Renhets TEKNIK

THE NORDIC JOURNAL OF CONTAMINATION CONTROL AND CLEANROOM TECHNOLOGY NR 2:2021

Five presentations from Webinar regarding Hospital Environment

- INTERNATIONELLA NYHETER
- NYHETER FÖRETAG & PRODUKTER
- MARKNADSGUIDE

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OMSLAGSBILD / COVER: Hosptial Environment / Operation theatre
FOTO: Friköpt bild från Stock Photo, Ingimage (AJ Consulting)

ORDFÖRANDE HAR ORDET

Kære medlem

Så står sommeren for døren. Endnu en sommer hvor coronaen, i hvert fald i et vist omfang sætter dagsordenen for vores udfoldelsesmuligheder og udfordrer kreativiteten (og måske også tålmodigheden) hos os hver i sær.

Teams er blevet den "nye vej frem" til afholdelse af alt fra møder og kurser til festlige virksomhedssammenkomster og (stor) familiemiddage.

-Men heldigvis for det, for så falder det os så meget lettere at opretholde forbindelsen på alle måder og i alle situationer.

R³ Nordics første online Symposium blev afholdt via Teams i Maj, med mange rigtig interessante indlæg. Så selvom det desværre ikke var muligt at mødes fysisk som vanligt, så var det en jo en glimrende måde at få formidlet viden på.

TAK GUN

Så samme vis har R³ Nordic holdt årsmøde. Ved denne lejlighed valgte Gun Wirtanen at fratræde betyrelsesarbejdet og Jukka Varsara tiltrådte bestyrelsen som ny finsk repræsentant.

Der skal lyde en stor tak til Gun for hendes mangeårige virke i R³ Nordics bestyrelse

Forhåbentlig varer det ikke længe før end vi kan komme i gang igen med og vedblive at afholde fysiske events. Indtil da må vi fornøje os på anden vis, eksempelvis ved læsning af nogle af de mange fine artikler her i Renhetsteknik.

Med ønsket om en dejlig sommer til alle.

Lene Blicher Olesen, ordförande

R³ NORDICS VALDA FUNKTIONÄRER 2021

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THANK YOU GUN!
Roses to Gun Wirtanen for her great comitment during many years within the R³ Nordic!

KALENDER

2021

Okt

12-13 CTCB-I certifiering, Associate level, Göteborg

12-14 CTCB-I certifiering, Professional level, Göteborg

26-28 EHEDG - Engineering and Contamination Control
Force Technology, Brøndby, Denmark

Nov

? Sjukhusdagar, Sverige
Plats och datum meddelas senare

Nästa nummer
beräknas utkomma den 13 september

Manusstopp / Annonsbokning:
17 augusti

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

REDAKTÖRENS SPALT

Dear R³ member

The current issue of RenhetsTeknik (RT) marks the start of four thematic issues, where we have focus for the on-line webinar to be held on May 19th and 26th 2021. The editorial board of RT is pleased that many of the speakers from the online webinar have accepted the invitation to submit a paper for publishing in our journal. The papers all pertain to cleanroom technology and are divided in two batches the first addressing hospital applications and the second on pharmaceutical industries.

NEXT ISSUE

From the next issue we also launch the upstart of publication of papers related to hygienic performance and quality of product contact surfaces. The idea is to bring one or two papers per issue depending on content and interest to publish such papers in RT. Papers may focus on engineered surface properties, relationship between topography and cleaning efficiency, anti-microbial surfaces, material composition, manufacturing technologies etc. We will also take a deeper look at some the commercial products available on the market and set up a small panel of experts to assist in a fact finding mission on the topic of surfaces and materials that claim to have improved hygiene features.

As usual we have collected relevant company news as wells as news and highlights from international work, new guidelines as well as information on relevant training courses.

JOIN THE EDITORIAL BOARD

We still have an open invitation for members of R³ to join the RT editorial board. The RT editorial board seeks new members to join us to make RT even better. Mainly we need more ideas about papers or themes for future issues, but all ideas are welcome. Your contribution need not be large, and you can decide yourself how much time you spend on this aside from our four short meetings.

Finally, I would like to wish you all a good summer and I hope that we will return to physical meetings in the autumn.

ALAN FRIIS
REDAKTÖR

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

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

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

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WEBINAR

Five presentations regarding Hospital Environment

On May 19th & 26th 2021 R³ Nordic held an online symposium based on some of the presentations originally intended to be given at postponed 2020 symposium. The presentations coved the use and applications of cleanroom technology and contamination control in hospital and pharmaceutical environments.

The Program Committee 2021-22 (PK21-22) has finalized the program for the two webinar days. The first webinar on 19th of May 2021, the program dealt with cleanroom solutions in hospital environments. On the second day, 26th of May 2021, the program focuses on cleanroom solutions for the pharmaceutical industry.

In collaboration with the Program Committee we at Renhetsteknik are happy to be able to bring full papers from selected presentations. The papers will be brought in this and the next three issues of Renhetsteknik. The first two focusing on cleanroom solutions in hospital environments and the later two focusing on cleanroom solutions for the pharmaceutical industry.

In this issue we present the following five presentations:

- **Factors influencing cleanrooms and operating rooms** by VILLE ALANEN, JUKKA VASARA, ALEKSANTERI SETÄLÄ, GRANLUND OY
- **Control of anesthetic gases and diathermy smoke in the operating theater** by PERTTU KARJALAINEN, GRANLUND OY
- **Development of a Technical Specification for ventilation in medical locations** by TRAVERSARI, A.A.L., NETHERLANDS ORGANIZATION FOR APPLIED SCIENTIFIC RESEARCH, DEPARTMENT OF BUILDING PHYSICS AND SYSTEMS, DELFT, THE NETHERLANDS & SAURWALT F., KROPMAN INSTALLATIEKECHBNIEK, NIJMEGEN, THE NETHERLANDS
- **Pass Through Boxes design and performance testing. Fundamental physics applied for adequate contamination control** by IR. FRANS SAURWALT, TECHNICAL MANAGER AT KROPMAN, CONTAMINATION CONTROL, THE NETHERLANDS
- **Room air distribution strategies in hospital isolation rooms** by PETRI KALLIOMÄKI & HANNU KOSKELA, TURKU UNIVERSITY OF APPLIED SCIENCES, BUILT ENVIRONMENT RESEARCH GROUP, FINLAND

Factors influencing cleanrooms and operating rooms

VILLE ALANEN, JUKKA VASARA, ALEKSANTERI SETÄLÄ · GRANLUND OY

As is well known, several factors affect the particulate matter concentrations of indoor air in cleanrooms and operating rooms. The room must be properly pressurised to prevent unclean external air from entering when the room doors are opened. Ventilation of the room must be efficient enough to allow particles to be quickly removed from the indoor air so that they do not come into contact with clean material or the patient. The supply air must be HEPA filtered so that most of the harmful particles remain in the filter and do not end up in the indoor air. The surfaces of the room as well as all equipment and instruments must also be well cleaned. The number of people involved in the operation also affects cleanliness, as in a properly functioning operating room, people are the most significant source of impurities.

VENTILATION FOR HOSPITALS, NEW TECHNICAL SPECIFICATION

A new draft European standard (technical specification) defines performance levels for operating room cleanliness. The standard also provides guidance on how the design and construction process should be implemented to achieve the desired end result. In the future, operating rooms will be classified as CL-1 and CL-2. Class CL-1 is for facilities with a particle concentration of less than 10 CFU/m^3 and Class CL-2 is for operating rooms with a particle concentration of 10–100 CFU/m^3. In the CL classification, notation 'a' denotes laminar air distribution and notation 'b' denotes mixing air distribution.

THE ROLE OF CLOTHING

Clothing plays a crucial role when it comes to particle concentrations of the air in operating rooms. The better we are able to isolate human particle-producing skin from the indoor air of the operating room, the better the outcome. The purpose of the clothing is to protect the patient from dandruff, secretions and other particles from the wearer, which may also contain bacteria or other microbes. The clothing protects the wearer from the patient's blood and secretions. Surgical operations can take hours, so the conditions for surgical staff need to be as comfortable as possible. Clothing should keep the person warm and prevent sweating and the wearer from getting hot so that they can perform challenging operations.

There have been no major changes in the appearance of operating room garments in recent years, but the materials used in them have evolved, enabling better fit, comfort and filtration efficiency. With the improvement of manufacturing and material technology, cotton clothing has been almost completely eliminated. It has been mainly replaced by clothing made of microfibre and other man-made fibres. The advantage of man-made fibres over cotton is the better breathability of the garments, which means they are more effective in removing moisture from the skin. In addition, the amount

of textile fibres released into the room air by microfibre is considerably lower, resulting in a significant reduction in airborne particles. The introduction of man-made textile fibres has also made it possible to develop more cost-effective and more environmentally friendly clothing, as clothes can be washed more than once without losing their properties.

SIMULATED MEASUREMENTS ACCORDING TO SFS-EN 13795-2:2019

On 3 December 2019, the Helsinki University Hospital District (HUS), Uusimaa Hospital Laundry, Halton and Granlund jointly carried out simulated surgical operations in the Halton test operating room, the results of which were analysed in accordance with the standard SFS-EN 13795-2:2019. The operation type was simulated operation with the exception that there were only four measurement rounds. Ten people were present in the measurements, the airflow rate per person was 180 L/s and the ventilation coefficient was 36 1/h. All measurements produced an end result that was in the CL-1b class, with measurements for the entire operating theatre being 2–3 CFU/m³. Based on the measurements, a source strength value of less than 1 CFU/s was obtained for the clothing used. From the measurements, it can be concluded that the desired CL-1-class cleanliness can be achieved for the operating room with proper ventilation (with appropriate design, capacity and implementation), well-sealed and hygienic structures and proper clothing of the operating room staff.

