JOB DESCRIPTION

Primary Responsibilities	• To file and maintain QAU records and reports. • To assist Head-Quality Assurance in coordination with Manager / Senior Associate in preparation and revision of SOPs and in imparting SOP training. • To archive all historical SOPs, QA audit reports, employee training records and other necessary documents. • To determine that, no deviations from approved protocols or standard operating procedures are made without prior authorization and documentation. • To review the final bio study reports to assure that such reports accurately describe the methods and SOPs and that the reported results accurately reflect the raw data of the conducted bio study. • To review protocols, informed consent forms and case report forms • To review clinical data, drug administration procedure and study conduction process • To maintain the training records of AnaCipher Clinical Research personnel. • To maintain and issue raw data forms and log books. • To archive SOPs, study related documents and log books. • To assist Manager-Quality Assurance in facility audits and tracking corrective and/ or preventive action plan. • Auditing of clinical lab activities in compliance to current SOPs of clinical lab. • Perform Internal Quality Audits as per current SOPs to ensure the compliance of Quality Systems in Clinical Research Department.

Secondary Responsibilities	• Responsible for maintaining day to day activities in archival. • Verification of all the documents that are submitted for archival. • Responsible for maintenance of archived documents and records. • Responsible for retrieval of archived documents upon receipt of request for retrieval. • Responsible for monitoring and recording of environmental conditions in the archival facility. • To prepare and review the general and archives SOPs. • Verification of archived documents periodically to check the status of documents. • Discarding of archived documents after completion of archival period.