Aseptic Component Wrapping Systems for Steam Sterilization

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Description:

Preparation of components used in aseptic drug manufacturing is critical for successful sterilization and protection throughout the manufacturing process. In order to maximize efficiencies in production, pharmaceutical, biotech and medical device organizations must streamline pre and post sterilization cycle productivity. Customized sterilization wrapping systems allow for improved operational efficiency, while effectively maintaining a sterility barrier to protect components / equipment throughout the process. This presentation discusses unique sterilization wrapping systems for improving quality and productivity pre and post sterilization.

In this session, case studies demonstrate specific methods for minimizing preparation variation and improving operational efficiency. Recommendations for sterilization cycle verification using biological and chemical indicators are discussed. Additionally, specific features of the wrapping system highlight improvements to sterility assurance and product quality during component storage and presentation to the filling line. Common challenges and solutions are addressed to streamline system implementation.

Background Information:

The session leader has nearly 20 years experience with sterilization and sterility assurance within the pharmaceutical industry. His personal experience as a Quality Assurance microbiologist at a large pharmaceutical company and then as a Technical Service Specialist at an equipment supply vendor presents a unique perspective for this presentation and case study.

Attendees to this session will realize the benefits of a novel approach in preparing components and equipment to be sterilized, as well as methods for implementing the new process.