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**ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Step 2b**

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609205.pdf>

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|  | **GENERAL COMMENTS ON THE DOCUMENT** |
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**Specific Comments on the Text**

ISPE indicates text proposed for deletion with ~~strikethrough~~ and text proposed for addition with **bold and underlining**.

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