Aseptic processing validation of the IV compounding robot in a hospital pharmacy

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ABSTRACT

When a health care product is intended to be sterile and cannot be terminally sterilized, aseptic processing provides an alternative. This is the case of the IV chemotherapy compounding.
Media Fill process simulation is a standard method to assess and validate the aseptic technique of the pharmaceutical manufacturing, using microbial growth media instead of drug.
The purpose of this study was to validate the aseptic process of the automatized IV compounding that represents, on average, 90% of the daily chemotherapy production of the University Hospital of Ancona.
According to the acceptance criteria defined by ISO 13408-1, the aseptic processing of the automated drug compounding were successfully validated.