GMP Cleanroom Course

Your trainers:
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Introduction

• Name
• Job description
• Where you are from or background
• Cleanroom experience
• Places where you work
• What you want to get from this training
Contamination control + training

Control Contamination

ISO 14644 ‘Cleanrooms and Associated Controlled Environments’

• Part 1: Classification of air cleanliness

• Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

• Part 3: Test methods

• Part 4: Design, construction, and startup

• Part 5: Operation

• Part 6: Terms and definitions

• Part 7: Separative devices (clean air hoods, gloveboxes, isolators, mini environments)

• Part 8: Classification of airborne molecular contamination

• Part 9: Classification of surface particle cleanliness

• Part 10: Classification of surface chemical cleanliness
KNOWHOW

About contamination control

Knowing how + Knowing why =

KNOWHOW

COURSE GOALS

• Know how
• Awareness
• Responsibility
• Teamwork
• Compliance
ISO 14644-5 Operations

4.1.3 a system for training personnel in cleanroom procedures shall be instituted. A method for monitoring compliance to those training procedures shall be specified.

4.1.4 A documentation system shall be maintained to provide evidence that all personnel have received suitable levels of training for their assignments.

4.3.4 Cleanroom personnel shall be trained to conduct themselves in a manner that minimizes generation of contamination which can be transferred or deposited on or into the product.

GMP

A.2 Assessing contamination risks

A.4 Education and training

C.1 Training

Only trained personnel should be allowed to enter and work in a cleanroom. All personnel should be given an introductory course when initiated into the cleanroom and further periodic retraining.
GMP Cleanroom Course

Risk Assessments
Contamination risks
Cleanroom technology
Establish Control
Gowning
Demonstrate Control;
Behaviour in the cleanroom
Cleaning
Cleaning Validation
Test
Closure

1. Start History

Joseph Lister
Discovered bacterial infection of wounds and devised bacterial-free surgery
Comparison of ‘mini environment’ and ‘ballroom’

A comparison of the S/MIF isolation and more traditional approach.

Comparison of ‘mini environment’ and ‘ballroom’

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Comparison of ‘mini environment’ and ‘ballroom’

A comparison of the S/MIF isolation and more traditional approach.

Comparison of ‘mini environment’ and ‘ballroom’

A comparison of the S/MIF isolation and more traditional approach.
Clean machine

Temperature Disturbance

The Internet of Things
Without Cleanrooms, An Impossibility (AT)
Evidence that we are living in the future

Innovative product

GMP Cleanroom Course

- Risk Assessments
- Contamination risks
- Cleanroom technology
- Establishing Control
- Gowning
- Demonstrate Control;
- Behaviour in the cleanroom
- Cleaning
- Cleaning Validation
- Test
- Closure
Workshop questions
Explanation:

Risk assessments:

1. What can go wrong inside the cleanroom?
2. What are the risks from outside the cleanroom?
3. Influences on products?

Workshop

• Work together
• Prepare presentation.

Cleanroom Suitable Materials
Risk assessment: Contamination Sources

- Particles and fibers
- Micro-organism
- Chemicals (including outgassing)
- Electrostatic charge

INFLUENCE ON THE PRODUCT

Depending on the application:

A. Technical products: economic loss

B. Pharmaceutical products: economic loss and personal damage

RISK ASSESSMENTS
What is contamination?

It is "the undesired introduction of impurities (chemical/microbial/foreign matter into or on to starting material or intermediate – during sampling, production, packaging or repackaging". Impurities could include products or substances other than the product manufactured, foreign products, particulate matter, micro-organisms, endotoxins (degraded microorganisms), etc.

What is Cross-contamination?

"Contamination of a starting material, intermediate product, or finished product with another starting material or product during production".

Cross-contamination can result from, e.g.
1. Poorly designed, operated or maintained air-handling systems and dust extraction systems
2. Inadequate procedures for, and movement of personnel, materials and equipment
3. Insufficiently cleaned equipment
Cross-contamination can be minimized by, e.g.

