QUALIFICATION OF ASEPTIC OPERATORS

Jaap Koster
TRAINING BEHAVIOUR MEDIA FILL QUALIFICATION

EXPERIENCE MONITORING PERSONAL "ATTRIBUTES"

GOWNING QUALIFICATION
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?
• 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.
• 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?
• 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?
• People are the most important source of (microbial) contamination in clean areas.

• Employees should report any contagious illness, disease or open lesions.
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

PHARMACEUTICAL CONSULTANCY SERVICES

Veluwemeer 112
3446 JD Woerden

T +31 (0)182 – 503 280
M +31 (0)6 – 23 047 982
F +31 (0) 182 – 502 589
info@pcs-nl.com
www.pcs-nl.com