

Managing Knowledge and Risk – A Literature Review on the Interdependency of QRM and KM as ICH Q10 Enablers



By

Martin J. Lipa, Kevin O'Donnell, and Anne Greene

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ABSTRACT Quality Risk Management (QRM) and Knowledge Management (KM) have been positioned as co-enablers to the Pharmaceutical Quality System since the 2010 issuance of ICH Q10. Yet these disciplines have remained largely distinct and disconnected in practice. This paper presents a two-part literature review on this topic. First is a review of how other industries have connected risk management and knowledge management. This is followed by a review of relevant biopharmaceutical industry regulatory guidance to explore expectations for how risk, risk management, knowledge...

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