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Performing microbial risk analysis on a standard compounding pharmacy aseptic fill process

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By the end of May 2013, 9 compounding pharmacies had recalled drug product due to lack of sterility assurance in the final product. Proper risk analysis of the compounding process would have identified control points, which if adequately monitored would have increased the sterility assurance of the finished product. This talk explores risk analysis and pharmaceutical development as defined in ICH Q9, and applies some of the risk management methods and tools to a fictional compounding pharmacy to illustrate their potential effectiveness at mitigating microbial risk.

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