Photo: Ismo Grönvall, Halton Oy

OPERATING ROOM MEASUREMENTS

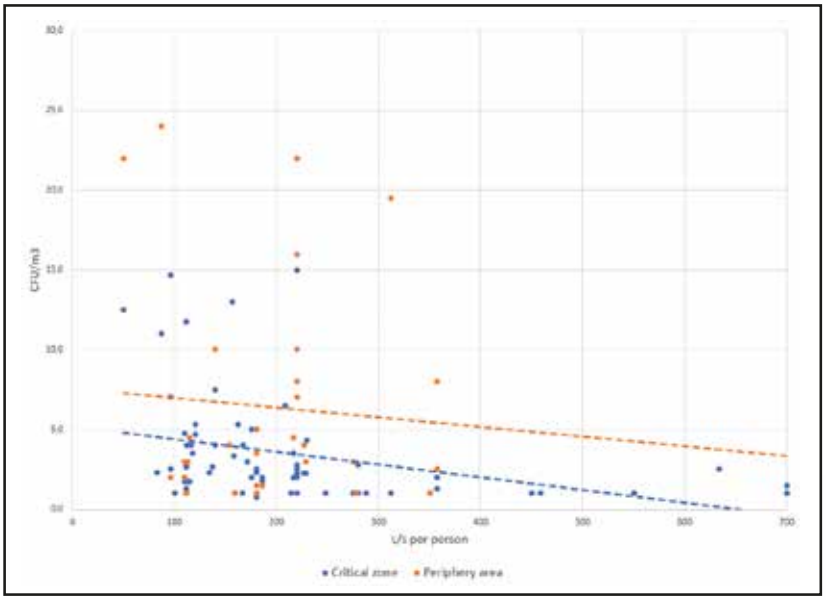
In recent years, there has been more than 70 measurements carried out on operating room air cleanliness. The measurement results show that the computational basis presented in the new draft standard is sound. With respect to clothing, microfibre-based clothes were worn in almost every case. Of particular importance was the protection or non-protection of the neck and face. Inadequate protection was negatively reflected in the results, increasing the amount of particles in the indoor air. According to the measurement results, when the airflow rate in the operating room is more than 200 L/s per person, results of less than 5 CFU/m3 are almost invariably achieved when considering the results from the critical zone close to the operating table.

Only a small average increase in the particle concentration in operating rooms with mixing air distribution was observed when considering the measurement results of the critical zone and the whole operating room. The measurement results that resulted in the CL-2 class were from operating rooms with ventilation rates less than 220 L/s per person. These CL-2 class measurement results were found to be caused by inadequate filtration levels, too low airflow rate, sub-optimal airflow implementation and inadequate protective equipment for personnel.

In the case of operating rooms with laminar ventilation, the CL-1a class was reached in all measured cases, with measurement results from the critical zone being less than 5 CFU/m³. With one exception, the airflow in the operating rooms was more than 160 L/s per person. Regarding the measurement results of the entire operating room, the rooms with laminar air distribution all achieved the CL-1a class.

CRITICAL ZONE AND PERIPHERAL AREAS

The measurement results obtained from the critical zones show that with an airflow of more than 220 L/s per person, the cleanliness level of class CL-1 is achieved in all cases. There are significantly fewer measurement results for peripheral areas due to the fact that the duration of the operations was not always sufficient to carry out more measurements. For operating rooms with measurement results from both critical zones and peripheral areas, the average of the measurement results from the critical zones was 3.3 CFU/m³ and the average of the results from the peripheral areas was 6.4 CFU/m³. Broken



down into laminar and mixing ventilation rooms, these rooms resulted in a critical zone value of 1.7 CFU/m³ and a peripheral area value of 4.8 CFU/m³ for the laminar ventilation rooms, and a critical zone value of 4.2 CFU/m³ and a peripheral area value of 7.4 CFU/m³ for the mixing ventilation rooms. When looking at the results from the critical zone, the airflow L/s per person vs the microbial concentration CFU/m³ gives almost the same ratio between the different air distribution methods.

The diagram to the left shows how increasing the airflow rate per person affects the measurement results obtained. The results for the critical zone and the peripheral area are shown in different colours.

CONCLUSIONS

The measured airflows in the operating rooms with laminar ventilation are on average two times higher than in the rooms with mixing ventilation. The same ratio is reached when considering the following figures: airflow (L/s), ventilation coefficient (1/h) and air change rate per person (L/s). The same ratio is inversely reflected in the CFU/m³ results. The CFU/m³ value for operating rooms with mixing ventilation is twice that of operating rooms with laminar ventilation.

Based on these figures, we can conclude that the CFU/m³ concentration in the operating room is more dependent on the airflow rate than on the air distribution method.

Control of anesthetic gases and diathermy smoke in the operating theater

PERTTU KARJALAINEN, GRANLUND OY

Local extraction systems (LEV) are commonly used in various industrial processes where it is necessary to protect staff from air pollutants like dust, smoke or chemical fumes generated in the process. There are not many studies about the health effects of pollutant emissions from hospital surgical operations and the LEV used to eliminate these. Although operating theater staff may be momentarily exposed to high levels of contaminants in their work, no authority yet requires the use of LEV in operating theaters. The multinational working group CENTC156-WG18 is preparing a European CEN standard for hospital ventilation, which will define the minimum requirements for the design, installation, classification measurements, operation and maintenance of a ventilation system.

HARMFUL CONTAMINANTS IN THE INDOOR AIR OF THE OPERATING ROOM

During the surgical operation, various harmful emissions are released into the air of the operating room, to which the people working in the operating room are exposed daily. These include anesthetic gases used in the patient's anesthesia and smoke from electrosurgery. The diathermy is a form of electrosurgery where tissue is vaporized with a high-frequency electric current and it is currently used in almost every surgical operation. Diathermy smoke contains a lot of chemicals and small particles that are harmful to health and can enter the bloodstream through respiration [1]. There are no data on the long-term side effects of smoke, but several studies compare exposure to smoke to passive smoking. Of the anesthetic gases used for anesthesia, nitric oxide has been shown in studies to have adverse effects on reproductive health and other commonly used substances are expected to have similar effects [2] [3]. Exposure to anesthetic gases can also cause immediate side effects, such as headache, dizziness or shortness of breath. [4]

A STUDY OF THE LOCAL EXHAUST VENTILATION SYSTEMS IN FOUR HOSPITALS

The research for the thesis investigated the usability and efficiency of the systems in use [4]. The study interviewed HVAC experts and operating theater staff in four hospital districts about smoke and anesthetic gas removal systems and related practices during surgery. The interviews revealed that the use of smoke extraction systems has only become more common in recent years. Smoke extraction uses local exhausts integrated or attached to the diathermy instrument. Such solutions are effective in reducing smoke exposure [5]. In the past smoke

has caused headaches and respiratory irritation, among other things, but because smoke extraction becoming more common, these symptoms have become less common. The use of anesthetic gases for anesthesia has decreased during the 21st century and techniques that reduce gas leakage in the first place have evolved. Anesthetic gases are usually removed from the anesthesia machine to an exhaust duct of general ventilation or with a separate central suction system. Two hospitals used stemmed hoods to eliminate gas leaks from anesthesia in operating theaters where more leaks occur due to the nature of the operation. However, these hoods currently in use are large and positioned so that they can rarely be brought close enough to the leaking point Some hospitals use anesthesia masks with integrated leakage removal suction, but their use is considered tricky due to their heavier structure.

MODELING OF IMPURITY CONCENTRATION USING BALANCE EQUATIONS

As a part of the study, indoor air pollutant concentrations were modeled by simple mass balance calculations. The calculation examined the effect of LEV on the required outdoor air flow to keep the anesthetic gas concentrations within the given limit values. The effect of smoke on the indoor air of the operating room was examined based on smoke particulate emissions. The leakage flow used to calculate anesthesia gas concentrations was an estimate of a typical gas leak during anesthesia maintenance. This estimate was obtained from operating theater staff interviews. Based on the calculations, a correctly placed LEV can significantly reduce the required amount of outdoor air flow in the operating room. According to the calculations, the particulate emissions from the use of diathermy are not very significant in terms of the concentration of particulate matter in the indoor air of the operating room, as the particulate emissions caused by the persons working in the operating room are much higher. However, the calculations were limited to a specific particle size range, and previous studies have shown that only about 30% of the smoke from the use of diathermy is in the particle size range under consideration. The mass balance calculation models a situation where the contaminant is completely spread into the indoor air and the concentration is the same throughout the space. In this case, therefore, this calculation model does not give a true picture of staff exposure, as the sources of impurities in the operating room are point-like and the concentrations of the resulting impurities in their vicinity are significantly higher compared to the rest of the space. Contaminant concentrations in the personnel's respiration zone could be examined in more detail, for example by CFD modeling.

DEVELOPMENT OF LEV SYSTEMS IN OPERATING THEATER

In conclusion, based on the research there is a lot of room for improvement in the implementation and use of LEV systems. Although there is yet no evidence of long-term health effects of exposure to diathermy smoke or anesthesia gases, the use of LEV's can be justified by significant improvements in work comfort. When designing a LEV system, it is important to consider the purpose of the operating room and the type of operations performed there. The staff working in the operating room want solutions that reduce exposure, as well as better practices and guidance ?on the use of the equipment.

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Development of a Technical Specification for ventilation in medical locations

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SAURWALT F., KROPMAN INSTALLATIEKECHBNIEK, NIJMEGEN, THE NETHERLANDS

ABSTRACT

The scope of this new TS develop within CEN Technical Committee 156 is ventilation in medical locations and applies to all healthcare premises where healthcare services are delivered. It is applicable for medical locations such as 'Healthcare premises' and 'Medical Centres', where clinical and health-related services are provided including specific risk areas. It will be a decision of an individual member state, who may decide, on national level, whether or not to adopt and publish it on national level (such as SS-CEN / TS), refer to parts of this TS form a national standard and/or add specific requirements if needed.

This TS is intended for project managers, designers, construction and commissioning engineers, estates managers and operations/ facilities managers and provides defined levels of air quality/cleanliness and comfort for these areas. This new technical specification addresses the requirements for ventilation systems. It specifies the design, installation, operation, verification process, maintenance and reverification of the ventilation systems.

The TS describes the following issues related to the ventilation system:

a) protection of patients, staff and visitors against biological and other harmful agents;
b) reducing the growth of microorganisms (e.g. clean-ability, accessibility, wet surfaces, accumulation of particles);
c) air quality (e.g. cleanliness levels, temperature, humidity, air quantity, thermal comfort);
d) control of the airflow direction (e.g. tightness of systems and constructions, pressure difference).

