Validation of aseptic processes by media fill

Muhammad Shahid Khan
NovaMed Pharmaceuticals (Pvt) Ltd., Pakistan

The validation of aseptic processing is carried out by media fill (also known as process simulation, simulated product fills, broth trials, broth fills etc.). The media fill is a technique in which a liquid microbiological growth medium is prepared and filled in place of actual product in a simulation of normal manufacturing process. This process normally includes exposing the microbiological growth medium to product contact surfaces of equipment, container closure systems, critical environments, and process manipulations to closely simulate the same exposure that the product itself will undergo. The final containers are then incubated and checked for microbial growth. Results are then interpreted to assess the potential for a unit of drug product to become contaminated during actual operations (e.g., start-up, sterile ingredient additions, aseptic connections, filling, and closing). The purpose of media fill study is to validate that the processes, systems, environment, container closure system, practices, equipment, personnel etc. are capable of producing a sterile product in a consistent and reproducible manner. The medium used should support the growth of a wide variety of microorganisms, including aerobic bacteria, yeasts and moulds (non-selective medium). Mostly Soybean Casein Digest Medium (SCD) also known as tryptone soya broth (TSB) is used.

Biography

Mr. Muhammad Shahid Khan has got more than 18 years of experience in Pharmaceutical Industry at different positions. He is currently working as Plant Manager in Nova Med Pharmaceuticals (Pvt) Ltd, a local firm but also manufacturing products for many multinational companies like Sanofi aventis, ICI, Getz Pharma and Searle. He is expert in product and process development and validation. He has developed many products. He has attended many training workshops, exhibitions and technical seminars in Pakistan and abroad.

shahid.khan@novamed.com.pk

Notes: