MAN_06 - Proposal for a management tool for georeferencing and tracking microbiota in a pharmaceutical industry

Paulo Vinicius Pereira Miranda[1]; Greice Maria Silva da Conceição[1]; Igor Barbosa da Silva[1]; Claudia Maria Alves de Souza de Oliveira Dias[1]; Josiane Machado Vieira Mattoso[1]; Luciana Veloso da Costa[1]; Ana Paula Roque da Silva[1].
[1]Fiocruz/Bio-Manguinhos

Introduction: Globalization has brought, among its effects, the need to harmonize Good Pharmaceutical Manufacturing Practices which aim to standardize regulatory concepts, discussed in the Contamination Control Strategy (CCS) of Annex I of the Pharmaceutical Inspection Convention. The CCS presents detailed guidelines for the aseptic production of medicines and other sterile products. The challenge of this process is to effectively manage the microbial contamination monitoring, correlating data originating from physical areas and processes. Therefore, systemic management is needed to make assertive decisions.

Objectives: This work aims to integrate a Business Intelligence tool to track and control contamination in the pharmaceutical industry.

Methodology: The database regarding the occurrence of contaminants was built from spreadsheets containing information on the geolocation of the points, the zoning of the floor plan of the manufacturing complex, information on deviations, the cleanliness degree of the areas, the pharmacopeial classification of the criticality of the microorganisms, and the composition of the inputs related to the products manufactured. Data from the Quality Control System including environmental and water monitoring reports and microbiological control of processes, were used based on the programs covered by the quality system. Dashboards for georeferenced visualization were created using the Microsoft Power BI tool.

Results: It was possible to observe the microbial profile, the behavior of the site's microbiota at different granularities (from the satellite to the events room), the temporal flow of growth, and the determination of the initial point of contamination in the building, as well as identifying trends by monitoring the georeferenced results. The dashboard made it possible to monitor contaminants over a shorter period, unlike the previous scenario, where the information was scattered across several documents, making it difficult to identify and conduct preventive and corrective actions quickly. The dynamic dashboard, which requires few filters, made it possible to assess multivariate factors, such as the need to validate points in the water system, engineering actions, and infrastructure that can influence the occurrences of microorganisms in the production chain.

Conclusion: The tool tracked contamination points, allowing the different hierarchical levels of the institution to make assertive decisions. This contributed to the unit's contamination control strategy. Further studies will be needed to assess the assertiveness of the tool's actions, and it could be applied in other industries and contexts.

Keywords: Contamination Control Strategy; Business Intelligence; Pharmaceutical Industry