The TS provides requirements for the ventilation systems on the level of:

- user requirement specification (URS),
- functional design requirements (FD)
- requirements for components in the detailed design (DD)

It focuses on general medical location and on operating suits and isolation rooms.

An important part of the TS is the organization of design, construction and operation. This shall be a structured approach based on a user requirement specification, functional design, detailed design as well as on a installation verification, operational verification and performance verification. During the operational phase the maintenance process, documentation and reverification are important aspects.

For operating rooms 2 cleanliness levels are divined. These cleanliness levels are in principle independent of the ventilation principle used. Both ventilation principles (diluting mixing and Unidirectional air flow) can be used for these cleanliness levels. However, for the different cleanliness levels other test methods are applicable. For the performance verification microbiological test may be used.

For Isolation rooms the TS deals with airborne isolation only. Based on this the airflow direction and pressure differences are of less importance in the new TS. The requirements of isolation rooms are now more based on the recovery time in the room and airlock. The following types of isolations are included in the TS:

- Source isolation
- Isolation level SA - Normal/Typical risk
- Isolation level SB - High/unknown/hidden risk
  - Protective isolation
  - Combined isolation

To make the TS as flexible as possible and align it as much as possible with national circumstances specific issues/requirements shall be decided on national level. This way the TS can also be used in support of national practices and national requirements. Member States can decide to add any additional national requirements by introducing a National Annex, which is an informative Annex, to a published CEN/TS.

The draft TS will be ready for format vote in the beginning of 2021.

INTRODUCTION

Within Europe some countries have national guidelines of even national standards like the HTM-03, DIN1946-4, Önorm, KWK for air handling and ventilation systems in hospitals.1–5 Other countries however do not jet have such a guideline or standard. To harmonize the requirements as much as possible CEN Technical Committee (TC) 156 "Ventilation for buildings" established a working group to create an European technical specification for ventilation in hospitals. A Technical Specification (CEN/TS), serves as normative document in areas where the actual state of the art is not yet sufficiently stable for a European Standard. The Technical Specification is announced and made available at national level, but conflicting national standards may continue to exist.

A Technical Specification may compete against another Technical Specification with the same scope, but a Technical Specification may not conflict with a European Standard.

CEN introduced the Technical Specification to provide an 'appropriate' consensus/transparency solution to a market need where there is no immediate need for national implementation and withdrawal of conflicting national standards.

The Technical Specification can act as a pre-standard, but it can also be accepted that the 'appropriate consensus' represented by the Technical Specification could continue to meet a market need without eventual conversion into an EN.

A Technical Specification may be established with a view to serving for instance the purpose of:

- publishing aspects of a subject which may support the development and progress of the European market but where a European Standard is not feasible or not yet feasible;
- giving guidance to the market on or by specifications and related test methods;
- providing specifications in experimental circumstances and/or evolving technologies.

In this working group approximately 16 member states (27 experts) joint efforts to come to consensus and write the TS. This is a very difficult and intensive process because the different member states have different histories and views on ventilation is hospitals. Some Member States believe that only a UDF system in operating theaters can adequately protect patients, while other Member States are more open to other solutions. In addition, some Member States want to prescribe on a detailed technical level what a system should look like. Other Member States want to focus more on the final performance of systems.

The TS has not yet been established within the working group. Everything presented in this manuscript and presentation are lines of thought that may still be subject to change. Therefore no rights can be derived from the manuscript or presentation.

DESIGN PROCESS

Healthcare ventilation systems shall be handled with great attention. The systems shall be specified, designed, detailed, constructed, commissioned, verified and maintained; in order to make sure the ventilation systems will provide the required indoor environment for performing healthcare services. Relevant contamination control principals shall be taken into account.

Depending on the nature of the project the stages can be combined and executed in one step.

The TS describes the designing, constructing, verifying and operating a ventilation system for hospitals in which the responsibilities of the various parties are indicated, Figure 1 and Table 1.

In the opinion of the experts, this process is not yet being carried out completely unambiguously and is to guarantee the desired quality of the ventilation system in hospitals. This process is frequently applied in the pharmacy, for example the Good Manufacturing Practices (GMP).

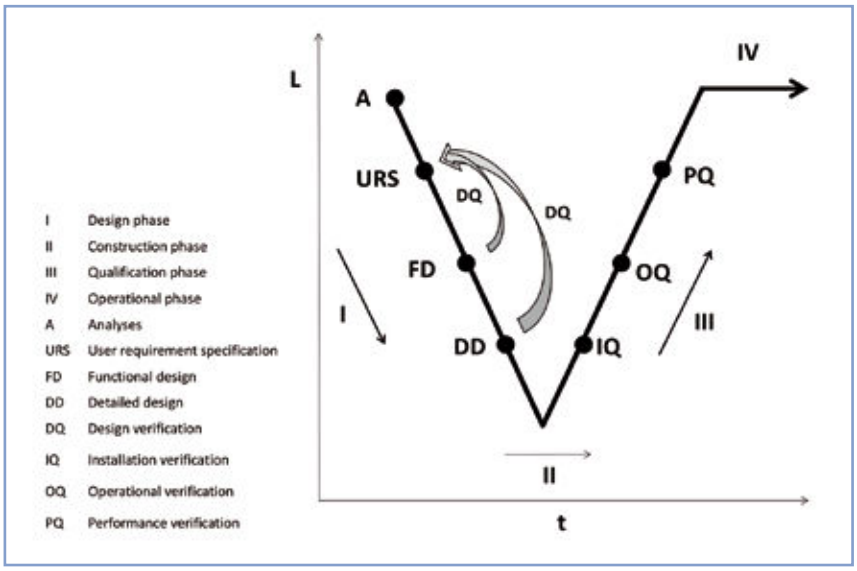

Figure 1. Process.

Project phase	Project Step	Objective	Responsible party (informative)
Design phase (I)	0. Analysis	Determination of actual condition and establishing the basis for the project	Consultant
	1. User requirements specification (URS)	Definition of project targets in terms of specifications specifications of the system as well as functional, operational and/or technical aspects of the system required to realise the desired air quality	Client (responsible duty-holder)
	2. Functional design (FD)	Translation of user requirements specification into specification of the functions of the components of a system and of the working relationships among them	Design team
	3. Detailed design (DD)	Translation of the user requirements specification and functional design into drawings, data, calculations and specifications from which constructed works, components and assemblies can be constructed	Design team
	4. Design verification (DV)	To verify that the proposed design of the facilities, systems and equipment is suitable for the intended use based on the URS	Client (responsible duty-holder)
Construction (II) and	5. Realisation	a) Application of URS; b) Documentation of the system.	Contractor
Verification (III) phase	6. Installation verification (IV)	To ensure that the equipment has been provided and installed or modified, in accordance with the approved detailed design and the manufacturer's recommendations	Contractor observed by the Client (responsible duty-holder)
	7. Operational verification (OV)	To ensure that the facilities and the ventilation systems, as installed or modified, perform as intended throughout the anticipated operating ranges based on the functional specifications	Contractor observed by the Client (responsible duty-holder)
	8. Performance verification (PV)	To ensure that the facilities and ventilation systems, as connected together, can perform effectively and reproducibly based on the URS	Client (responsible duty-holder)
Operation and maintenance phase (IV)	9. Operation and maintenance	a) Training of personnel; b) Updating and supplementing of the system and its documentation; c) Maintenance management; d) Disposal of consumables.	Client (responsible duty-holder)
	10. Reverification	a) Reverification; b) Optimisation of operation.	Client (responsible duty-holder)
NOTE 1	*The installation verification (IV) can start during the construction phase specially for components and systems that are concealed by structural facilities or are hard to access at a later time.*		
NOTE 2	*Performance verification is performed after the system is handed over to the end user. It does not form part of the legal transfer of the system between the client and contractor*		

Table 1. Design, construction and operation process.

DIFFERENT WAYS TO ACHIEVE THE FINAL GOAL

As in most countries who have a guideline or standard for ventilation of operating rooms (OR) different ventilation classes are divined. In the TS only the requirements are given and it is up to the medics to define the type of procedure where the ventilation class is suitable for.

For ORs 2 ventilation classes are defined, CL-1 and CL-2, Table 2.

CHOICES FOR THE MEMBER STATES

For the aspects there no consensus between the member states regarding the requirements was reached choices are open. This is because the situation in health care premises can be quite different due to national building codes, building or health care tradition and other matters that cannot be changed immediately. The choices are collected with a limited number of options. The annex can be used when prescribing the TS in a private contract, the parties can then agree on the choices. The annex can also be used as a basis for a national annex, or for national/regional legislation or regulations.

Choices can be made regarding:

- Size of the critical area (m2)
- Final filter grade (H13 or H14 for CL-1 and CL-2)
- Minimum relative humidity
- Minimal amount of outdoor air (ODA)
- Test method for the segregation test (National methods)
- Performance verification (Active or passive sampling)

Table 2. Ventilation classes.

Ventilation Class	Type of airflow	Supply air quality (SUP)	Flow direction	Sound level of the ventilation system** dB(A)	Performance quality (At rest) (ref. section 5.4.3)	Comment	Operational Performance (ref: 5.5.4)
CL-1a	UDAF	SUP 1*) + H13 or better	Outward flow from clean to less clean	≤48	ISO 5 Segregation	Additional required air to achieve the performance can be SEC	CZ ≤ 10 cfu/m^3 Per ≤ 50 cfu/m^3
CL-1b	DMAF				ISO 5 rec ≤ 10 min		CZ ≤ 10 cfu/m^3 Per ≤ 50 cfu/m^3
CL-2	DMAF			≤45	ISO 7 rec ≤ 20 min		≤ 100 cfu/m^3

UDAF = UniDirectional Air Flow
DMAF = Dilution Mixing Air Flow

** Comments to SUP (EN 16798-3):*

1) Supply (SUP) can be supported by secondary (SEC) of equal quality. SUP, SEC and extract (ETA) air in ventilation systems shall be designed, controlled, operated and maintained such that unacceptable contamination e.g. by inorganic or organic substances, harmful gases within the system, are controlled.

