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eClinical solutions: Boosting the clinical trial efficiency

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eClinical solutions are a combination of technology, products, and services that work together as solutions to automate the management or conduct of clinical trials with the aim of replacing manual, ad hoc or paper-driven methods. eClinical solutions refer to a number of different technologies, such as EDC solutions (Electronic Data Capture), CTMS (Clinical Trials Management System), Randomization and Trial Supply Management systems, IVRS (Interactive Voice Response Systems), electronic patient diaries and other common types of electronic solutions widely used in clinical trials. Early trends and talk around eClinical focused around how data from disparate systems could be integrated to remove duplication of data and activities. One way in which eClinical has changed the way in which we do business is that integration of key clinical trial systems have become expected rather than exceptional. Vendors and sponsors are investing in infrastructure and standards to ensure capabilities can be scaled up and applications integrated in a rapid, efficient, and supportable manner—like the cargo industry analogy. The market for eClinical solutions can be analyzed with respect to three delivery modes, i.e. licensed enterprise (on-premise), web hosted (on-demand), and cloud-based. eClinical solutions are being used more frequently in upstream site on-boarding and qualification processes, and in managing site-sponsor collaboration during a clinical trial. A large number of investigator groups are still ignorant of the benefits offered by eClinical solutions and continue to depend on paper-based work or spreadsheets. Compliance benefits and user-friendly access of software are yet to penetrate the clinical trial community well.

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An introduction to automations in pharmaceutical industry

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Pharmaceutical manufacturing is increasingly competitive, and the ability to guarantee consistent quality, reduce direct manufacturing costs and immediately evaluate test results can be paramount in maintaining a competitive edge. Despite this cost pressure, some production activities and physical tests including the recording of measured results are often performed manually. This manual operations and manually calculated reports make the entire process slow and also create more opportunities for error occurrence and time consuming. Many companies are relentlessly pursuing new technologies and automating the various production and evaluation steps in order to avoid specification input errors, wasted production and long product release processes. The introduction of automation into pharmaceutical production will reduce the cost of manufacture and they will also have an added benefit of greatly reducing the cost of achieving a validated operation and maintaining GMP standards. This present study deals with the automation processes used at various stages of production and inspection systems in pharmaceutical industry. As there is not many automations involved in the manufacture of solids like tablets and capsules when compared to the manufacture and handling of parenteral preparations. Hence my current study emphasizes the importance of automations in parenterals.

Biography

Sudheep Goud Sandhil is presently a student of JSS College of Pharmacy, JSS University Mysore. He has completed his B.Pharm from JSS College of Pharmacy, Mysore. He is presently pursuing his M.Pharm in Pharmaceutical Quality Assurance Programme in the same college. His areas of interests are QMS, GMP, SIX SIGMA, ICH guidelines.

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