Validation of API Manufacturing Operations: Impact of Q7A

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From the introduction section of the Q7A document to its final chapter, validation is noted more than 70 times in the guidance. Validation is noted in the following sections of the guideline: Validation, according to the Food and Drug Administration's (FDA) “Guideline on General Principles of Process Validation” (May 1987), includes: “Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes." We will look at the most significant words in this...

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