1. Personnel procedures
2. Adequate premises
3. Use of closed production systems
4. Adequate, validated cleaning procedures
5. Appropriate levels of protection of product
6. Correct air pressure cascade

The installation further focuses on three concepts of the system:

- Product protection
  - Contamination
  - Cross-contamination
  - Environmental conditions
- Personnel protection
  - Prevent contact
  - Comfort conditions
- Environment protection

CONTAMINATION CONTROL PROGRAMME

- WILL FOCUS ON:
  - ENGINEERING CONTROLS
  - PEOPLE CONTROLS
  - ONGOING CLEANING REGIME
Cross Contamination in daily life

Are you still with me??

GMP Cleanroom Course

- Risk Assessments
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The manufacturing environment is critical for product quality. Other factors to be considered include:

1. Light
2. Temperature
3. Relative humidity
4. Air movement
5. Microbial contamination
6. Particulate contamination
   - Uncontrolled environment can lead to product degradation
     - product contamination (including cross-contamination)
     - loss of product and profit

• Particles in 3D size

<table>
<thead>
<tr>
<th>Term</th>
<th>Shape</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cylindrical</td>
<td><img src="image" alt="Cylindrical" /></td>
</tr>
<tr>
<td>Discoidal</td>
<td><img src="image" alt="Discoidal" /></td>
</tr>
<tr>
<td>Spherical</td>
<td><img src="image" alt="Spherical" /></td>
</tr>
<tr>
<td>Tabular</td>
<td><img src="image" alt="Tabular" /></td>
</tr>
<tr>
<td>Ellipsoidal</td>
<td><img src="image" alt="Ellipsoidal" /></td>
</tr>
<tr>
<td>Equant</td>
<td><img src="image" alt="Equant" /></td>
</tr>
<tr>
<td>Irregular</td>
<td><img src="image" alt="Irregular" /></td>
</tr>
</tbody>
</table>
Product contamination

- Contamination by particles.
- Particles can be viable or carry micro-organisms.
- Contamination by:
  - Deposition
  - Contact transfer
- Cleanliness of contact surfaces changes by particle deposition.
- Main cause of product contamination is deposition of particles and microbe carrying particles.

---

No particles no fog!!!
Particles

Carbon nanofibres -3nm

Viable particles are everywhere
Particles are not just there

What is generating particles?

- Everything that is alive
- Everything that ages
- Everything that changes or moves

Particles

Bacterial growth

Examples of micro-organism
Time to develop

• 35 degrees 48 hours
• 25 degrees 72 hours

**Viruses:** Ebola is not alone in keeping the world alert

**Malaria:** Although the number of people infected with malaria has gone down since 2000, the number of infected people was still over 198 million people in 2013. 584,000 people died, most of these were children.

**Influenza:** Three to five million people become ill due to influenza, up to 500,000 people die from this illness. Influenza is the illness which causes the most deaths in Germany.

**Hepatitis:** Nearly 50% of all malignant liver tumors are caused by the hepatitis virus. 1.4 million people worldwide die from this disease yearly in Germany, 14,000.

**Aids:** Since the beginnings of this disease, 50 million people worldwide have become infected and more than 10 million have died. 2,000 of these are in Germany.

**Sars:** This disease first broke out in China in 2003. The source was the one to that time unknown, Coronavirus. The Sars pandemic caused from 2002 to 2003, 1,091 deaths.

**Ebola:** This lethal fever is transmitted by a virus and is very infectious. In West Africa, 195,000 to 305,000 people are infected yearly. About 50% of all cases end in death. In cases of pregnant women, the death rate lies between 30% and 50%. 
WORKSHOP AWARENESS

• Why do we need a cleanroom?
• What is important?
• How to prevent contamination?

Why do we need a cleanroom?

• Clean environment to prevent unwanted contamination
  • Product
  • Patient
• Contamination by:
  • Particles and fibers
  • Micro-organisms
  • Chemicals
  • Nanoparticles

Nanotechnology in medicinal market
A cleanroom is a room that is kept very clean by a limited access, overpressure and ventilation with filtered air.

Construction materials are smooth and do not contain any cracks or seems and can easily be cleaned.

