GRRMDP
Global Regulatory requirements for Good Manufacturing and Distribution practices in Pharmaceutical /Biopharma industries

We have document and data control Standard Operating Procedure which covers implementation of Standard Operating Procedure, Instrument Operating Procedures, General Test Procedures and other procedures. Master copy in original and contemporaneously recorded is kept in the custody of Quality Assurance Department.

The documents are controlled and issued for use. Any change / modification is followed through Change Control approval system. Distribution is done manually and it is ensured that previous version of Standard Operating Procedure, Instrument Operating Procedures, General Test Procedures and other documents are retrieved and Master copy of previous version is superseded.

Circulation of Controlled copy is restricted through Quality Assurance. This Controlled Copy is printed and issued as per document control sop. All SOPs, Instrument Operating Procedures and master Batch Manufacturing Records and Master Packing Records are reviewed and approved by Head Quality/Designee.

The Quality Assurance Department reviews the documents, data like executed Batch Manufacturing Records, Batch Packing Records, Cleaning Records, Analytical Records, Raw data, Process Validation Protocols, Reports, Cleaning Validation Protocols, Reports, Qualification Protocols and Reports, Calibration records, Preventive Maintenance Records, Stability data, Usage Log books etc. for its completeness, consistency and accuracy of data and we ensure that data is attributable, legible and contemporaneously recorded. We have online review mechanism in Quality Control Laboratory.

Instrument Backups are taken periodically in server. Qualification of instruments, Equipment and area are ensured prior to use. All the utilities are reviewed and qualified for its intended use.

Computers are validated with the help of consultants and software / hardware is evaluated for its intended use throughout the Life cycle. The computer system usage is restricted and authentic user IDs and passwords are assigned to each user.

In _____, we have document and data control Standard Operating Procedure which covers various documents and its retention period. The physical copy of documents is preserved in document room. Soft copies of back-up are taken by IT server at server room.

In _____ we have qualified the Equipment's and Instruments against its intended use and Risk Assessment is part of Qualification procedure. We have SOP for Audit trials of the analytical instruments and audit trial is reviewed. The authorisation levels of usage of Laboratory instruments are established and User ID and Pass word protection is given to individual analysts.

The audit trial for HPLC includes the name, date/time of the run, the integration parameters used, including change justification for the reprocessing. The authorisation levels include system administrator role, including any rights to alter files and settings, be assigned to personnel independent from those responsible for the record content.

Quality Assurance Department assure that only authorized personnel make changes to computerized Master documents, or other records, or input laboratory data.

In _____**,** all worksheets, laboratory note books, Log books and Registers are bonded, numbered and controlled issued by Quality Assurance Department. The issuance of loose formats is covered in SOP for "Document Control". All the completed usage log books are retrieved by QA Department and preserved as per retention time period.

In _____**,** all print out or static record is kept along with analytical raw data in original and contemporaneous and print out is reviewed and signed by the reviewer.

The privileges are provided for instruments related software's and policy is established thereof. We have back servers and daily back-ups are maintained.