

Trend analysis on repeats, a way through.....

Neerja Somyajee

Head QA, Piramal Clinical Research, Hyderabad, India

The subject samples for a PK/PD/ Bio-equivalence and Bioavailability studies are been analysed using a mass spectrophotometer. In the current industrial practices the subject samples are repeated due to various reasons like Batch failures, processing errors, aberrant values, IS variations etc. This is acceptable by all regulatory bodies. But what is required is something beyond this.

Not only analyzing the repeats we also need to have a trend on all the repeats for each project analyzed, month wise, in a year. A graphical representation of this data will help us to find the gap in the system. The data will present frequency of the recurring processing errors, IS variation etc. With this data you can analyze where the defect lies, what is the root cause analysis and how this can be fixed.

The presentation shall talk about

- Preparing a trend of all the repeats
- Analysing the trend
- Root cause analysis
- Corrective and preventive action plan
- Fixing the corrective and preventive action plan

Biography

Neerja S is a pharma graduate from Behrampur University and PG in IPR and Regulatory Affairs from Nalsar Law university. She is the Heading the QA for Piramal Clinical research. She has a vast experience of 10 years working in various departments (Quality Assurance, medical writing, Regulatory Affairs, site coordinator for Phase III trial) of leading CROs and pharma companies of India.

neerja.somyajee@piramal.com