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Review Article

"GLP" For Aseptic Techniques in A Microbiological Laboratory

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Abstract

The activity of the microbiological laboratory for the correct application of the aseptic techniques should be monitored with new personnel and in any case, at regular intervals to control the effective application.

The reported check list provides a concise list of questions about the aseptic procedures to give a guide to achieve a solid aseptic technique.

The presented subjects are: Working area, personal hygiene, personal dressing, workflow manipulation within aseptic workstation, cleanroom handling and working activity, culture media, microbial air monitoring.

Keywords: Air Sampler; Aseptic Techniques; Bacteria; Contact Plate; Contamination; Disinfection; Hygiene; Isopropyl Alcohol; Non-Viable; Sterilization; Viable

Abbreviations

GLP: Good Laboratory Practice; GMP: Good Microbiological Practices; USFDA: USA Food and Drug Administration

Introduction

Aseptic techniques are a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing microorganisms' contamination. The more frequent microbial contamination in an aseptic process involves the personnel. The principles of Good Laboratory Practice (GLP) define a set of rules and criteria for a quality system concerned with the conditions under which laboratory and environmental quality control procedures and studies are planned, performed, monitored, recorded, reported and archived. The Good Microbiological Practices (GMP) defines a set of rules and criteria to reduce the risk of microbial contamination during the microbiologist activity. Viable samples are living microorganisms; the reverse is true of nonviable samples: they are non-living particles. These include dust, clothing particles, skin cells and more. They do not reproduce or spread, but they can still be problematic in a risk environment like cleanroom, operating theater, etc. Good Manufacturing Practices (GMP or 'cGMP' 'current Good Manufacturing Practice') is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification [1-12].

Examples of infractions in aseptic processing reported by the US Food and Drug Administration (FDA) are the more effective way to introduce the involved subject [4-6,11]:

- The cleanroom operator was observed re-using coveralls that were hanging on a hook in the anteroom
- Your cleanroom is maintained in a manner that could lead to product contamination. We observed that contaminated items (waste, used gloves, etc.) were not correctly disposed according the specified protocol
- The personnel operating in the vertical laminar flow bench was not using the mask in a correct way
- The certificate of analysis showing sterility of the sterile containers were not correct

The basics of aseptic technique:

1. Perform appropriate hand hygiene
2. Use standard precautions
3. Maintain a sterile field and equipment
4. Apply and safely remove sterile gloves and personal protective equipment
5. Dispose of contaminated wastes appropriately

The activity of the microbiological laboratory for the correct application of the aseptic techniques should be monitored with new personnel and at regular intervals, to control the effective application. The reported Check list provides a concise list of questions about the aseptic procedures to give a guide to achieve a solid aseptic technique.

Check List

Working Area (Table 1)

	Action	Completed
	Working surfaces	
1	Is the working surface uncluttered and does it contain only items requested for your specific activity?	
2	Did you wipe the working surface with 70% sterile ethanol before to start the activity?	
3	Are incubator, refrigerators, freezers and other material routinely cleaned and sterilized?	
4	Are waste bins available, clean and in the right position?	

Table 1: Working surfaces.

Personal Hygiene (Table 2)

	Action	Completed
	Personal hygiene: hands and forearms	
1	Do you wash the hands at the correct time?	
2	Are the hands and forearms washed for at least 30 seconds with soap and water?	
3	Are the hands and forearms dried using either lint-free disposable towel or an electronic hand dryer?	
4	Are you using the hands cleaner according manufacturer recommendation?	
	Personal hygiene: head covering	
5	Are the correct protective equipment weared?	
6	Are the hair totally covered by the cap?	
7	Are the long hair tied in the back of the head?	
8	Is the beard correctly covered by the facial hair cover?	
9	Are all skin, including wrists and arms covered?	

Table 2: Personal hygiene: hands and forearms.

Personal Dressing (Table 3)

	Action	Completed
1	Are cosmetics, artificial nails, scarves, sweates, vest, jewelry, bandanas, coats, visible piercing removed?	
2	Are the gloves correctly dressed according a protocol?	
3	Are the sterile gloves the last item donned?	
4	Are the gloves in contact with non-sterile surface or component during the activities?	

Table 3: Personal dressing.

Workflow Manipulation Within Aseptic Workstation (Table 4)

	Action	Completed
1	Are all sterile products within the hood taking place at least 15 cm into the hood?	
2	Is the air flow working for at least 20-30 minutes before use from when the hood is turned on?	
3	Are paper, pens, calculator, labels protected under the laminar flow?	
4	Are all the items inside the hood outside from the air grates to avoid the regular outward of air?	

Table 4: Workflow manipulation within aseptic workstation.

Cleanroom Handling and Working Activity (Table 5)

	Action	Completed
1	Are you working slowly and deliberately, mindful of aseptic techniques?	
2	Are the non-shedding gown with slevees fit correctly around the wrist and the neck	
3	Are you replacing shoes covers, hairs and facial hair covers, face mask, eye shields, gloves with new ones before re-entering the critical areas?	
4	Are the disposable gowns properly discarded after appropriate time and re-used inappropriately?	

Table 5: Cleanroom handling and working activity.

Culture Media (Petri dishes, Contact plates, test tubes and bottles with liquid media) (Table 6)

	Action	Completed
1	Are the culture agar plates stored at the correct temperature indicated by the producer?	
2	Are the culture agar plates with the correct expiration date?	
3	Are the culture agar plates the correct media as indicated by the documentation?	
4	Are the culture agar plates identified before their use?	
5	Are the culture agar plates stored at the correct temperature and humidity?	
6	Are the culture agar plates correctly packed and inserted in the incubator?	
7	Are the culture agar plates correctly eliminated after their use?	

Table 6: Culture media details.

Microbial Air Monitoring (Table 7)

	Action	Completed
1	Is the date of microbial air sampler calibration, correct?	
2	Is the air sampler cleaned and disinfected according the SOP?	
3	Is the aspiration chamber cover of the sampler sterilised?	
4	Is the volume of aspirated air of the sampler correctly programmed?	
5	Is the culture plate correctly inserted in the aspiration chamber of the sampler?	
6	Is the culture plate lid on a sterile surface during sampling time?	
7	Is the culture plate correctly recovered from the aspiration chamber avoiding possible contamination?	
8	Are the culture plates transferred to the laboratory at the correct temperature and time?	

Table 7: Microbial air monitoring.

Conclusion

The personnel should be actively involved in the filling of this document to reduce the risk of microbial contamination.

Conflict of Interest

The author has no conflict of interest to declare.

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