



Text information Management system

- Text : Word or, group of words
- Information: processed data or fact
- Management: an art to make the things done with proper resource at correct cost, place and schedule.
- System: to store the data & facts



Text information Management system

The name "text information management system" is not as widely used as the name "laboratory information management system." Nevertheless, a text document management system is essential in preclinical development because huge numbers of text documents and other related information such as images, drawings, and photographs are generated in the area. All these documents and information are considered intellectual property and require protection and easy access.



Text information Management system

- Text information management systems help the pharmaceutical Industry to improve efficiency in managing business –critical text documents.
- The objective of an information retrieval system is to organise and store large amounts of text so that information can be retrieved from the repositories in response to users information requests.



Text information Management system

- Text information management systems deals with bibliographic documents, legal documents, official memos, patient records & case history, letters, correspondences, complete text articles and books and so on.



TIMS: documentation requirements in preclinical development

- In preclinical development, the GMP/GLP regulations are enforced not only for scientific data but also for text documents. This section discusses several types of controlled text documents used in preclinical development. Most of these documents are managed by the fully validated TIMS.



TIMS: documentation requirements in preclinical development

- **In pre-clinical development, these (Product specification documents and analytical test methods) are important documents and they evolve along with the development phases. Drug substances and products for clinical trials are tested based on these documents, and so are the stability samples.**



TIMS: documentation requirements in preclinical development

- It is critical to ensure that the analyst will perform the right tests against the right specifications with the correct version of the test method. Therefore a mechanism must be in place to control these documents. This can be done manually or with TIMS.



TIMS: documentation requirements in preclinical development

Most of these documents are managed by fully validated TIMS:

- SOP
- Research report
- Laboratory data
- Product specification & Analytical Tests



BENEFITS OF TIMS

- ❑ Save time and energy
- ❑ Faster method of report generation
- ❑ Ensure accuracy Improve efficiency in managing critical data
- ❑ Strict security & reduce paper work