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Developing a practical quality risk management scheme in accordance with vial's dimension deviations in aseptic filling process

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Risk assessment in pharmaceutical industries is a regulatory expectation and it can increase process understanding and provides safe and effective product for patients. Risk analysis and management is an acceptable way to determine the appropriate level of validation and controls. Risk management can be applied in various areas of pharmaceutical processes, from early process providing raw materials through final product post marketing. The risk of contamination during the vial filling process of a sterile product has not been well defined yet. Based on ISO8362-1 vial dimensions should be in particular ranges. In this study the risks of vial dimensions effect of aseptic filling process was investigated. We found that the most critical point are vial entry surface like d2, d3, d4 and h4, which in turn affect rubber sealing and capping. Other dimensions like h1, h2, h3 and d1 affect rubber sealing and capping indirectly. Therefore, these two groups of dimensions have a very high probability risk of contamination. External surfaces of container components which are fully exposed to the laminar airflow and are in contact with equipment parts may transfer environmental contaminations. Underweight vials may increase vial breakage probability and glass particle contamination. Due to decrease the risk of contamination, pharmaceutical companies should provide validated vials for injectable products and related quality control laboratory equipments should be calibrated according to the approved protocols.

Biography

Nasim Rahmani has completed her Pharm D at the age of 25 years from Jundi Shapour University of medical science. She is Technical assistant of Pasteur Institute of Iran, a Production and Research complex. She has published a paper.

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