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GMP in the Food Industry

Contamination Control and the Food Industry

- RAPPORT SAMT STORT BILDKOLLAGE FRÅN NAANTALI FINLAND
- INTERNATIONELLA RAPPORTER · STANDARDISERING · INBJUDNINGAR

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INNEHÅLL

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Phone numbers and e-mail addresses you will find to the left, at page 2.

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ORDFÖRANDE HAR ORDET

Njuter av den en helt otroliga maj-värmen som hållit oss i ett fast grepp. Vilken inledning på sommaren!

Jag vill börja med att rikta mig till programkommittén i Finland med ett stort tack för ett välordnat symposium på i Nådendal. Trevligt program, härlig plats och ett väl genomfört arrangemang med ett riktat tack även till utställarna.

STYRELSEMÖTE/ ÅRSMÖTE

I samband med symposiet träffades styrelsen för att avhandla vårt ekonomiska resultat. Vi har kraftigt minskat det negativa resultatet, vilket förstås är glädjande.

Vi diskuterade även hemsidan, vårt nya kansli samt vad vi skall erbjuda våra medlemmar för att vara en attraktiv förening. Efter semestern kommer vi att träffas igen för att diskutera föreningens framtid. Vi tar gärna emot synpunkter och feedback från er medlemmar. Skriv ett mail till föreningen eller till någon av oss i styrelsen. Adresserna finns på vår hemsida.

I vanlig ordning avhölls ett årsmöte i samband med symposiet där en ny styrelsemedlem Geir Valen Pettersen, från Norge, hälsades välkommen till styrelsen. Samtidigt avtackades Conny Lindqvist och Arild Svendsen, som båda lämnade styrelsen samt valnämndens ordförande Torbjörn Skoog.

Efter mötet framförde en av våra hedersmedlemmar ”Nu känner jag att föreningen är på rätt väg”. Denna synpunkt känns väldigt värdefull för vidare arbete i vår förening.

HUR SVÅRT KAN DET VARA ATT GÖRA RÄTT?

TV-programmet Dokument inifrån sände den 2/5 och 9/5 två program i en serie med titeln ”Den stora sjukhusstriden”, som belyste en statlig utredning ”Träning ger färdighet”, vilken har letts av Måns Rosèn. I serien gavs en inblick i de konsekvenser denna utredning leder till på mindre sjukhus, som exempelvis Västervik. Under ledning av doktor Magnus Fröstorp har man där sett att det över tid kan bli svårt att bedriva akut kirurgiskt uppdrag på landsbygden. Utredningen presenterades för regering och riksdag och en av slutsatserna var att man kunde spara 500 personers liv om man koncentrerade ”högspecialiserad kirurgisk vård” till färre kliniker. Rekommendationen var minst 50 operationer/år för att detta scenario skulle undvikas.

Alla riksdagspartier höll samstämmigt med om att utredningens förslag skulle genomföras. Inget parti eller ingen ledamot vill väl ha på sitt samvete att inte kunna erbjuda den bästa av vården. I TV-programmet belyses att det statistiska underlag som presenterades i utredningen var bristfälligt. Körningar som gjordes från Socialstyrelsens register var på flera punkter ofullständigt och valet av underlag var märkligt utifrån det man utredde.

Professor Ulf Gunnarsson menar att det inte finns något samband mellan volym och kvalitet och professor emeritus Ulf Haglund menar att det inte finns något stöd i forskningen, som visar att man måste utföra minst 50 op/år för att säkerställa god kvalitet. Däremot kan man finna en förhöjd risk vid 3-5 op/år.

Den 9 januari 2008 skrev norska Dagbladet att tio personer dör varje dag p g a vårdrelaterade infektioner. Det var det norska Folkhelseinstitutet, som enligt beräkning av Professor Björg Marit Andersson, konstaterade att 3 400 personer dör av sjukhusinfektioner årligen. Vidare ansåg man att 20-30 % borde kunna undvikas ”enkelt”; Alltså att 700-1 100 personer per år dör i onödan.

Sjukhusinfektion är den fjärde vanligaste dödsorsaken inom I-länderna efter cancer, hjärtinfarkt och stroke. Gör man en jämförelse, förvisso inte helt statistisk vetenskaplig, så skulle man kunna undvika cirka 2 000 dödsfall om året i Sverige.

Varför diskuteras inte denna fråga i regering, riksdag, eller media? Var råder samsynen över denna utmaning? Här finns, enligt min mening, en frågeställning av mycket stor dignitet som inte hörs i debatten!

Vår förening har mycket att bidra med för att minska detta tal, höja vårdkvalitén och säkerställa en högre patientsäkerhet.

Släpp in oss på arenan!

LENNART HULTBERG
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0760-399 500

KALENDER

2018

Sep

11 PHSS & UCL Annual Conference, PHSS, London, UK

12-14 Livsmedeldagarna i Tylösand

17 Ventilation Solution Day Camfil, Trosa, Sweden

23-26 ICCCS Internationellt Symposium Haag, Holland

Okt

2-4 CTCB-I Certifiering Chalmers, Göteborg

3-4 Grundkurs RenhetsTeknik Köpenhamn

9-11 EHEDG Advance Course in Hygienic Engineering & Contamintaion Control Alfa Laval, Tumba, Stockholm

15-17 13th Annual PDA Conference on Pharmaceutical Microbiology Bethessda, USA

Nov

2-4 CTCB-I Certifiering, Glasgow, Scotland

29-30 Grundkurs RenhetsTeknik Chalmers, Göteborg

2019

Maj

6-7 R³ Nortdic 50th Symposium & Exhibition in Stockholm

Nästa nummer
beräknas utkomma den 5 september 2018

Manusstopp / Annonsbokning:
9 augusti 2018

Företag och medlem som vill delta med artikel eller release, skall sända detta i god tid före manusstopp till redaktören Berit Reinmüller.

REDAKTÖRENS SPALT

Föreningen R³ Nordics namn har sedan starten också varit **Renhetsteknik och Rena Rum – Contamination Control and Clean Room.** Namnet förpliktigar, renhetsteknik behövs idag inom ett mycket större område än inom konventionella renrum. När jag fört föreningens arbete på tal har jag ofta fått höra: *"Vi har inga renrum här och behöver inte heller den kunskapen"*. En bred erfarenhet av renhetsteknik har samlats inom R³ Nordic. Kunskap om mikrobiologisk renhet kan tillämpas inom ett brett område, t ex inom hälsovården, inte bara för operationsrum, och inom livsmedelsindustrin. Kunskap om partikulär renhet behövs bl a inom verkstadsindustrin – med allt från mikroelektronik till lastbilstillverkning.
Erfarenhet finns inom föreningen av hur man kan bygga in framtida renhet med en genomtänkt layout och med renhetstänkande i botten. Om man inte ser helheten är det lätt att suboptimera delar. Kommunikation mellan konstruktörer och användare är vitalt för ett hållbart resultat. Det är inte alltid "så har vi alltid gjort" är det bästa argumentet för att uppfylla dagens och morgondagens krav på anläggningar.

I DETTA NUMMER

Denna gång innehåller tidningen mycket från det 49:e R³-symposiet i Naantali. Symposiet var välplanerat och finska PK har - som vanligt - gjort ett utmärkt arbete. Alla presentationer hölls på engelska och Proceedings är omfattande.
GMP Good Manufacturing Practice, har vi ofta uppfattat som reserverat för farmaceptisk och biotech industri, visades här vara tillämpligt också inom livsmedelsindustrin. Två av dessa presentationer om GMP redovisas i detta nummer av RenhetsTeknik. Utan kunskap om sin process och dess risker kan inte brukaren låta bygga lämpliga lokaler eller välja lämplig utrustning för den aktuella processen. Kommunikation mellan kunniga användare, som kan sina processer och dess risker, och ett lika kunnigt konstruktionsteam initierar nytänkande och framsteg.

I NÄSTA NUMMER

Vi presenterar ytterligare utdrag från symposiet i Finland. Programkommittén för föreningens 50:e symposium i Stockholm kommer att presenteras utförligare. Att jubileumssymposiet går av stapeln i Stockholm betyder inte att det är enbart svenskt utan hela den nordiska föreningen står bakom det.

Kom ihåg att kunskap och erfarenhet bara ökar i betydelse när de delas med andra. Dela med dig av din erfarenhet genom att delta i symposiet, föreläsa eller skriva ett inlägg till RenhetsTeknik.

BERIT REINMÜLLER
REDAKTÖR

Good Manufacturing Practice (GMP) in the Food Industry

– Requirements in manufacturing unit design

TEXT: RIINA BRADE, ELOMATIC OY, FINLAND

Key good manufacturing practices include adequate and suitable utilities and services (such as water, steam, air, compressed air), the cleanability of the building and equipment, a suitable process flow with process design that minimises the potential for cross-contamination, effective pest control, as well as proactive maintenance and personnel hygiene. The fundamental principle of good manufacturing practice is to ensure that foodstuff contamination is minimised and products are consistently produced, traceable and controlled according to the quality and safety standards appropriate for their intended use.

However, good manufacturing practice (GMP) guidelines provide only minimal guidance. Even when complemented with EU and national regulations, the guidelines and available product safety standards are not prescriptive instructions on how to manufacture products, nor do they provide guidelines for a single perfect plant design solution.

The GMP requirements for food are deliberately general to allow individual variations by manufacturers to implement the requirements in a manner that best suits their needs. When a company sets up its quality program and manufacturing process, there are many ways to fulfil GMP requirements. The manufacturer (project customer) and the food safety authorities set the requirements for food establishments. These requirements are the starting points for plant design. Thereafter, it is a joint effort to determine the most effective, efficient and suitable procedures, facilities, materials, equipment and controls in advance and to ensure that safety objectives are consistently met.

DEFINITIONS AND REGULATIONS

Good Manufacturing Practice, commonly abbreviated to GMP or PRP (prerequisite programme) is a term that is recognized worldwide for the control and management of hygiene manufacturing, as well as the quality control of foods, pharmaceutical products, medical devices, and even packaging and materials that come into contact with food.

Codex defines GMP as: A combination of manufacturing, testing and quality control procedures aimed at ensuring that products are consistently manufactured to their designated specifications and safe for human consumption and use.

According to the regulations illustrated in Figure 1, every food manufacturing business has to establish and implement a food safety management system (FSMS in Figure 2) appropriate for the products being manufactured, supported by the principles of good manufacturing practice (GMP). Based on hazard and risk analysis, all reasonable precautions should be taken and the FSMS should be fully and effectively implemented and maintained. A process for control measure validation and FSMS and QMS verification and improvement supports the dynamic functioning of the system during any change in production, equipment or the product itself. It is vital that the FSMS and associated GMPs (prerequisite programmes) are continuously appropriate for the products and processes involved and the inherent level of food safety risk.

