposium including registration form will be available in RT3:2021 and on www.r3nordic.org/symposium-2022, in autumn 2021.

SPECIAL OFFER "GO 3 PAY FOR 2"

Our early-bird special offer "Go 3 Pay for 2" for industrial delegates is valid before 1st of April 2022. Please, note that prices will raise from that date onwards. The participant fee for persons coming from hospitals, educational institutions etc. is also available and those prices can be found in the column under "Public & Municipal".

The 51st R³ Symposium will be held at Naantali Spa, (Nådendal Finland), 9th - 11th of May 2022.

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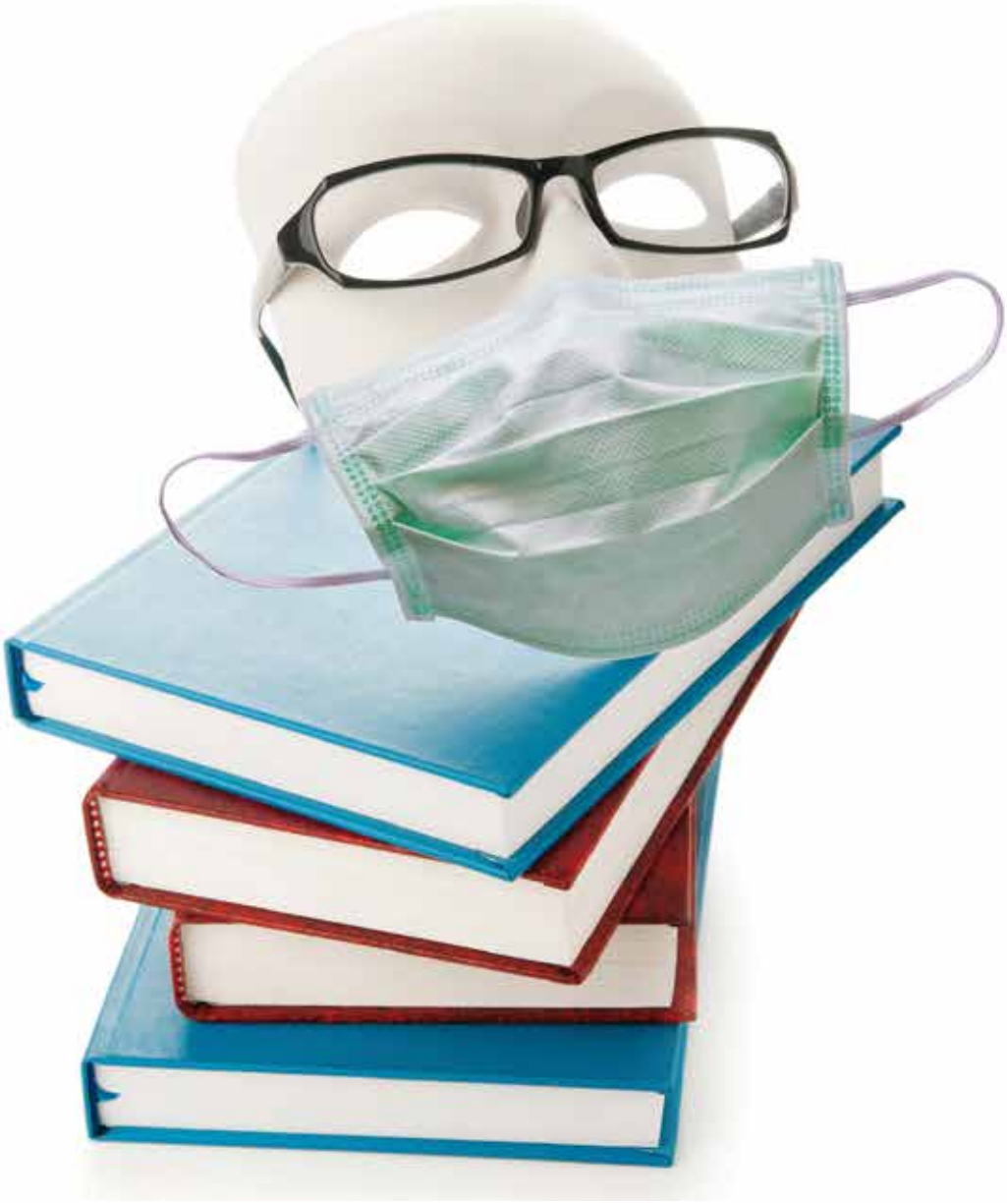
Does face masks used in public reduce the risk of COVID-19 infections?



The effect of using face masks in public has recently been investigated in separate medical studies performed in Sweden, Finland and Denmark.

SWEDEN

The Swedish study debates if the Swedish recommendation of not using face masks in public areas is right or wrong. It is known that they work and that is why they have been used them for over a hundred years in previous pandemics, and in everyday in hospitals. Still it is a complicated thing to introduce a general recommendation for public use as people need to be educated how to use the face masks correctly.

An international study investigated the filter ability of mouth guards of fabric in a so-called meta study, where results from previous research is reviewed. The meta study included 25 published articles comparing fabric mouthguards of different types. Several of these studies are made with fabric filters on model heads where you let an air stream pass, and then measure how much of the particles, viruses or bacteria the filter captures. The tests were carried out in slightly different ways, which made them difficult to compare. But the researchers conclude that some fabric mouthguards provide good protection, both against spreading viruses and against inhaling them.

For health care professionals, it is obvious with mouth protection even if it does not provide 100% protection. But it should be remembered that face masks complement other measures in the medical environment. And if they are use in wrong ways, they do not protect at all. It requires knowledge and training. Face masks are often pulled up and down and then the virus may come on the hands, and then on from there. Therefor the conclusions are not clear that face masks are the right way to deal with the pandemic. The effect of oral protection to reduce the virus is proven in a laboratory environment, but despite this, the evidence is weak that face masks have an effect against the spread of corona infection in a larger population group. The study conclude that more data is needed before general recommendations should be made. When face protection is needed some guidelines are:

* Use face masks to do not infect others: A common one-time mouthguard is a so-called surgical mask (FFP1). It is made of some type of synthetic fabric, usually light blue and acts as a splash guard that prevents the wearer from spreading small drops of saliva that come with the exhale. Surgical disposable protection can be washed and reused but will provide less protection. Protective fabric masks can look in many ways but requires several layers. At least 3-4 layers of cotton and flannel are needed but as much as six layers may be needed to prevent the small virus particles from penetrating. It is also important that the fabric is woven tightly. Fabric mouthguards should be washed hot between each use. A fabric mask should be CE-labled.

* Respiratory protection also protects yourself: The mouthguard has the shape of a cup and is available in the protection classes FFP2 and FFP3. Most common in the Swedish healthcare system is FFP2. In order for a respiratory protection to be effective, it must be well fitted to the face and that the wearer is smooth-shaven. Respiratory protection is primarily intended for persons working in hazardous environments. These masks are always CE-labled.