**Cleanroom**

### Heating Ventilating Air Conditioning

**General**
- Design of HVAC is dependent on required degree of air cleanliness
- Filter Quality and Air Changes.
HVAC Main subsystems

- Exhaust air treatment
- Fresh air treatment (make-up air)
- Central air handling unit
- Terminal air treatment at production room level
- Production Room

Straining or Sieving

- The Particle is Larger Than the Opening Between Media Fibers
- A Dominant Method of Particulate Removal in Low Efficiency Air Filters (Pleated Prefilters)
Impaction

- A large, dense particle collides with the fibers and attaches to the media
- Adhesives or tackifiers can be used to enhance capture efficiency
- A dominant method of particulate removal in low efficiency air filters (flat panel pre-filters)

Interception

- Particle follows airstream at lower velocities and contacts fiber through weak intermolecular attractions (Van Der Waals forces)
- The dominant method of particulate removal in medium efficiency air filters (bags and extended surface final filters)

Diffusion

- Small particles collide with the air molecules and move in an erratic path (Brownian movement) and attach to the media fibers
- The dominant method of particulate removal in high efficiency air filters (HEPA filters)
EN1822:2009 – Classification

Table 1—Classification of DPA, HEPA and ULPA filters

<table>
<thead>
<tr>
<th>Filter Class</th>
<th>Integral value</th>
<th>Local value *1</th>
<th>Local value *2</th>
</tr>
</thead>
<tbody>
<tr>
<td>E 10</td>
<td>6.5</td>
<td>6.5</td>
<td>6.5</td>
</tr>
<tr>
<td>E 11</td>
<td>6.5</td>
<td>6.5</td>
<td>6.5</td>
</tr>
<tr>
<td>E 12</td>
<td>6.5</td>
<td>6.5</td>
<td>6.5</td>
</tr>
<tr>
<td>H 13</td>
<td>99.7</td>
<td>99.73</td>
<td>99.73</td>
</tr>
<tr>
<td>H 14</td>
<td>99.73</td>
<td>99.73</td>
<td>99.73</td>
</tr>
<tr>
<td>H 15</td>
<td>99.73</td>
<td>99.73</td>
<td>99.73</td>
</tr>
<tr>
<td>U 16</td>
<td>99.995</td>
<td>99.995</td>
<td>99.995</td>
</tr>
<tr>
<td>U 17</td>
<td>99.996</td>
<td>99.996</td>
<td>99.996</td>
</tr>
</tbody>
</table>

*1 Local penetration values lower than those given in the table may be agreed between supplier and purchaser.
*2 Group E filters classes E01, E1 and E12 cannot and must not be tested for classification purposes.

Label to EN1822

Typical airflows
What is better?
What is cleaner?
Which needs more investments?
Which one has higher running costs?

Airflow mixed: unidirectional and non-unidirectional
Air Cleanliness

ISO 14644-1: 2015

Table for classification of air cleanliness by particle concentration

<table>
<thead>
<tr>
<th>ISO Class Number (N)</th>
<th>Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1 µm</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>3</td>
<td>1,000</td>
</tr>
<tr>
<td>4</td>
<td>10,000</td>
</tr>
<tr>
<td>5</td>
<td>100,000</td>
</tr>
<tr>
<td>6</td>
<td>1,000,000</td>
</tr>
<tr>
<td>7</td>
<td>10,000,000</td>
</tr>
<tr>
<td>8</td>
<td>100,000,000</td>
</tr>
<tr>
<td>9</td>
<td>1,000,000,000</td>
</tr>
</tbody>
</table>

Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

Sample collection limitations for both particles in low concentrations and sizes >1 um make classification of this particle size inappropriate, due to potential losses in the sampling system.
The certification state of the Cleanroom must be defined in advance testing; three stages exist within the context of ISO 14644-1:

- **AS BUILT**, a completed room with all services connected and functional, but without production equipment or personnel within the facility.

- **AT REST**, a condition where all the services are connected, all the equipment is installed and operating to an agreed manner, but no personnel are present.

- **OPERATIONAL**, all equipment is installed and is functioning to an agreed format, and a specified number of personnel are present working to an agreed procedure.

