Data Integrity – Industry Approach to Compliance

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Data Integrity – What it is?

- Data Integrity is not a new regulatory expectation
  - How data is generated has evolved over the years
  - Increasing Globalization
  - Reliance on outsourcing of Operations (testing, manufacturing, clinical, etc.)
  - Documentation Practices

Therefore, how we ensure data integrity needs to evolve along with our environment!

Data Integrity – Recent Guidances

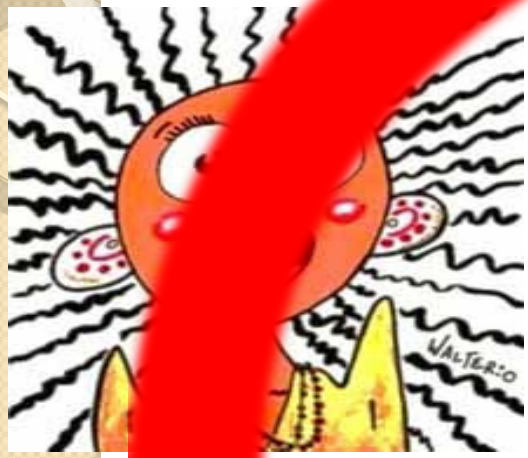
- FDA Draft Guidance Data Integrity and Compliance with cGMP – April 2016
  - For the purposes of this guidance, *data integrity* refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA).

- MHRA GXP Data Integrity Definitions and Guidance Draft, July 2016
  - The extent to which all data are complete, consistent and accurate throughout the data lifecycle. Data integrity arrangements must ensure that the accuracy, completeness, content and meaning of data is retained throughout the data lifecycle.

Data Integrity – ALCOA

- A- Attributable
  - Traceable to unique individual
- L - Legible
  - Permanent, Readable with ability to track changes
- C - Contemporaneous
  - Performed activities recorded at time they occur
- O - Original
  - Unaltered complete data set
- A - Accurate
  - Data/records must be accurate - GDP

Data Integrit[illegible] Do?



PANIC?!?!?!

Bury our [illegible]ds in the

Data Integrity – Compliance Approach

- **DI Compliance Plan**
  - Risk Based Assessment
  - Understand data process flows
- **Policy/Practice** Revisions
  - Good Documentation Practices should include GDP for electronic records
  - Data Review Policy, Procedures, and Work Instructions specific to data process
- **Training**
  - Tailored to each level/role within the organization

Data Integrity Compliance Approach - Continued

- **Team Members – Cross Functional**
  - Computer Software Validation
  - Process Validation
  - Operations
  - Clinical
  - IT
  - Quality Auditors
  - Maintenance
  - Engineering
- **Governance Framework**
  - Senior Leaders Responsible for Data Integrity Compliance
    - Data Integrity Compliance Officer
    - Behavioral Management – Patient First
  - Management Review to ensure continued suitability and effectiveness

Data Integrity Compliance Plan

- Structured approach to evaluating state of compliance
- Multi – Phase Approach with defined deliverables and timing associated with each phase
  - Planning Phase
  - Assessment Phase
  - Implementation Phase
  - Effectiveness Check Phase
  - Maintenance Phase

Data Integrity Compliance Plan - Continued

- Planning Phase
  - Determine which tools to use for DI assessments
  - Develop training materials
  - Identify key DI Team Members/Champion/PM
  - Define the Deliverables/timing
  - Write the plan

Data Integrity Compliance Plan - Continued

- **Assessment Phase**
  - Assess all systems which generate data
  - Evaluate impact and prioritize
  - Identify gaps in each data process
    - Data Process Mapping (DPM)
- **Implementation Phase**
  - Evaluate Risks in DPM's
  - Determine mitigation actions and implement

Data Integrity Compliance Plan - Continued

- **Effectiveness Check Phase**
  - Re-assess risk in DPM's after mitigation actions implemented
  - Document results
- **Maintenance Phase**
  - Close out Plan
  - Maintain DI Assurance
    - Organizational/Procedural Controls
    - Technical/System Controls

Data Integrity – Challenges

- Mindset/Behaviors
  - Taking away the safety of paper!!!
- Resources
  - Dedicated resources at each site
- Segregation of Duties
  - At smaller companies – more of a challenge

Data Integrity – Challenges

- CMO's/CRO's
  - Build into Quality Agreements – DI for CMO
- Legacy equipment
  - Replace – if not feasible, control through procedures
- What do to with Historical data?
  - Need to maintain in true accurate state - all the while

Example Audit Trail

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Results Tables Audit Trail For:	Training_090115	**Report Date:**	1/16/2017 6:15:27 PM
File Name	D:\Analyst Data\Projects\Training_090115 \Results\WZ_10-7-15.rdb	**Number of Records:**	29 Total

Date/Time Stamp

User Name

Record #	Date and Time	User Name	Full User Name	Module	Change Reason	Change Description	ESig	History
29	10/7/2015 11:01:28 AM	QQQ6500-PC\QQQ 6500	QTRAP 6500	Results table - Saved new table	N / A	A new results table "D:\Analyst Data\Projects\Training_090115 \Results\WZ_10-7-15.rdb" was saved. The IntelliQuan (MQ III) algorithm was used to process the data.	No	
28	10/6/2015 5:42:26 PM	QQQ6500-PC\QQQ 6500	QTRAP 6500	Results Table - Integration	N / A	Peak "764.200 / 732.100" for "090215_std_2" (file "D:\Analyst Data\Projects\Training_090115 \Data\Oct 2015\3.wiff", sample 1) was re-integrated, but no parameters were actually changed.	No	
27	10/6/2015 5:36:53 PM	QQQ6500-PC\QQQ 6500	QTRAP 6500	Results Table - Integration	N / A	Peak "762.200 / 730.000" for "090215_std_4" (file "D:\Analyst Data\Projects\Training_090115 \Data\Oct 2015\5.wiff", sample 1) was re-integrated, but no parameters were actually changed.	No	
26	10/6/2015 5:31:40 PM	QQQ6500-PC\QQQ 6500	QTRAP 6500	Results Table - Concentration	N / A	Concentration for peak "762.200 / 784.200" for "090215_std_4" (file "D:\Analyst Data\Projects\Training_090115 \Data\Oct 2015\5.wiff", sample 1) was changed from "0.00" to "6".	No	
						Concentration for peak "764.200 / 732.100" for		

Change Description

Case Study - Data Process Map/Risk Management