Preventing Contamination and Cross Contamination in shared Equipment/Facilities in shared Equipment/Facilities.

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Abstract

The FDA regulatory concerns about High potent/toxic compound handling/containment. Update Annex 1 Draft.

With the new Draft Annex 1, the requirements for product protection are growing in aseptic manufacturing. The regulatory authorities call for the use of barrier systems such as isolators as well as a robust cycle for the decontamination with hydrogen peroxide. New highly efficient pharmaceutical products and thus also highly potent or highly toxic like ADC (Antibody Drug Conjugates) demand not only product protection but also the prevention of cross-contamination as well as occupational safety for the production staff.

The Aseptic & Toxic fill/finish concerns

Three special features characterize the design of isolators for the handling of ADCs and other highly active/toxic pharmaceutic substances. The first feature is the air handling unit, which processes air for the aseptic area inside the isolator to achieve ISO5 / Grade A air quality. The requirements of the Air Handling Unit for highly active/toxic substances also include ensuring that released highly active/toxic substances do not get into the recirculation air and, for example, contaminate other areas. The second feature is surface decontamination within an isolator utilizing hydrogen peroxide. The regulatory authorities are calling for a valid and robust process. The company SKAN has developed this process through its scientific publications and is also featured in the FDA Guideline for Aseptic Processing. Also, the requirements are for shorter decontamination cycle times. How this can be achieved will be shown in the lecture. The third feature is the toxic design of the isolator. Here, the critical area of the aseptic space is also reduced and shielded in such a way that the spread of the highly active/toxic pharmaceutical substance is reduced to the lowest possible level.

The cleaning validation concerns in Aseptic/toxic filling line

The cleaning requirements have increased since the EMA published the Guideline on "Setting Health-Based Exposure Limits for Use in Risk Identification in the Manufacture of Different Medicinal Products in Shared Facilities." For each product, a PDE "Permitted Daily Exposure" is now required, which is now also used as a limit for cleaning in shared equipment/facilities. In aseptic manufacturing, the requirements of cleaning within an aseptic fill & finish process/ isolator were not precisely specified before. These Cleaning Specifications requirements are now published by Richard Denk and a global team of experts as well as the involvement of a GMP Inspector in November 2017 from the PDA “Parenteral Drug Association" called "Isolator Surfaces and Contamination Risk to Personnel and Patient." Due to its importance and its Table of Cleaning Limits for Non-Product Contact Surfaces, the document is one of the highest downloads of PDA published. The presentation of the document and its implementation of product and employee protection will be presented in the lecture.