

Shelf-Life Extensions For Pharmaceutical Products



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Risk-based Assessment of PACs and Determination of Regulatory Reporting Category

This One-Voice-Of-Quality (1VQ) paper is part of a series of industry case studies intended to demonstrate the standard application of the principles outlined in the publication “Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches Industry; One-Voice-of-Quality (1VQ) Solutions” in *PDA Journal of Pharmaceutical Science and Technology*, 2020 [1]. Furthermore, this 1VQ paper provides a practical application of the concepts described in ICH Q9, Quality Risk Management [2], ICH Q10, Pharmaceutical Quality...

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