### TABLE 2.6. Selected ISO airborne particulate cleanliness classes for cleanrooms and clean zones.

<table>
<thead>
<tr>
<th>Classification numbers (N)</th>
<th>Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the considered sizes shown below</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 1</td>
<td>10 2 2</td>
</tr>
<tr>
<td>ISO Class 2</td>
<td>100 24 10 4</td>
</tr>
<tr>
<td>ISO Class 3</td>
<td>1000 237 102 35 8</td>
</tr>
<tr>
<td>ISO Class 4</td>
<td>10 000 2370 1020 352 83</td>
</tr>
<tr>
<td>ISO Class 5</td>
<td>100 000 27 750 10 200 3020 832 29</td>
</tr>
<tr>
<td>ISO Class 6</td>
<td>1000 000 237 000 102 000 35 200 832 293</td>
</tr>
<tr>
<td>ISO Class 7</td>
<td>352 0000 832 000 29 300</td>
</tr>
<tr>
<td>ISO Class 8</td>
<td>35 200000 8 320 000 293 000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class</th>
<th>Maximum permitted number of particles per m³ equal or more than</th>
</tr>
</thead>
<tbody>
<tr>
<td>At rest (h)</td>
<td>In operation</td>
</tr>
<tr>
<td>0,5µm</td>
<td>5µm 0,5µm 5,0µm</td>
</tr>
<tr>
<td>A</td>
<td>3.520 2,00 3.520 2,00</td>
</tr>
<tr>
<td>B(a)</td>
<td>3.520 2,00 352 000 2,900</td>
</tr>
<tr>
<td>C(a)</td>
<td>352 000 2,900 3.520 000 29 000</td>
</tr>
<tr>
<td>D(a)</td>
<td>3.520 0000 29 000 Not defined Not defined</td>
</tr>
</tbody>
</table>
EU GMP Cleanroom Grades – ANNEX 1

<table>
<thead>
<tr>
<th>Classification</th>
<th>EU</th>
<th>FDA</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5</td>
<td></td>
<td>Grade A</td>
<td>Critical: Aseptic preparation and filling, filling of open ampules and bottles</td>
</tr>
<tr>
<td>ISO Class 5</td>
<td></td>
<td>Grade B</td>
<td>-</td>
</tr>
<tr>
<td>ISO Class 5</td>
<td></td>
<td>Grade C</td>
<td>Controlled: Surrounding of class A, transfer of aseptic products in closed receptacles</td>
</tr>
<tr>
<td>(0.5 micron At Rest)</td>
<td></td>
<td>Grade D</td>
<td>Controlled: Preparation of solutions, when unusually at risk</td>
</tr>
<tr>
<td>ISO Class 8</td>
<td></td>
<td>Grade D</td>
<td>Critical: Filling of finally sterilised products</td>
</tr>
<tr>
<td>(0.5 micron At Rest)</td>
<td></td>
<td></td>
<td>Controlled: Surrounding of isolators (closed cabinets)</td>
</tr>
<tr>
<td>CNC/UNC</td>
<td></td>
<td>Unclassified</td>
<td>Laboratories, administration, technical areas, workshops, storage, etc</td>
</tr>
</tbody>
</table>

Farmaceutical products

- Chemical pharmaceutical products
  - External products (eye suspenses, crèmes and ointments)
- Vascular products
- Biofarmaceutical products
  - Vaccines, 
  - Stem cells,
  - Cell growth

ICH Q10 Pharmaceutical Quality System (PQS)

- Vision: Move from regulatory guidance to scientific guidance
- A harmonized pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to quality risk management and science
- Objectives of the Guideline
  1. Achieve product realisation
  2. Establish and maintain a state of control
  3. Facilitate continual improvement
ICH Q10 Pharmaceutical Quality System

Scope of the guide
• applies throughout the product lifecycle
  • Pharmaceutical Development
  • Technology Transfer
  • Commercial Manufacturing
  • Product Discontinuation
• applies to the systems supporting the development and manufacture of
  • pharmaceutical drug substances (API=active pharmaceutical ingredient) and
  • drug products, including biotechnology and biological products
• application is appropriate and proportionate to lifecycle stage
• includes...new and existing products.