2) Extract air (ETA) from healthcare premises is defined as ETA 2 "Extract air with moderate pollution level" or a higher pollution level according to EN 16798-3.

3) Recirculation of air and mixed air (RCA, MIA according to EN 16798-3) are only allowed in medical locations where:
a) the ventilation system serves only one room secondary air (SEC, according to EN 16798-3);
b) the ventilation system employs overflow to a set of associated rooms (air-locks /-ante rooms)

** *According to EN-ISO 16032*

*** *See section 5.5.2 for specifics*

**** *See for complete performance specifications section 5.4.3*

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Pass Through Boxes design and performance testing

Fundamental physics applied for adequate contamination control

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Wherever cleanrooms are used, items need to be transferred into and out of the processing rooms. Although common in pharmaceutical facilities, especial autologous ATMP facilities do require extensive application of pass through boxes to provide transfer of materials without the need for personal access. The design of pass through boxes can vary widely relative to the application. The EU GMP Annex 1 revision states it does not recommend not active ventilated pass through boxes.
Various forms of active, combined and passive ventilated types can be evaluated.
As contamination control performance aspects like flow/pressure cascade, order of magnitude of the cleanliness transition from less clean to cleaner or clean to less clean are considered. For a typical GMP / ATMP cleanroom situation a design study, proof of concept tests and qualification tests of a 'continues flow' pass through box in an actual project show it capable of effectively recovering 100:1 within 2 minutes after opening at the less clean side.

INTRODUCTION

The transfer of personnel and materials in and out of cleanrooms are a common concern in the design and operation. Transfer implies there is a transition from one cleanliness level to another one, as there apparently are separated rooms that require the transfer.

Transferring of personnel nor large materials nor continues process feeds are covered in this article. The topic to address is the transfer of materials via pass through boxes (PTB's).

PTB's are generally known and used in cleanrooms. They play a role in a number of functions: 1) They allow materials to be transferred, 2) they provide a barrier between the two adjacent clean rooms, 2) they protect the cleaner clean room against ingress of less clean air during the transition.

Commonly a PTB consists of a space within two interlocked doors, so only one door can be opened at the time.

APPLICATIONS

PTB's can be seen in many applications. The use of them and the required dimensions and volume largely depend on the scale of the operation the cleanroom is used for.

The use can be categorised in terms of inbound or out bound

Inbound transfers typically include: Contained supplies (process materials, media, process utensils, environmental monitoring (EM) materials, cleaning materials and agents)

Outbound transfers typically include: (half) products, product samples, EM samples, used instruments, product and utensils packaging waste, cleaning waste

PTB's can also be identified by the cleanliness level the entrance is from to the cleanliness level it is transferring to. This is shown in Table 1 at next page.

Notably Table 1 only refers to the airborne particle concentrations. Comparable relations can be made based upon the EU-GMP grades (1)

Table 1		Cleanliness of room transferred to from PTB			
	ISO	5	6	7	8
Cleanliness of room transfer into PTB	5		0.1	0.01	0.001
	6	10		0.1	0.01
	7	100	10		0.1
	8	1000	100	10	

Table 1: relative increase/decrease in cleanliness level by particles in air.

For an inbound pass through situation, there are other aspects that need to be considered as well: the surface contamination of the materials to be transferred. Additional to particles contaminants like bio-contamination can be of relevance as well. Normally there is a transition activity during the transfer. That transition can be: wiping, unwrapping or uncovering of one protecting layer.

Also methods like illumination using UV and surface decontamination by VHP are being used. For many years also a complete sterilisation by a pass through autoclave have found its application. Those special cleaning and disinfection steps are not considered in this article.

TYPES OF VENTILATION IN PTB'S

PTB's can be found either actively ventilated, passively ventilated or not ventilated.

The ventilation principle can be either balanced flow (supply and extract), positive flow by air blown into the PTB, negative flow: the air is extracted from the PTB. The latter can be applicable when containment aspects need to be taken care of (Sink).

All types with active ventilation require supply and/or extract air volume control as well as a form of pressure control. As the internal volume of a PTB is limited, the pressure control aspects need adequate design. (2)

One widespread common type of PTB ventilation is based upon passive ventilation: overflow via the PTB from the room with the higher pressure towards the room with the lower pressure. This can be either by the limited leakage path of the PTB or by defined overflow design.

ANNEX 1 PROPOSED DRAFT

In the latest proposed draft of the EU GMP Annex 1, the place of PTB's, referred to as Pass-through hatches, are included in view of the overall 'contamination control strategy' [CCS]. This CCS considers all steps with regard to personnel, material and equipment movement and operation.

For PTB's specific the draft Annex 1 contains two specific statements:

1. "Pass-through hatches should be designed to protect the higher grade environment, for example by effective flushing with an active filtered air supply.
2. The movement of material or equipment from lower grade or unclassified area to higher grade clean areas should be subject to cleaning and disinfection commensurate with the risk and in line with the CCS."

Statement 2 is typical for the kind of materials and equipment to be transferred as described above. Statement 1 requires more careful analysis.

First of all there is the requirement for protection of the higher grade environment. This can be referenced to the table 1 analysis. Transferring from an ISO 8 into an ISO 7 requires a cleanliness step of 10 times better. In EU-GMP-Annex-1 terms this would be from Grade C to B (operational).The method suggested as example is flushing by active filtered air. It can be observed that the protection is applicable to both inbound as well as outbound PTB's. The direction of movement of the material or equipment makes the difference. When moving outbound, (from a higher grade to a lower grade or not classified area) there is a decrease in cleanliness. When considering (half)product they need to be protected by a suitable container or wrapping. When considering waste materials there is no important cleanliness consideration unless it is waste that requires containment.

APPLICATION IN AUTOLOGOUS ATMP PLANTS

In autologous ATMP plant lay-outs, many transitions into and out of processing rooms and towards supporting rooms, are necessary. This is caused by the laboratory scale of operations autologous production are characterised by. This means multiple patients materials, many separate items and culturing fluids for processing as well as in process control sampling and EM-sampling materials, need to be transferred in to the production. Also a substantial flow of the samples to be checked, patients specific product as well as all the waste materials will need to be transferred outbound.

Per production suite this will require sufficient space to transfer both in and out of the cleanroom. For ease of transportation modular clean baskets can be selected that can be circulated throughout the facility and regularity cleaned/disinfected in the process.

For a facility with multiple production suites and the associated logistics a large number of PTB's are required ,each designed to hold 5 – 7 baskets for transfer. Using active ventilated units with internal fans, HEPA's, controls and monitoring would require significant space, budget, qualification, maintenance and monitoring.

Another approach was therefore evaluated based upon the 'continues flow' concept that will occur when PTB's are provided with distinct overflow openings only.

This concept is widespread but not well documented. Commonly PTB's can be constructed at specific locations without a door seal, so leakage airflow is provided, given the pressure differential over the PTB. This practice could be further developed given the B-grade (ISO 7 operational) production suite and a D+ (ISO 8 operational) corridor, based upon the following considerations:

- air in a Grade B room is actively filtered
- environmental conditions in a grade B room are operational qualified and frequently monitored
- horizontal flow over the stages of multiple baskets is more effective than vertical flow.
- a controlled pressure difference is maintained from production suite to corridor
- the airflow inside the PTB will be expected to have a recovery rate when doors are closed in range of 2-5 minutes for 100:1 reduction (ISO 14644-3)
- by physical nature the overflow will increase by √2=1.41 when opening one door with overflow openings increasing the pressure drop over the interlocked closed door by 2x.
- considering the flow velocity in the openings will be in the range of 3 - 5 [m/s] at 10 – 20 [Pa] pressure drop.

A proof of concept was prepared in plywood to show the effect and determine the airflow at the given overflow design.(Fig.1) The test setup consisted of a speed controlled fan, a flow measurement duct, a connection to a HEPA filtered 'B' section, connected to a mock-up PTB, as well as pressure differential sensors, particle counters and an aerosol generator.

All mock-up experiments were performed at a room differential pressure of ?P=20 ± 2 Pa. At 20Pa the measured continues flow through the discrete openings of the pass through box was 115m3/h. The recovery test was performed by challenging the 'B' compartment to above 100 times the actual concentration.

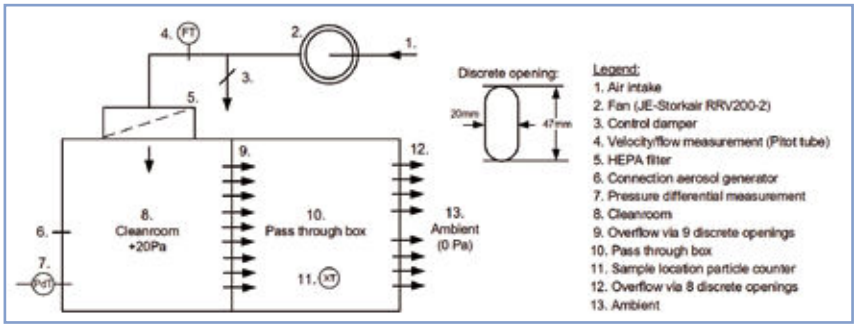

Figure 1: PDF measurement set-up

Figure 2: Test arrangement proof of concept

Figure 3: PTB test at location

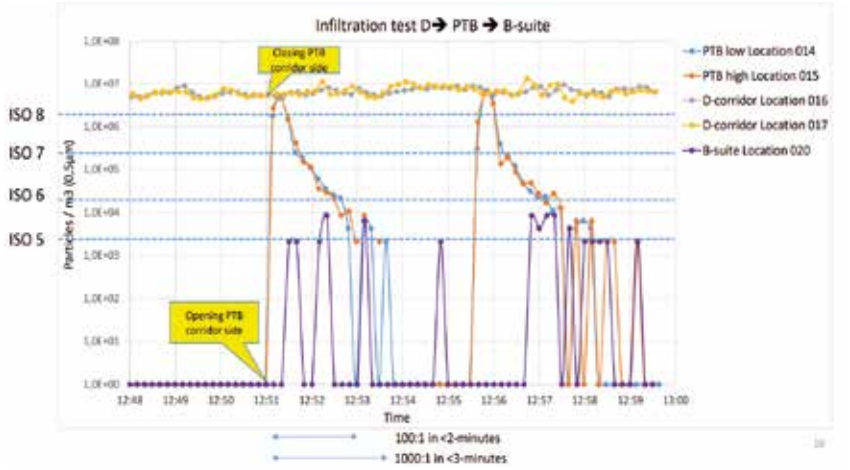

Figure 4: test result example of infiltration test

- The recovery test clearly showed the 'strength' of the non-unidirectional flow in the pass through box.
- A recovery time of 2 minutes by a recovery of 100:1 in contamination has been demonstrated where the EU-Annex 1 gives a guidance value of 15-20 minutes between operation to at rest status.
- Good mixing ventilation in the pass-through box has been demonstrated by the smoke test. This confirms the expected horizontal flow pattern fitting to the use of staged racks.
- The designed airflow-pressure cascade is achieved with the size, shape and arrangement of the openings in the doors.

