



Part 11 and Computer Validation Guidebook

Daniel Farb

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This is a package of Agent GXP FDA Part 11 and Pharmaceutical Computer Validation Introduction. These two related titles will give the learner an excellent introduction to computer issues in the pharmaceutical industry. Agent GXP FDA Part 11 teaches the FDA regulations on electronic signatures and records in the context of a spoof on a hostage rescue supervised by Pharm Mission Control. The many difficult regulations of Part 11 are broken down into episodes that make the learning more memorable. This thorough section will teach you the history of Part 11, the regulations of Part 11, the implementation of Part 11, the applications of Part 11, the ideas behind Part 11 in order to apply them to new situations, and how to prepare for enforcement of Part 11. This is particularly important for both pharmaceutical/medical device manufacturing and clinical research personnel in FDA-regulated industries, and provides an excellent glimpse of the issues that are likely to face HIPAA implementation of electronic records security measures. This course has been used by thousands of people in the pharmaceutical industry. Pharmaceutical Computer Validation Introduction gives you a comprehensive introduction to computer systems validation as the computers come to life while the head of computer systems at a pharmaceutical company has to prepare for an FDA inspection. You will learn about regulations, the personnel responsible for computer validation, how to accomplish validation, examples of regulatory problems, and so on. It is also relevant for the medical device, food, and cosmetic industries. 224 pages in the manual include handy printouts of many relevant FDA regulations. For convenience, the CD contains the text of some of the regulations. Those readers who wish to have an accompanying program with video and interactivity should also purchase the CD version.

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