Based on interview with Juan Jesus Carrero, professor in epidemiology at Karolinska Instituttet, Åsa Melhus, professor of clinical practice at Uppsala University, Kjell Torén, professor and senior physician at Sahlgrenska Hospital in Gothenburg, Department of Community Medicine and Public Health. Published at forskning.se https://www.forskning.se/2020/11/04/munskydd-eller-inte-det-ar-fragan/

FINLAND

The Finish study performed at VTT Technological Research Centre show that face protection of fabric allows us safely to be closer to each other - and polyester is better than cotton. The face mask studied are of the FFP1 type and the conclusion is that they do not protect the person using it but merely protects against that person spreading aerosols and thereby reduces the risk of spreading infection. In practice, it is a matter of facial protection slowing down the drops that are formed when coughing, sneezing or breathing. The results are in line with what WHO has already said that the face protections are primarily protecting people in one's proximity. This face masks may be efficient to limit the spread of virus when we cannot keep a safety distance of at least two meters. This can be in public transport or stores. For face masks to have a significant effect on the virus's reproductive rate, half the population would have to use face masks regularly

According to VTT's face masks made of ordinary textiles filter out between 20 and 45 percent of the small particles, and polyester is significantly better than cotton. An explanation for this may be that polyester create static electricity. It can be compared with the fact that FFP2 respiratory protection filters out 96% and FFP3 respiratory protection filters out 99%. The study concludes that you can work 8 hours with a professional filter cover but only have about 10 minutes of time on you with a face protection fabric.

It is also important not to use fabric face protection too long time because even after an hour they are less effective, so they should not be used longer than that. Fabric face masks is best cleaned in a washing machine at 90°C. This meant that polyester would probably shrink if you have a protection of that material.

Extracted based on a study performed at VTT Technological Research Centre and an interview with research professor Ali Harlin.

DENMARK

The Danish study involved more than 6,000 Danes to provide new knowledge about the degree to which face masks protect the wearer from corona infection when the mask is used in addition to the authorities' other recommendations against corona infection. This including social distance, hand hygiene and isolation of patients with COVID-19. In the DANMASK-19 study, one half of the participants were selected to wear surgical face mask when out of home, and the other half of the participants were not required to wear a mask. All participants were strongly encouraged to follow all other government recommendations regarding COVID-19.

After one month of follow-up, 1.8% of participants in the mesh group and 2.1% of participants in the control group had infection. Thus, the study does not confirm the expected halving of the risk of infection of the carrier of the face masks, but the results could indicate a more moderate level of protection of 15-20% – although the study cannot rule out that the mask does not protect the wearer. At the end of the study, there was no static significant difference in infection rates between the two groups.

It is stressed that the study did not examine the function of the masks as a source control, i.e. to limit infection from an infected person wearing a mask to others. The study also did not illuminate the effect of face masks in situations where it is not possible to maintain social distance. It should therefore be stressed that these results cannot be used to concluded that the widespread use of masks outside the health care system can be an effective means of reducing SARS-CoV-2 infections.

Professor, chief medical officer, Dr.med. Henning Bundgaard, Rigshospitalet and professor, chief medical officer, dr.med. Kasper Iversen, Herlev-Gentofte Hospital, led the study, which is published in the journalAnnals of Internal Medicine and the text is extracted from https://www.rigshospitalet.dk/presse-og-nyt/nyheder/nyheder/Sider/2020/november/dansk-studie-er-nu-offentliggjort.aspx

Protection against Covid-19 – How do we do in the Nordic countries?

The Nordic countries were long restrained with recommendations on mouth protection (face masks), which were otherwise introduced in early summer in other European countries. The strategy to combat the spread of COVID-19 has been very different in the Nordic countries, but there has been a common recommendation that people should keep a good distance and not meet too many in the same place. For example, Norway and Denmark closed-down schools, colleges and universities, as well as several public jobs, while Sweden closed high schools and universities but did not shut the society down as was the case in Finland and Norway too. In all countries it was recommended that, as far as possible, work at home should be carried out.

In Sweden, only a small minority wear face mask. Norway, Denmark and Finland have done so after the summer of 2020 for some public places. At the end of October, Denmark introduced requirements for wearing mouth-protection in supermarkets and other places with public access. Sweden takes a special position, the Swedish Public Health Agency says that there may be situations "where face masks can be of value", but do not give any more specific recommendations or requirements. Since June 2020, the World Health Organization (WHO) has been recommending mouth protection in situations where it is difficult to keep a distance.

FACTS ABOUT FACE MASKS

Face masks sold in EU must be CE labeled and tested according to EN 14683:2019 to demonstrate that the face mask meets the necessary safety standards. The manufacturer must indicate the filtering rate of the equipment and obtain. The use of facial masks in the medical environments are documented to reduce the risk of spreading bacteria, however the effect of using them in public is debatable. The standard covers surgical face masks which are grouped in three classes FFP1, FFP2 and FFP3, which all are single use only:

FFP1 comprise of three types: I, II and IIR depending on filtering capacity. Type II or IIR face masks have the highest filtering capacity. Type IIR is also designed to withstand splashes and splashes from liquids, which can lead to less breathability. FFP1 face masks are commonly used for protection in public health care but are now sold for public use with Type I being the most common.

FFP2 offer more protection than FFP1, at concentrations up to 12xOEL (occupational exposure limit) or 10xAPF (assigned protection factor). For FFP1 the limits are 4xOEL and 4xAFP. They are the European equivalent of the N95 respirator masks used in the US and this kind meet the requirements from the World Health Organization (WHO).

The masks that offer the highest level of protection are labeled **FFP3**, which protect against materials in concentrations up to 50xOEL or 20xAPF. This is substantially higher than FFP2 and they can block both liquid and solid aerosols. Current NHS guidelines stipulate FFP3 (N99, the higher the number, the higher the fiber density of the mask and thus also the protection, although none of them can provide 100% protection) face masks for virus and bacterial infection control when the contagion is spread through coughing and sneezing (such as with the coronavirus). They are also often used by healthcare professionals when handling hazardous pharmaceutical chemicals.

Community face coverings, also known as fabric face masks and cloth face masks, DIY masks, community masks, etc., are widely used to limit the spread of droplets and aerosols. These are intended for multiple uses and filtering effects of these varies greatly with the fabric, number of layers and the number of times they are used between washing. Community face coverings can be tested according to the standard CWA 17553, which is published by the European Committee for Standardization (CEN). Hereby the manufacturer documents that the product meets the requirements of e.g. filtration efficiency and breathing resistance meets minimum levels.

RECOMMEND

1. Go into self-isolation if you have symptoms of COVID-19, have tested positive or are in close contact with someone infected with coronavirus
2. Wash your hands often or use hand alcohol. Hand washing and hand sanitizer with hand alcohol work equally well. However, hand washing is always recommended for visible dirt on hands, in damp hands, after toilet visits, after diaper changes and before handling food. Hand alcohol only works properly when the hands are dry and are not visibly dirty.
3. Cough or sneeez in your sleeve. Cough down your sleeve or in a paper handkerchief. Wash or drain your hands afterwards. If you are going to cough down your hands, then wash or drain your hands afterwards.
4. Avoid handshakes, cheek kisses and stuff. Contact infection is probably the main source of infection from people who are sick even if they do not have symptoms. Therefore, we recommend that you limit physical contact with others – e.g. handshakes, cheek kisses and hugs – even if you do not have symptoms.
5. Pay attention to cleaning - both at home and at work
6. Keep your distance and ask others to respect distancing. We therefore recommend that you generally stay at least one meter away from others, but at least two meters in special situations, e.g. to people who are or may be infected with coronavirus.

There are legal requirements for face mask or visors in the following places:

1. When travelling by public transport.
2. For visits to restaurants, cafés, patisseries, bakery shops, fast food restaurants, etc., where indoor serving is available. The requirement for face masks or visors applies as long as you walk or stand, but not when you sit down.
3. In retail, i.e. shops, convenience stores, department stores, department stores, department stores, bazaars, arcades, etc. to which the public has access.
4. For indoor areas in secondary education, adult education, higher education institutions, music and cultural schools, driving schools, public schools, day schools and evening schools, e.g. canteen and hallways. Requirements do not apply in classrooms and in certain other places.
5. Indoors in cultural institutions and sports facilities including museums, sports halls, gyms, art halls, venues, libraries, cultural centres, zoos, cinemas, theatres, association rooms, etc. The requirement for a face mask or a visor does not apply when sitting down, if it cannot be used due to the nature of the activity, as well as to performers and practitioners, etc. during their performance, etc.
6. In the health and elderly care, e.g. hospital, clinic in the practice sector, e.g. at the doctor's house, practicing psychologist, physiotherapist, municipal health services, in nursing homes.

www.sst.dk/da/corona/Forebyg-smitte/Generelle-raad

+ RECOMMEND

Everyone can slow down the spread of coronavirus with their own actions. In everyday life you can reduce infection risk by

- following good hand, coughing and sneezing hygiene
- keeping a safety distance of at least 1 to 2 meters from other people
- wearing a face mask if you cannot keep a safe distance from others
- getting tested, if you have any symptoms that suggest a coronavirus infection.

The restrictions in the Helsinki-area is that max. 10 persons are allowed to be on the same place. In the rest of Uusimaa it is a strong recommendation. In Helsinki area workers in offices and the students in middle schools must use face masks from Monday November 23rd for at least 3-weeks onwards.

The proper use of face mask can reduce infection by preventing droplets from spreading into the environment. There are many types of face masks: different home-made or shop-bought masks made of cloth or other materials. A cloth mask is not an actual respiratory protective device and does not provide effective protection for the person wearing it. Mask effectiveness is partly reliant on as many people as possible wearing masks correctly.

thl.fi/en/web/infectious-diseases-and-vaccinations/what-s-new/coronavirus-covid-19-latest-updates/transmission-and-protection-coronavirus

RECOMMEND

In some situations, it is recommended or mandatory to use a face mask specific rules may apply to certain geographic areas and situations.

It is mandatory to use a face mask if you are over 12 years of age when You are going into travel quarantine and use public transport from place of arrival to quarantine.

The authorities also recommend that face masks be used in the following situations (not time-limited):

- When people who are infected or have symptoms of Covid-19 must break their isolation to travel to and from the health institution or for testing.
- When people with suspected or proven covid-19 are closer to other members of the house than 1 meter, if the state of health permits.

Face masks are recommended as part of measures to reduce the risk of spread of infection in situations where one has increasing or high infected pressure, but it cannot replace other measures. The main infection control advice is therefore to keep a distance from others, remember good hand hygiene and stay at home if you are sick. In areas with little or no known infection, general recommendations on the use of face masks are not introduced. The Norwegian Institute of Public Health does not discourage it either.

There are both medical face masks and cloth face masks:

- Medical face are disposable mouthpieces that are manufactured for use in the health service and meet the requirements of applicable standards. Medical face masks are designed to prevent infection from the person wearing it to others, but it also has a protective effect for the person carrying it. That is, you primarily protect others from getting infected by you. But at the same time, you also reduce the risk of being infected by others. The prerequisite is that the face mask is used correctly.
- Cloth face masks are intended for use outside the health service for single-use or reuse. They can be homemade, or factory manufactured. They are made of textiles or other washable material. If you want to use cloth face mask, we recommend fabrics with a proven effect of at least 70% filtration of particles.

The research done so far suggests that there is a poorer effect of cloth face masks compared to medical face masks, and that there is a wide variation in the effect of the cloth face masks based on the type of material and fit.

www.helsenorge.no/koronavirus/munnbind

RECOMMEND

Keep your distance and take personal responsibility

1. Stay at home even if you just feel like you have a cold.
2. If you have new symptoms of covid-19 that do not pass within 24 hours, you should be tested for covid-19, provided that the symptoms cannot be explained by other probable causes such as known allergy, migraine or tension headaches.
3. Keep an arm's length away from others both indoors and outdoors.
4. If possible, travel in a different manner than by public transport or public transport, such as walking or cycling.
5. Choose a means of transport where you can book a seat or one where you can avoid congestion.
6. Keep your distance from others on the bus, metro, tram and other public transport.
7. Avoid participating in larger social contexts.
8. Keep your distance from others at sports grounds, bathhouses and gyms and avoid changing in public changing rooms.

Wash your hands frequently with soap and warm water, for at least 20 seconds. Always wash your hands when you get home or when you come to work, as well as after being out, before meals, during food handling and after a toilet visit. Hand sanitizer may be an option when you are not able to wash hands. Always wash your hands with soap and water if your hands are visibly dirty.

Cough and sneeze in the arm fold or in a paper handkerchief, you prevent infection from spreading around you or from contaminating your hands. Always throw the paper handkerchief in a trash can and wash your hands.

Avoid touching eyes, nose and mouth. Infection is spread through mucous membranes of the eyes, nose and mouth. A general preventive measure against respiratory infections is to avoid touching the eyes, nose and mouth.

There are regional recommendations in which instruct people to avoid places like shops and public indoor places other than if it is essential.

www.folkhalsomyndigheten.se/smittskydd-beredskap/utbrott aktuella-utbrott/covid-19/skydda-dig-och-andra/

Dead legs in piping systems

- how to design them hygienically?

ALAN FRIIS,
FORCE TECHNOLOGY

In the design of production piping systems in the food and pharma industry, there is often a recurring discussion about dead legs: How can they be avoided? And which criteria should apply to their depth in pipe systems to keep it hygienic?

The answer is 'it depends on which reference is relatable in your case'. However, it is agreed that in hygienically designed systems there is a limit to the depth of dead legs, as it has real influence on the cleaning time. Longer dead legs will require more time to be cleaned, as well as more time to achieve the necessary temperature during the process of sterilization with steam or hot water.

