

The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals

José Rodríguez-Pérez



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This guidance book is meant as a resource to manufacturers of pharmaceuticals, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards themselves and texts on the specific processes and activities contained within the QMS.

This book includes chapters on US current Good Manufacturing Practice (GMP); international GMP; global GMP guides and harmonization; detailed analysis of the requirements and guidances; missing subparts; what inspectors are looking for; and the price of noncompliance. It also includes an appendix with two tabulated comparisons: the first compares US, European-PIC/S, Canadian, and WHO cGMPs, while the second compares US cGMPs with effective quality system elements.

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