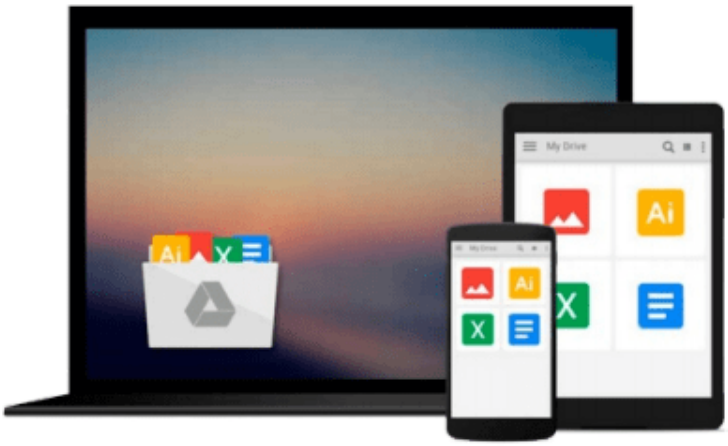

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Jose Rodriguez-Perez

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Good Manufacturing Practices (GMP) for human pharmaceuticals affects every patient taking a medicine. GMP covers all aspects of the manufacturing process, from defining manufacturing processes to systems for recall and investigation of complaints. Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective. GMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards. 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. A companion CD contains dozens of FDA guidance documents as well as international harmonization documents (WHO, PIC/S, and ICH). A check list for cGMP audit is also included based on risk management criteria. An exam complements the material included in the CD.

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