DATA INTEGRITY:
EXPECTATIONS & EXPERIENCE IN GLP

DR. L.U. SANGHANI
DIRECTOR – QUALITY ASSURANCE UNIT, JRF GLOBAL

Indian Regional Forum

Presented by : Labhu Sanghani, Director - Global QA, Jai Research Foundation

SCOPE OF PRESENTATION

- Data Integrity
- Expectations
- Common Pitfalls
- DI Contributing Factors
- DI Audit in GLP Quality System
- DI Audit- Audit Trail
- User Authentication Procedure
- Data Integrity - Self Audits
- DI: Chromatography Concerns
- Typical DI Audit Observations
- Data Integrity – Procedures / SOPs

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DATA INTEGRITY

- Data integrity is the degree to which data are complete, consistent, accurate, trustworthy, reliable and these characteristics of the data are maintained throughout the data life cycle.

- Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate(ALCOA).

- Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices.

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EXPECTATIONS

- Adequately validated computerised systems
- Sufficient controls to prevent unauthorized access or changes to data.
- Implement a data integrity lifecycle concept
- Security, user access and role privileges (Admin)
- Activate audit trail and its backup
- Procedure and records for audit trail review
- Backup, archiving arrangements
- Disaster recovery plan
- Verification of restoration of raw data
- Qualification and change control

COMMON PITFALLS INCLUDE

- Perception of a lack of quality culture
- Design and configuration of systems are poor
- Data review limited to printed records - no review of e-source data
- System admin within Analyst/QC, can delete data
- DI is not only a QC lab issue
- DI awareness training/refresher absent
- DI verification not part of self inspections
- QA oversight of CS negligible
- Shared Identity/Passwords

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DI CONTRIBUTING FACTORS

- Leadership and KPIs can drive wrong behaviours
- Inappropriate system design encourage bad practices
- Culture of fear, blame and punishment
- Poor attitude to problems- miss learning opportunities
- Poor training, staff lack DI awareness
- Don’t care, won’t get caught attitude
- Lack culture of quality, doing it right when nobody is watching
- Insufficiently controlled processes and Poor documentation practices
- Suboptimal quality oversight
- Wilful, intentional data falsification
- Old computerized systems

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DI AUDIT EXPERIENCE-GLP

- Review of paper only systems, controls, loose sheets
- Review of networked systems at a PC
- Review of data on standalone equipment
- More audit time in the analytical lab and for manual records
- Traceability of raw data-test item receipt to use
- Review of raw data for ongoing studies
- Review of time specific activities and access control data

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DI AUDIT IN GLP QUALITY SYSTEM

- What document systems used?
- GLP computerised inventory list?
- Review of the Procedures dependent on pre-set parameters
- Audit of Test Item and Reference Standards inventory
- Review of sensitive equipment calibration and maintenance
- Dose formulation preparation, dilution and sampling
- Work distribution to study personnel and technicians
- Corrections/modification of data-justification and authorization

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DI AUDIT- SAMPLE HANDLING

- Test Item receipt log- date, time, name, quantity, use and disposal
- Sample container labels, verify physical sample
- Check the retained samples, periodic examination
- Check for QC samples without evaluation criteria
- Test time reflects time of sample collection etc.
- Re-sampling events

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DI AUDIT- AUDIT TRAIL

- ❖Is the audit trail activated? SOP?
- ❖Record of reviews?
- ❖Training of staff on audit trail review?
- ❖Is predicate rules followed for changes?
  - ✓preserve original data
  - ✓corrected data
  - ✓date of correction
  - ✓name of person who corrected the data
  - ✓justification comment for correction

USER AUTHENTICATION PROCEDURE

- Procedure to add, modify and delete users
- Employees leaving the company removed from system?
- Training requirements before access is granted.
- Clear roles and responsibilities of users
- Procedure for (re-)activating passwords, including identification process of the user requesting a new password and procedure for the communication of the password.
- Administrators should not have a conflict of interest.
- Periodic reviews performed?
- Do you have sufficient user licences for your systems

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DATA INTEGRITY - SELF AUDITS

- Train auditors using industry & in-house examples
- Do unannounced audits, Quality walks etc.
- Focus on raw data handling & data review/verification procedure
- Verify signatures against a master signature list
- Look for unofficial or private records
- Check inventory system – Receipt against actual usage.
- Check test system source, receipt and use records
- Check adequate control of lab records – re-issues, discard of raw data
- Verify use & existence of equipment in laboratory
- Interview study personnel and technicians

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DI: CHROMATOGRAPHY CONCERNS

- Deletion of data, Folders & individual data files
  - ✓ Software not properly monitored
  - ✓ Non-compliant software used
  - ✓ Analysts not properly trained
- Overwriting of data
- Altering integration parameters
- Performing sample trial/test/demo injections
- Administration and user privileges
- Lack of audit trail and data reviews

TYPICAL DI AUDIT OBSERVATIONS

- Trial injections.
- Results failing specifications are retested until acceptable results are obtained.
- Over-writing electronic raw data.
- OOS not investigated as required by SOP.
- Appropriate controls not established.
- Records are not completed contemporaneously
- Back-dating, Fabricating data.
- No saving electronic or hard copy data.
- Records completed for absent employees

FDA 483 OBSERVATIONS

- Overlap of time for different experimental stages
- Records filled prior to actual execution
- Copy & rename existing data as new data
- Mismatch between reported data and actual data
- No traceability of reported data to source documents

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DATA INTEGRITY – PROCEDURES / SOPs

A set of SOPs to be in place to support Data Integrity and minimise risk within GLP facility:

- IT policies.
- System administration (CDS access, roles and privileges).
- Data management and storage.
- Data acquisition and processing.
- Data review and approval.
- Data archiving and back-up.
- Anti-fraud monitoring.

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CONCLUSION

- Data integrity is not always easy to detect -educate
- Understand the strengths and weaknesses of the systems used to collect, store and process raw data
- Comply with the regulatory expectations
- Staff training awareness and refresher programs
- Establish an integrated self audit program
- Develop a strong quality culture
- Speak up for quality

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