After positive evaluation of the 'continues flow' PTB, the concept and design has been implemented in the project.

During the start-up, commissioning and qualification phase a series of test were performed to verify the concept:

1) A smoke visualisation test was performed to verify no smoke would move from the inside of the PTB into the B-suite in normal closed conditions.
2) A smoke visualisation test was performed to show that the flow was from the PTB towards the corridor in normal closed conditions
3) The cleanliness inside the PTB was equal to the cleanliness of the B-room from which the 'continues airflow' was coming.
4) In an ISO 8 operational corridor a significant number of challenging particles were emitted to simulate the operation. The production room was challenged by personnel inside close to the PTB. The door from the corridor was opened, activities simulated and the door closed. During the test the particle concentration in the corridor were measured left and right of the PTB, as well as the particle concentration high and low in the PTB. Also the particle concentration in front of the PTB inside of the production suite was measured.

Some results of the test are shown in figure 4. Applicable particles size: ≥ 0,5 µm.

Having the corridor well above ISO 8 during explicit movement for the test, the particle concentration within the PTB rose to that level, to drop rapidly after closing the door.

The concentration in the B-suite were influenced only by the activities of a test person while no infiltration from the PTB was noticed. The peaks in the B-suite reading are the result of the conversion of 0,1CFM counter data at concentrations. In the infiltration test the recovery time 100:1 showed to be within 2 minutes and for the 1000:1 recovery time within 3 minutes after closing the corridor door.

EVALUATION AND CONCLUSION

A 'continues flow' PTB can perform adequately when properly dimensioned at a controlled pressure difference. When doors are opened and closed the internal air cleanliness can be designed to reduce 100:1 in less than 2 minutes. This is valuable during inbound transfer as the transferred materials can be collected from the cleaner side in short notice without compromising the cleanliness conditions.

This test did not evaluate the surface cleanliness of the transferred materials as that aspect is governed by the unwrapping, uncovering and/or wiping/cleaning action, performed when introducing the materials to be transferred.

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Room air distribution strategies in hospital isolation rooms

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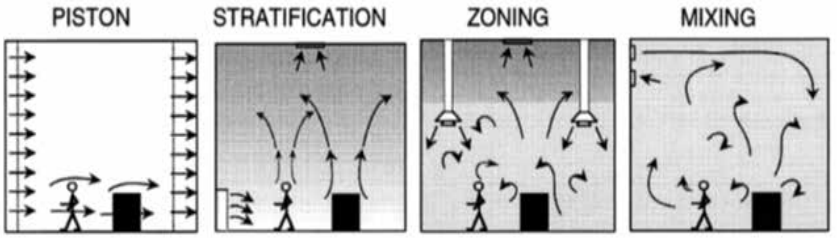
BACKGROUND

In healthcare settings, patients with airborne diseases (such as mycobacterium tuberculosis, measles, chickenpox) are typically placed in negative pressure isolation rooms (NPIRs, also known as airborne infection isolation rooms, AIIRs). In NPIRs the negative pressure directs the airflow towards the isolation room and hence prevents the spreading of the possibly pathogen laden air to the adjacent spaces. However, the negative pressure vanishes when the isolation room door is opened and therefore the airborne contaminants are free to escape the space during door opening and occupant movement through the doorway, which can lead to containment failures (Tang et al., 2013; Kalliomäki 2021). More importantly, the negative pressure does not affect the air movements inside the isolation room and hence does not prevent exposure to patient emitted airborne pathogens inside the NPIRs. Inside the isolation rooms, healthcare workers use personal protective equipment (such as face masks, gloves, gowns etc.) to protect themselves against infections. However, respirators might be leaky, eyes might be uncovered etc. and hence complementary protection is needed. Ventilation can offer this complementary protection.

Many guidelines (ASHRAE 170-2017; CDC, 2005; HTM 03-01 Part A, 2007) suggest general principles for arranging space ventilation (i.e. room air conditioning) in hospitals (including hospital isolation rooms). Typically, mixing strategy with sufficiently high air change rates is recommended aiming for quick and effective dilution of contaminants inside the rooms. However, there seems to be no clear consensus on what are the optimal supply air distribution methods and exhaust locations to realize this strategy in practice. Additionally, although the role of ventilation in airborne transmission of infections in the built environment is clear, there seems to be no clear consensus on the minimum ventilation requirements for hospital isolation rooms (Li et al., 2007). Despite these shortcomings in our knowledge regarding hospital ventilation and especially isolation room ventilation, the authors discuss in this article the different factors affecting the isolation room ventilation, like different supply air distribution methods, exhaust locations, thermal comfort and the related literature.



SUPPLY AIR DISTRIBUTION

In general, room air distribution strategies can be classified into four main categories: piston, stratification, zoning and mixing flows (see Figure 1). They each have their advantages and disadvantages, which are shortly discussed below and put into context of hospital isolation room ventilation.

Piston strategy is the most effective air distribution method (in ideal cases). In piston strategy the air flow controls the whole room flow pattern by creating a unidirectional flow through the whole space in horizontal or vertical direction.

Air contaminants are transported towards the exhaust, and mixing is prevented. However, high air flow rates are needed in this strategy and hence it is usually applied only in special applications, such as operating theatres. Actually, only partial piston method is used in laminar flow operating theaters as only part of the ceiling area is typically used for the laminar supply flow. However, there are some studies examining the effect of piston flow on particle dispersion in isolation rooms. For instance, Yang et al. (2015) investigated the ventilation needed to control thermal plumes and particle dispersion in a unidirectionally ventilated isolation room and found that up to 0.25 m/s downward flow would be needed to control the thermal plumes and particle dispersion from breathing. Also, Arribas et al. (2015) have examined a piston flow in an isolation room context. They found that 0.35 m/s flow velocity was needed to overcome thermal plumes present typically in isolation rooms. Both studies point out the very problem of the piston flow: very high supply airflow rates are required for the piston strategy to perform as designed.

Stratification strategy (displacement ventilation) is an effective air conditioning strategy which can be utilized in various cases. In displacement ventilation, low momentum supply air is introduced directly into the occupied zone (typically to the low levels of the room) so that room airflow patterns are controlled mainly by the convective flows. The convective flows ideally transport heat and contaminants to the upper parts of the space (away from the occupied zone) where they are stratified and extracted from the room. Although there can be relatively high contaminant and temperature removal effectiveness, the method is sensitive to disturbances and in some cases stagnant areas with high local contaminant concentrations can occur. However, displacement ventilation method can be utilized in isolation rooms under certain conditions, like pointed out by Berlanga et al. (2018). Additionally, displacement ventilation was recently suggested as a viable ventilation strategy for makeshift hospitals to contain COVID-19 patients and other airborne diseases (Bhagat and Linden, 2020). On the other hand, due to possible stagnant areas and lock-up phenomena, displacement ventilation is not generally recommended to be used in patient or isolation room settings (Qian et al., 2006; Zhou et al., 2017; Villafruela et al., 2019).

Zoning strategy is a mixture of displacement and mixing principles. Its target is to have control of a selected zone and allow the stratification of heat and contaminants in other room areas. There does not seem to be much research about zoning strategy in isolation rooms. This is possibly because typically zoning (as also displacement) requires relatively high spaces in order to function as designed. However, some zoning strategies have been suggested and examined in the isolation room context. For instance, protected occupied zone ventilation (POV) aims to protect occupants from indoor contaminants by dividing an indoor space into zones by a downward plane jet (Cao et al., 2013). Aganovic and Cao (2019) found that POV could reduce the risk of cross-infection in hospital isolation rooms compared to traditional ventilation systems. Additionally, Kalliomäki et al. (2020) recently introduced a zonal downward ventilation method for isolation rooms. In this method, the supply air was directed downwards to the whole bed area capable of flushing that local zone with low velocity air. The results showed potential to reduce the healthcare worker exposure to the exhaled air of the patient with the zonal downward ventilation method. Despite the promising results, much more research is needed in the future to confirm these laboratory and CFD simulation based zonal ventilation results (e.g. in real hospital settings).

Mixing strategy is probably the most generally applied air distribution method in hospital isolation rooms in mechanically ventilated buildings. It is recommended by many standards and guidelines (ASHRAE 170-2018, CDC, HTM 03-01) together with sufficiently high ventilation rates (typically around 12 air changes per hour). This approach aims to mix and dilute the whole room air volume and hence to prevent contaminant and thermal stratification and local gradients (i.e. to produce uniform conditions throughout the space). Nevertheless, mixing ventilation is not always the most optimal strategy in reducing exposure to airborne contaminants as dilution of high local concentrations might be inadequate (Richmond-Bryant et al., 2006 A; 2006 B) and high air change rates are not always the best measure of ventilation system performance (Pantelic and Tham, 2013). Hence, healthcare workers can be exposed to high pathogen concentrations emitted by the patient especially in care giving scenarios (i.e. when close to the patient). However, mixing and air delivery systems performance in the occupied zone can be enhanced locally by different means. For example, Qian et al. (2008) examined the effect of different downward ventilation systems on exposure to patient exhaled pathogens in a two-bed hospital isolation ward. In general, they noticed that directing the supply air towards the breathing zone of the patient can reduce the exposure to the exhaled air. They concluded also that more research should be done to examine the effects of the positions of supply air diffusers and exhausts. Later Qian and Li (2010) came into conclusion to recommend the use of a downward ventilation supply and a ceiling-level exhaust for future isolation room designs. Also, Kalliomäki et al. (2020) came into conclusion that a local downward ventilation (combined with background mixing ventilation) supplying air to the breathing zone of the patient performed better compared to a more traditional overhead mixing ventilation.

