



A Guide to Archiving of Electronic Records

By Tim Stiles, Dr Julia Lawrence, Neil Gow

Scientific Archivist Group, United Kingdom, 2014. Slide bound. Condition: New. Language: English . Brand New Book ***** Print on Demand *****.The retention and archiving of study materials and process records, raw data and source data, is a critical part of compliance with both Good Laboratory Practice (GLP) and Good Clinical Practice (GCP). The maintenance and retention of such records provides the means by which a study, trial, process or procedure can be reconstructed and thus enabling the information and results generated to be verified. Requirements for the operation of an archive and the archiving process for electronic records are no different to the requirement of physical records which are required to be retained for regulatory or business requirements. However, due to the variety and fragility of electronic records some additional features are required. The purpose of this document is to identify and discuss these features and provide guidance on how these challenges can be met.

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