In order to achieve GMP objectives, it is necessary to have the following in place:

1 *Quality Assurance.* To comply with the product specification: that is, to design and plan relevant raw material and packaging specifications, ingredient formulation, labelling, processing methods and conditions, processing equipment and processing environment, intermediate specifications, specifications for management and control procedures, distribution system and cycle, appropriate storage and handling with relevant instructions and documentation.
2 *Effective Manufacturing.* Operations: that is, to validate and manage operational practices and personnel qualifications to ensure that the process meets it's specific design parameters and that the resultant products consistently comply with product specifications.
3 *Quality control.* That is, to have an effective monitoring system in place with appropriate corrective action procedures supported by systematic verification procedures (covering e.g., management review) of the overall quality plan and compliance throughout the product´s shelf life.

SCOPE AND AVAILABLE GUIDELINES

For food manufacturing and food handling establishments, the original and most widely known guideline is **"the General Principles of Food Hygiene"** (a set of GHPs that form the foundation of GMPs) published by the Codex Alimentarius Commission, a body that was established in the 1960s by the FAO and WHO. Codex codes and principles define general practices for production, processing, manufacturing, transport and storage, but also practices for individual foods or food groups

Figure 1. Many countries have created their own GMP guidelines for food and pharmaceutical manufacturers that correspond with their legislation.

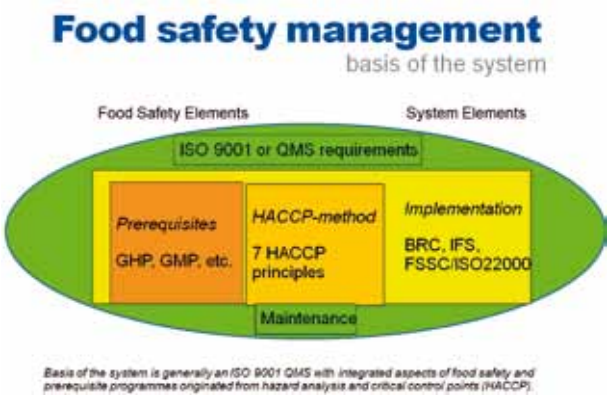

Figure 2. An illustration of a food safety system based on the HACCP plan with prerequisite programmes.

that are considered essential to ensure the safety and suitability of food for consumption.

In the UK, the Institute of Food Science and Technology has published a guide to the responsible management of GMPs – the current issue is the 6th edition (GMP6).

In the United States, GMPs are enforced by the U.S. Food and Drug Administration (FDA), under the title 21 CFR (cGMP). The FDA regulations use the phrase "current good manufacturing practices" (CGMP) to describe these guidelines, applicable e.g., in food, drugs, medical device manufacturing and even in cosmetics.

In summary, many countries have legislated that food manufacturers are required to follow GMP procedures and have created their own GMP guidelines that correspond with their legislation. Regulatory agencies (including the FDA in the U.S. and regulatory agencies in many European nations) are authorised to conduct GMP inspections.

In addition, voluntarily ISO management systems audits other product safety certifications/schemes can be certified by accredited certification bodies. Some of these schemes (e.g., BRC Food & IoP, IFS Food, FSSC 22000) are recognised by The Global Food Safety Initiative (GFSI) international trade association. In line with the main sub-parts of Codex, GMP6 and cGMP, the GMP sub-parts according to FSSC 22000 and its technical specification ISO /TS 22002-1 are presented in Table 1.

1-3 Scope, normative references, terms
4 Construction and layout of buildings
5 Layout of premises and workspaces
6 Utilities – air, water, energy
7 Waste disposal
8 Equipment suitability, cleaning and maintenance
9 Management of purchased materials
10 Measures for prevention of cross-contamination
11 Cleaning and sanitizing
12 Pest control
13 Personnel hygiene and employee facilities
14 Rework
15 Product recall procedures
16 Warehousing
17 Product information and consumer awareness
18 Food defence, biovigilance, and bioterrorism

Table 1.
Scope of prerequisite programmes according to ISO 22002-1:2009 (a technical GMP part of FSSC 22000 system):

WHAT ARE THE CHALLENGES IN HYGIENIC DESIGN?

Firstly, **uniform conformance** with product specification is difficult with food and drink products. The main raw materials for food and drink manufacture are derived from nature, and are subject to natural variation in primary production. Wide variations may occur, for example, among cultivars due to regions and seasonal and weather-related cultivation differences. Therefore, the food and drink manufacturer has to make a reasonably uniform product from variable raw materials, a combination of raw material selection, pre-treatments, formulation adjustments and processing variations.

Secondly, the GMP guidelines, even when complemented with EU and national regulations on structural and functional requirements, traceability, temperature and personnel requirements, are not **prescriptive instructions** on how to manufacture products, nor do they suggest a single perfect solution for the hygienic design of a facility and process. There is, for example, not only one preferred flooring material or drainage system, or one proper manufacturing zoning and segregation solution. GMPs are merely a series of general principles that must be observed during manufacturing or taken into consideration during design and construction. Concisely put, when a company sets up its facilities, a quality program and a manufacturing process, it can fulfil GMP requirements in many different ways.

Thus, there are several feasible solutions for hygienic design of a food factory. The requirements for food, are deliberately general to allow individual variations by manufacturers to implement the requirements in a manner that best suits their needs. It is the company's responsibility to determine the most effective and efficient procedures, facilities, materials, equipment and controls. It all comes down to the products manufactured and the food manufacturer´s preliminary hazard analysis and finally, to the estimated CAPEX and OPEX **costs and available financing**.

INVESTMENT PLANNING STARTS WITH PRE-ENGINEERING STUDIES

The manufacturer is responsible for employing appropriate and technically-competent personnel to specify the product for-

mulation, factory processes and procedures, and to design suitable facilities to support safe production of food products. **By planning** these aspects **ahead** with appropriate validation and verification activities, as required by GMP guidelines, the manufacturer has exercised adequate precautions and diligence necessary to **comply with the law**.

For engineering and consulting companies, CAPEX- investment planning starts with a feasibility study in cooperation with the manufacturer in the so-called pre-engineering phase. Although investment costs will materialise during implementation, the costs will be mostly determined by the decisions and choices made during this pre-phase. The output from pre-engineering will, to a great extent, also determine how straightforward the implementation is and what the execution time of the project is.

In addition to the impact on future turnover and efficiency, the chosen process and plant concept have an impact on product safety and product quality. Therefore, a crucial part of pre-engineering is cooperation with the manufacturer in **setting user requirements** on effective and hygienic manufacturing operations, based on preliminary risks identified for the targeted products and their end users. As an output of the pre-engineering phase, this means specifying the following in the form of a study:

- Adequate design of premises and suitable manufacturing and storage spaces
- Suitable process flow with process design to streamline the process and minimise the potential for cross-contamination
- Choosing correct and easily maintained main equipment
- Appropriate storage and transport facilities
- Adequate and suitable utilities and services.

During the design phases, the targeted production and distribution capabilities are translated into specific design parameters that result, after appropriate validation and verification activities, in the intended product quality and production amounts. **The most crucial design guideline is to ensure that contamination is minimised in every decision made.**

The manufacturer (project customer) and the food safety authorities set the requirements for food establishments. These requirements are the starting point for plant design.

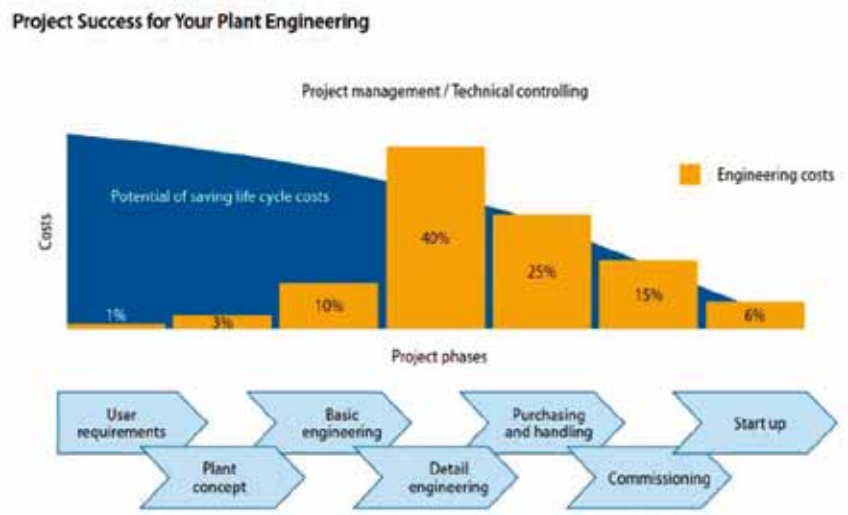

Figure 3.
The success of an investment project is supported by EPCM services (engineering, procurement and contruction management) and step-by-step project management.

The most common investment types are greenfield and revamp projects, but also production efficiency related improvement projects are done frequently. Product and consumer safety requirements need to be built into plans while simultaneously considering the quality, hygiene, cost and schedule. It is the designer´s duty to find a balance between these requirements. Nowadays, HSE requirements and environmental impacts are also taken into consideration in food manufacturing unit design.

For manufacturing unit investments, at least the following documents are prepared:

- Conceptual capacity study of production
- Preliminary manufacturing space requirement and layout with hygienic zoning
- Preliminary material and personnel flows
- A site plan with building layout and locations for production, service, storage areas and surrounding areas and main air intake/outlet locations etc.
- Investment cost estimate (target around ± 25-40?% depending on the complexity of the process) based on main equipment selection
- Preliminary project scheduling.

Reviews and acceptance of the concept design, purchasing specifications and estimated investment costs against set requirements from the manufacturer (customer) and authorities are vital parts of securing the success of the investment project.

Before making any further decisions to proceed the manufacturer should, at the latest in this investment phase, already contact the

food safety authorities and inform them of the investment plans. This obligation stems from the Finnish Food Act (23/2006), according to which a food establishment must notify the relevant supervisory authority prior to commencement of operations or a substantial change of activity. Food establishments of animal origin products have to get approval from the authorities. Thus, a documented food establishment concept and other design documents from the pre-engineering study and a hazard analysis are prerequisites for a proper application.

During the next phases (basic and detail design) and construction, designers ensure that both the equipment and new manufacturing unit (or expansion of it) are further designed, fabricated and finally constructed and installed according to sound hygienic design parameters. This entails cooperation between all design disciplines (process, building, EIA, HVAC, steel structures and plant), equipment and system suppliers and the food manufacturer.

In terms of output documentation, more detailed decisions need to be made by the project team related to all areas of the factory:

- Buildings and their surroundings
- Construction of specific elements of the building
- Factory and industrial services
- Equipment, layout and installation
- Cleanability of the building and equipment
- Ease of maintenance.

The accuracy level of documents depends on the specified guidelines and regulations of the product category, as well as the chosen contractors and their capabilities.

Suppliers should be selected based on their ability to supply products or services that meet the defined requirements. Only approved suppliers with hygienic application references should be used, if possible. In addition, the control of incoming products and services is a key prerequisite within a good manufacturing practice (GMP) system.