The above discussion of different air distribution strategies is not complete as there are several other supply air distribution methods that could be utilized in hospital isolation rooms. The focus of the discussion was only on the ideal strategies. The general performance of various other air distribution methods are discussed and reviewed in Yang et al. (2019), where the authors considered different types of air distribution methods, from local and personalized solutions to whole-room air distribution methods. However, although the various methods considered by Yang et al. (2019) could be applied to isolation rooms, the focus on that review is not on hospital buildings but rather on office, educational and residential sector.

EXHAUST LOCATION

As discussed above, different supply air distributions together with buoyancy/convective flows control the room flow patterns and hence also the dispersion of aerosol contaminants around the room. On the other hand, exhausts have only a short-range local effect on the airflow patterns and contaminant capture efficiency. However, if the whole ventilation system is designed well, optimal exhaust location can have substantial effect on the room concentrations and hence also on the exposure to the patient released aerosols.

Although there seems to be no clear consensus in the literature regarding the optimal exhaust location in isolation rooms, there appears to be cumulating evidence that high-level exhausts might be more effective in reducing the possible exposure to the patient released airborne contaminants (Huang and Tsao, 2005; Qian and Li, 2010; Villafruela et al., 2013). The results reported in a recent study by Kalliomäki et al. (2020) also support the conclusion that low-level exhausts do not work as well as higher-level exhausts. On the other hand, there is also evidence that low-level exhausts can perform well in some cases (Cheong and Phua, 2006; Berlanga et al., 2018; Cho, 2019). However, there seems to be insufficient evidence to show which would be better in general. Evidently, this topic needs more research before any final conclusions can be drawn.

Also, exhaust hoods can be used to capture the contaminants before they spread to the room air. For instance, Chau et al. (2006), Nielsen (2009) and Sadrizadeh and Holmberg (2015) have studied local exhaust ventilation in hospital rooms, among others. In principle, an exhaust hood can be placed above the head of the patient to capture exhaled air. Additionally, other promising novel bed-integrated local exhaust systems have also been suggested (Melikov et al., 2011; Bivolarova et al., 2016). However, especially the exhaust hoods can be impractical during patient care and can have a negative effect on patient comfort and hence might not be easily accepted in healthcare settings.

Although exhausts have typically only local effect on room airflow patterns, their location can have influence on the exposure to the patient exhaled aerosols. The optimal location of exhausts is sensitive to room airflow patterns, supply air distribution, contaminant source location and their relative locations inside the room. In optimal cases the exhaust should be located downstream in the overall flow direction of the aerosol contaminant sources and as close as possible to the source. In other words, the effect of the location of the exhaust grilles is highly case dependent. It is difficult to say that a certain location would be optimal universally, but it appears more like that the question is about whole system and control of it.

THERMAL COMFORT ASPECTS

Thermal comfort is one of the main factors of a good indoor environment and as such a key element when designing HVAC systems of buildings. Ventilation affects the indoor environment parameters like temperature, relative humidity and air speed and by controlling and keeping them at favorable levels one can promote comfort and wellbeing of the occupants.

In hospital isolation rooms, the air distribution system should be capable of diluting, directing and exhausting airborne contaminants from the occupied zone effectively. In theory this should be realized in a way that causes as little discomfort as possible to the occupants. This might be challenging due to the high air change rates, which might cause draught and also thermal discomfort. Indeed, Berlanga et al. (2018 A) measured thermal comfort of the patient and healthcare worker inside an isolation room with different mixing air distribution systems and found that the thermal comfort varied according to ventilation rate and air distribution mode. The predicted mean vote (PMV) values were found to be slightly negative (cool) for the patient (-0.07-(-0.52)) and slightly positive (warm) for the healthcare worker (0.28-0.72) depending on the examined case. Very similar results were found also when displacement ventilation was used in an isolation room mock-up (Berlanga et al., 2018 B), indicating that there we no substantial difference between mixing and displacement modes. Also, Kalliomäki et al. (2020) examined the thermal comfort aspects in isolation rooms. They concentrated only on the thermal comfort of the patient and found (using thermal manikins to measure the thermal comfort) that local downward ventilation (flushing the upper body of the patient) induced only slightly cooler PMV value (-0.4) compared to mixing ventilation (0.1).

Typically, the thermal comfort has been measured with thermal manikins or other probes in isolation room studies as mentioned above. However, recently Maula et al. (2021) examined perceived thermal comfort, air movement and symptoms under mixing and local downward ventilation air distribution modes in an isolation room model with real test subjects. They concluded that the mean thermal sensation vote in both test conditions was "Neutral" and the thermal comfort did not differ statistically significantly between studied ventilation modes. These initial findings imply that air distribution methods flushing the patient breathing zone could produce acceptable thermal environment despite notable air movement. However, more research is needed in this topic in the future.

SUMMARY

The air distribution in hospital isolation rooms has been examined in many studies in the past. Yet, it seems that the research is still at an early stage and no clear consensus has yet been reached on the relative performance of different air distribution principles and methods. The published results are often valid for specific systems in specific conditions, and it is challenging to draw general conclusions. Therefore, more research is needed to gain a more systematic approach to air distribution design in isolation room settings.

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PDA

All workshops and training events within PDA are virtual, (https://www.pda)

PDA Letter reports among other things from PDAs 75th Anniversary in March, 2021

PDA Journal of Pharmaceutical Science and Technology, Vol.75, issue 2. March/April 2021 contains e.g., two peer-reviewed research articles, and a discussion report

- People as a Contamination Source in Pharmaceutical Clean Rooms—Source Strengths and Calculated Concentrations of Airborne Contaminants by Bengt Ljungqvist and Berit Reinmuller
- Optimizing the Filtration of Liposomes Using Sterilizing-Grade Filters by Kalliopi Zourna, Aude Iwaniec, Stephen Turner, Nigel B. Jackson and John H. Welsh

A Discussion on Bio-Fluorescent Particle Counters: Summary of the Process and Environmental Monitoring Methods Working Group Meeting with the FDA Emerging Technology Team, meeting proceeding byAllison Scott, Ren-Yo Forng, Mike Russ, Gilberto Dalmaso, Scott Hooper, Philip Villari, James Cannon, James Francis and Mike Dingle

New Technical reports have been published

- PDA Technical Report No. 85 (TR 85) Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers (single user digital version).
- PDA Technical Report No. 86 (TR 86) Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing (single user digital version).

PHSS

PHSS holds virtual workshops in 15th and 16th of June PHSS Sterile Product Manufacture Virtual Conference 2021 and Challenges in Sterile Products Manufacture 2021, 29th of June Overview of Monoclonal Antibodies (Mabs) Manufacturing process & Challenges for Quality Unit - VE, and the PHSS Annual Virtual Conference - EU GMP and ATMP's 15-16 September.

Latest issue of European Journal of Parenteral & Pharmaceutical Sciences

Vol 26, issue 1 contains, two peer reviewed articles, two opinion papers, one impact paper, editorial and PHSS news, and regulatory updates by Malcolm Holmes, (EJPPS Online: European Journal of Parenteral & Pharmaceutical Sciences)

- A global disinfectant standard for cleanrooms: presenting a harmonized approach, peer-reviewed paper by Tim Sandle.
- Some observations on protective efficacy of surgical clothing systems with additional clothing components concerning airborne bacteria-carrying particles measured during ongoing surgery, peer-reviewed paper by Bengt Ljungqvist and Berit Reinmüller
- Insight into the New EU GMP Annex 1, opinion paper by F Panofen, PhD, EMEA, D Pandolfi, Systems, Software & Services, M Della Pietra, Life Sciences, A Campanella and G Artalli, Micro & Sterility.
- Brexit: TCA and the Life Sciences sector, opinion paper by Cliodhna McDonough, Fieldfisher LLP.

Three Impact statements and a Regulatory update by Malcolm Holmes

Editorial Reflection paper on Good Manufacturing Practice and Marketing Authorisation by Kay O'Hagan, Editor in Chief.

Clean Air and Containment Review

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Latest issue 44 #4 2020 contains except John Neigers Editorial, Pearls of wisdom, and Live-lines, three main features, an introduction to ISO 14644-16, a book-review, news and dates for training events. The journal can be found at R³ Nordic member area https://r3nordic.org

- Reducing cleanroom HVAC energy use by following a scientific approach by Nigel Lenegan.
- Containment leakage testing by Joshhua Magor
- Face masks: Lesson from COVID-19 research by Tim Sandle
- Energy efficiency in cleanrooms and clean air devices: ISO 14644-16 by Richar Gibbons, Convenor, ISO/TC209 WG13
- Advances in Practical Safety Ventilation by Bengt Ljungqvist and Berit Reinmüller, reviewed by Tim Sandle.

Elis Cleanroom öppnar ny anläggning i Nyköping

En ny Elis Cleanroom-anläggning slår upp portarna i Nyköping i december och ersätter därmed den nuvarande renrumsanläggningen på samma ort.
– Renrumsverksamhet bedrivs under ständigt ökande krav och mycket strikta regelverk. Med den nya anläggningen säkrar vi våra förutsättningar för att kunna möta såväl nuvarande som kommande krav, och fortsätta leverera med hög kvalitet till våra kunder, säger Göran Nilsson, platschef på Elis Cleanroom Nyköping.

Elis-koncernen, i vilken före detta Berendsen ingår sedan 2017 är Sveriges och Europas marknadsledande textilserviceleverantör. Varje år hanterar koncernen mer än 75 000 ton textilier i form av arbetskläder, hygienutrustning, mattor, lakan och handdukar. I över 100 år har Elis arbetat efter en cirkulär affärsmodell som erbjuder textil- och hygienlösningar åt bland annat hotell, restauranger, vårdgivare, industrier och fastighetsägare.

