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Linking Simulation and Risk Approach for a Bulk Vaccine in Clinical Phase— Part I. Effect of Interventions

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Interventions can be classified as routine and nonroutine. Routine interventions (RI) are activities that are inherent parts of the aseptic process performed on every batch. Non-routine interventions (NRI) are predominantly corrective and may not be performed on every batch. Although theoretically NRI are not required, such interventions are frequently performed to correct unexpected problems (3). The Simplified Akers-Agalloco Method was published in 2006. It recognizes human activity as the main factor for risk handling in aseptic processing. According to this method, the aseptic compounding...

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