Figure 4.
As EPCM service providers, designers can be involved in every project phase on behalf of the customer.

During the construction and installation phase, the designer can act as the site supervisor that coordinates material and equipment deliveries to the site, performs delivery inspections, and supervises installations. In this supervision work, HSE and GMP coordination plays a major role in **ensuring safety during construction and that contamination is again minimised on site**. Finally, a commissioning plan is generated that also includes validation and inspection steps to secure that the manufacturing lines and supporting systems are approved for full-scale production. This usually includes production test runs with microbiological sampling and shelf-life testing.

HOW DO DESIGNERS TURN GENERAL GMP PRINCIPLES INTO DESIGN PARAMETERS?

To ensure that

- the equipment and factory can be effectively operated,
- does not contain hazards, does not rapidly deteriorate and
- can be appropriately cleaned and disinfected,

designers and those responsible for construction of food factories rely on their experience of industry best practises and applied technology in previous food industry revamp projects. Furthermore, designers follow the applicable EHEDG guidelines in addition to local legislation and national building standards.

EHEDG (The European Hygienic Engineering and Design Group) has developed and published a variety of **practical guidance documents on adequate hygienic design** in different areas of food production equipment and machinery, as well as on the construction materials and food manufacturing infrastructure in general. Currently, EHEDG also participates in the GFSI Working Group on the topic of "Hygienic Design of Food Facilities and Equipment" for GFSI recognition and acceptance.

The EHEDG organisation has identified five key areas of hygienic design in line with Codex GHP/GMP principles – hygienic building design, utilities, equipment and process design, cleaning and sanitation and personnel hygiene. In order to assist the

implementation of these key areas, supporting hygiene engineering guidelines exist. The guidelines include, for example, cleaning validation, hygienic design of belt conveyors, construction materials for equipment in contact with food, hygienic welding of stainless steel tubing, air handling, water treatment and its storage and distribution, food-grade lubricants, hygienic design of pumps, homogenisers and dampening devices, and valves for food processing. Altogether, 47 guidelines currently exist.

Some examples of design parameters provided by the EHEDG guidelines that support pre-engineering and the basic and detail design phases are provided in the following paragraphs.

During the pre-engineering phase, the focus is on premises, equipment and facilities that need to be located, designed and constructed to ensure that contamination is minimised; design and layout that allow appropriate maintenance, cleaning and disinfections and minimise airborne contamination.

Examples of EHEDG- design parameters for pre-engineering - Layout and segregation:

- Building design provides internal separation with walls between departments in which edible (e.g. food and food ingredients) and non-edible materials (e.g. boiler rooms, workshops, and machinery rooms) are handled. In addition, air, waste and drainage flow effectively out of higher hygiene zones into lower hygiene zones.
- Cross-contamination is reduced by segregation that takes into account the flow of the product, the nature of materials, equipment, personnel, waste, airflow, air quality and utility provisions and lastly, the isolation of microbiology laboratories, particularly those handling pathogens.
- A minimum clearance under the equipment is specified dependent on equiment widths: E.g., for equipment approximately one meter wide, there should be a minimum clearance of 30 cm. For equipment access, a minimum clearance of 90 cm from walls and between equipment of 120-150 cm is suggested.
- Waste routing – waste should be moved out of high hygiene areas via openings in the segregated barrier. Waste storage should be in a separate room or in an external area that is constructed with impervious materials and suitably sloped and drained.

The fundamental issue to remember, is that the degree of hygienic design applied and appropriate hygienic zoning (basic, medium and high hygiene areas) will depend on:

- the product range (perishable foodstuffs, low moisture foods, frozen and chilled ready-to-eat foods etc.),
- the degree of microbiological decontamination undertaken (processing),
- the likelihood of spoilage and pathogenic microorganism growth or survival in the product and
- the risk of cross-contamination from the external environment.

Thus, the hazard analysis and decisions require a multidisciplinary approach and cooperation between the manufacturer´s specialists and engineering specialists in every investment phase, covering procurement steps and finally the supervision of construction and commissioning. During later design phases, all areas of the factory and manufacturing process are further planned and dimensioned with descriptions, procurement specifications, plant models and drawings to support the construction and installation phase.

Examples of EHEDG – design parameters for basic and detail design phases - Factory services, utilities and materials:

- Steam should be generated from potable water and should be adequate to meet operational requirements and should have traps to ensure adequate condensate removal and the elimination of foreign materials.
- Conditioned air should have a relative humidity below 55?% to restrict the growth of microorganisms, in particular moulds.
- Air control facilities including temperature, humidity and filtration, appropriate to both the operations undertaken within the processing area and to the external environment.
- Air flow from a higher to lower hygienic zone and from lower to higher dust loaded areas.
- Sufficient air changes per hour in medium hygiene processing areas (typically between

5-25 changes per hour, filters EU-class M5 to F7) and high hygiene areas (>10 changes per hour, filters F7 or greater).

- Compressed air, CO^2, nitrogen and oxygen shall be filtered through a micron filter (to remove particles of 5 microns or greater) located close to the point of use and should have non-return valves to preclude the entry of food.
- Process and transport air should be drawn from the atmosphere outside the process plant building through an inlet at least 3 meters above ground level. Any air intake should be sited as far as possible (min 10 m) from any outlet air streams or other exhaust ducts, wet scrubbers etc.
- EHEDG Guidance document no. 32 deals with materials of construction for equipment in contact with food. Stainless steel, hot dipped galvanised steel, aluminium, fiberglass, polyvinyl chloride and nylon are examples of applicable food grade materials.
- Wall exteriors should not have horizontal surfaces (gradients >/= 45°). External walls are commonly constructed out of concrete, brickwork, steel plating or sandwich panels. Internal walls of reinforced concrete in production areas should always have a finishing consisting of mould-resistant coating approved for food use. Plastic panels made of uPVC and glass fibre reinforced polyester or epoxy resin, stainless steel panels for high wet use targets, are available.
- Floors may have to meet requirements for chemical resistance – against acids (spirit vinegar or mineral acids etc.), alkalis, oils, fats, cleaning products (solvents such as alcohol or even peppermint oil) and disinfectants (sodium hypochlorite, per acetic acid, hydrogen peroxide etc.) – for abrasion, resistance, temperature and thermal shocks. All joints are weak points in a floor and should be positioned away from areas of regular discharge of liquid.

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5. www.fda.gov/Food/GuidanceRegulation/CGMP/ucm110877.htm

SUMMARY

The prevention of contamination of food products is the fundamental reason why hygienic design principles are applied. Poor GMP-level indicators include e.g., inadequate drainage leading to ponding of water on the floor, surface defects, equipment with dead pockets with product residues, signs of corrosion, traces of lubricants or detergents in products, untight doors and transport docks, open windows, and pipework with visible dirt accumulation. In addition, indicators such as seasonal variations in hygienic conditions in production resulting, at worst, in quality complaints and high operating costs related to maintenance and cleaning, can result from poor GMP practises.

Hygienic food processing equipment and manufacturing units should be easy to maintain in order to ensure they perform as expected to prevent food safety and quality issues. Furthermore, it must be possible to monitor and control all the functions that are critical for food safety. The engineering design process is a series of steps that engineers use in creating functional products, processes and even manufacturing units based on user requirements. Sometimes, the requirements of hygienic design are in conflict with functionality and costs. An acceptable compromise, preferably pre-planned already in the pre-engineering phase, must never **put food safety at risk.** Other than securing safety, the targeted benefits of the pre-engineering phase are also the potential of increasing the life expectancy of equipment, reducing maintenance measures, enhancing sustainability and lowering operating costs.

It is the responsibility of designers and each manufacturer to establish a GMP framework and requirements for each product type or family that will result in quality products that are safe, from raw material handling though production and warehousing all the way to distribution.

It is a complex task balancing costs, safety regulations and user requirements. However, with step-by-step project management, EHEDG hygienic engineering guidelines, equipment suppliers and contractors that are familiar and experienced in GMP and with appropriate validation and verification activities, our **joint preventative and pre-designed efforts** will secure food products that meet the quality and hygiene system requirements and attract consumers now and in the future.

Call for papers

R³ Nordic Symposium & Exhibition
Hotel Birger Jarl • Stockholm
6-7 May 2019

Main subjects

The latest development in cleanrooms and controlled environments and contamination control areas

Pharma manufacturing and monitoring

Current standards and ongoing standardisation work, such as e.g., Annex 1 of the EU GMP

Hospital - cleanliness requirements. Requirements of today and tomorrow

Call for Papers

The program committee is open to New ideas and proposals - What do you want to learn more about?

Abstracts on controlled environments and contamination control, in the field of hospital, pharmaceuticals, biotech and food.

Presentations are accepted in English or in the Nordic Languages.

Send Your proposals to the Programme Committtée

Programme Committée

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Standardiseringsarbete i Sverige

TEXT OCH BILD
BERIT REINMÜLLER

Två av många deltagare på SIS Seminarium i april 2018: Sarah Sim, projektledare SIS och Ellenor Lennarth, ordf. i TK 332 Sjukvårdstextilier.

Under våren hölls mötenpå SIS i TK 108 Renhetsteknik, som arbetar bl a med ISO/TC 209 Cleanrooms and associated controlled environments, CEN/TC 243 Cleanroom technology och ISO/TC 131 SC6 - Fluid power systems – Contamination control,

TK 333. Operationstextilier var i januari värd för ett möte i Stockholm för CEN/TC 205 WG14 ”Surgical clothing, drapes and medical facemasks. Ett uppföljande möte hölls i maj där det bl a beslutades att SIS TK 333 tillsammans med TK 332 anordnar ett seminarium kring operationstextilier på SIS 2018-11-21.

TK 527 ”Renhet i operationsrummet” möttes i mars där en genomgång skedde av arbetet i CEN/TC 156 WG18 Ventilation in hospitals. TK 527 kommer att vara värd för ett möte i WG 18 den 18-19 oktober på SIS i Stockholm

SIS SEMINARIUM

I slutet av april arrangerade ett välbesökt seminarium och utsåg årets standardiseringskommitté och årets kommittéordförande. Seminariet avslutades med mingel och buffé.

– Alla våra ordförande och experter i standardiseringsarbetet är viktiga och gör ett fantastiskt jobb. Genom dessa utmärkelser vill vi uppmärksamma och premiera den kommitté samt ordförande som utmärkt sig med särskilda insatser under året, säger Thomas Idermark, Vd för SIS. Utmärkelsen som årets ordförande gick till Magnus Karlsson som leder SIS tekniska kommitté för innovation management, SIS/TK 532. Till utmärkelsen, som årets tekniska kommitté var fem kommittéer nominerade. Utmärkelsen gick till SIS tekniska kommitté för brandsäkerhet, SIS/TK 181, som leds av ordförande Michael Strömgren.

