CLEANING/DISINFECTION

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AGENDA

• Definition
• Types of Desinfectants
• Basic Principles of Cleaning/Desinfection
• Cleaning/Desinfection in Practice
• Monitoring
• Validation
DEFINITIONS
THE IDEAL DISINFECTANT

- Effective against all micro-organisms
- Works at every temperature, pH etc.
- Works on every surface
- Does not corrode the surface
- Does not expire
- Not toxic to humans
- No residues
- Cheap

But unfortunately, it does not exist!
DEFINITIONS

• Bacteriostatic (not for disinfectants but for antibiotics)
  – Slows bacteria down
• Bactericide
  – Kills bacteria (not their spores)
• Virucide
  – Kills viruses
• Fungicide
  – Kills moulds and yeasts
• Germicide
  – Kills all micro-organisms
• Sporicide
  – Kills all spores
CLEANING AND DISINFECTION (1)

• Cleaning
  1. Removing (chemical) materials, dust (then)
  2. Vacuuming / Soap / Water

• Disinfecting
  – Reducing the number of micro-organisms
  – Only if sterilization is not possible, or when it is less important

• Sterilizing
  – Killing “all” micro-organisms (max. 1 per 1,000,000 is left alive)
CLEANING AND DISINFECTION (2)

- What will be cleaned?
- What will be disinfected?
- What will be sterilized?
TYPES OF DISINFECTION
**DISINFECTANTS AND HOW THEY FUNCTION**

- **Quaternary ammonium compounds** change the surface tension so that structures (pili) on the cell wall are removed.

- **Aldehydes** damage the protein structure.

- **Halogens** (chlorine, iodine) and **Peroxides** oxidate organic materials.

- **Alcohol** coagulate proteins.

- **Peracetic Acid, Peroxides** oxidizes the outer cell-membranes of the micro-organism.
## DISINFECTANTS AND HOW THEY FUNCTION

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SENSITIVITY TO DISINFECTANTS

- Vegetative Cells: Easy
- Mould Spores
- Bacteria Spores: Hard
- Enveloped virus
- Non-enveloped virus
TYPES OF DISINFECTANTS

• What will be used?

• Is there circulation?
  • Why?

• Combination cleaning/disinfectants
BASIC PRINCIPLES
CLEANING/DISINFECTIO1N
WHAT CAN INFLUENCE THE DISINFECTION

- Contamination
- Contact (surface and fumigation)
- Exposure Time
- Types of Micro-Organisms
- Disinfectant
  - Concentration
  - Material
  - Solvent
- Surface material
- Temperature
THE USE OF CLEANING

- Removing visible contamination, because contamination
  - Reacts with disinfectants
  - Shield bacteria
  - Are a source of nutrition

- With vaccine- or bio-technological production:
  - Disinfection (killing a specific organism)
  - Cleaning
  - Disinfection
  - Washing
PRINCIPLES; DESIGN

- Smooth surfaces, not porous
- No edges
- No corners, smooth surface
- Use materials that can handle disinfectants
- No non-essential materials in the clean room
- No shelves, ridges, etc.
- Sanitary Design
PRINCIPLES; USE

• Make sure that as little as possible is present in the clean room
• A clean room is not a storage room
• Clean everything up first
• Make sure everything is accessible
• Leave no materials behind
• Store materials (where?)
PRINCIPLES: CLEANING/DISINFECTION

• Work from high to low
• Work from clean to dirty
• Work from back to front (or to the door)

• Make sure that cleaning/disinfection is not spreading contamination
  – Ensure the use of sterile solvents (where needed)
  – Ensure clean/sterile aids

• Keep cleaning materials away from production
• Cleaning- and disinfectants may (usually) leave no residues (wash afterwards)
TYPES OF CONTAMINATION

• Depends on the process
• Glas
• Product
• Metal (aluminium)
• Skin, hairs
• Micro-organisms
PRINCIPLES: CLEANING

• Proper exposure time
• Proper concentration
• Correct scheduling
• Right type of cleaning agent/disinfectant
• Keep to all the behavioral rules
I'm fed up with cleaning your room!
From now on, wipe your feet!
CLEANING AND DISINFECTION IN PRACTICE

- **Procedure**
  - Frequence (how long will a room remain clean?)
  - Roulation regime
    - Is this always necessary? It is, according to the new guidelines!
  - Concentration
  - Making the agents, expiration dates
  - Exposure times
  - Follow-up
CLEANING AND DISINFECTION IN PRACTICE

• Procedure
  – What rooms, spaces?
    • All positions always or changing schedule
  – Will cleaning agents/disinfectants be qualified, if so which tests?
  – Cleanroom disinfectants will have to be sterile before use (Class A/B)
  – During the infeeding of materials into the cleanroom, a sporicide is advised to be used (PIC/s)
CLEANING AND DISINFECTION IN PRACTICE

Reporting:

• Used materials
• Creating materials
• What materials have been used?
• Cleaner/operator
• Date/time
• Specifics
• Signing off by supervisor and customer?
• Logs
CLEANING AND DISINFECTION IN PRACTICE

• Training
  – Training in GMP
    • Personal Hygiene
    • Basic principles microbiology/desinfection
    • Dress qualification
    • Practical training cleaning en desinfection
    • Filling in logs
  – Who checks this and how?
VALIDATION DISINFECTANT

• 3 distinct phases

• **Phase 1** theoretical effectiveness:
  – Literature
  – 5 log reduction
  – 5-5-5 test (European Suspension Test)
    • 5 minutes
    • 5 log
    • 5 stams (gram +, gram -, mould, sporeformer, Pseudomonas)
**Phase 2** effectiveness on surfaces

- Choose worst case surfaces
- “Contaminate” surfaces with bacteria
- Treat with disinfectants according to the procedure
- Sample the surface
- Determine reduction

- A minimum of 3 log reduction is required
- Choose standard panel + in house stems

- Watch for the formation of residu
Phase 3 effectiveness in practice

- Follow EM-results during certain period of time
- Disadvantage: not specific

- Sample before and after and examine reduction
- Disadvantage: low numbers don’t say much

- Sample for the formation is residues
MONITORING

• How can cleaning/desinfection be monitored?
  – Log
  – Visual checks
  – Presence during cleaning
  – EM-results

*House Flora shifts/drifts*
THANK YOU FOR YOUR ATTENTION