

QRM - Design and implementation of an effective quality risk management program

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Quality risk management is the identification, assessment and control of risks related to the production, storage and shipping of pharmaceuticals. Methods vary in the manner in which risks are identified, categorized and managed. However, some approach to risk management is expected by regulatory authorities under current good manufacturing practices. The international conference on harmonisation provided the most prominent approach to risk management with the release of the 2006 guidance "Q9 quality risk management." Although this guidance document identifies multiple methods that may be implemented, pharmaceutical companies must identify which approach is most effective for their specific processes and environment. That decision should be based on pre-determined goals, assurance that risk determinants include all relevant variables and a measurable method for assessing significance in order to appropriately categorize risk. These elements should be inherent in the design phase or of the QRM program. For a program to be effective, a company must employ commensurate measures to control or eliminate that risk with measurable key indicators. Elements of those control measures should be applicable to the root cause and applied universally.

Biography

DeVaughn Edwards is a former FDA investigator who has performed pharmaceutical inspections in more than 20 countries. He has inspected API manufacturers, sterile drug facilities as well as oral solid dose companies many resulting in significant actions including warning letters and an injunction. He has given speeches on several quality-related topics domestically and abroad. Additionally, he has held various executive positions with pharmaceutical companies in quality and compliance roles. He is the Director of Quality Operations with Johnson and Johnson.

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