

A Practical Approach Towards Disinfection Challenges in Sterile Manufacturing Area

Authors : Doris Lacej, Eni Bushi

Abstract : Cleaning and disinfection procedures are essential for maintaining the cleanliness status of the pharmaceutical manufacturing environment particularly of the cleanrooms and sterile unit area. The Good Manufacturing Practice (GMP) Annex 1 recommendation highly requires the implementation of the standard and validated cleaning and disinfection protocols. However, environmental monitoring has shown that even a validated cleaning method with certified agents may result in the presence of atypical microorganisms' colony that exceeds GMP limits for a specific cleanroom area. In response to this issue, this case study aims to arrive at the root cause of the microbial contamination observed in the sterile production environment in Profarma pharmaceutical industry in Albania through applying a problem-solving practical approach that ensures the appropriate sterility grade. The guidelines and literature emphasize the importance of several factors in the prevention of possible microbial contamination occurring in cleanrooms, grade A and C. These factors are integrated into a practical framework, to identify the root cause of the presence of *Aspergillus Niger* colony in the sterile production environment in Profarma pharmaceutical industry in Albania. In addition, the application of a semi-automatic disinfecting system such as H₂O₂ FOG into sterile grade A and grade C cleanrooms has been an effective solution in eliminating the atypical colony of *Aspergillus Niger*. Selecting the appropriate detergents and disinfectants at the right concentration, frequency, and combination; the presence of updated and standardized guidelines for cleaning and disinfection as well as continuous training of operators on these practices in accordance with the updated GMP guidelines are some of the identified factors that influence the success of achieving sterility grade. However, to ensure environmental sustainability it is important to be prepared for identifying the source of contamination and making the appropriate decision. The proposed case-based practical approach may help pharmaceutical companies to achieve sterile production and cleanliness environmental sustainability in challenging situations. Apart from the integration of valid agents and standardized cleaning and disinfection protocols according to GMP Annex 1, pharmaceutical companies must be careful and investigate the source and all the steps that can influence the results of an abnormal situation. Subsequently apart from identifying the root cause it is important to solve the problem with a successful alternative approach.

Keywords : cleanrooms, disinfectants, environmental monitoring, GMP Annex 1

Conference Title : ICPMI 2022 : International Conference on Pharmaceutical Manufacturing and Industry

Conference Location : Rome, Italy

Conference Dates : April 07-08, 2022