# Regulatory Actions Taken in Response to Issues in Aseptic Processing and The Quality System

By **Jeanne Moldenhauer**

**Jan 28, 2020 8:00 am EST**


Your firm failed to follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21CFR 211.113(b)). Examples of the FDA concerns include: Poor Aseptic Behavior The operators displayed poor aseptic practices during aseptic set-up and filling operations. Examples of the types of concerns (abbreviated from the observation) are: Interventions were performed with operators place body parts into the filling cabinets prior to clearing open vials. (Meng,...