Electronic Laboratory Notebook

For a GLP, data integrity is an essential component. Terminologies like "complete, legible, and trueness" are frequently used in a GLP study by the regulatory inspectors, questioning the reliability as well as the authenticity of data generated in the laboratory. Sometimes it is very difficult to define and defend the concerns expressed in terms of these words, which can be understood differently. Very often, a set of raw data describing "what, when, and where" is considered complete. To meet the regulatory requirements, a well versed and flawless data recording system is required and it plays a very critical role.

We, the Jai Research Foundation (JRF) - a GLP compliant laboratory, are concerned about maintaining data integrity. We always look for a possible advancement which is more reliable and widely acceptable.

At JRF, we have implemented a customised Electronic laboratory notebooks (ELN), meeting the GLP requirements. Our ELN is a mature electronic lab notebook which captures data electronically in the laboratories to record test results, thus, eliminating the need of pen and paper. It inches us closer to a paperless environment and at the same time it improves compliance with the regulatory requirements like GLP, 21 CFR Part 11, Eudralex Annex 11.

Nowadays, the regulatory inspectors are expecting such tools to ease the audit process. ELNs have gained a lot of prominence amongst laboratories, for the discovery, research, quality control, and research and development of any product, due to their user- friendliness and systematic representation of data.

About The Author

Jignesh Patel, M.Sc. specialization in **Chemistry** is a senior research officer leading a team for physicochemical studies, and analytical method validation most of which are conducted under GLP compliance for EPA and EU registration having experience of more than 12 years in CRO and Pharma Industry.

"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."

JRF GLOBAL