Elis Cleanroom – koncernens renrumsverksamhet med tvätt och sterilisering av textilier i samma rena, partikelfria miljö som de används i – utgörs i dagsläget av tretton certifierade anläggningar runt om i Europa. Nu förstärker koncernen den svenska renrumsverksamheten med en ny anläggning i Nyköping som ersätter den ursprungliga anläggningen. Full produktion är planerad till december 2021.

Planeringen av den nya anläggningen har pågått sedan 2016 med målet att kunna utveckla anläggningen ytterligare. Placerad vid Arnö Västra Företagspark i Nyköping får den nya byggnaden ett betydligt bättre läge, lämpat för sin industriverksamhet, menar Göran Nilsson. Det första spadtaget togs i början av 2020 och nu, våren 2021, står byggnaden så gott som klar. Den mäter 2500 kvadratmeter och är byggd i ett plan till skillnad från den ursprungliga anläggningen som bestod av tre våningar. Verksamhet i ett plan möjliggör ett mer effektivt och säkert flöde.
Produktionen uppfyller kraven i standard ISO 14644 och GMP. Verksamheten täcker alla behov från ISO 5 upp till ISO 8.

– Kraven i Grade B har ökat och ställer nu krav på användning av sterila goggles vid varje inpassering i renrum. Detta ställer krav på oss att hitta hållbara lösningar för detta, som ett alternativ till sterila engångsgoggles som slängs efter varje användning. Därför har vi nu utökat verksamheten med tvätt- och steriliseringsservice av goggles, säger Annika Yngwe, Quality Assurance Manager på Elis Cleanroom i Nyköping.
Därtill kommer även autoklavering, av bland annat städmaterial, goggles och textilier, att bedrivas i ett separat autoklaveringsrum. Den nya byggnaden utgörs även av ett separat vattenbehandlingsrum där anläggningens vatten kommer att renas och partikelfiltreras, samt kemikalierum, mediarum, reparationsverkstad och förråd. Verksamhetens samtliga produktionsflöden leder sedan ut i en gemensam avdelning för utleverans av textilierna.

Den ursprungliga anläggningens väletablerade rutiner för testning medföljer naturligtvis till den nya, berättar Annika Yngwe. Kontinuerlig testning av partikelhalt och mikrobiologiska nivåer, enligt ISO 14644, genomförs regelbundet. Därtill utförs även mikrobiologiska tester av renrummens ytor, luft, vatten och personalkläder, för att kontrollera att eventuell mikrobiologisk tillväxt inte överstiger satta gränsvärden. För testning av partikelsläpp från dekontaminerade textilier är Elis Cleanroom Nyköping försett med testverktyget Helmke Drum

- På Elis-koncernens innovationscenter i Nederländerna finns fler avancerade testmöjligheter. På vårt testcenter finns det möjlighet att utföra tester i en så kallad Body Box. Där kan vi mäta partikelnivåer efter mänsklig rörelse av en person i komplett renrumsklädsel, vilket beskrivs i Recommended Practice IEST-RP-CC003.4. Att ha sådana testmöjligheter är en stor tillgång, fortsätter Annika Yngwe.

För samtliga verksamheter inom Elis-koncernen ligger hållbarhetsarbetet ständigt i fokus. Som en del i det arbetet har vi blivit det första företaget i Sverige att certifieras mot FN:s globala mål. Certifieringen utfördes år 2020 av Bureau Veritas och innebär en verifiering och tredjepartsgranskning av hur de 17 globala målen för hållbar utveckling är integrerade i Elis Sveriges verksamhet.
Tidigare har den ånga som använts i anläggningens maskiner och torkutrustning producerats genom eldning av olja – ett bränsle som på den nya anläggningen kommer att bytas ut mot det förnybara alternativet pellets.
– Tack vare att vi i samband med flytten nu byter bränsle, blir den nya anläggningen en plats där vår verksamhet kan bedrivas mer hållbart och med låg klimatpåverkan. Det känns väldigt bra, säger Göran Nilsson.

En ytterligare hållbarhetsåtgärd, är att koncernen framåt har starkt fokus på att ta tillvara på kasserade textilier. Egle Hammering är regional produkt- och marknadschef för koncernens renrumsverksamhet i norra Europa, och hon understryker vikten av ett hållbarhetstänk som löper genom produktionskedjans alla steg.
– Ett av våra stora fokusområden inom hållbarhet kommer framöver att vara hur vi hanterar kasserat material – avfall av textilier i allmänhet, och polyester i synnerhet. Vi utforskar nu flera olika möjliga återvinningsmöjligheter och åtgärder som vi ser fram emot att så småningom börja implementera, och på så sätt bli än mer cirkulära i produktionen, säger Egle Hammering.

Under sommaren och hösten kommer de anställda att genomgå utbildningar för att lära känna den nya anläggningen. Därtill kommer även interna tester och valideringar att genomföras innan anläggningen slutligen kan presenteras för verksamhetens kunder – som i sin tur då kommer att utföra egna kontroller och granskningar. Kontrollerna väntas vara slutförda i november och därefter står nya Elis Cleanroom i Nyköping helt redo att slå upp sina portar.

Med anledning av ovissheten kring hur smittspridningsläget kommer att se ut under hösten, är planerna för öppningsceremonin ännu inte fastställda. Någon typ av firande blir det i alla fall, hoppas Göran Nilsson.
– Det återstår att se vad omständigheterna tillåter, men vi hoppas förstås kunna fira öppningen på ett bra och roligt sätt tillsammans med kunder, anställda och Nyköpings befattningshavare, avslutar Göran Nilsson.

PP4CE finishes biological production facilities for Fujufilm

The new plant in Tilburg, Netherlands will produce cell culture media for the biopharmaceutical industry in Europe. Life science, is a growing business segment within FUJIFILM.

The originally Japanese multinational FUJIFILM Cooperation (FUJIFILM) is best known for its world- wide activities in the graphics industry and in the production of photo paper. Possibly less known are the activities that for 80 years have also been within the scope of FUJI, such as electronic imaging, photofinishing equipment, medical systems, life sciences, graphic arts, flat panel display materials and office products, based on an extensive portfolio of digital, optical, fine chemical and thin film coating technologies.

One of these activities is operated within the Fujifilm Irvine Scientific division. In this Biopharmaceutical segment, FUJI develops and produces cell culture media and has production facilities in the United States and Japan. In Europe, the Tilburg facility has now been added and will start production at the end of 2021.

The new plant will produce cell culture media for the biopharmaceutical industry in Europe. This material is used in both large bioreactors and smaller laboratories. Depending on the nutrients contained, specific cells, bacteria and fungi grow in or on the media. The culture media are used in the production of vaccines, the growth of cytogenetic products (such as bone marrow and blood cells) and as an aid in in vitro reproduction techniques, among other things. FUJI expects to realise an annual production of 320,000 kg of powder and 470,000 L of liquids in the first phase.

The project comprised the construction and fitting out of 1,725 m^2 of cleanroom, 30 rooms in total, an R&D laboratory of 360 m^2 as well as a 60 m^2 sampling lab.

DNA printer to be released by DNA Script

Paris-based DNA Script will launch the world's first DNA printer, which allows scientists to develop DNA strands on demand. "The disruption is really happening on the biochemical side where we are the first one, basically, to be able to train or adapt the enzyme to build the de novo molecule for building DNA," said Thomas Ybert, DNA Script's CEO and co-founder.

Hipp, Hipp Hurra Ventilator fyller 90 år!

Inget företag överlever och fortsätter utvecklas i över nittio år i en extremt konkurrensutsatt bransch utan starka idéer, hög teknisk kompetens och stora ambitioner. Nöjda och återkommande kunder har alltid varit ryggraden i Ventilators verksamhet. Att påstå att vi alltid arbetar långsiktigt känns därför inte som någon överdrift.

Ventilator föddes 1931 ur Sven Romedahls idé om mekanisk bostadsventilation. I stället för att dra en självdragskanal från varje rum i huset, kom Sven på idén som var lika enkel som genial:
En fläkt skulle föra bort den förorenade luften från kök och badrum medan övriga rum tillfördes uteluft via don ovanför radiatorerna. Denna form av kontrollerad ventilation revolutionerade och rationaliserade snabbt bostadsbyggandet i Sverige. Uppfinningen gav det nya företaget Ventilator en rivstart.

En annan uppfinning som Ventilator konstruerade var industrifläkten som hade formen av en flygplansvinge. Fläkten hade avsevärt bättre aerodynamiska egenskaper vilket gjorde att effektbehovet kunde minska med en tredjedel. Det blev snabbt Ventilators starkaste varumärke och vissa fläktar snurrar än i dag.

I dag är Ventilator fortfarande ett ledande företag inom luftbehandlingsteknik. Sven Romedahls revolutionerande ventilationsidé har fått ge vika för mer effektiva och flexibla ventilationslösningar som t ex FTX-ventilation. FTX ger en mycket mer kontrollerad tillförsel av tilluft och evakuering av frånluft. Eller VAV-system (Variable Air Volume) som skapar luftflöden som kan regleras efter rumstemperatur, koldioxidhalt eller personnärvaro. Utöver luftbehandling står Ventilator i dag stadigt på flera affärsben inom ny teknik. Affärsområdet Ventilator Renrum har en lång och bred erfarenhet av rum med förhöjda renhetskrav inom olika branscher (sjukvård, elektronik- och läkemedelsindustrin m. fl.) och erbjuder byggnation av renrum, konsultation och produkter anpassade för renrum. Ventilator har en djup kunskap gällande GMP för läkemedelstillverkning och validering/kvalificering av renrum.

I dag är Ventilator ett tjänsteföretag som kombinerar kreativa lösningar med affärsmässighet och gediget hantverkskunnande. Hög kompetens och yrkesskicklighet i kombination med kreativitet och stort engagemang är de ledord som för företaget in i framtiden. Ventilator ingår i företagsgruppen Energivärden som har ca 150 anställda och omsätter ca 350 Mkr.

Att fylla 90 år mitt i en pandemi, gör det svårt att planera något firande – men självklart ska det firas på något sätt. Vi återkommer!

