Audit

Audits (independent evaluations of activities, processes and product quality) are an element of quality management in industry, finance, commerce and public service. They are typically performed by an independent auditing service, but may also be conducted as an internal audit (self-inspection) by the company through a specific audit department usually directly reporting to the board.

In medicines development, two audit types are routine and required:

1) Good Manufacturing Practice (GMP) audits (self-inspections) to monitor the implementation and compliance with good manufacturing practice principles (required as per Directive 2003/94/EC) and other quality standards like ICH Q10 and to propose necessary corrective measures.

2) Good Clinical Practice (GCP) audits, a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data was recorded, analysed and accurately reported according to the protocol, sponsor™s standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s) (ICH E6 Directive 75/318/EEC as amended