

Integration of Risk Management Principles into the Quality System: Risk-based Impact Assessment



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Introduction As the principles of quality risk management have become increasingly pervasive in the biopharmaceutical and medical device industries, a point of saturation has been reached with respect to the risk toolkit. Standard risk assessment techniques such as hazard operability analysis (HAZOP), hazard analysis and critical control points (HACCP), and failure modes and effects analysis and its derivatives (FMEA, FMECA, FMEDA) have proven effective in increasing understanding of the general level of risk inherent in products and processes and have allowed the industry to realize tangible...

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