Nytt dokument om operationskläder

The document ”Surgical Clothing Systems – People as a Contamination Source (PDF)” is now avaiable from https://safetyventilation.com/

The hospital environment is contaminated by microorganisms; some of them are antibiotic resistant. In the operating room the number of airborne bacteria-carrying particles is considered an indicator of the risk of infections to the patients undergoing surgery susceptible to infection. Today, when the supply air to the operating room is HEPA-filtered, the main source of airborne microorganisms is people (patient and personnel/staff). The filtration efficacy of the fabric in surgical clothing systems plays an important role. The design of the clothing systems also affects the number of particles emitted from people to the air of the operating room. In operating rooms for surgery susceptible to infections, the selection of clothing systems for the operating personnel should not only be considered in terms of comfort but also in terms of patient safety. The work presented here deals with practical safety ventilation in operating rooms regarding bacteria-carrying particles and describes the protection efficacy, source strength, of different clothing systems. Results of source strength values achieved from dispersal chamber tests as well as measurements from ongoing surgery in operating rooms are reported. Some of the results have earlier been reported in Licentiate and PhD theses in the field of Safety Ventilation by Johan Nordenadler (PhD, 2011), Pedro Gandra (Lic. Eng., 2019) and Catinka Ullmann (PhD, 2019). This work is designed as a text for educational purposes and as a reference for practical applications. Every chapter has its own topic and could be read separately. All the chapters give an overview of the protection efficacy, source strength, of surgical clothing systems and people as a contamination source.

This publication was written during the quarantine time. due to the COVID-19 pandemic in 2020. Even if the work is limited to describing the protection efficacy of surgical clothing systems for infection prone surgery in operating rooms, the authors dedicate this publication as a reminder of all the persons in the Swedish geriatric care , who contracted COVID-19 due to insufficient protective clothing and the shortcomings of hygienic routines. A special thanks to Mr. Russell Madsen, MSc, President of the Williamsburg Group, LLC, Gaithersburg, Maryland for linguistic support.

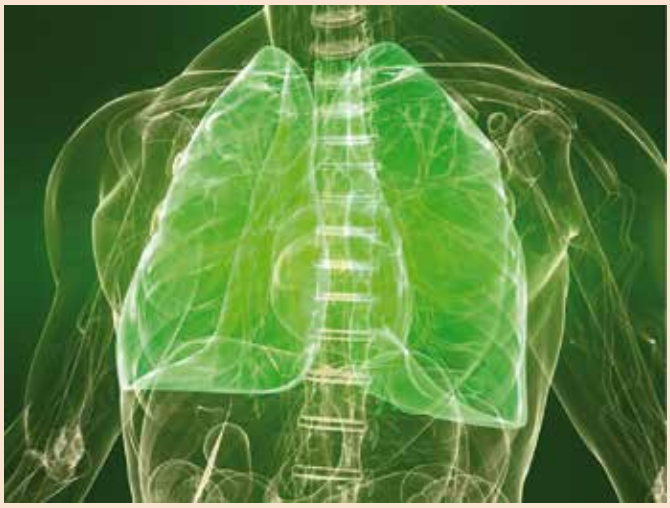
By Bengt Ljungqvist and Berit Reinmüller

Eight new guidance documents from FDA

FDA, Mai 2021

- M9 Biopharmaceutics Classification System-Based Biowaivers
- E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials
- Q3D(R2) – Guideline for Elemental Impurities
- S5(R3) Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Guidance for Industry
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycl Management Annex
- S11 Nonclinical Safety Testing In Support of Development of Pediatric Pharmaceuticals
- Qualified Infectious Disease Product Designation Questions and Answers

Three are revised versions of previously issued guidances, but all are ICH-based, with a “mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner”.



Nytt biobläck – ett steg närmare 3D-printade mänskliga organ

Vetenskapshälsa april 2021. Illustration: Dreamstime

Forskare vid Lunds universitet har utformat ett nytt biobläck som gör det möjligt att använda 3D-bioskrivning för att skapa luftvägar i naturlig storlek och med hjälp av mänsklig vävnad. De utskrivna luftvägarna är biokompatibla och forskarna har i djurmodeller sett att materialet stöder tillväxt av blodkärl inne i luftvägens vägg. Detta är ett viktigt första steg på vägen mot att skriva ut biokompatibla organ i 3D.

Kroniska lungsjukdomar är den tredje vanligaste dödsorsaken i världen som i EU kostar mer än 380 miljarder euro årligen. För många kroniska sjukdomar finns inget botemedel och det enda alternativet för patienter i slutskedet är lungtransplantation. Det saknas dock lungor från donatorer för att möta behovet för alla dem som väntar på transplantation.

Det är därför angeläget att kunna öka mängden tillgängliga lungor för transplantation. Ett möjligt tillvägagångssätt är att tillverka lungor genom att kombinera celler med ett biotekniskt framställt stödjematerial. Men exakt vilka material och metoder för att skapa stödjematerial som är mest lämpliga för transplantation är inte kända.

Forskarna bakom den aktuella studien, Martina De Santis och Darcy Wagner, i forskargruppen Lungbioengineering och regeneration vid Lunds universitet, har utformat ett nytt biobläck (ett utskrivbart material) för så kallad 3D-bioskrivning av mänsklig vävnad. Biobläcket tillverkas genom att kombinera två material: ett material som härrör från tång, alginat, samt bindväv (extracellulär matrix) som härrör från lungvävnad.

Genom att använda vårt nya biobläck med stamceller framrenade från patienters luftvägar kunde vi bioskriva små luftvägar som hade flera lager av celler

Som ett koncepttest används detta nya biobläck till 3D-bioskrivna små mänskliga luftvägar med två typer av celler som normalt finns i mänskliga luftvägar. Detta biobläck kan emellertid anpassas för samtliga vävnads- eller organtyper.

– Vi började smått genom att tillverka små rör, eftersom detta är en struktur i såväl luftvägar som i blodkärl. Genom att använda vårt nya biobläck med stamceller framrenade från patienters luftvägar kunde vi bioskriva små luftvägar som hade flera lager av celler och som förblev öppna över tid. förklarar Darcy Wagner, universitetslektor och docent i lungbioengineering och regeneration, som är huvudförfattare till studien.

Nästa generations biobläck

– Denna nästa generations biobläck främjade också framväxten av luftvägsstamceller till flera celltyper som normalt finns i en vuxen människas luftvägar, något som förenklar processen att skriva ut vävnad som består av många olika celltyper, berättar Darcy Wagner.

https://www.vetenskaphalsa.se/nytt-bioblack-ett-steg-narmare-3d-pr

Two new guidelines from EHEDG

EHEDG Guideline Document 54 - Testing of Hygienic Weld Joints. Setting up food and pharmaceutical processing equipment inevitable will also involve some sort of welding procedure. This will be the case if you are adjusting an existing one or making a new one. Practical study results show that bad welds are one of the main causes for compromised product safety and quality in the food and pharmaceutical industry. It is why the EHEDG Working Group Welding defined a set of hygienic welding design requirements in their newly published EHEDG Guideline Document 54 that provides guidance on the testing of hygienic weld joints.

EHEDG Guideline Document 55 - Hygienic Design Requirements for Bakery Equipment. After EHEDG Document 49 on the hygienic design requirements for the processing of fresh fish, EHEDG published yet another guideline that specifically focuses on equipment applied in the production of one type of food. The reason is that bakery processes are special because they encompass various process steps, each of which have very different requirements, from dry to wet processes in the dough preparation step, and again back to dry processing following the baking stage. Cleaning 'dry' requires a different approach than cleaning 'wet', various cleaning regimes and different types of food processing equipment are needed. This new EHEDG Guideline provides clear overviews on where to clean dry and where to clean wet and the hygienic design requirements that align with that."

Are ultra fine particles in air toxic?

New use of a method for characterization of particle pollution - developed at DTU Nanolab - has led to an improved and more precise analysis of aerosols in indoor work environments. As part of his PhD Project, Anders Brostrøm developed a new application of a well-known method to collect aerosol particles. He demonstrated that electron microscopy analysis of such samples gives a reproducible and representative result - if certain guidelines are followed. The results are published in an Open Access Journal and are available for all researchers or companies that would like to take this method into use. One of the companies that has done exactly that is Saxocon. Together with Anders Brostrøm they have developed a "high efficient Particle Device", which is used when Saxocon offers to characterize aerosols from e.g. indoor work environments, in order to assess whether the air is toxic or safe.

Engineering nature like nanostructures.

Professor Rafael Taboryski from DTU Nanolab is inspired by the microstructures of nature, including the surface of the lotus flower's petals. He has now been awarded a doctorate for his scientific work to recreate similar surface structures. The methodology involves copying the structures found in nature and reconstructing them on other surfaces. It has been demonstrated that it is possible recreate these amazing properties in plastic, for example. Where the lotus flower leaf has a surface that is moisture repellent, the surface of rose petals binds the moisture so that the petal does not dry out. These are primarily the two categories of properties in surface structures with which Rafael Taboryski has worked; microstructures and nanostructures which reject certain liquids or are moistened by them, respectively. Both are about the wetting of surfaces, hence the title of the doctoral dissertation: 'Engineering of wetting properties for solid surfaces'.

R³ NORDIC, CTCB-I OCH CHALMERS INVITE TO

Cleanroom Testing & Certification

12-14 Oktober 2021

Installationsteknik, Chalmers, Göteborg

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 two 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 five (5) years. Recertification is required in order to maintain certification on Professional Level beyond five years.

COURSE FEES 2021

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

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

Note 1: Candidates who are not already members of R³ Nordic or another ICCCS affiliated society will also be charged the cost of one year's individual membership - currently SEK 650,- in R³ Nordic.

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

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

Further information is available at www.safetyventilation.com
Questions and application form: Lars Ekberg,
ctcb-gothenburg@cit.chalmers.se /+46 (0)703 15 11 55

The number of seats is limited. ***Apply no later than August 10, 2021.***

R³ NORDIC INVITES TO

EHEDG Advanced Course in Hygienic Engineering & Contamination Control

26th - 28th of October 2021

FORCE Technology, Park Allé, Brøndby, 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.

REGISTRATIONS AT LATEST ON 11TH OF MAY 2021

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 four 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 Fris, Ferdinand Schwabe and Gun Wirtanen.

Day 1

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

Day 2

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

Day 3

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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Tel 020-740116 / goran.nilsson@elis.com

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