SIS har cirka 300 tekniska kommittéer som arbetar med att utveckla internationella standarder inom allt från skruvhylsor till socialt ansvarstagande, maskinsäkerhet, Internet of things, miljöpåverkan, förpackningar och mycket mer.

Internationellt ISO arbete

I samband med ISCC konferensen i Nederländerna kommer flera arbetsgrupper i ISO/TC209 att träffas, TC 209 kommer att ha sitt möte där alla arbetsgrupper redovisar pågående arbeten. ISO/TC 209 WG 4 ”Design and construction” hade ett möte i Lindon under försommaren.

Europeiskt arbete i CEN/TC 156 WG 18 Ventilation in hospitals

TEXT OCH BILD
BERIT REINMÜLLER

Vid det senaste mötet för arbetsgruppen ”Ventilation in hospitals” i Helsingfors 24-25 maj var finsk standardisering METSTA värd. Av de fjorton närvarande representanter var 2 från Finland, 5 från Sverige, 1 från Norge, 1 från Spanien, 2 från Tyskland, 1 från Schweiz, och ordförande och sekreterare från Nederländerna. Fortfarande tycks oklarheter gälla angående dokumentens status i CEN. Experter, som inte deltar regelbundet, gör att mångt och mycket behöver repeteras och motiveras. Arbetet mot en gemensam standard bedöms gå sakta framåt trots stora skillnader i åsikter, som t ex nyttan av att få brukarens/sjukhusets synpunkter på operationsrummet. I vissa fall anses det helt ointressant i andra fall bedöms information från brukaren bidra till nytänkande och framsteg.En annan åsiktsbrytare är nyttan av mikrobiologisk provtagning under pågående operation.

Kommande möte i WG 18 fastställdes till den 18-19 oktober 2018 i Stockholm med SIS som värd.

Från finsk sida rapporterades om en mätstudie av mikrobiologisk renhet från 47 operationsrum på 13 sjukhus. Resultatet av studien redovisades på R^3-symposiet. Totalt hade nästan 200 prov tagits från operationsrum med UDF system (1-2,8 m^3/s) och från operationsrum med konventionell omblandande strömning (0,5-1,2 m^3/s).Medelvärdet av samtliga prov angavs till runt 20 CFU/m^3. Vissa oklarheter fanns angående redovisning av operationstyp, antal personer i rummetoch vilken typ av kläders som använts. Också i Nederländerna har mikrobiologiska mätstudier utförts. Resultat av redovisade mätstudier ledde till frågan om man skulle ändra det mikrobiologiska kravet från 100 CFU/m^3 till 50 CFU/m^3 för s k allmänna kirurgi.Resultatet av en fråga runt bordet blev att det kanske är för tidigt att ändra rekommendationen för allmän kirurgi. I Norge planeras liknande mätstudier, Sverige har sedan lång tid mätresultatfrån utförd mikrobiologisk kontroll i operationsrum. Det diskuterades om man skulle kunna ha en gemensam och utförligare ram för mikrobiologiska mätningar än den som tagits från SIS TS 39:2015. Den norska experten skull ta fram ett förslag baserat på finsk och svensk erfarenhet.

På samma sätt som vid tidigare möten accepterades del 1 - General. Del 3 - Ventilation of isolation units rapporterades av den finske experten.Vid nästa möte räknar man att kunna godkänna det färdigställda arbetet i hela WG gruppen.

Längsta tiden ägnades åt del 2 Operation suites version 23. En lång diskussion uppstod kring ”Air quality” och vad som ingår i begreppet, resultatet blev att ett klargörande ska utformas av ordföranden. ”Ultraclean air” var också ett ifrågasatt uttryck främst av dem som inte har kontakt med vården och den medicinska vokabulären. För att komma vidare i arbetet blev en tillsvidare lösning arbetsnamnen A och B, där A står för luftrenhet <100 CFU/m^3 och B står för <10 CFU/m^3!

Under mötet gick man igenom inkomna kommentarer, som lämnats på avsedd blankett. I stort sett godkändes de svenska och finska kommentarerna medan de tyska kommentarerna om ändring av definitioner, som t ex critical area avslogs efter diskussion.

Förslag till en gemensam segregationstest har tagits fram av den schweiziska och tyska experter i samråd med ordförande i arbetsgruppen. Den föreslagna testen ska presenteras till det kommande mötet i Stockholm.

I senaste **PDA Letter** finns bl a aktuell information om:

- PDAs 3rd Annual European Meeting in Berlin,
- Growing Acceptance of Real-Time Monitoring, *May 29 2018, Frank Panofen, Particle Measuring Systems*
- A Not-So-Sweet Smell: Part I *May 29, 2018, Siegfried Schmitt, PhD, and Anthony Newcombe, PhD, PAREXEL Consulting*
  A Review of Contamination Concerns for Wooden Pallets

PDA Technical Report No. 79 Particulate Matter Control in Difficult to Inspect Parenterals
This Technical Report is intended to provide logical pathways to DIP product inspection and testing to support continual process improvement in the industry

PDA has released the **2017 Glass Quality Survey,** designed to assist in the identification of glass container quality concerns and development of solutions to overcoming them.

Companies from around the world completed the survey. Respondents included representatives from branded and generic pharma, biopharma, and medical devices companies. The data within the survey report presents a comparison of responses from the 2012 Glass Quality Survey to the identical questions from the 2017 survey, thus providing insight as to whether there have been any changes in the cause and effect of certain glass quality issues or improvement in the overall satisfaction with supplier quality. The survey topics include glass sampling and inspection practices, product complaints and recalls due to glass defects, and quality oversight, among others.

European Journal of Parenteral & Pharmaceutical Science

Tidningens e-version är tillgänglig för PHSS medlemmar via föreningens hemsida.

Issue 23 nr 1 innehåller:

- Editorial: Managing the global suppliers by *Kay O'Hagan*
- Designing of nanoparticulate systems of kappa carrageenan containing antihypertensive drugs by *Ankit Mishra* and *SK Yadav*
- Rational for the selection of microbial monitoring locations on personnel working in aseptic processing areas by *Ravikrishna Satyada* and *Tim Sandle*
- Parenteral pharmaceutical future: from blockbuster products to specially medicine by *Gert Moelgaard*
- Regulatory review by *Malcolm Holmes*

Clean Air and Containment Review (CACR) (finns nu på vår hemsida)

Articles in Issue 34, April 2018:

- ISO/TC 209 launches new cleanroom standards
  Roberta Burrows, David Ensor
- Standards update summar
  John Neiger
- HEPA versus ULPA: which filter for your biosafety cabinet+
  Bill Peters, Daniel Hillman
- Achieving contained (dustfree) milling
  James Ellis
- Equipment Requirement Specification – a way to clarity
  Helen Hale

EU GMP
Den nu publicerade draft **Annex 1 "Manufacture of Sterile Medicinal Products"** kommenteras från flera håll. En stor mängd kommentarer har lämnats in. En gruppering av kommentarerna har utförts av PHSS.

Bearbetning av de inkomna kommentarerna pågår. PHSS ordförande James Drinkwater informerade om detta vid det 49:e R³-symposiet i Naantali.

The International Symposium in October 2018, will cover a variety of topics related to contamination control: physical, chemical and biological in gases, fluids, and on solid surfaces as well as process contamination.
We invite contributions in these and related fields relevant to contamination control and cleanliness.
From the 23rd to the 26th of September, 2018, The Hague in the Netherlands will be the capital of "contamination control and clean controlled rooms".
VCCN is working on a high quality programme with participation of national and international expertice. The theme of this year's symposium will be "The world behind contamination control".

The theme will be divided in seven important disciplines:

- Health Care
- Life Sciences
- Micro-Nano Electronics
- Photonics
- Micro Assembly
- Food
- Space

Scientific Steering Committee ISCC 2018; Eric Stuiver, Koos Agricola, Frans Saurwalt och Remko Noor, bjuder in till en mycket innehållsrik konferens i höst.
Tekniska studiebesök anordnas dagen efter symposiet..

Uppdaterad information finns på https://iscc2018.com

Rapport från Naantali

Symposieplatsen Naantali bjöd på strålande sommarväder under symposiedagarna. Ett stort antal deltagare, intressanta föreläsningar inom föreningens hela intressesfär, ca 20 utställare, ett duktigt team vid registreringen samt 100% engagerade PK-medlemmar gjorde symposiet till en succé.

Symposiet öppnades av PK:s ordförande Leila Kekko och inleddes med musik, varefter två key-note speakers från Finland belyste aktuella delar av GMP och automatisering på sjukhusapotek. Efter den gemensamma inledningen delades föreläsningarna upp i tre spår; Pharma and Hospital Pharmacy, Hospitals och en allmän del. Kaffe och lunch serverades i utställningen, vilket gav goda möjligheter till kontakt med utställare. Den första dagen avslutades med att PHSS ordförande James Drinkwater gav en sammanfattning av inkomna kommentarer till den publicerade Annex 1. Traditionsenligt hölls föreningens årsmöte efter dagens föreläsningar.

Symposiets första dag avslutades med en bankett på hotellet. Under banketten bjöds förutom god mat och dryck, på musik av mycket hög klass med kantelestjärnan Ida Elina som underhöll gästerna med flera uppskattade inslag. Middagen avslutades med sedvanlig avtackning av funktionärer.

Symposiets andra dag inleddes med en uppskattat presentation kring Virtual reality model in cleanroom design. Efter detta delades föreläsningarna upp i tre spår; Livsmedel och Biotech, Pharma & Hospital Pharmacy och ett tredje för General. Symposiet avslutades med en gemensam föreläsning av Frans Saurwalt, ordförande i ICCCS om renrumszoner med hjälp av luftflöden resp tryckskillnader.

Ett väl arrangerat och genomfört symposium, med ett utmärkt fackligt innehåll och en intressant utställning.

Stort bildkollage på nästa uppslag från Naantali. Bilderna är tagna av Kim Vuorenpää om inget annat anges.

**Bilden t v när Ida Elina uppträder för symposiets deltagare.
Foto: Berit Reinmüller**


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Presentation
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Vedenpuhdistuksen edelläkävijä


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ALPIQ
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ALPIQ


CLETEC

Finland tackar för 2018 och lämnar över stafettpinnen till Sverige och föreningens 50:e symposium & utställning

Bilder nedan är tagna av Raimo Pärsinen

Contamination Control and the Food Industry

FRANS W. SAURWALT, KROPMAN CONTAMINATION CONTROL. NJIMEGEN, THE NETHERLANDS

Clean room facilities for the micro-electronics, the pharma-biotech, the medical devices and healthcare do differ significantly from high care / high risk food processing facilities. Still food processing is an interesting area for professionals with a contamination background and vice versa. In a world full of classifications and requirements(ISO-14644-1, EU-GMP, FDA, e.g.) the lack of distinct cleanliness requirements in for the food is noticeable. This is obvious for there are many different types and formats of food products. As hygiene in food processing includes contamination control, the vast variety in substances, processes and the huge volumes make the food processing world take a different approach. The main elements of difference will be addressed, the challenges discussed and based on a specific case the results illustrated.

