COVID-19 RESPONSE

Incident Specific (Gross Contamination) Decontamination and Cleaning

Purpose

The purpose of document is to provide instruction regarding the enhanced cleaning and decontamination responsibilities due to a gross contamination event.

Scope

A. The scope of this document covers all entities and is not limited to manufacturing facilities.

B. The controlled manufacturing areas (CMA) and their cleanings and sanitization/decontamination are governed by the Quality Management System (QMS). CMAs reference multiple cleaning and sanitization/disinfection solutions. The solutions used within the CMAs should not be used within the non-controlled areas, so not to disrupt the supply of solutions to support manufacturing. Over the counter cleaning and sanitization/disinfection solutions are recommended, reference below section for guidance on solutions to purchase

C. Ensure the following concerning choice of cleaning and sanitization/disinfectant solutions used:

- Sanitization solutions do not degrade surfaces used on
- Sanitization solutions do not have adverse effects on products being made (Embryo Toxicity)
- Sanitization solutions are effective against what they are trying to clean and disinfect.

Roles and Responsibilities

A. Housekeeping personnel have overall responsibility for performing the cleaning and disinfection of each facility.

B. Manufacturing personnel are responsible for following the Quality Management System guidance.

C. Leadership is responsible for awareness of these requirements and the promotion of compliance among all personnel. Leadership is also responsible for reporting any cleaning and disinfection need to Housekeeping.

Terms

A. Cleaning - removes germs, dirt, and impurities from surfaces or objects. Cleaning works by using soap (or detergent) and water to physically remove germs from surfaces. This process does not necessarily kill germs, but by removing them, it lowers their numbers and the risk of spreading infection.

B. Contamination – General term referring to the potential ability of a situation or item to have an adverse effect to the environment, manufacturing process or product

C. Decontamination – The removal of microorganisms / contaminate which can be achieved by disinfection or sterilization

D. Disinfecting - works by using chemicals to kill germs on surfaces or objects. This process does not necessarily clean dirty surfaces or remove germs, but by killing germs on a surface after cleaning, it can further lower the risk of spreading infection.

E. Quarantine – A defined location that is contaminated or potentially contaminated and has been cordoned off due to the presence of / or suspected presence of a contaminate

F. Spot Clean – Cleaning observable soils from a surface

G. Sick Room – Room which has been identified to keep personnel segregated from other employees. This room can be a first aid room or designated location that can be isolated and has limited access. These rooms may vary from site to site, where location and identification of these rooms will be determined by site management.

H. Sanitize / Sanitizing / Sanitization – Process that reduces the presence of viable microbial life / viruses

I. Sanitizer – A chemical solution that reduces microbial populations on inanimate surfaces. Typically, they can provide a bacterial reduction of 99.9% (3 log reduction). This can include products made from Hydrogen Peroxide, Quaternary or Phenolic Solutions

- Hydrogen Peroxide: Hydrogen peroxide is available as an aqueous solution, usually at 3 or 6 percent concentrations for household use. This chemical may be used as a disinfectant.
- Quaternary Solutions: Quats (quaternary ammonium compounds) are potent disinfectant chemicals commonly found in household cleaners that are designed to kill germs on high touch environmental surfaces and floors.
- Phenolic Solutions: Phenolic solutions are antiseptics and disinfectants. Phenolic disinfectants disrupt the cell membrane of microorganisms.

Tools and Equipment

A. Cleaning mops, wraps or cloths

B. Cleaning and sanitizer / disinfectant solutions

C. Vacuum

D. Personal Protective Equipment (PPE) (i.e. disposable coverall or frocks, disposable gloves, safety glasses and a mask if necessary)

Enhanced Cleaning and Decontamination Guidelines

Enhanced cleaning and decontamination of the CMA and/or non-manufacturing areas will occur once an area has been determined to be contaminated. An appropriate cleaner and disinfectant as described in the scope section above should be used to perform the cleaning and disinfection of each area.

A. Gross Contamination Event

- A gross contamination event may occur when a situation may have an adverse effect on the environment (i.e. workstation, sick room, restroom, etc) thereby compromising the facility and preventing future activities until the area can be decontaminated.

B. Quarantine

- Based upon the extent of a potential contamination, areas may be quarantined. Quarantine includes the segregation of the affected site/sites including the materials/ tools that exist within the location. This may include the traffic flow of personnel or where the personnel have been working.

C. Decontamination

- All surfaces within the quarantined area should be cleaned and decontaminated with a suitable disinfectant which is effective at killing most microorganisms and viruses. Items that are not crucial to business operations may be discarded if necessary and based upon management guidance. All other materials should be cleaned and decontaminated with the appropriate sanitization agent. An area may be decontaminated if one or multiple personnel have a contagious illness and decontamination of the area is required to prevent spread of the contamination.
- All cleaning materials used in the decontamination should be disposed of in appropriate waste container and removed to biohazard waste area.
- For items that can be sterilized, sterilization to decontaminate is permitted.
- Products manufactured within the CMAs that may be contaminated should be further evaluated as a non-conforming product.