GMP FDA: 21 CFR 11
• CFR - Code of Federal Regulations Title 21
• Title 21—food and drugs
  chapter i—food and drug administration department of health and human services
• Subchapter a—general part 11
  • electronic records; electronic signatures

Comparisation of standards
**Active Air Sampler: Principle of operation**

*Before Impaction*

*After Impaction*
Cleanroom classifications:

Surface Cleanliness for Particle concentrations

- Concentration particles on surfaces (m²)
- ISO 14644-9, Surface Cleanliness by Particles (SCP)
- SCP N: \( n_d = 10^n / d \geq 1 \mu m \)
- \( n_d \cdot d = \text{constant} \)
- SCP 5, \( 10^5 \geq 1 \mu m \)
- \( 100.000 \geq 1 \mu m \) per m²
- \( 20.000 \geq 5 \mu m \) per m²
- \( 2 \geq 5 \mu m \) per cm²

Proposed ISO 14644-9 Surface Cleanliness Classes

<table>
<thead>
<tr>
<th>Particle size in μm</th>
<th>Max number of particles per m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>0,1</td>
<td>100.000</td>
</tr>
<tr>
<td>1</td>
<td>10.000</td>
</tr>
<tr>
<td>10</td>
<td>1.000</td>
</tr>
<tr>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>1,000</td>
<td>1.000</td>
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<tr>
<td>10.000</td>
<td>100</td>
</tr>
<tr>
<td>100.000</td>
<td>100</td>
</tr>
</tbody>
</table>

Particle deposition animation

**WHY ONLY MEASURE PARTICLES IN THE AIR**

Conclusion

- Direct measurements of surface cleanliness are complicated.
- Getting grip on the cleanliness via particle deposition monitoring is a good path to follow.
- UV is still a good alternative for direct inspection if the relation between UV and non UV contamination is known.
Microbiological surface cleanliness

EC GMP Microbiologische Contaminatie

<table>
<thead>
<tr>
<th>Klasse</th>
<th>55 mm contactplaats</th>
<th>Handschoen (5 vingers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>C</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

25 CFU per 55 mm contactplate equals 1 CFU per cm².

Testing of persons
GMP Cleanroom Course

Risk Assessments
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Workshop gowning

• Why do we need gowning?

• What is important at gowning?

• Make checklist for gowning sequence

Workshop

• Work together

• Prepare presentation.

Presentation

• Presenter of group:
Not only the skin is a source of human particles. Coughing and talking generates particles into air. Also hairs can be released.
Effect of clothing design on bacterial dispersion

<table>
<thead>
<tr>
<th></th>
<th>own clothes</th>
<th>gown over own clothes and gown</th>
<th>open-necked shirt and trousers</th>
<th>cleanroom overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>total dispersed per minute</td>
<td>610</td>
<td>180</td>
<td>113.9</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Gowning sequence

- Street clothing
- Training suit
- CR clothing

1. Cleanroom ISO 8
2. Air
3. CR class ISO 7
4. CR class ISO 5
Different disciplines of gowning

* Depending upon the type of protection needed
GMP=Good Manufacturing Practice

Ten GMP Principles
1. Writing procedures
2. Following written procedures
3. Documenting for traceability
4. Designing facilities and equipment
5. Maintaining facilities and equipment
6. Validating work
7. Job competence
8. Cleanliness
9. Component control
10. Auditing for compliance

- Make functional analyses
  - Determine when product fails
- Make process/personal flow (critical places or moments)
- Determine parameters for risk analyse:
  - Killer particlesize
  - Critical surface
  - Contacts
  - Exposure time
- Prepare presentation.

Transfer through deposition or contact

Packing
Media
gasses
fluids
Gowning
Parts
Equipment
process, measure, and apparatus
Air surrounding
Infrastructure
transfer, handling, logistics

Transfer through deposition or contact

Packing
Media
gasses
fluids
Gowning
Parts
Equipment
process, measure, and apparatus
Air surrounding
Infrastructure
transfer, handling, logistics
Example of Materials and People Flow

Arrival of goods  Entrance for visitors  Entrance for Workers  Shipment of goods

Example of design: Product OK?
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'no touch' techniques
no touch’ techniques
**Behaviour**

- Take a shower or bath in the morning when you plan to go to the cleanroom.
- Keep your nails short.
- Don’t put any make up when you are going to work in the cleanroom.
- Make no unnecessary movement in the cleanroom.
- In case you smoke wait at least 30 minutes before you enter the cleanroom (again).
- Follow the garment changing procedure.
- In case there are questions contact your supervisor, before entering the cleanroom.