CONTAMINATION CONTROL IN THE FOOD?

Within the approach of the ISO TC209 on the ISO 14644 and ISO 14698 cleanroom standards a 'cleanroom' has to have a classification by particle concentration in air as per ISO 14644-1. One might suppose that any room, not having such a classification, will not be of interest considering contamination control. Typical for food production plants this is not the case. Basic guidance on this is given in the Codex Alimentarius. This Codex standards are based on sound science provided by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO.

The code of practice "General Principles of Food Hygiene, CAC/RCP 1-1969 (2003) addresses contamination. It contains the following definitions:

- "Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability."
- "Contamination - the introduction or occurrence of a contaminant in food or food environment."
- In section IV on Establishment: Design and facilities the Objectives are given:
- "Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:
  - contamination is minimized;
  - design and layout permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination;
  - surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;
  - where appropriate, suitable facilities are available for temperature, humidity and other controls; and
  - there is effective protection against pest access and harbourage.

RATIONALE: Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled."

TYPICALS - Product specific requirements

The essential aim of the Codex Alimentarius is the requirement to secure the product safety to the customer. This is comparable to the pharma industry to the extent that the production has to be controlled, as well as the traceability from raw materials all the way to finished products. Where for pharmaceutical products (especially the aseptic ones) rather

Level of hygiene	Wet cleaning	Controlled wet cleaning	Dry cleaning
High	Hw	Hew	Hd
Medium	Mw	MCw	Md
Basic	Bw	Bcw	Bd

Table 1: hygiene zones and cleaning methods from EHEDG Guideline 26

clear levels of cleanliness of are established, for food products only limited levels for certain pathogenic species are given. This is very much in line with current thinking in CEN TC243 WG13 on bio contamination, where a difference is made between levels of specific harmful microbiology and the overall non-specific non harmful general microbiology level. This might add to the improvement of control and monitoring. An increase in products shelf life and the reduction of preservatives are drivers for better production processes and environmental control when exposed. In recent years additional substances are identified as contaminants: allergens and in some cases endotoxins. This has already led to major changes in production facilities. Essential is the worldwide requirement to implement a quality management system that covers the essential quality and safety aspects. The approach used usually is HACCP (Hazard Analysis and Critical Control Points).

Hygiene and cleaning and zoning

Focusing on process steps where contamination can occur the (European Hygienic Engineering & Design Group EHEDG has defined principles for hygienic design. EHEDG Guideline 8 Hygienic design principles (draft) taking a look at process equipment and its surroundings.

Furthermore levels of hygiene are identified. There is not a very stringent definition of those levels, as they are determined by the HACCP analysis. It has been identified that the design of the surroundings where product matter is or can be exposed needs to allow for the way the cleaning will be accomplished.

Three types of cleaning are identified: (a) Wet cleaning; such as high pressure, high temperature and/or high detergent water based fluids, (b) Controlled wet cleaning; using wetted cloth or wipers and (c) Dry cleaning; using dry cloth or wipers.

A combination of each hygiene level and each cleaning procedure can be used to identify zones in a facility. The typical zones are given in table 1.

An important reason for this approach is the nutritious nature of all food products and the much larger quantities. Water and nutrition are the key factors to support live from molds, yeast, bacteria up till rodent. For that reason contamination control in starts in the landscaping and fencing around a facility to avoid easy intrusion of animals and insects, all the way through gowning rooms, air locks, towards areas of food processing.

Reduction and (re-)contamination

To control microbial growth in raw material and product various reduction treatments are utilized, such as blanching, pasteurization, sterilization, additives, ph-changes. Apart from very specific cases such as parenteral food, all food products are not sterile. Sterility is not feasible because the taste and constitution of the product would be lost. As bio contamination continues to grow such reduction steps require stringent hygiene to avoid additional or recontamination. The effect is indicated in figure 1.

As control over the cleanliness of product when exposed to the environment is so important the best way is to reduce the area to be cleaned by minimizing the exposure of the product. Comparable to ISO 14644-4 Annex A figure A1 indicating zoning and material and personal flows a food facility can be designed.

Figure 1:
The effect of hygiene to control the level of biocontaminants.

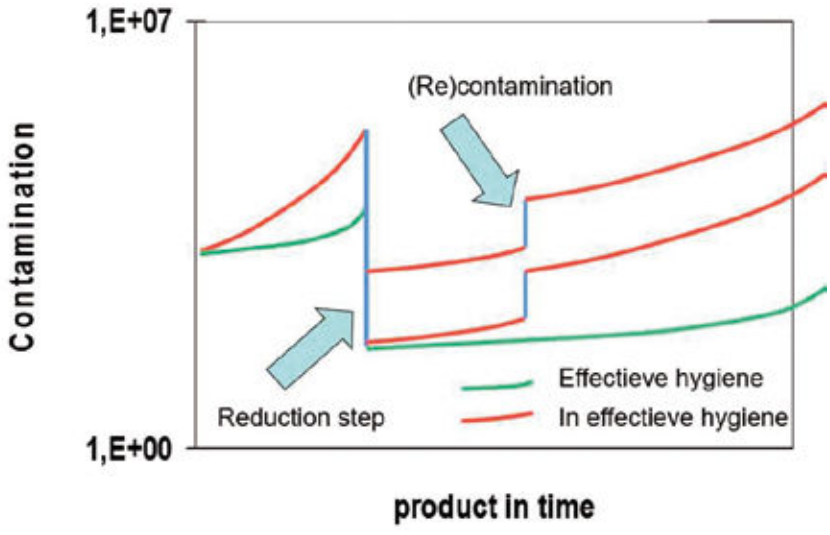

Figure 2: Cleanable arrangements of control cabinet and cabling

Figure 3: Un-cleanable bioreactor by con-gestion and poor design

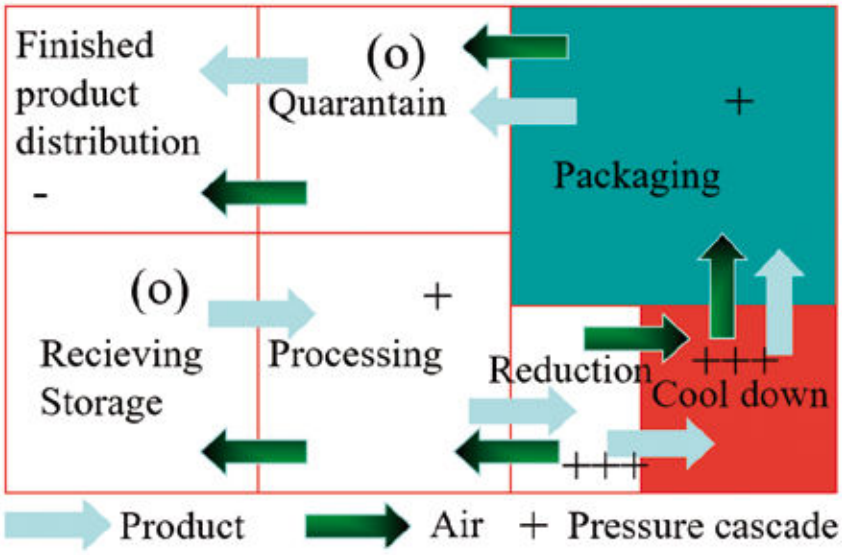

Figure 4: Schematic routing showing segregated zones and pressure flow cascade

Product specific requirements

Product spilling can abundant and wet cleaning is quite frequent in food processing facilities. Paying much attention to cleanability, not only inside process equipment but outside as well has made EHEDG define various guidelines on the hygienic construction of equipment and facilities.(Figure 2) this has much more focus than many pharma-biotech plant crowded with formulation vessels, bioreactors, downstream processing equipment.(Figure 3)

The challenge then is to avoid any un cleanable areas and surfaces. Where pharmaceutical plants especially for sterile products put emphasis in concealing as much as possible inside walls and above spaces in technical voids to reduce exposed area that needs to be and remain clean, a food production zone where some waste material is nearly unavoidable, needs to have no hidden areas were pest nor microbial control can be survive and grow. Therefore in hygienic design piping, cabling, equipment are all at sufficient space to walls, ceilings etc. as to be able to clean them, or outside a critical hygiene zone at the other side of a boundary.

The humidity challenge

Another important factor is the need to control the humidity and avoid condensation, as water is a very important factor to microbial growth. This implies that surfaces that are or can be cold below dew point need to be well insulated. At the same time the relative humidity needs to be below a certain level. Especially when high pressure high temperature water cleaning takes place this is a great concern. The impulse of the water will remove the soil but also adds vast amounts of live giving water. Whenever these types of cleaning are needed only very solid walls and ceilings can be recommended. Special care should be taken when recirculation is employed in the air handling and filters can become saturated. In such cases HEPA filters can be found showing fungi growing through.

Product specific requirements

A more effective way is to separate equipment in such a way that it can be outside a zone of high classification. This requires a close study of the logistics of a production process. The various zones are segregated by physical barriers in combination with a pressure-flow cascade. A schematic example is given in Figure 4.

Case Study

In designing the specific spray dry plant for small scale production (≤ 1 MT/yr) for VitaSquare Wolvega Netherlands many design considerations are implemented.

First of all process steps are identified and assessed for: product susceptibility, the risk of spilling, the method to clean in place as well as the exterior, including the room. Logistics of materials, product, staff and waste are planned for.

Dosing and fine ingredients mixing

Logistics are set up to handle most raw material in bulk containers, positioned outside the process rooms, are hooked up to the process lines. (Figure 5).

This all is done in a non-classified but controlled area of basic hygiene level. Spilling is not expected as all raw materials here are in containers or per piping such as feed water. Also the CIP and waste flows are run as fixed piping. Specific additives are added in the processing room via a tank lid. (Figure 5) The tank itself is at the other side of the wall, with all its pumps, valves, sensors, actuators, wiring and supports. This leaves the processing room quite easy to clean. The various connections for the process and transfer steps can be made by transfer panels. The fine ingredients come to this processing room by an elevator from the ground floor. The elevator acts as an airlock as it is interlocked and flushed by overflow air maintaining the pressure flow cascade.

As shown in figure 5 and 6 the logistics are well separated as well as the majority of the process equipment located in a non-classified hygienic zone. The area of exposure is very limited and in a controlled; ISO 9, ≥0,5?m, operational environment. Where the product is transported and processed further in closed equipment basic hygiene is maintained although not particularly necessary unless a breakdown or maintenance situation would occur. All fluid piping is designed and equipped to be clean in place (CIP) treated. A specific part of the facility is designed around the spray dry tower and equipment. Unique design features are:

- Clean corridor concept in combination with a pressure flow cascade design. This implies the corridors surrounding the process equipment areas to be cleaner and better controlled than the process area. The benefit of this is twofold: a) any

Figure 5: Process vessels and stacked raw material containers at 1st floor level in not classified basic hygiene zone as back side of Figure 5.

