

ABSTRACT

Media Fill Challenges at the PDA-TRI

Case Studies during Aseptic Processing Training Courses

The Aseptic Processing Training course at the PDA's Training and Research Institute (www.PDA-TRI.org) in Baltimore, Maryland, is an intensive, two-week, "hands-on" curriculum composed of both lecture and laboratory modules. The first week focuses on the basic principles of aseptic processing culminating with two media fills in the aseptic processing area (APA). Media fill protocols are followed that include defined personnel interventions, including manual stoppering of vials on the filling line. During the second week, which is separated from the first week by 3-4 weeks, the students are divided into Manufacturing and QA "Departments," which includes Managers of each department. The focus of the week is an investigation into a media fill failure, corrective action, and manufacture of a real product, including all documentation required in a Batch Record and related forms. For sessions in 2000 and 2001, prior to the media fills performed in Week 1, and unbeknownst to the students, various APA facility surfaces or materials were inoculated with known levels of *Bacillus* spores. Environmental monitoring was performed in conjunction with each media fill. Data will be presented that demonstrates the relative level of cleanliness of the facility and personnel after each fill and the results of the incubated media filled vials. By using known *Bacillus* species and identifying recovered isolates from the environment, personnel and contaminated vials, the "challenge" microorganisms could be tracked and distinguished from naturally occurring contamination. Following that methodology, the route of vectoring non-human origin environmental contamination from the APA to open vials of media could be illustrated.

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