All criteria are based on the ratio of the diameter of the tube (D) to the depth of the dead leg (L), where L is usually measured from the pipe wall. In general, the acceptable depth is specified by a depth to the diameter ratio expressed by L ≤ x?D. The magnitude of x depends on the reference, and to make the confusion complete there are different rules which under different conditions specify requirements as: 1D; 1.5D; 2D; 3D or 6D. Which one is the right to choose then?

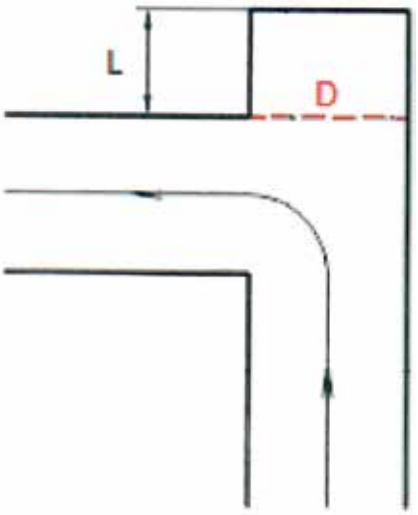


Figure 1. Acceptable if unavoidable (L < D)

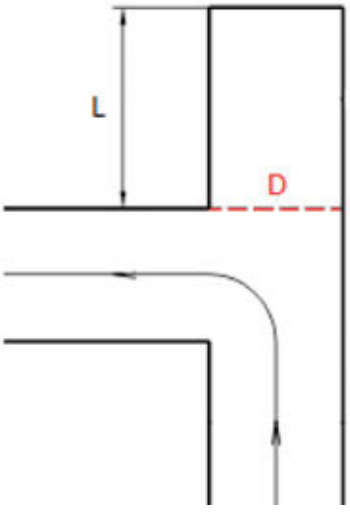


Figure 2. Unacceptably long dead leg (L > D)

EUROPE AND THE FOOD INDUSTRY INCLUDING EHEDG

The European criteria on dead legs are the toughest to meet. The harmonized standard EN1672-2 states that dead ends should preferably be avoided, and if they cannot be, they must be as short as possible. Figure 1 shows a dead leg which is shorter than the pipe's diameter: therefore, this design is acceptable if it cannot be avoided. For comparison, Figure 2 shows a dead leg, which is posing hygienic risk as it is deeper than the pipe's diameter.

The European Hygienic Engineering and Design Group (EHEDG) specifies that the depth of dead legs must be less than or equal to the diameter of the pipe, i.e. a 1D rule, which can also be considered appropriate in relation to EN1672-2.

THE US, BIOTECH AND PHARMA INDUSTRIES INCLUDING FDA, 3-A, ASME-BPE, ISPE AND WHO

In the 'Guide to Inspections of High Purity Water Systems' from 1993, the FDA has described a 6D rule that is the only one where the length of the dead leg is measured from the

pipe's center line. This document is still used by FDA inspectors as a guidance for GMP inspections. However, the pharmaceutical industry standard seems to be a 3D rule, which is also supported by WHO TRS 970 (2012) and ISPE who have adopted the 3D rule in their guidelines on water production systems for pharmaceutical use.

3-A Sanitary Standards Inc and ASME BPE-2019 (American Society of Mechanical Engineers for Bioprocessing Equipment) describe a slightly stricter criteria in the form of a 2D rule and occasionally the biotech industry applies a 1.5D rule, this is supported by WHO TRS 929 (2005), which has been replaced by TRS 970 in 2012.

WHERE DO THE RULES COME FROM?

Before starting to apply the rules, it is a good idea to dig a little deeper into their background and decide, which application resembles our case the most. That is due to the fact that they come from different industries:

1. The 3D and 6D rules are originally described for sterilized water systems for pharmaceutical use.

2. The 2D and 1.5D rules come from the biotech and pharma industries and focus on equipment that is cleanable and sterilizable. 3-A applies the 2D rule to the certification of general sanitary equipment as well as for use in food production.

3. The 1D rule has direct relevance to the hygienic design of process equipment for food production and the EHEDG applies this criterion when certifying processing equipment. The European harmonized standard EN1672-2 is developed purely for food applications and specify that the dead leg should be even shorter.

HOW TO APPLY RULES ON DEAD LEGS IN PRACTICE?

There is no doubt that the best hygienic design is achieved by the complete absence of dead legs, but it is not always possible. In practice, the following rules of thumb can be applied:

1. In systems to produce food, ingredients etc. which are cleaned using Cleaning in Place (CIP) methods and are subsequently disinfected with common disinfectants, dead legs should comply with EHEDG's criteria of L < D.

2. In systems where biological products are produced and where steam or hot water is used to create a level of sterilization of the production plant, the criterion of L < 1.5D used by the biotech industry or L < 2D, as specified by 3-A and in ASME-BPE-2019, may be applied based on the relevant risk assessment.

3. Longer dead leg should only be used in systems where the medium is very clean and preferably sterile. Such systems could be water facilities as prescribed by ISPE, where steam is also used for sterilization. Therefore, it can be allowed to apply dead legs according to the criterion L < 3D.

It is not recommended to go beyond these criteria for specific applications. In all the criteria mentioned above, the depth of the dead leg (L) is measured in the same way - from the pipe wall. Dead legs larger than the 3D should be applied with the utmost care and cannot be characterized as part of a hygienic or sanitary design. However, it does not exclude the possibility that they can be used in particularly favorable situations.

IS IT REALLY A DEAD LEG OR IS IT A CLEANABLE BRANCH?

In practice designs must be subjected to a risk assessment which will judge which criterion

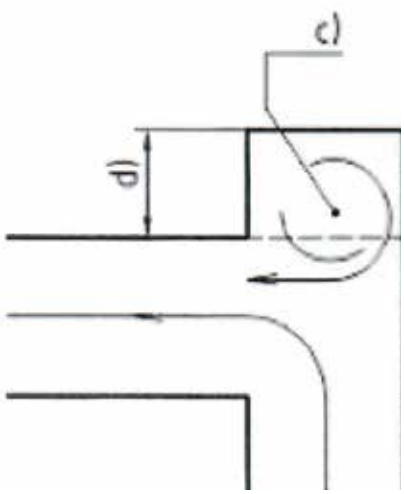


Figure 3. Recirculation in T-piece (correct)

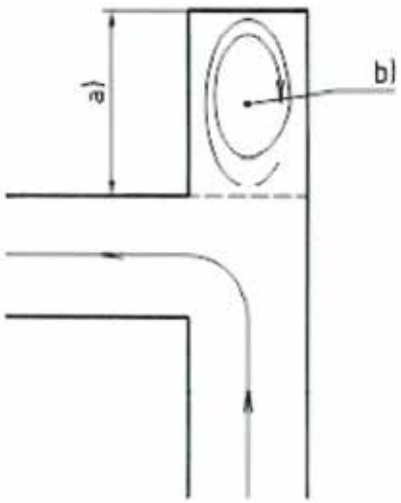


Figure 4. Recirculation in T-piece (incorrect)

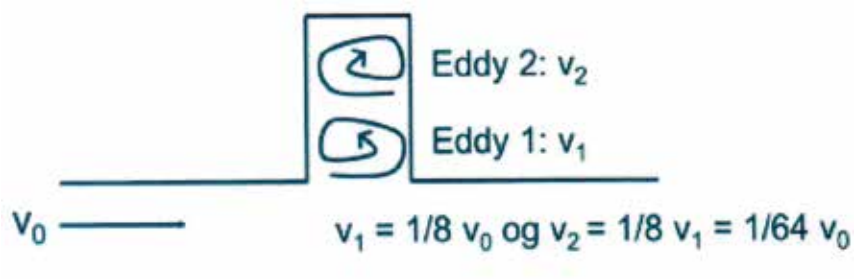


Figure 4. Recirculation's in upward facing T-piece (V is the mean veolcity of the flow)

may be suitable in each application. A branch in a processing plant may only be temporarily shut-off and thus in practice not really being a dead leg. The criterion presented are valid for static dead legs but temporary stagnant zones in a processing plant longer leg may not hamper food safety if the plant is operated correctly. ASME-BPE-2019 applies a risk assessment approach in which they label a branch only to be a dead leg if it cannot be sanitized using the normal cleaning or steam sterilizing procedure.

BACKGROUND TO THE CRITERIA BASED ON FLOW MECHANICS

Figure 3, Figure 4 Figure 5 show how a recirculation occurs in a branch of a pipe. This happens whether it is an up-stand as shown in Figure 5 or an upward facing dead leg on a pipe, as shown in Figure 3 Figure 4. If the dead leg is appropriately short, then the recirculation does not reside entirely in the dead leg (see: Figure 3). The mean flow rate in the recirculation is usually significantly reduced compared to the mean flow rate of the main flow, but locally the velocities can be much lower. If the dead leg becomes very deep (it may even be one at a depth of 3D), then two recirculation may occur, with the mean velocity again dropping dramatically in number two. The phenomenon and typical mean flow rates are shown for an up-stand in Figure 5.

In practice, there is very limited movement at the bottom of a dead leg with two recirculation and it will affect the effect of the cleaning and exchange of fluid. Exchanging the liquid is necessary to bring fresh detergent to the surface. In general, conditions especially for fluid exchange are significantly improved if there is a sensor of a kind that sticks into the dead leg. This information is also carried forward in EN1672-2.

CONCLUSION

Dead legs should be avoided as much as possible in hygienically designed processing plants and if they appear, they should be as short as possible. Rules of what design is hygienically acceptable depend on the specific situation, industry, application and often geographical region.

The recommendations for length of dead ends are listed below, in order of priority:

1. A dead leg with the flow direction going towards the dead leg, as shown in Figure 3, has the best conditions for exchanging fluid and there is a reasonably good effect of the flow into the dead leg. Small additions to such solutions can improve the hygienic performance significantly, like e.g. a temperature sensor placed in the dead leg.

2. An upward facing ded leg on a pipe should always be as short as possible, and they should only exist if a sensor is placed in them. This may contribute to improved fluid exchange conditions, but in general this structure will take a lot longer to clean than the T-piece construction.

3. Dead legs with the flow direction going away from the dead end are not recommended under any circumstances.

These recommendations provide a good indication of how dead legs can exist in different types of processes included in producing products that must be safe for the consumer. Therefore, risk assessment is pivotal in any application. These guidelines should be perceived as minimum requirements and one should know that if the product has a complicated rheology (e.g. high viscosity), then the recommendation will be to apply the strictest requirements for dead legs and even better, to completely avoid them at all cost.

Acknowledgements: Thank you to Bo Boye Busk Jensen, Alfa Laval Cleaning and Mixing for comments and suggestions.

PDA fortsätter med virtuella konferenser och evenemang. Under 2020 har PDA givit ut fyra Technical Reports: TR 84 Integrating Data Integrity Requirements into Manufacturing & Packaging Operations och 3 Points to Consider TR, (PUPSIT 1 och 2 och Isolators). PDA's Letter, tillgänglig för medlemmar på nätet, har bland sina senaste artiklar "Keeping Biopharma's Essential Services Lifeline Afloat during COVID" av Subrata Chakraborty, GxPFONT Consulting och "Virtual Audits in the Time of COVID-19; For the Auditors and the Host" av Anna Gilbert, BDO; Robert Greathead, Catalent Pharma Solutions.

PDA JPST VOL 74-5

Senaste numret av PDA JPST, Vol 74, Issue 5, September/October 2020 innehåller bl a följande:

- Guest Editorial Scientific Studies and Interpretation
Edward C. Tidswell and James Akers
- Facilitated Active Listening Meeting between Industry and FDA Identifies Common Challenges for Adoption of New Biopharmaceutical Manufacturing Technologies
Jennifer L. Mantle and Kelvin H. Lee
- Investigating Aberrant Results in Microbiological Examination of Nonsterile Product Assays
Crystal Booth
- Probable Scenarios of Process Contaminatio with Cutibacterium (Propionibacterium) acnes in Mammalian Cell Bioreactor
Angel L. Salaman-Byron
- Currently Available Recombinant Alternatives to Horseshoe Crab Blood Lysates: Are They Comparable for the Detection of Environmental Bacterial Endotoxins? A Review.
Jay Bolden, Chris Knutsen, Jack Levin, Catherine Milne, Tina Morris, Ned Mozier, Ingo Spreitzer and Friedrich von Wintzinerode

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PHSS fortsätter med att arrangera webinars, bla med uppdatering och kommentarer kring GMP Annex 1 och digital konferenser.

Senaste numret av European Journal of Parenteral & Pharmaceutical Scinces Vol 25 no 2 online innehåller följande artiklar:

- Validation of the Growth Direct System for Microbial Environmental Monitoring and Define Optimal Incubation Conditions
Courtney Russell, Niloufar Parsaei, David L Jones- Rapid, Micro Biosystems
- Gender Influences Bacterial Contamination of Reusable Cleanroom Operators' Garments following Wear
Laurie M. Smith, Noëlle H. O'Driscoll, Andrew J. Lamb - Robert Gordon University
- Review of the efficacy of HEPA filtered air to control coronavirus risks in cleanrooms
Tim Sandle - BPL Ltd
- The effect of a pandemic on the Life Sciences industry
Cliodhna Mc Donough and Emily Lockey, Fieldfisher LLP
- Barrier Technologies proposed text from PHSS Annex 1 Focus Group
James Drinkwater and Di Morris
- Guest Editorial
Pam Turner
- PNR Pharma Ltd discusses Delivery of Medical Supplies/Pharamceuticals by Drone within the UK, Regulatory Update
Malcolm Holmes

Issue 43 #3 2020 innehåller förutom John Neigers redaktionella kommentar och branschnyheter följande artiklar:

- Real-time optimisation of vapor phase hydrogen peroxide bio-decontamination cycles using a new combined sensor
Tim Coles and Sanna Lehtinen.
- GMP-compliant environmental monitoring systems in stem cell and tissue laboratories:seven frequently asked questions
Hasim Solmaz.
- Cleanroom known unknowns: 4 Airlocks
Andrew Watson.
- Coronavirus pandemic shortages and the risk of using ineffective hand sanitisers in cleanrooms
Tim Sandle.

