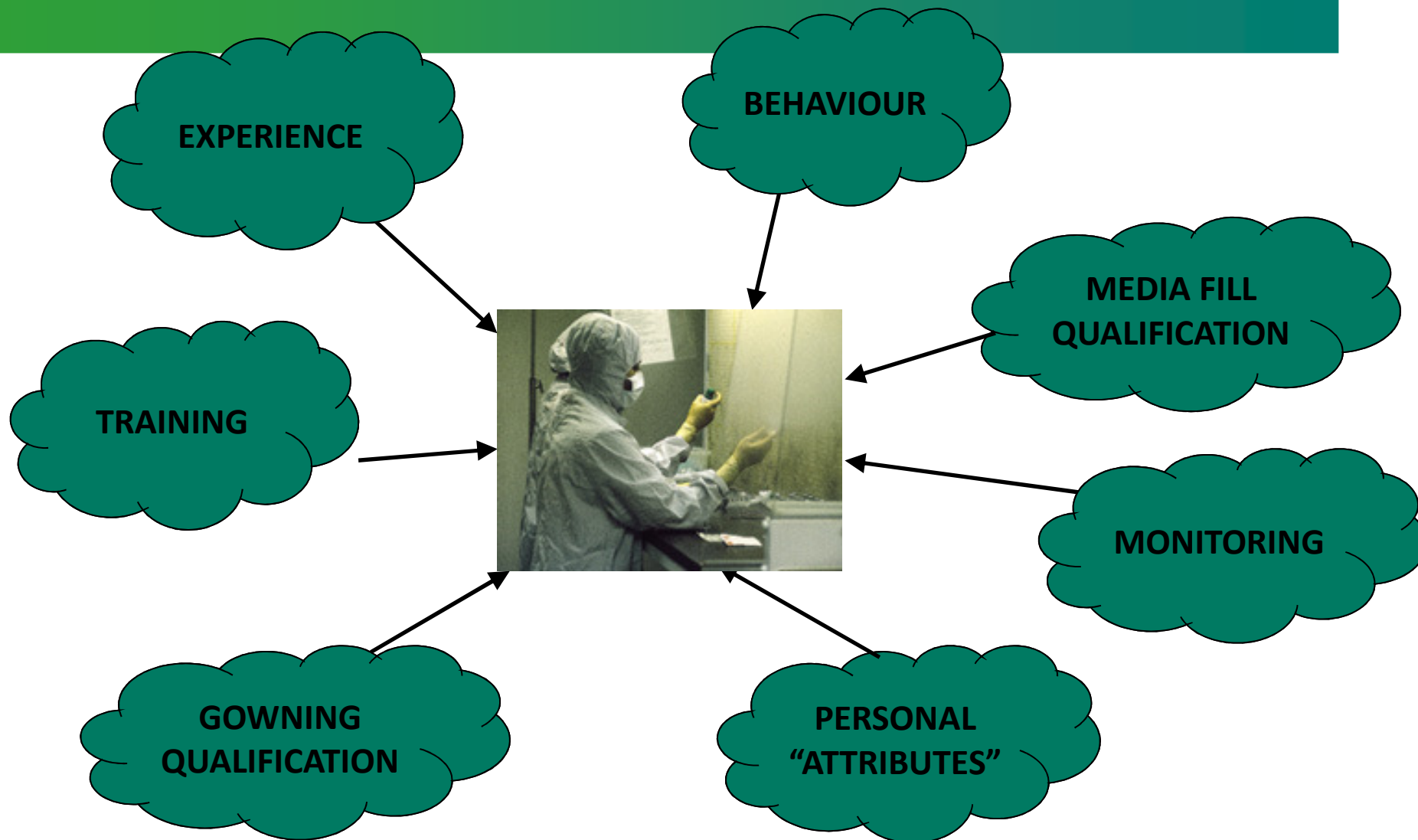




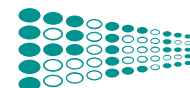
QUALIFICATION OF ASEPTIC OPERATORS

Jaap Koster



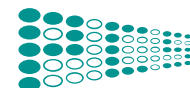
TRAINING – GENERAL PRINCIPLES

- Personnel should have the right background, experience and training to perform their job.
- Training should be continuous, on theoretical, practical and GMP aspects. Also microbiology and hygiene should be part of the training program.
- Training should be documented.
- Training should be effective.



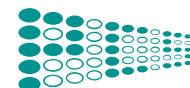
TRAINING – POINTS TO CONSIDER (1)

- What is the “curriculum” for an aseptic operator?
- Is this curriculum a “controlled document”, signed by the departmental manager?
- Is training planned? What is the plan?
- How often is re-training performed? For what reasons?



TRAINING – POINTS TO CONSIDER (2)

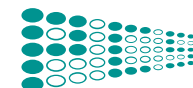
- If personnel work in more than one area, are the employees trained to ensure that they take adequate precautions to prevent cross-contamination when they pass from one area to another?
- How is effectiveness of training measured?
- Is there any feedback to the employees on their aseptic performance?



EXPERIENCE – GENERAL PRINCIPLES

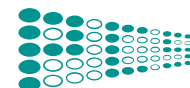


- Aseptic operations are very difficult to perform continuously correct since feedback on performance comes always too late (E.M.).
- The more fluent you can perform an operation, the easier it is to perform it aseptically.



