Navigating the manual to electronic transition

for new drug application bioanalytical data submissions

The use of manual data for new drug application submissions is becoming progressively outdated, as electronic versions can offer increased efficiency, traceability, data preservation, and a comprehensive audit trail for companies navigating the drug development continuum.

This infographic explores how Labcorp Bioanalytical Services navigated this transition in China to achieve the first New Medical Products Admininstration (NMPA) approval for bioanalytical sample analysis submissions in 2022.

6 years of manual to electronic bioanalytical process flow transition, including:

- Preparation and use of standard stock solutions, working solutions, standard curves and QC samples
- Management of reference standards, blank matrices, reagents, and consumables
- Clinical trial sample extraction process and checking of samples
- Instrument sampling process of the test samples and equipment used

4-day on-site inspection reviewing bioanalytical methodology verification and test sample analysis by state National Medical Products Administration (NMPA) in China

1st clinical bioanalytical sample analysis project using an electronic end-to-end management system to successfully pass on-site inspection of the National Medical Products Administration in 2022

国家药品监督管理局
National Medical Products Administration

This infographic has been created as part of a Bioanalysis Zone feature in association with Labcorp.