Figure 6: Connecting, dosing fine ingredients area

Figure 7: The clean corridor as a distribution duct towards process rooms

Figure 8: The box in box design with the production zone at the left

Figure 9: The fan area for the spray dryer inlet on the 4th floor

Figure 10: The fan area for the spray dryer inlet on the 3rd floor

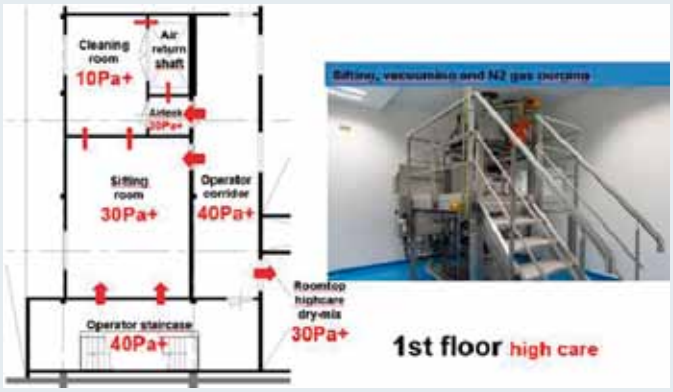

Figure 11: The spry dryer filtermat bottom at the 2nd floor

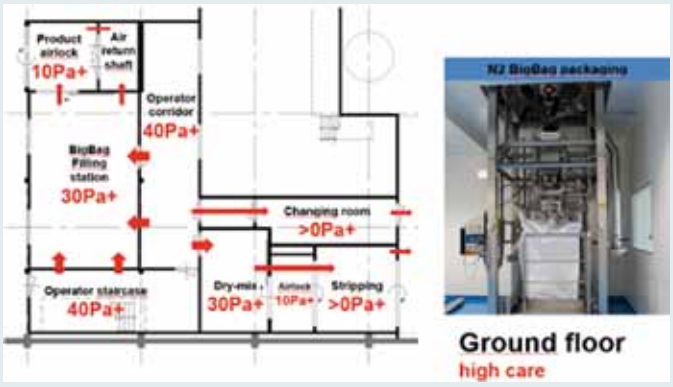

Figure 12: The sieve for the spray-dryed product on the 1st floor

product residues spreading out of the equipment is prevented to spread around and b) only clean supply ducting outside the process perimeter is needed. (Figure 6-7)

- Box in Box design. The influence of any pressure/flow dynamic from wind attack is taken away by a surrounding extra envelope. This also allows visitors to gain visual access to the plant without gowning up and entering. (Figure 8)
- Gravity settling of product spill. The extract air is returned via a wide shaft with a very low air velocity upwards to the air handling system. This will allow any relative large spillage particles to settle at the bottom. Only airborne particles will be carried upwards and away.
- For areas that require wet cleaning a specific exhaust is opened when cleaning and drying to avoid undesirable damp air recirculating.

Specific data of the system:

- Supply air filtering: F7 , F9 (EN779) and final filtering E11 (EN1822)
- Classification by particles in air in operation ISO 8 at 0,5 ≥µm
- Process air E12 (EN 1822) to the spray dryer at ISO 7 at 0,5≥µm
- Passive overflow cascade design with nominal highest pressure of 40 Pa.
- Twice or trice reused all overflow air in clean corridor concept reducing the required total air volume by factor 2,5.

Differences in Approach

The hygienic design aspects of food processing plants are not specified in required cleanliness levels as for example is the case for sterile pharmaceutical products. In the EHEDG DOC 47 (sept 2016): 'Guidelines on air handling systems in the food industry', information is given on how an air handling system should be designed and constructed.

For those areas of High hygiene no direct criteria for levels of contaminants are given. For the design only the essentials to be considered and the recommended filtration steps are given as shown in Figure 14.

In the section on Air Quality monitoring (section 7.5) the recommendation is given: " Air quality monitoring in a food manufacturing environment should be implemented to control dust and microbiological contamina-

tion risks caused by people, the processes and the environment…". ….”Air quality monitoring may include:……Airborne particle concentration monitoring….Microbiological monitoring based on zoning hazard analysis, optional for zone B, recommended for zone M and essential for zone H”

Comparing the above to the EU-GMP Annex 1 on Sterile manufacture of medicinal products, it is clear the food industry has a challenge in establishing and demonstrating control on the safety of their products.

CONCLUSION

Contamination control is essential in high hygiene production zones, but no specific classes or levels of contaminants are given. Microbial(re-)contamination is the most important concern, where specific pathogenic contaminants are of special focus. The HACCP approach is essential to establish and demonstrate control.

EHEDG guidelines contribute to the design for processes and their surroundings. Integrated design is mandatory and has the most optimized outcome with respect to investment, operation, and cleanability.

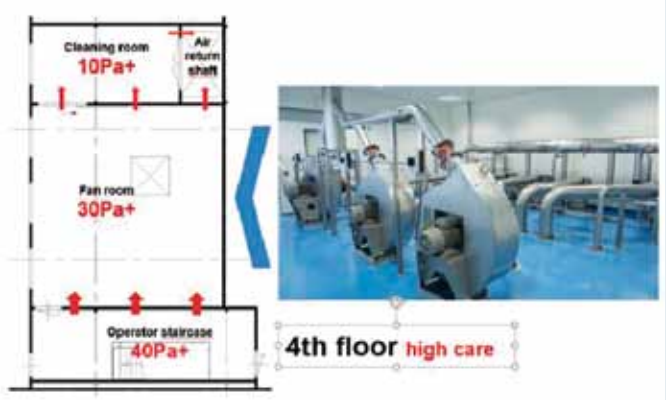

Figure 13:
Big bag filling, dry mixing, gowning and airlocks on the ground floor

Overview of system recommendations for air handling			
Filtration of environmental (First, second or third filter stage) See also Sect 5.8.7	Minimum one filter stage: 1 Stage M5-F7	Minimum two filter stage: 1 Stage F7 (+GF if required) 2 Stage F9	Minimum three filter stage: 1 Stage F7 (+GF if required) 2 Stage F9 3 Stage E10-H13 (depending on risk)
Positive air movement higher to lower zone (Controlled ocverpressure)	-	optional	**essential**
Temperature control	optinal	**essential**	**essential**
Humidity control	-	Optional depending of risk evaluation	Optional depending of risk evaluation
Minimum air changes per hour to maintain air quality		5	15

Figure 14:
Recommendations from EHEDG DOC 47 ‘Guidelines on air handling systems in the food industry’, including zone H (High hygiene)

Högre krav ställs på offentliga toaletter

Fler oroar sig över hygien i städerna. Ju större stad desto mer oro, visar en global studie. I storstäder oroar sig mer än hälften över bristande hygien. Den ökande urbaniseringen leder också till nya hygienvanor. Människors förväntningar på offentliga toaletter förändras, och de ställer högre krav på företag att leverera hygienlösningar. Idag är världen mer urbaniserad än någonsin – 54 % av världens befolkning bor i städer. När städerna växer förändras även livet i dem. Arbetsdagen flyter ihop med fritiden, och det är inte säkert att man åker hem mellan jobb och fritidsaktiviteter. Offentliga toaletters roll förändras och blir mer än en plats för de mest basala behoven.

- Idag spenderar vi mycket tid utanför våra hem, vilket har gjort offentliga toaletter till en slags frizon. De blir en salong för att fixa till sminket, omklädningsrum för klädbytet innan middagen, det uppenbara stället att tvätta händerna innan måltiderna – och mycket mer, säger Helena Taghizadeh, Produktchef för Tork på Essity.

Food trucks är ett växande fenomen som idag är en naturlig del av många stadsmiljöer men många anser att bristande hygien är ett problem. Street food äter man ofta med händerna vilket gör att hygien blir en avgörande faktor till var människor väljer att äta. 32 % har avstått från att äta street food på grund av bristande hygienprodukter som tvål, handdesinfektion och servetter. För att undersöka hur bättre tillgång till handhygienlösningar påverkar street food-kunder utförde varumärket Tork ett pilotprojekt med en ”Soap truck”. Placerad vid en populär food truck-festival i Rio de Janeiro utrustades en truck med tvål och pappershanddukar, istället för mat. Effekten var omedelbar – en folksamling samlades direkt för att tvätta händerna innan de beställde mat vid luckorna bredvid.

Nyckelresultat från studien
- 52 % av invånarna i storstäder oroar sig ofta för att bli sjuka på grund av bristande hygien, jämfört med 22 % av invånarna i mindre orter.
- 4 av 10 har avstått från att använda en offentlig toalett på grund av bristande hygien och renlighet.
- 7 av 10 anser att bristande hygien begränsar deras liv och har därför avstått från vardagliga aktiviteter, till exempel att resa med kollektivtrafik.
- 32 % har nyligen avstått från att äta från en food truck på grund av oro för hygienen.
- 43 % har avstått från att äta på en restaurang på grund av det saknades produkter för hygien.

För ytterligare information, kontakta: Helena Taghizadeh, Produktchef för Tork på Essity 031-7460730, Helena.taghizadeh@essity.com

Bohus Biotech bygger ut sitt renrum!

Ventilator har fått i uppdrag av Bohus Biotech att bygga till det befintliga renrummet med ytterligare ca 100 kvm samt att installera en större LAF-enhet. Projekteringen pågår och byggnation samt installation sker under sommaren 2018.

Ventilator Renrum har tidigare byggt det befintliga renrummet som är på ca 700 kvm åt Bohus. Biotech. Det nya projektet är en tillbyggnaden som blir en egen sektion och ska bl a användas för montering. Det nya renrummet byggs i renhetsklass C.

BioArctic - årets SwedenBIO Award

BioArctic AB fick motta utmärkelsen SwedenBIO Award 2018. Priset delas ut till ett företag som utmärkt sig genom att bidra till samhällelig nytta som understryker betydelsen av en framgångsrik life science-industri i Sverige.

SwedenBIO uppmärksammar BioArctic för bolagets starka samarbeten med både akademin och globala läkemedelsbolag samt en hög vetenskaplig ambition vilket har gett BioArctic en portfölj av innovativa projekt för behandling av sjukdomar i det centrala nervsystemet. Ett område där de medicinska och samhälleliga behoven är växande. Vidare understryker SwedenBIO att BioArctic har uppmärksammats internationellt och har sedan starten 2003 byggts upp och skickligt finansierats av dedikerade grundare och en stark och jämställd ledning till att år 2017 noteras på Nasdaq Stockholm Mid Cap. Noteringen är en av de största emissionerna som gjorts inom svensk biotech sedan år 2000.
SwedenBIO:s VD Jonas Ekstrand menar att BioArctic är ett utmärkt exempel på de stora synergier som kan skapas då forskning inom olika sektorer effektivt kan samverka för att hitta lösningar på medicinska utmaningar. ”Vi är glada över att ge årets SwedenBIO Award till BioArctic. Förhoppningsvis leder bolagets forskning till att patienter kan få tillgång till sjukdomsmodifierande behandling för Alzheimers och Parkinsons sjukdom, vilket skapar värde även för anhöriga och samhället”, säger Jonas Ekstrand.