EXPERIENCE – POINTS TO CONSIDER

- How long have employees been working in the pharmaceutical industry? And in clean rooms?
- Is there differentiation between activities for more and less experienced personnel?
- Look at connections and transfers and evaluate “routine”
- Do new employees practice operations (and how many times?) outside the clean rooms before they perform them inside?

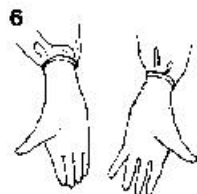
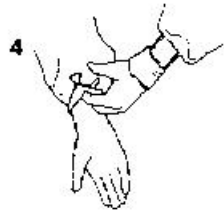
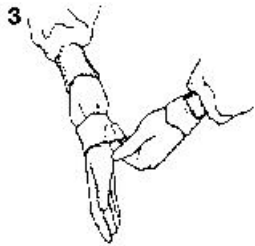
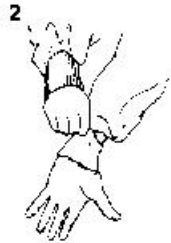


GOWNING – GENERAL PRINCIPLES

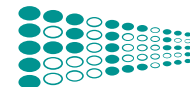
- Employees should be gowned according to the appropriate classification of the area.
- No jewelry nor make-up should be worn.
- No eating, drinking, smoking.
- A good personal hygiene is the basis of proper gowning.



GOWNING – POINTS TO CONSIDER (1)

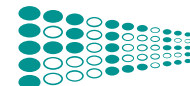


- What are the rules for good personal hygiene?
- Are the operators trained in proper gowning technique? How often is retraining?
- Is there a cheat-sheet in the gowning area? If so, is it in line with the SOP?
- How is qualification of gowning measured?



GOWNING – POINTS TO CONSIDER (2)

- How is assured that only qualified people enter the areas?
- Is all make-up and all jewelry really removed?
- Is there a mirror in the dressing room so people can verify correct clothing from top to bottom before entering?
- How frequently are people resanitizing/changing their gloves?



MONITORING – GENERAL PRINCIPLES



- Gloves, but also gowns, will be monitored for microbial contamination.
- Glove fingers, facemask, forearm and chest are typical locations for sampling.
- Daily/lot related (what ever is more frequent) samples should be taken from each operator.
- Investigations on exceeding levels or adverse trends should be conducted.



MONITORING – POINTS TO CONSIDER

- How is monitoring personnel trained? What is their “curriculum”?
- Is understanding the sources of contamination involved with sampling part of that training for monitoring personnel?
- When are the operator samples taken?
- What are typical conclusions on investigations related to operators exceeding limits/showing adverse trends?



MEDIA FILL QUALIFICATION – GENERAL PRINCIPLES

- Participation on media fills should be a standard part of operator qualification.
- Requalification should follow normally twice a year per shift and per process.



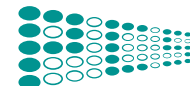
MEDIA FILL QUALIFICATION – POINTS TO CONSIDER

- What are the results of media fills split up by operator?
- Is there any adverse trend on an operator level? And (how) was this investigated?
- What happens if a media fill fails with a specific shift or team?
- What are operators doing before they pass a media fill?



BEHAVIOUR – GENERAL PRINCIPLES

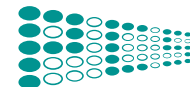
- Operators should move slow and deliberately.
- Their body(-parts) should be kept out of the laminar airflow.
- Necessary manipulation should be approached avoiding compromising sterility.
- An operator should try to keep his/her gown as clean as possible.



BEHAVIOUR – POINTS TO CONSIDER

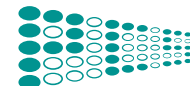
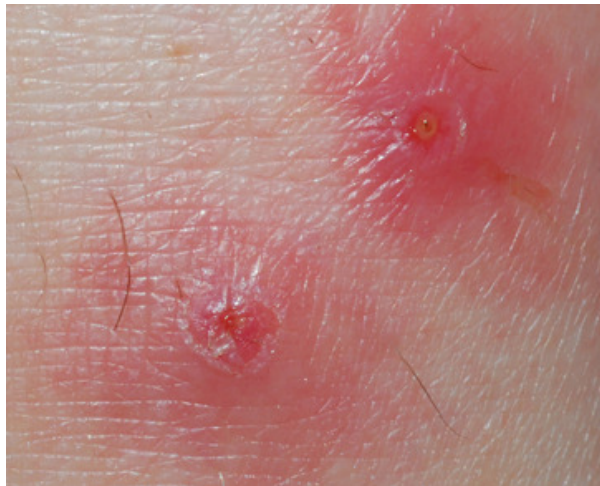


- Are people behaving relatively slow and deliberate?
- Are they touching their clothing / face?
- Are they touching sterile surfaces, equipment, product etc. with gloves or gowns?
- How are they manipulating, if needed, related to the airflow?



PERSONAL “ATTRIBUTES” – GENERAL PRINCIPLES

- People are the most important source of (microbial) contamination in clean areas.
- Employees should report any contagious illness, disease or open lesions.

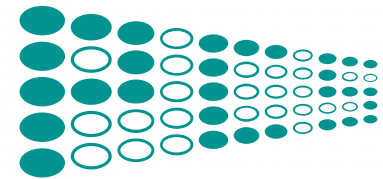


PERSONAL “ATTRIBUTES” – POINTS TO CONSIDER

- What happens to people that have an infectious disease?
- Is this described in an SOP?
- Are also e.g. athlete's foot and heavy dandruff included?
- Is there any restriction for smokers working in the aseptic core?



**THANK YOU FOR
YOUR ATTENTION**



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