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ICCCS hade ett virtuellt möte i samband med ISO/TC209. Den planerade konferensen i Turkiet ställdes som så mycket annat in under hösten. Kommande aktiviteter ska diskuteras vid ett fortsatt möte on-line i december med representanter från de olika medlemsorganisationerna.

CTCB-I certifiering 2020

TEXT & BILD: LARS EKBERG

I början av oktober, på Chalmers Göteborg, hölls CTCB-I:s certifieringskurs i Norden för mätspecialister och beställare/granskare/utvärderare av mättjänster för renrum. Certifieringen utfördes 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. I år kom deltagarna från Danmark, Norge, och Sverige.

Under dag 1 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 dag 2 med 60 frågor på kursavsnitten, genomfördes under ledning av Mari-Liis Maripuu.

I försökshallen hade Håkan Larsson, Chalmers, tillsammans med Lars Jansson, MyAir, förberett allt inför eftermiddagens demonstration - där såväl mätutrustning som mätteknik belystes.

Under dag 3 genomfördes de praktiska proven, som bedömdes av fyra examinatorer, Mari-Liis Maripuu, Lars Ekberg och Stefan Aronsson från CIT Energy Management, Göteborg samt Lars Jansson, MyAir, Linköping.

Efter dagens avslutade praktiska prov samlades lärarna för att gemensamt bedöma resultaten under ledning av Lars Ekberg. När Berit Reinmüller rättat teoriproven stod det klart att elva personer var godkända och därför erhöll certifikat; åtta på nivån Associate, två nya på nivån Professional och en förnyad certifiering på nivån Professional.

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

Nästa tillfälle för certifiering i Göteborg planeras till hösten 2021. Exakta datum publiceras i kommande nummer av RenhetsTeknik, på hemsidan 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 för närvarande är maximerat till 12 deltagare, varför du som ska förnya ditt certifikat efter fem år bör anmäla ditt intresse så snart som möjligt till Lars Ekberg lars.ekberg@cit.chalmers.se. För Associate Level är inte antalet lika begränsat.

Två av arrangemangets medarbetare: Victoria Edenhofer (t.v.) och Mari-Liis Maripuu (t.h.).

Den Fan-Filter-Unit (FFU) som användes för demonstrationslaboration och praktiskt prov.

Det testade HEPA-filtret och en av de fotometrar som fanns tillhands i laboratoriet.

De fyra lärarna och praktiska examinatorerna, från vänster: Stefan Aronsson, Lars Jansson, Mari-Liis Maripuu och Lars Ekberg.

CERTIFIERADE 2020 - LEVEL: ASSOCIATE

Niklas Dan Jensen
Nordsjællands Hospital, Danmark

Ronny Ekman
MyAir AB, Sverige

Amer Mousleh
Nordsjællands Hospital, Danmark

Laila Bitar
Swedish Orphan Biovitrum AB, Sverige

Frank Hofman Johnsen
Nordsjællands Hospital, Danmark

Lotta Rosenqvist
Camfil, Mölndal, Sverige

Michael Jamson
Sahlgrenska Universitetssjukhuset, Sverige

CERTIFIERADE 2020 - LEVEL: PROFESSIONAL

Jürgen Luik,
Camfil, Trosa, Sverige

Tomas Jansson
TOJAB, Sverige

Milan Glasovic
Caverion Sverige AB, Sverige

Nicolai Njie
GK Inneklima AS, Norge

ISO TC209 møde

AV LENE BLICHER OLESEN

I år afholdtes 32nd ISO TC 209 møde som så mange andre møder som Zoom møder. Møderne foregik som tre timers møder hver dag GMT 12.00-15.00 i perioden 26. – 29. oktober.

Det er første gang at møderne blev afholdt på denne måde men det fungerer egentlig rigtig fint, da hver mødedag dækkede over prædefinerede mødeagendapunkter. Dette gav de enkelte lande mulighed for at prioritere deltagelse, hvis ikke det var muligt at deltage alle dage og gav endvidere mulighed for de enkelte lande kunne have nationale eksperter med til udvalgte punkter på dagsordenen og ved hver dags åbning af mødet blev de enkelte landes "fremmødte" repræsentanter så registreret.

På årets møderække blev igangværende arbejde i de respektive arbejdsgrupper (WG) fremlagt. For indeværende arbejdes der i

- WG4 på ISO 14644-4: Design & Construction,
- WG8 på ISO 14644-8, -9 & -10: Air Cleanliness/Surface Cleanliness,
- WG11 på ISO 14644-18: Assessment of suitability of equipment and materials for cleanrooms/consumables
- WG14 på ISO 14644-17: Particle deposition rate

Desuden skulle der tages stilling til om arbejdet i de hvilende arbejdsgrupper skulle genoptages, hvilket drejer sig om:

- WG2 på ISO 14698 -1 & -2: Biocontamination Control
- WG5 på ISO14644-5: Operations
- WG7 på ISO14644-7: Separative devices

Hvor det for alle 3 områders vedkommende blev besluttet at genoptage arbejdet.

Desuden blev det besluttet at der skulle åbnes en CIB (Commitee internal ballot) med henblik på at vurdere et på mødet fremsat forslag på en guide vedrørende: "General Technical Requirements of Modular Isolation Units for Emergency Medical Use", hvilket jo er yderst relevant pt.

Derudover blev det besluttet at der nedsættes en ad hoc gruppe der skal forestå en undersøgelse af hvorvidt det er nødvendigt at der udarbejdes en Technical Report på uklarheder med hensyn til particle sampling requirements med baggrund i ISO 14644-1 & -2.

Grundet CoViD19-situationen blev det besluttet at afvente stillingtagen til om næste års ISO TC 209 møde skulle afholdes på tilsvarende vis eller om møderne skiftevis fordelt på geografiske områder skulle genoptages

Mødet afsluttedes med vedtagelse af 10 resolutioner på beslutninger og overenskomster indgået over de 4 mødedage.

R³ NORDIC, CTCB-I AND CHALMERS INVITE TO

Cleanroom Testing and Certification 2021

Prel October 2021

Installationsteknik, Chalmers, Gothenburg

The course material is intended for self-study prior to attending the lectures. The content of the course notes, written in English, forms the basis for the lectures. The course notes 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 notes 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 2 years' experience. If you apply for, and have suitable qualifications, you will be required to:

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

Note that certificates on Professional Level are valid for 5 (five) years. Recertification is required in order to maintain certification on Professional Level beyond five years.

