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Recent changes in the interpretation and enforcement of 21 CFR Part 11 have shifted the focus of Good Laboratory Practice (GLP) regulations to concentrate on the acceptance of electronic signatures, the archiving of data, the security of electronic documents, and the automation of laboratory procedures. This all-encompassing Fourth Edition addresses every critical aspect of Good Laboratory Practice (GLP) regulations and demonstrates effective strategies for implementation in a variety of laboratory settings. This updated and expanded classic text contains new information about applying 21 CFR Part 11 to the laboratory environment, GLP documentation systems, laboratory risk analysis, system validation and inspection, process analytical technologies, and cost control for the prevention of pitfalls and the assurance of compliance in numerous research environments.

Providing insights for the application of GLP regulations and emphasizing the latest regulatory developments, this reference discusses the implementation of PAT and emphasizes the importance of electronic audit trails and data controls as laboratories rely more on automated procedures…gives clear rules for the acceptance of electronic signatures, archiving of data in formats accessible by electronic recovery and human retrieval, and the security of electronic documents…and details the FDA’s GLP inspection program.

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