ASEPTIC AREA

Introduction

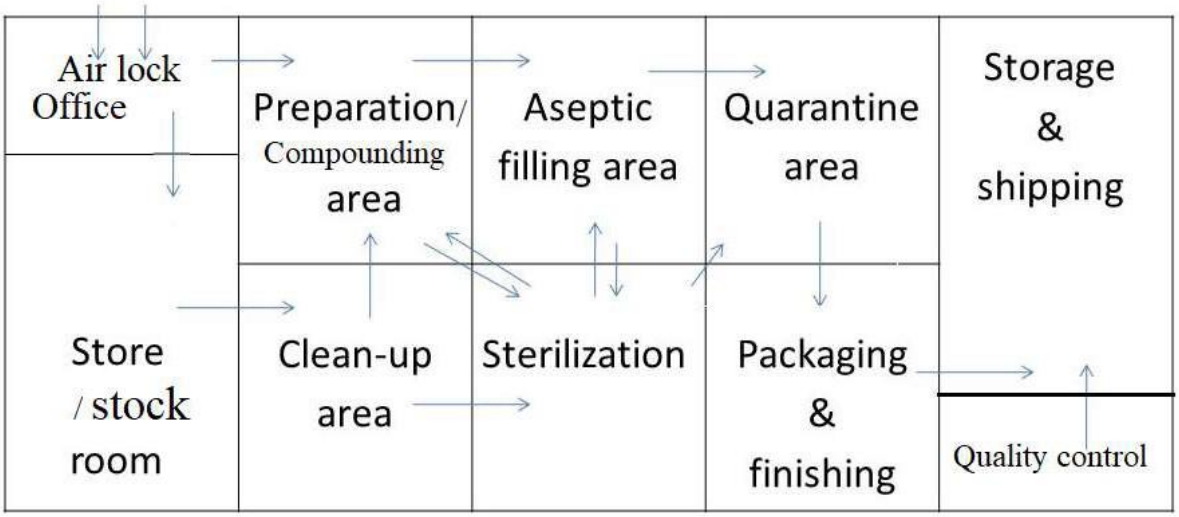
Aseptic techniques are employed to provide protection to ophthalmic and parenteral products by preventing the entry of microbial and particulate contamination. Prevention of microbial contamination is also required to remove pyrogens and toxic bacterial products. The terminally sterilised products (product sealed in container and then sterilised) are prepared in clean areas: while products not terminally sterilised are prepared under aseptic conditions using sterile materials or are sterilised by filtration before being packed in sterile containers. Such aseptic products are formulated or prepared in an aseptic area, which is a room within a clean area designed, constructed, serviced, and used for controlling and preventing microbial contamination of the product.

Like sterile medicinal products, vaccines containing dead microorganisms, microbial extracts, or inactivated viruses are also filled in aseptic areas; while live or attenuated vaccines are filled in separate areas.

The goal of any facility is to design such an aseptic or sterile environment which provides a controlled environment so that the entrance of viable (microbial) and non-viable (particles) contaminants can be minimised. A controlled environment prevents cross- contamination of Compounded Sterile Preparations (CSPs). To reduce the contamination-related risk, all compounding should be done within primary engineering controls, like a Laminar Airflow Hood (LAFH), also known as workbenches, Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CA).

Designing of Aseptic Area

The sterile production unit and the general manufacturing area within the hospital pharmacy or factory should be located separately. The sterile production unit should be buffered, i.e., unauthorised personnel should not gain access to this unit.



Flow Diagram of Aseptic Area

The aseptic unit is designed to carry out each stage of production separately. The unit should also ensure a safe and organised workflow so that the need for personnel to move around the clean rooms is minimised. The unit is built and the equipment is positioned in such a manner that the product remains protected from contamination.

The layout of aseptic area should be such that cleaning can be done easily and dust accumulation can also be reduced. Arrangement should be such that the risk of cross-contamination (contamination of one product or material with another) is reduced.

The filling area should be adjacent to the compounding area where the personnel assemble and prepare materials utilised by the staff in the filling area. In figure 4.1 the layout of areas and rooms for preparing terminally sterilised products (such as small or large volume injections) is shown.

Design and Construction

Only authorised personnel can gain access to the clean and aseptic filling areas. The personnel enter the clean rooms by passing through the changing rooms where they put on and remove their clean room uniform.

A pass-Over (or cross-over) bench extends across the changing room to form a physical barrier for separating the different areas for changing by the personnel.

Special precautions are taken for preventing clean and aseptic filling areas from getting contaminated while materials are being passed through airlocks or hatchways. Thus, sterilisers and entry ports are fitted with double-sided doors, which are interlocked to prevent simultaneous opening of both the doors.

Surfacing Materials

The floor, wall, and ceiling surface of clean rooms should be smooth, impervious, and unbroken to reduce the release and accumulation of contaminating particles and organisms. The surface material should be such that they can withstand the effects of cleaning agents anddisinfectants. The ceilings are scaled so that the contaminants do not enter from the space abovethem.

Uncleanable recesses should be avoided within the clean rooms to minimise the accumulation of contaminating particles. Thus, the wall and floor junction should be covered. Minimum shelves, ledges, cupboards, and equipment should be present. Non opening and sealed windows should be present to prevent the entry of contaminants.

Services

The piped liquids and gases entering the clean rooms should be filtered first, thus ensuring that the liquid or gas at the work position is as clean as the air in the clean room. The position of pipes and ducts should be such that they can be easily cleaned. Other fittings, like fuse boxes and switch panels should be placed outside the clean rooms.

Sinks and drains should not be present in areas where aseptic procedures are carried out within the clean room areas. They should nowhere be present in the complete unit. The areas having sinks and drains should be designed, positioned, and maintained such that the risk of microbial contamination is reduced; therefore, they are fitted with easily cleanable traps, installed with electrically heated disinfection devices.

A limited number of doors and ports should be present for entry of personnel and materials, respectively. The entry doors should be self-closing to allow easy movement of the personnel.

Airlock doors, wall ports, through-the-wall autoclaves, and dry heat sterilisers should have interlocked doors to prevent simultaneous opening of both the doors. All the doors should have an alarm system which should ring when more than one door are being opened.

Lights in clean rooms should be fitted with the ceiling so that dust accumulation reduces and also the airflow pattern within the room is not disturbed. The equipment in clean rooms should be positioned such that accumulation of particles and microbial contaminants does not Occur.