CTCB Associate Level - 2 days
Included: Course notes, lecture course, written exam, practical demonstration and lunch both days.
Registration fee: SEK 3 950
Course and exam fee: SEK 11 250

CTCB Professional Level - 3 days
Included: Course notes, lecture course, practical demonstration, written and practical exams, and lunch day 1 and 2.
Registration fee: SEK 3 950
Course and exam fee: SEK 14 500

Exam Re-sit
Upgrading Associate to Professional Level – 1 day
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/exam SEK 3 500

Recertification CTCB Professional Level - 3 days
Included: Course notes, lecture course, 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
ctcb-gothenburg@cit.chalmers.se, +46 (0)703-15 11 55

An Innovation in the Cleanroom Industry.

The Revolve™ line of cleanroom products by Texwipe® (patent pending) is an evolutionary innovation in the way polyester wipers and mop covers are manufactured.

Until the introduction of the Revolve™ line of products, polyester (PET) yarn has always been manufactured from virgin material. In contrast the Revolve™ line of cleanroom consumable products is made from post-consumer polyester (rPET) yarn made by upcycling plastic water bottles.

Texwipe® did extensive research on the performance characteristics of rPET-made polyester compared to virgin polyester material. The rPET materials were processed through Texwipe's manufacturing lines and demonstrated equivalent properties as virgin material.

With these results, a new line of products was born, culminating in the launch of Revolve™ products. All products are made from 100% upcycled polyester material.

The polyester yarn used to make Revolve™ products is dervied from post-consumer bottles. The bottles are collected and sent to the recycling center where they are sorted, cleaned, ground, repolymerized into chip, and extruded to make the REPREVE™ yarn. Texwipe uses the REPREVE™ yarn to make the wiper fabric and then further cleans it to meet Texwipe's standards for the cleanroom industry. Using the upcycled yarn substantially reduces the consumption of natural resources and thus lessen the carbon footprint.

Sex nya bolag till KI Innovations

NORDISKA MEDIER, Erika Lindbom Sierakowiak, november 2020

Vinnova har gett Karolinska institutets inkubatorbolag KI Innovations utökat stöd samt fortsatt förtroende som excellent inkubator för åren 2020–2022. Det har lett till att inkubatorn idag har 23 bolag. De sex nya bolagen är:

Amyloidia utvecklar en ny metod för att detektera peptid- och proteinaggregat på molekylär nivå, samt för att mäta deras storlek och koncentration.

Leira Therapeutics fokuserar på kognitiv beteendeterapi, KBT, för personer med adhd eller psykisk ohälsa.

Molecular Attraction utvecklar lösningar baserade på kemikalieblandningar, som på ett hållbart sätt påverkar beteendet hos djur som kan infektera människor.

Omnious Nanobiosciences / Aplex Bio utvecklar reagens som möjliggör parallell detektion av biomarkörer på ett enkelt och kostnadseffektivt sätt.

Stratipath har fokus på medicin genom AI-baserad precisionsdiagnostik för cancer.

Seqcure Immunology utvecklar en cellbaserad och skräddarsydd immunterapibehandling mot cancer.

Begränsad nytta med munskydd

Av Tobias Bergman, november 2020

Enligt en dansk studie ger munskydd inte nödvändigtvis bättre skydd mot covid-19. I studien som utfördes av forskare från Köpenhamns universitet deltog 4.862 personer. Deltagarna rörde sig utomhus minst tre timmar om dagen under 30 dagar i april. Under Efter 30 dagar hade 1,8 procent (42 personer) av de som bar kirurgiska munskydd smittats av covid-19 och 2,1 procent (53 personer) av de som inte bar munskydd hade smittats. Under perioden som studien utfördes var det få som bar munskydd i Danmark men andra skyddsåtgärder hade vidtagits som rekommendationer om social distansering.

Studien har fått en del kritik bland annat för att den utfördes under en period då smittspridningen var låg i Danmark. Forskarna har endast undersökt om munskydd skyddar bäraren mot viruset men inte i vilken utsträckning munskydd hindrar från att smitta andra. Andra forskare har tidigare nämnt att munskydd skulle kunna minimera mängden virus som man infekteras med och en lägre virusbörda har kopplats till lindrigare symptom i covid-19.

Forskarna i studien menar att munskydd ger ett begränsat skydd eftersom det används på fel sätt, att de inte bärs hela tiden och att vanliga munskydd ger ett tre gånger sämre skydd än kirurgiska munskydd. Munskydden täcker heller inte ögonen vilket kan vara en väg för viruset att ta sig in. I studien angav 46 procent av deltagarna att de inte hade burit munskyddet på rätt sätt. Samtidigt påpekar forskarna att munskydd i vården enligt tidigare studier minskar smittspridning med 50 procent. Desto fler som använder munskydd minskar på stigmat att bära dem och kan öka uppmärksamheten på smittspridningen.

Vetenskapsakademien rekommenderar munskydd

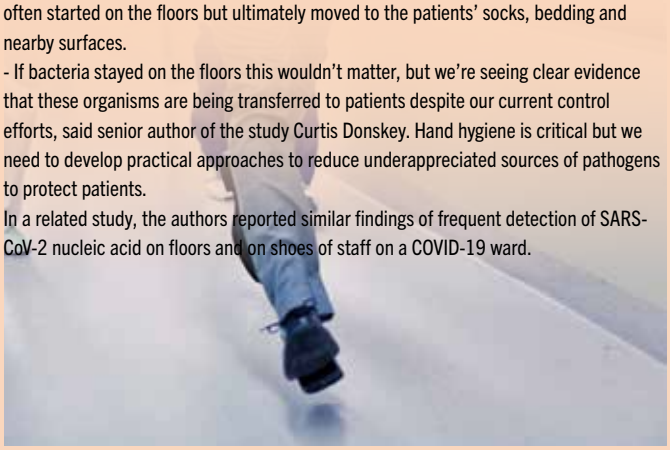
Av Tobias Bergman den 20 november 2020 15:17

Igår släppte Kungl. Vetenskapsakademiens expertgrupp om covid-19 en rapport där de går igenom kunskapsläget om viruset. Nuvarande smittskyddsrekommendationer som går ut på att hålla avstånd och god handhygien baseras på att smittöverföring sker via virusinnehållande droppar som snabbt landar på marken eller ytor.
I rapporten fokuserar expertgruppen istället på luftburen smitta som sker genom att små droppar blir kvar i luften en längre tid om luften inte ventileras. Expertgruppen kommer fram till att det finns belägg för att covid-19 sprids i dåligt ventilerade inomhusmiljöer och att munskydd minskar risken att smittas. De rekommenderar därför god ventilation med luftutbyte och användning av munskydd för att minska smittspridning inomhus men även i kollektivtrafiken och särskilt inom sjuk-och äldrevård.
Expertgruppen har inte hittat något belägg för att munskydd skulle öka smittspridningen till exempel genom ökat riskbeteende.
– Det finns i dag nya experimentella och epidemiologiska belägg för att munskydd minskar risken för luftsmitta men inga för att de skulle ha motsatt effekt. Vi anser att de skärpta restriktioner som regeringen gått ut med nyligen är bra och det är oerhört viktigt att alla följer dem. Men för att nu snabbt få ner smittan behöver vi använda alla verktyg i verktygslådan, och dit hör munskydd och ventilation, säger Staffan Normark, professor i molekylär mikrobiologi och smittskydd samt ordförande för expertgruppen om Covid-19, i ett pressmeddelande.

