Paperless Audit Management System How does it work?

Scheduling, executing, documenting, reporting, and closing of various types of audits by GLP QA necessitate a need for a robust traceable and uncompromisable system. GLP QA involves auditing of study plan/protocols, review of study plan amendments, selection and auditing of critical phase(s) of each study, raw data & report audit, final report review, facility-based inspection, process-based inspection and much more. This process requires enormous paper work to capture the information for each activity. As the paper-based auditing system has its limitations for effective scheduling, precise reporting, traceability of real time information, as well as it requires excessive time and efforts, a strong need was felt for a paperless management system.

JRF IT experts QA & IT experts got together and developed a URS for designing an online Audit Management System (AMS). After several iterations and dry and wet test runs, the package was validated.

The important features of this paperless AMS developed at Jai Research Foundation, are:

1. Facilitate scheduling of audits and auditors activities
2. Link with master schedule and test item management system for ready-to-use information in respect of each study and the relevant test item
3. Audit forms with checklist of parameters to be assessed while undertaking each audit
4. Audit observations and their classification pinpointing to the precise issue (if any) and their severity levels
5. "High-alert" for critical audit observations
6. Online information on status of each of the audits performed
7. Generate QA statement for each study, which can be printed and archived at the end of the study as a study specific QA data.
8. Facilitates assessment of quality system based on defined quality indicators for each study, study director, study type/phase, section/department
9. Online access to TFM for individual QA audit report and QA audit summary report.
10. The data in AMS is backed in real time, ensuring no loss of data.

This has turned out to be a boon to audit management at JRF. This not only saves several thousand papers each year. The system presents well-organized and precise documentation procedure for QA audits, inspection and review. This system has helped JRF to ensures full GLP compliance and effective corrective and preventive action (CAPA) system.

About The Author

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Dr. Sanghani an Agricultural Chemist by training has a sound understanding of audits (Internal/External) and quality and has been actively involved in the development of several SOPs, validation plans and policies under GLP. He is actively involved in the establishment of Indian Chapter of Society of Quality Assurance (ICSQA), holding a position of director at ICSQA. He is an expert on Global Regulatory requirements such as that of the OECD, US-EPA and FDA GLP requirements.

"JRF Global, a leading non-clinical GLP compliant CRO, offers comprehensive research services, in accordance with the worldwide regulatory requirements, for product registration.

The key services of JRF are dedicated to the establishment of the discovery and development of a drug, as well as the efficacy and safety of products, in our well established and highly credible state of the art research facilities, pertaining to the Analytical, Bio-analytical chemistry, and Organic synthesis, IND enabling Mammalian Toxicology and Mutagenicity under endorsement of the OECD GLP."

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