

ICH Q9 (R1) Quality Risk Management Revision



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By

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This topic was endorsed by the ICH Assembly in November 2019. Two primary activities are addressed: Limited and specific adjustments to specific chapters and annexes in the current ICH Q9 Specific training materials with examples to supplement current ICH Q9 and the proposed revisions. Rapporteur for this project is Dr. Kevin O'Donnell (EC, Europe). Regulatory Chair is Alex Viehmann, FDA. The current ICH status is Step 1. The following summarizes key points associated with the revision as expressed in ICH documents. FINAL CONCEPT PAPER The final concept paper was endorsed by the...

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