Hospital floors – a hot spot for bacteria

Report - ECJ (europeancleaningjournal.com)

Researchers at the Cleveland VA Medical Centre in the US closely tracked contamination levels in rooms occupied by 17 newly-admitted patients. Each of the rooms were thoroughly cleaned and sanitised and the patients were screened for MRSA plus other healthcare-associated bacteria before the environments were tested.
The floors of a hospital room can become contaminated with antibiotic-resistant bacteria within hours of a patient's admission, according to a study. There is clear evidence to suggest that such organisms may be transferred to the patients despite efforts to prevent this, claims the author. Researchers then observed patients' interactions with healthcare staff and portable equipment, collecting cultures from their socks, beds and other high-touch surfaces as well as the floor.
Within 24 hours, surfaces in nearly half the rooms had tested positive for MRSA. And within four days of admission, MRSA, C. difficile and vancomycin-resistant enterococci (VRE) pathogens were identified in 58 per cent of the patient rooms. Contamination often started on the floors but ultimately moved to the patients' socks, bedding and nearby surfaces.
- If bacteria stayed on the floors this wouldn't matter, but we're seeing clear evidence that these organisms are being transferred to patients despite our current control efforts, said senior author of the study Curtis Donskey. Hand hygiene is critical but we need to develop practical approaches to reduce underappreciated sources of pathogens to protect patients.
In a related study, the authors reported similar findings of frequent detection of SARS-CoV-2 nucleic acid on floors and on shoes of staff on a COVID-19 ward.



4.000 kvm med Covid-19-vaccin

Fastighetsvärlden (fastighetsvarlden.se. Text: Philip Wallin

Har vi ett corona-vaccin på gång? 4.000 kvm står i alla fall redo i Tomtebod för paketering och logistik av vaccinet med start under första kvartalet 2021. Valneva Sweden, ett dotterbolag till vaccinföretaget Valneva SE, har tecknat ett tioårigt hyresavtal om cirka 4.000 kvadratmeter – i den gamla postterminalen Tomteboda i södra Solna.

I den tidigare spårhallen i Tomteboda planerar bolaget att fylla vialer, det vill säga små flaskor, med Covid-19- och koleravaccin samt distribuera paketerad produkt. Fastigheten, som uppfördes 1983 av Postverket, ägs sedan fem år av Blackstone och Areim. JLL har haft uthyrningsuppdraget. Inflyttning är planerad under första kvartalet 2021. När Valneva Sweden flyttar in gör de bland annat Myndigheten för samhällsskydd och beredskap (MSB), Thorengruppen med fyra skolkoncept och PostNord sällskap. Under 2021 flyttar även SL in.
– Vi är mycket stolta och glada över att ha tecknat ett långsiktigt hyresavtal med Valneva Sweden AB. De har en gedigen historia inom sitt verksamhetsområde och vi ser fram emot att välkomna dem till Tomteboda. De passar väl in i den mix av hyresgäster som vi vill ha här, säger Morten Wettergreen, head of asset management på Obligo Real Estate i Sverige med ansvar för den övergripande utvecklingen av Tomteboda.

Valneva SE driver ett globalt vaccinprojekt för Covid-19 – förhoppningen är att de ska ha ett vaccin redo till 2021. API, Active Pharmaceutical Ingredient, produceras i Valnevas anläggning i Skottland och skickas till Sverige. Fyllning av vialerna samt slutlig packning och logistik av vaccinet kommer att hanteras av Valneva Sweden AB i de nyrenoverade lokalerna i Tomteboda.

Welcome Waters!

By Jamie Smith - October 2020

Waters Corporation announced it has established a team in the AstraZeneca BioVentureHub in Gothenburg, Sweden. By locating in the AstraZeneca BioVentureHub, the dedicated team of 7-10 Waters analytical technology specialists will interact closely with AstraZeneca scientists to catalyse innovation opportunities in analytical science.
* Waters and AstraZeneca already have a close collaboration when it comes to specialty measurement tools and technologies.
* The co-location at the R&D Gothenburg site, brings together Waters and AstraZeneca scientists in analytical science, software development and systems integration.
* Being based in the BioVentureHub will help to promote collaborative effectiveness and shared best practices that will influence the joint development of next generation instrumentation and data analysis tools.
Anders Holmén, Vice President and Head of Pharmaceutical Sciences, R&D, AstraZeneca, says, "At AstraZeneca, we are continuously building and investing in scientific capabilities and technologies with the aim of advancing science and achieving the next wave of breakthroughs. Having Waters' know-how and expertise close at hand in the BioVentureHub will help us accelerate the design and delivery of innovative analytical systems and workflows.

Facility of the Year

ISPE's Facility of the Year Awards program honors pharmaceutical industry projects that leverage technology and innovation to improve the quality of products, optimize production costs for high-quality therapies and forge advances in project delivery. ISPE announced Sanofi as the 2020 FOYA Overall Winner at the 2020 FOYA Banquet during the virtual 2020 ISPE Annual Meeting & Expo. Sanofi, the 2020 FOYA Facility of the Future Category Winner, won for its Digitally Enabled Integrated Continuous Biomanufacturing Facility in Framingham, Mass., in the US.

Sanofi is the 2020 Facility of the Year Award Winner for Facility of the Future **for t**heir Sanofi Digitally Enabled Integrated Continuous Biomanufacturing Facility in Framingham, Massachusetts.
Projects selected for the Facility of the Future Award have applied or implemented innovative design concepts, new technologies, and unique solutions that exemplify the next generation of agile, flexible, efficient, and effective Life Sciences facilities.

Sanofi pushed the concepts of digitization to fully integrate process control, data collection, and analytics and built a fully integrated bioprocessing facility that takes the application of disposable process technology and flexible facility design to a new level.

R³ NORDIC INVITES TO

EHEDG Advanced Course in Hygienic Engineering & Contamination Control

9th - 11th of March 2021

FORCE Technology, Copenhagen, Denmark

AIM

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

PARTICIPANTS

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

CONTENT

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

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

REGISTRATION

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

The prices are excl. VAT.'

FURTHER INFORMATION

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

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

CANCELLATION POLICY

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

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

THE COURSE TRAINERS ARE

Alan Friis, Ferdinand Schwabe and Gun Wirtanen.

Tuesday 9th of March 2021

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

Wednesday 10st of March 2021

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

Thursday 11th of March 2021

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

MARKNADSGUIDE

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NINOLAB, AB (SE)
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Tel 08-59096200 / cja@ninolab.se

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

MIKROBIOLOGI STERILISTERING

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Peter Holmberg
Tel 040 900 4620 / peter.holmberg@getinge.fi

MICLEV AB (SE)
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Tel 040-365400 / info@miclev.se

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

RENRUMSKLÄDER TEXTILIER TVÄTTNING

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