GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry

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As manufacturing and distribution practices get more complex and more global, manufacturers cannot just focus on one or two sets of requirements - it is too difficult to operate a quality system that has a multitude of variations to meet the individual requirements of a particular national authority. Most multinational firms and those supplying global markets have done what national authorities have not - they have created quality systems and quality system elements that internally harmonize GMP expectations. Yes, there still are some unique requirements that need to be met, but having a majority of requirements harmonized reduces duplication and increases flexibility. GMP in Practice, 4th Edition is intended to help with that harmonization. In it, we will look at more than 30 elements that are typically included in a modern pharmaceutical quality system. Each quality system element has an overview section, some risk-related questions, and 3-10 expectations. Each expectation is explored in a bit more detail and examples from GMP references from the US FDA, Health Canada, the European Union, the World Health Organization, and the International Conference on Harmonization (ICH) are presented.

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