”Det är en stor ära för BioArctic att få ta emot denna utmärkelse. Detta är glädjande och inspirerande för oss alla på BioArctic. Vi är stolta över våra framgångar. Utmärkelsen är en bekräftelse på BioArctics bidrag till life science branschens fortsatta positiva utveckling i Sverige”, säger Gunilla Osswald, VD för BioArctic.

BILD: NYRÈNS ARKITEKTKONTOR

Unikt Superlabb

Biomedicin är ett av Europas mest avancerade laboratorier med när man flyttade in i april, gjorde man det före utsatt deadline och dessutom till lägre kostnad än vad som budgeterats!

Biomedicum, med sina cirka 80 000 kvadratmeter, blev 350 miljoner billigare än vad som presenterades för tre år sedan. Den totala investeringen stannar på ca 2 miljarder kronor. Hyresgästen kommer genom den lägre byggkostnaden undan med en lägre hyra på ca 20 miljoner kronor per år.

Den nya byggnaden är långt ifrån vad som vi flesta ser framför oss när vi tänker på stålprydda laboriatorier med ljusa tak, väggar och golv. Hjärtat i byggnaden är den öppna ljusgården i mitten med gatlyktor, växter och ett kafé. Färgerna går i grönt och blått kombinerat med trädetaljer i ask.

Ventilationskanalerna i Biomedicin är så stora att man kan köra in med en långtradare med släp i kanalen. I labben är luftflödet hela 440 liter per sekund.

I det nya laboratoriet, som kallas Biomedicum, samlas fem institutioner med ca 1 600 forskare och ytterligare medarbetare under ett och samma tak. Man har medvetet också bara planerat in två entréer bara för att blanda den experimentella och kliniska forskningen. På så sätt blir Karolinska Institutet en unik samlingspunkt för gränsöverskridande forskning och samverkan samtidigt som dyrbar utrustning kan utnyttjas effektivt av flera. Därmed ökar förutsättningarna för att bedriva forskning i världsklass.

Visionen för nya Hagastaden är att skapa världens främsta område för life science. Under det gemensamma namnet Stockholm Life skapas ett centrum för högspecialiserad sjukvård och världsledande biovetenskaplig forskning för att förbättra människors hälsa. Framtidens laboratorium Biomedicum är en viktig kugge i denna satsning.

Berendsen i nytt samarbete

5 april 2018 07:55 | Av Christer Åkerlundh | Tipsa redaktionen

Textilleverantören Berendsen inleder ett samarbete med Skydda, en expert inom personlig skyddsutrustning. Berendsens kunder erbjuds därmed skyddstillbehör såsom hjälmar, skyddsglasögon och hörselskydd.

PPE, personlig skyddsutrustning, är en viktig faktor för att göra arbetsplatserna säkrare. Medvetenheten har under senare år ökat om hur risken för skador och allvarliga olyckor kan förebyggas med hjälp av olika slags personlig skyddsutrustning.
– Många av våra industrikunder har ett stort behov av personlig skyddsutrustning. Vi vill helt enkelt kunna erbjuda en säkrare vardag. Samarbetet med Skydda hjälper oss att göra vårt erbjudande komplett, säger Eva Jönnerheim på Berendsen.

Berendsen erbjuder bland annat arbets- och skyddskläder via tvätt- och hyrservice. Det innebär att Berendsen äger och hyr ut kläderna och tar hand om allt kringarbete; distribution, reparationer och kontroll av plaggen. Fram tills nu fick kunder med behov av annan personlig skyddsutrustning än kläder och skor, vända sig till andra leverantörer.

Nytt patientförflyttnings-system i flerfunktionella hybridoperationssalar

PILOT - det nya patientcentrerade förflyttningssystemet, innebär att personalen kan flytta patienter mellan bildsystem och behandlingsrum utan ompositionering. PILOT är den allra senaste nyheten i en mängd innovativa resultat från Getinges strategiska partnerskap med Siemens Healthineers. Den är avsedd för användning tillsammans med nexaris Angio-CT-MR (1), Siemens Healthineers unika multimodala bildhanteringslösning för bättre behandlingsresultat. Frédéric Pette, t.f. President Surgical Workflows på Getinge, förklarar: ”Målet med detta gemensamma projekt var att ta fram ett nytt flerfunktionellt koncept för hybridoperationssalar för att patienten inte skulle behöva ompositioneras inför tagning av multimodala bilder under pågående ingrepp. Som globala marknadsledare har Getinge och Siemens Healthineers en gemensam vision för kirurgins framtid som vi strävar efter att förverkliga genom innovationer som nexaris Angio-MR-CT (1) och PILOT-tekniken.”

PILOT möjliggör inte bara intraoperativ bildtagning utan även smidig patientförflyttning inom sjukhuset.
”PILOT-lösningen kommer att innebära en revolution för sjukhusinterna transporter och ett viktigt bidrag till att effektivisera arbetsflödet på operationsavdelningen och förstärka patientsäkerheten. När PILOT används tillsammans med vår Maquet Transmobil TT-M Patient Transporter (2) kan patienten transporteras från helikopterplattan till valfri plats på sjukhuset utan att behöva ompositioneras”, förklarar Klaus Christian, Director Product Line Hybrid OR på Getinge. Detta gynnar såväl personal som patienter eftersom man slipper den ansträngande och riskfyllda uppgiften att ändra patientens position för olika åtgärder.

A publich from Cay Poly Pomona

Cleanroom Technology June 2018

A scientific team at Cal Poly Pomona, based in California (US), have published findings of the first biochemical evidence to suggest why spacecraft contamination occurs, despite assembly in a cleanroom.

In its cleanroom facilities, NASA implements a variety of planetary protection measures to minimise biological contamination of spacecraft. However, despite extensive cleaning procedures, molecular genetic analyses shows that cleanrooms harbour a diverse collection of microorganisms, or spacecraft microbiome, that includes bacteria, archaea and fungi.

"We designed the project to give students hands-on experience and to support the learn-by-doing philosophy of Cal Poly Pomona. The students did the research, mostly as thesis projects in the areas of enzymology, molecular microbiology and analytical chemistry," said Rakesh Mogul, lead author and Cal Poly Pomona professor of biological chemistry.

The Acinetobacter, a genus of bacteria, are among the dominant members of the spacecraft microbiome. To figure out how the spacecraft microbiome survives in the cleanroom facilities, the research team analysed several Acinetobacter strains that were originally isolated from the Mars Odyssey and Phoenix spacecraft facilities. They found that under very nutrient-restricted conditions, most of the tested strains grew on and biodegraded the cleaning agents used during spacecraft assembly. The work showed that cultures grew on ethyl alcohol as a sole carbon source while displaying reasonable tolerances towards oxidative stress. This is important, because oxidative stress is associated with desiccating and high radiation environments similar to Mars...

Reference: Rakesh Mogul et al. Metabolism and Biodegradation of Spacecraft Cleaning Reagents by Strains of Spacecraft-Associated Acinetobacter, Astrobiology (2018).

Uppsala Life Science

Strong growth for Uppsala's life science companies. Powerful force of attraction for other businesses. It is very pleasing to note that Uppsala's industrial development continues unabated. Our region is home to many prosperous and profitable businesses. Particularly pleasing is that medium-sized companies with 10 to 100 employees continue to grow strongly. Together with the universities, hospitals and national authorities in the region, they exert a powerful force of attraction that can draw other companies to Uppsala, writes Erik Forsberg, Managing Director at Uppsala BIO.

Uppsala's life science companies produce equipment, software, technical and biological 'test-tube' solutions as well as different types of systems for users worldwide. These technology and knowledge-intensive businesses make up a strong foundation of Uppsala County's business community, and in the municipality itself, the largest companies operate exclusively in the life science sector.

Erik Forsberg, Managing Director at Uppsala BIO.

Ny rapport kartlägger svensk precisonsmedicin

Av Boel Jönsson | Tipsa redaktionen

Branschorganisationen SwedenBio har kartlagt de svenska företagen inom precisionsmedicin i en ny rapport.
"Vi vill skapa en överblick över detta spännande life science-segment och exponera svenska företag inom området för globala aktörer. Vi vill stimulera till fler samarbeten och investeringar i Sverige", kommenterar Sara Gunnerås, redaktör och analyschef, SwedenBio, rapporten.??Läs också: Bättre stöd till nystartade bolag

Sjukdoms- och teknikområden som särskilt lyfts fram är onkologi, infektionssjukdomar, bildbehandling och liquid biopsies.Företagen finns i fem regioner: Stockholm-Uppsala, knappt 50% av företagen; Malmö-Lund-regionen, drygt 25%, Göteborgsregionen 14% och 7% i Umeå. I Linköping finns 5% av företagen, främst inom bildteknik.

Rapporten, som tagits fram med finansiellt stöd av Business Sweden och Vinnova, kan hämtas här: www.swedenbio.se/reports.

Global lab has acquired two subsidiaries of the Finnish research centre VTT Group

Eurofins Scientific, the international bioanalytical testing specialist, has acquired VTT Expert Services Ltd and Labtium Ltd, two wholly owned subsidiaries of VTT Technical Research Centre of Finland Ltd. These subsidiaries cover all of VTT's testing, inspection and certification (TIC) operations.

The acquisition of VTT ES will complement Eurofins existing product testing services portfolio while the acquisition of Labtium will strengthen its leadership in environment testing. Both acquisitions reinforce the Group's presence in the Finnish market. Eurofins entered this market last year with the acquisitions of Nab Labs, Ramboll Labs and Ahma.

VTT ES offers its clients versatile expert services including calibration services, certification services, structural safety testing, building material testing, electronics testing, fire safety testing and product failure and safety testing. It has accreditations covering over 1,300 standards.

R³ NORDIC, CTCB-I OCH CHALMERS INBJUDER TILL CTCB CERTIFIERING

CTCB certifiering av Cleanroom Testers

2-4 OKTOBER 2018
INSTALLATIONSTEKNIK, CHALMERS, GÖTEBORG

Kursmaterialet för "Cleanroom Testing Certification" är på engelska och skickas efter inbetald registreringsavgift tillsamman med Question/Answers-häfte till kursdeltagaren för självstudier, senast en månad före kursstart.
Efter godkänt resultat erhålls ett certifikat. OBS. Certifikat på Professional Level är giltiga i endast 5 år.