(Why could that be important?)

**Hygiène**

Hygiène programm consists of
- Personal hygiène
  - Yearly education and examination
  - Special checks in sterile rooms
- Cleaning and disinfection plans
- Design of
  - Material locks
  - Personal locks
- Zone concept for cleanroom classes
- Gowning procedure
- Temperature and humidity regulation
- Disposable processing
- Monitoring of activity
- Pest reject

**Hand hygiene**

- The most used tools in preparation of medicines are – the HANDS

- Are always contaminated. Hands are a risk and must be disinfected and covered with gloves
Forbidden in the cleanroom

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Preparing to clean the cleanroom

• Cleaning: the removal of contaminants which can be seen with the naked eye

• Decontamination: the removal of contaminants which cannot be seen by the naked eye
Reporting and testing of cleaning

- Surface cleaning tests include:
  - Ultra violet light
  - Witness plate
  - Surface particles detectors

- Microbiological cleaning test methods include:
  - Settle plates
  - Proprietary test systems

The key question is: "how to clean something that is visible clean?"

The answer is simple: we assume that particles are on all surfaces!

Which basic cleaning supplies do we need?

- Wipes
- Swiffer
- Vacuum cleaner with HEPA-filter
Cleaning and disinfection

Cleaning in the concept of cleanrooms is the process of removing residues and soils from surfaces to the extent that they are visually clean. Often a detergent is used.

Cleaning can arguably be seen as a form of disinfection in its own right as the cleaning process can remove or dilute microbial populations and many detergent have chemical additives that can disinfect.
Cleaning and decontamination

Detergent is a chemical used to clean before decontamination

Disinfectant is a chemical agent that reduces number of desinfectans either by removing or destroying decontamination

Sanitiser
Sanitisation is a general description for reducing microbial population = this is a low level of decontamination

Antiseptic
Antiseptic is the term applied to the use of a disinfectant on living tissue. (substance on the skin and is less effective in reducing microorganisms = this is not decontamination

• What does sterile mean?
• Free from all living things
• How do we achieve sterility?
• Through sterilisation
Definitions in Disinfection

- **Sanitization**: Germ reduction by cleaning using germ-inhibiting substances. Also continuous disinfection and disinfection without control of reaction time. — 80% to 99.99% germs killed off.

- **Disinfection**: Killing off, respectively de-activating (irreversible impairment) all pathogenic germs so that an object is no longer infectious. — Low germ contamination 99.999%.

- **Sterilization**: Killing off all micro-organisms, including their perennial form, spores. — Low germ contamination 99.9999%.

- **Nosocomial Infection**: Infection by pathogens or their toxins during an in-patient or out-patient medical procedure (hospital infection).

**Disinfectant classes**
- Class A: bacteria, fungi
- Class B: bacteria, fungi, viruses
- Class C: bacteria, fungi, viruses, bacteria spores including anthrax spores
- Class D: bacteria, fungi, viruses, bacteria spores and clostridium (gangrene, tetanus, etc.)
Pharmaceutical products for injection must be free of bacteria and dirt

workshop

• Cleanroom is contaminated: what causes can you think of?

• Materials, external, machines, manpower, methods, measurements
PROCEDURES

A basic procedure is that anyone who enters the cleanroom contacts the cleanroom manager to learn all applied procedures when entering and working in the cleanroom.

Safety procedure:
• Keep all exits free.
• Safe working methods.

All people entering the cleanroom should know all access procedures.
A well known abbreviation in pharma is GMP: ‘Good Manufacturing Practice’

GMP-guideline are written in a book. It contains a set of guidelines how work in a cleanroom and how to prevent bio-contamination.

Procedures

Standard Operating Procedure

You Are In Control
KNOWHOW =

Knowing how + Knowing why

Procedures

GMP Cleanroom Course

Risk Assessments
Contamination risks
Cleanroom technology
Establish Control
Gowning
Demonstrate Control;
Behaviour in the cleanroom
Cleaning
Cleaning Validation
Test
Closure

Instruction
• Colour the circle in front of the correct answer black or blue.
• In case you want to change a given answer, draw a cross through this answer and fill the right circle.
• This test should be made without any help, otherwise the test will be disqualified.

Good luck !!!