Sharmeen Reza, Pharm Regul Aff 2017, 6:2 (Suppl)
DOI: 10.4172/2167-7689-C1-027

Quality control in statistical programming under GCP

Sharmeen Reza
Cytel Statistical Software and Services Private Limited, India

Statistical programming to support clinical research and data analysis is vital in the drug discovery process. GCP is a prerequisite for any submission to regulatory authorities for drug approval and licensing. Quality control (QC) comes with different measures and tools following Standard Operating Procedures (SOPs), established by sponsor companies and/or Contract Research Organizations (CROs). The SOPs are mainly based on GCP guidelines. This presentation exhibits brief overview of QC in overall clinical trials, with focus on QC done right for statistical programming in a R&D environment. It gives relevant definitions, processes followed, reasons for QC, challenges faced, deviations and expectations. The topic also describes roles, expertise, requirements, documentation and responsibilities involved. Given a drug's prospects, the impact of a solid QC process outweighs resource investments. Since quality is a key performance indicator and helps to select preferred partnership, pharmaceutical companies highly value CRO capabilities in conducting QC.

Biography

Sharmeen Reza is the Director of Statistical Programming at Cytel Inc., a major functional service provider for pharmaceutical and biotech companies. Previously, she was the Biostatistical Programming Manager at Amgen. She has 20+ years of clinical background. On many occasions she gave presentations on quality control, trained new hires and helped them come up to speed. She has presented papers at conferences emphasizing the nature of collaboration in R&D and discussing statistical programming solutions.

Sharmeen.Reza@cytel.com

Notes: