

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

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INTRODUCTION In 2010, when ICH published Q10 Pharmaceutical Quality System [1], Quality Risk Management (QRM) and Knowledge Management (KM) were clearly identified as key enablers to supporting an effective Pharmaceutical Quality System (PQS). While the authors of ICH Q10 recognized the role, both play in ensuring

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