First Day Lecture Course:
Associate and Professional candidates

- **Lecture course** revising the course notes
- **Tutorial** revision

Second Day Written Exam and Practical Training:
Associate and Professional candidates

- **Written Exam:** This will examine the candidate's knowledge of the course notes. The questions will be short and of the type that can be answered by no more than 10 words; no essays are required. The questions will be similar, or identical, to those given in the question and answers handbook. The pass mark is 55%.
- **Installed filter leakage testing**. Information will be given on an aerosol smoke generator and photometer, and how these are used to test filter integrity.
  The technique will be demonstrated and each student will have an opportunity to use the method.
- **Air velocity and volume flow measurement**. Information will be given on how to carry out testing using an anemometer, hood capture method, averaging pressure flowmeter, and Pitot-static tube. The techniques will be demonstrated and there will be an opportunity for each student to use the methods.
- **Microbiological airsamplers and documentation requirements.** Information will be given on common instruments and their characteristics. The requirements on adequate documentation will be discussed.
- Possibility to **Hands-on**. Associate candidates only. Work two an two on installed filter leakage test and air velocity and volume flow measurements with comments from teachers.

Third Day Practical Exam:
Professional candidates only

- The candidate will be required to show their ability to carry out the following important tests:
  - Determine the average air velocity and uniformity, as well as the volume of air passing through a HEPA fan/filter unit by use of an anemometer. The use of the hood capture method must also be demonstrated.
  - Demonstrate that they can operate a smoke generator and photometer to find leaks in a filter and filter gasket.

The candidate will be required to competently write up reports on the two tests. Professional candidates are expected to carry out the above tests competently, and accurately measure the airflow and find filter leaks.
The exams will be marked in two parts i.e. practical and theoretical, so that it is possible to pass none, one or both exams. It is necessary to pass both exams to be certified on professional level.
The candidate's exam results are assessed by an Examination board. It is anticipated that about 70% of the candidates will pass their exams in the first attempt. The CTCB has an examination appeals procedure.
Anyone failing an exam can re-sit it at the next examination within a year. This can be done in Sweden, or at another CTCB Cleanroom Testing Certification course in Ireland and UK.
Certificate on Professional Level valid for 5 (five) years!

SISTA ANMÄLNINGSDAG 2018-08-06

CTCB Associate Level - 2 days, 2-3/10 2018
Registration: SEK 3 950 · Course and exam: SEK 10 250
Lecture course. Written exam. Practical training and hands-on.

CTCB Professional Level - 3 days, 2-4/10 2018
Registration : SEK 3 950 · Course and exam: SEK 13 500
Lecture course. Practical training. Written and practical exams.

Fullbokad!

Exam Re-sit and Upgrading (Assoc to Prof) 4/10 2018
Candidates can re-sit their or upgrade their exams within a year. **Registration: SEK 2 950. Practical exams will be SEK 2 500 for one exam and SEK 5 000 for two.**

CTCB Prof Level Recertifikation - 3 days, 2-4/10 2018≈
Registration: SEK 3 950 · Course and exam: SEK 11 500
Lecture course. Pracital training. Written and practical exams.

Note: 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: Any costs required for accommodation are the responsibility of the candidate.
Moms tillkommer på samtliga angivna priser.

Questions and application form: +46 (0)703 15 11 55
Lars Ekberg, e-post: lars.ekberg@cit.chalmers.se
Information also available at www.safetyventilation.com

LAU DANMARK INBJUDER TILL

Grundkursus i renhedsteknik

3.-4. oktober 2018
København

PREL PROGRAM DAG 1

09.00 – 09.10 Velkomst
09.10 – 10.00 Arbejde i et rent miljø, særlige krav og forudsætninger
10.00 – 11.00 GMP/Mikrobiologi og Dokumentation - SOP
11.00 – 11.15 Kaffepause
11.00 – 12.15 Standarder for klassificerede rene områder, ISO/CEN/GMP
12.15 – 13.00 Frokost
13.00 – 14.00 Design af rene rum, design, layout, sluser og materialer
14.00 – 15.00 Beklædning og omklædningsprocedurer i rene miljøer
15.00 – 15.15 Kaffepause
15.15 – 16.15 Eksempler på renrumsprojekter bl.a. i hospitalsmiljøer, fokus på konflikter og synergier inden for GMP forhold

PREL PROGRAM DAG 2

09.00 – 10.00 Design af ventilation i rene miljøer, herunder forskellige former for ventilation, LAF, UDF, opblanding mm.
10.00 – 11.00 Besøg i klassificeret miljø / renrum
11.00 – 11.15 Kaffepause
11.15 – 12.15 Test og kvalificering af renheden i rummet
12.15 – 13.00 Frokost
13.00 – 14.00 Sterilisation – Validering og monitorering
14.00 – 15.00 Desinfektions- og rengøringsprocessen i rene miljøer
15.00 – 15.15 Kaffepause
15.15 – 15.30 Evaluering og afslutning

Kursusafgift DKK 5.100,- (R^3-medlem 4.600,-)
Inkluderer kursusmateriale, diplom, frokost og kaffe.

Information/kursansvarig: Alan Fries, R^3 Nordic
+45 42 482 482 · info@tech4bizz.dk

Tilmelding
www.r3nordic.org

R^3 NORDIC INBJUDER TILL

Grundkurs i renhetsteknik

29-30/11
Chalmers, Göteborg

Med fokus på Läkemedeklstillverkning, Sjukhusmijöer och GMP

PROGRAM DAG 1:

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

PROGRAM DAG 2:

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

Kursavgift SEK 6.150,- (R^3-medlem 5.500,-)
Inkluderar kursmaterial, diplom, lunch, kaffe fm och em.
Information om kursen lämnas av Lennart Hultberg (se nedan)

Kursansvarig:
Lennart Hultberg, R^3 Nordic
+46 (0)760 399 500 · lennart@processhygien.com

Anmälan
www.r3nordic.org

Anmälan till kursen skall vara skriftlig och är bindande. Avbokning skall ske skriftligen och inkomma minst en månad före kursstart för att kursavgiften, minus avdrag med 500 kr, skall återbetalas. Vid avbokning senare, minst 14 arbetsdagar före kursstart, återbetalas halva kursavgiften. Vid avbokning senare än 14 arbetsdagar före kursstart sker ingen återbetalning. Ersättare kan registreras fram till och med första kursdagen. R^3 Nordic förbehåller sig rätten att ändra kursinnehåll och föreläsare utan att meddela deltagare eller att ställa in kursen. Föreningen ansvarar inte för merkostnader i samband med kursens inställelse. Vid inställelse återbetalas kursavgiften i sin helhet.

R³ NORDIC AND CAMFIL

INVITATION TO Ventilation Solution Day

17 september 2018 · Camfil Sweden, Trosa

R³ Nordic in corporation with Camfil, arranges a solution day with ventilation theme including following topics:

- New international air filter standard - ISO16890
- Basic ventilation principles
- Isolation rooms within healthcare
- Bio-decontamination by VHP (Vaporized Hydrogen Peroxid)
- VHP sterilization - new developments
- HEPA-filter handling during installation, filter change and how does it work in operation.

The solution day is held at Camfil Sweden head quarter in Trosa, Industrigatan 3, **17 september 2018 at 10 am - 5 pm.**
Maximum participants are 30 people and registration fee for members of R³ Nordic is SEK 2 500 including lunch and coffee. Non-members pays an additional fee of SEK 650 and become members for 1 year in the association R³ Nordic.

Registrate at info@r3nordic.org

Last day of registration will be the 3th of September and after this date the participant fee will be non refundable. In the event of written cancellation before the 3th of September the fee will be refundable minus a cancellation fee of SEK 250.

Some of the presentations will be in English, the rest will be held in Swedish.

For more information about the day contact:
Evelina Zettervall, board member of R³ Nordic, at
+46 70 344 20 96 or on evelina.zettervall@camfil.com

For participants that needs accommodation in connection to the solution day, Trosa Stadshotell could offer limited number off single room at a better rate of 1050 SEK including breakfast.

R³ NORDIC AND ALFA LAVAL INVITES TO

EHEDG advanced course in Hygienic Engineering & Contamination Control

9th - 11th of October 2018

Alfa Laval Tumba AB, Hans Stahles väg 7, Tumba, Stocklholm

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.

Previous training and working experience

Participants should have 2 years of relevant practical experience. Participants with equivalent training/experience can also participate.

Content

The course is given 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 as aids). EHEDG certificate will be mailed to approved participants attending the full course.

Course Fee

The course fee is 1950 € / participants. EHEDG 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.

For more information, please, contact Dr. Gun Wirtanen by e-mail.

Cancellations must be sent in writing to guliwi@luukku.com. Participation in this training course can be cancelled free-of-charge (except for an administration fee of 100 € for already invoiced course fees) four weeks prior to the event (last day is 10th of September). In cancellations, thereafter, we will charge 50 % of the participation fee and one week or less before the event the full participation fee will be charged. (Note: the name of the participant can be changed until one week before the course start).

R³ NORDIC AND ALFA LAVAL INVITES TO

Programme

Tuesday 9th of October

8.45 – 9.15	Registration with Coffee/Tea
9.15 – 9.45	Welcome to Alfa Laval, Introduction to EHEDG, Presentation of participants & Why EHEDG ADVANCED COURSE - A Motivation
9.45 – 11.15	Legal requirements
11.15 – 11.45	Coffee/Tea -break
11.45 – 13.00	Hazards in hygienic processing
13.00 – 13.50	Lunch
13.50 – 15.00	Hygienic design criteria
15.00 – 15.15	Coffee/Tea -break
15.15 – 16.45	Construction materials
19.30 – 21.00	Dinner in the hotel restaurant

Wednesday 10th of October

8.45 – 9.45	Welding stainless steel
9.45 – 10.00	Coffee/Tea -break
10.00– 10.50	Static seals and couplings
10.50 – 12.10	Cleaning & Disinfection
12.10 – 13.00	Lunch
13.00 – 14.30	Valves & Pumps
14.30 – 14.45	Coffee/Tea –break
14.45 – 15.15	Demos e.g. on demo of traceability system in food processing
15.15 – 16.00	Verification of hygienic design, test methods and certification & Video
16.00 – 16.45	Group work (groups of 3-5): equipment design pictures & discussion
19.30 – 21.00	Dinner in the hotel restaurant

Thursday 11th of October

8.45 – 10.25	Building and process layout
10.25 – 10.45	Coffee/Tea -break
10.45 – 11.15	Lubricants
11.15 – 12.15	Integration, installation & maintenance
12.15 – 13.15	Lunch
13.15 – 14.30	Final exam (1 h) in the EHEDG Advanced Course – QUESTIONNAIRE
14.30 – 15.00	Coffee/Tea -break
15.00 – 16.30	Case study

The course language is English.

The course trainers are Alan Friis, Ferdinand Schwabe and Gun Wirtanen.
Information on possible accommodation at Quality Hotel Globe at registration.
Please, contact Gun Wirtanen by e-mail guliwi@luukku.com to sign up.

Deadline for registration: September 14, 2018.
At registration, we need: 1) Name of participant, 2) Company, 3) Contact address (incl. e-mail), 4) Invoicing address (incl. e-mail) and 5) Additional information e.g. food allergies, diets.

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