BEST PRACTICES FOR CONDUCTING DATA INTEGRITY ASSESSMENTS

ONLINE WEBINAR

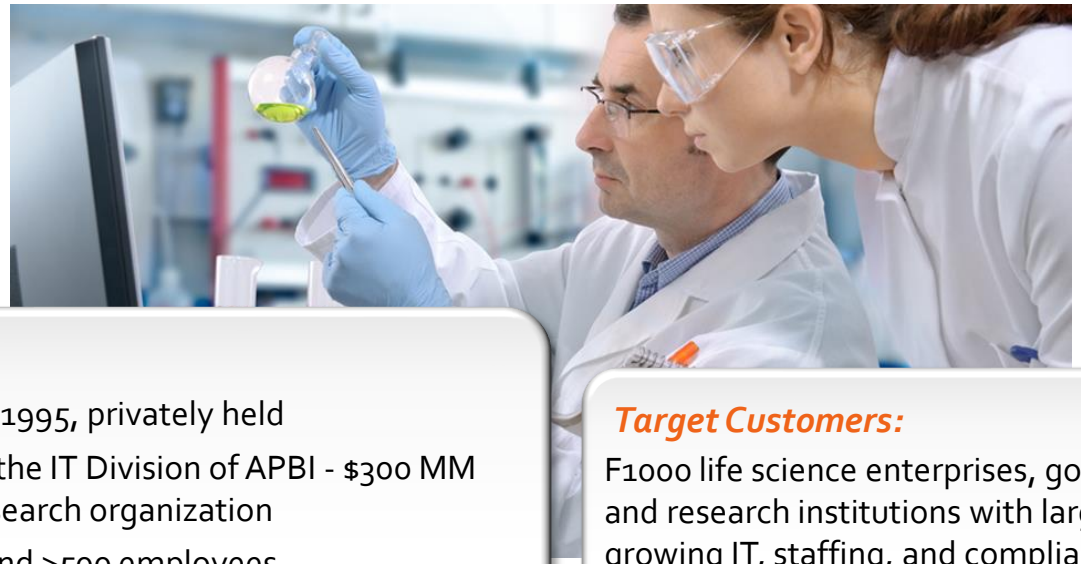
MARCELO SOARES

27/FEB/2020

astrix
TECHNOLOGY GROUP

COMPANY SNAPSHOT

*"**Informatics Professional Services** and **Staffing** Company Dedicated to Servicing the **Scientific Community**"*



Quick Stats:

- Established in 1995, privately held
- Originated as the IT Division of APBI - $300 MM life science research organization
- Eight offices and >500 employees
- Headquarters: Red Bank, NJ
- **Staffing Division** offers private and public staffing of scientific and IT resources
- **Professional Services Division** focused on supporting science based organizations

Target Customers:

F1000 life science enterprises, government and research institutions with large & fast-growing IT, staffing, and compliance needs.

Mission:

To deliver scalable, sustainable solutions in IT and staffing for the scientific community

SERVICES

STRATEGIC PLANNING

- Business Case
- Application
- Data Migration
- Solution Options
- Integration Planning
- Roadmaps
- Risk Analysis
- Enterprise Architectures

PROFESSIONAL SERVICES

- COTS Evaluations
  - LIMS
  - LES
  - ELN
  - CDS
  - SDMS
- Business Analysis
- Project Management

DEV/IMPLEMENTATION

- System Implementation
- Integration
- Data Migration
- Custom Development
- Cloud Migrations

COMPLIANCE & QUALITY

- Validation
- Assessments
- Risk Management Framework
- Risk Mitigation and Remediation
- Quality Management
- HIPAA, GxP, FISMA, ISO

MANAGED SERVICES

- Laboratory Operations
- Staffing Vendor Management
- Information Technology
- Solution as a Service

ASTRIX MARCH WEBINAR

- **Webinar Topic:** Enterprise Architectural Assessments for Integrated Laboratories

- **Date:** Thursday, March 26th, 2020
- **Time:** 1:00 PM EDT / 10:00 AM PDT

- **Some of the topics covered in this webinar include:**
  - The benefits of conducting an architectural assessment
  - The importance of alignment with the scientific process to maximize business and technology goals
  - Use of a roadmap to guide transition to the future state
  - The importance of risk identification and risk analysis

TOPICS

- What is Data Integrity?
- How can I develop Data Integrity within my company?
- Data integrity assessment best practices
- Benefits of periodic reviews of data integrity

WHAT IS DATA INTEGRITY?

DEFINITION

As per FDA[1]: *"…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)."*

ATTRIBUTABLE

This refers to the fact that a reviewer must be able to determine who collected the data, when it was collected, from which instrument it was collected, and who made any data modifications or manipulations. Note that the use of shared passwords in a LIMS or other informatics system makes it impossible for a reviewer to attribute the data to a specific person.

LEGIBLE

Data must be legible/readable. Electronic data must have the capability to be made readable by humans.

CONTEMPORANEOUS

Data must be recorded at the time it is created, not transcribed at a later date. Data is not transcribed from scrap paper to "official" documents such as laboratory notebooks or batch records.

ORIGINAL

Data must be recorded in the file or format in which it was originally generated (original paper record from a manual observation or electronic raw data file from a computerized system), preserving the accuracy, completeness, content and meaning of the record. The paper printout from an instrument would not be considered official, original GMP data, as it is lacking the necessary complete information – audit trail, metadata, system configuration, etc.

ACCURATE

Recorded data needs to be accurate and 2nd person verified when appropriate. Data that is recorded in multiple locations should be in agreement.

1. Data Integrity and Compliance With Drug CGMP – Guidance for Industry, December 2018, www.fda.gov

WHAT IS FDA'S PERCEPTION ON DI OVER THE YEARS?

As per FDA[1]:

"In recent years, FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections. This is troubling because ***ensuring data integrity is an important component of industry's responsibility*** *to ensure the safety, efficacy, and quality of drugs, and of* ***FDA's ability to protect the public health****. These data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees.*

DATA INTEGRITY EXAMPLES OUTSIDE OF PHARMA

- VW "Dieselgate"
  - Diesel powered vehicles had their ECU's programing altered to reduce gas emissions during emission testing.
  - Estimate 5000 deaths related to NOx emissions in Europe.
  - VW Group was charged over $30B (and counting) by multiple regulatory agencies in different countries.

DATA INTEGRITY EXAMPLES OUTSIDE OF PHARMA

- NASA's Mars Climate Orbiter
  - Space probe launched by NASA in 1998 to study Mars climate and atmosphere, estimated at $125M.
  - Lost communication with Earth as soon as it tried to orbit Mars for deceleration.
  - Post investigation discovered that integration between two systems was the issue: one system reported values as imperial units, and a second system interpreted these same results as SI units.

*"The problem here was **not the error**; it was the **failure of NASA's systems engineering, and the checks and balances in our processes**, to detect the error. That's why we lost the spacecraft."*

(Edward Weiler, NASA associate administrator for space science, 1999)

HOW CAN I DEVELOP DATA INTEGRITY WITHIN MY COMPANY?

WHAT AM I EXPECTED TO HAVE?

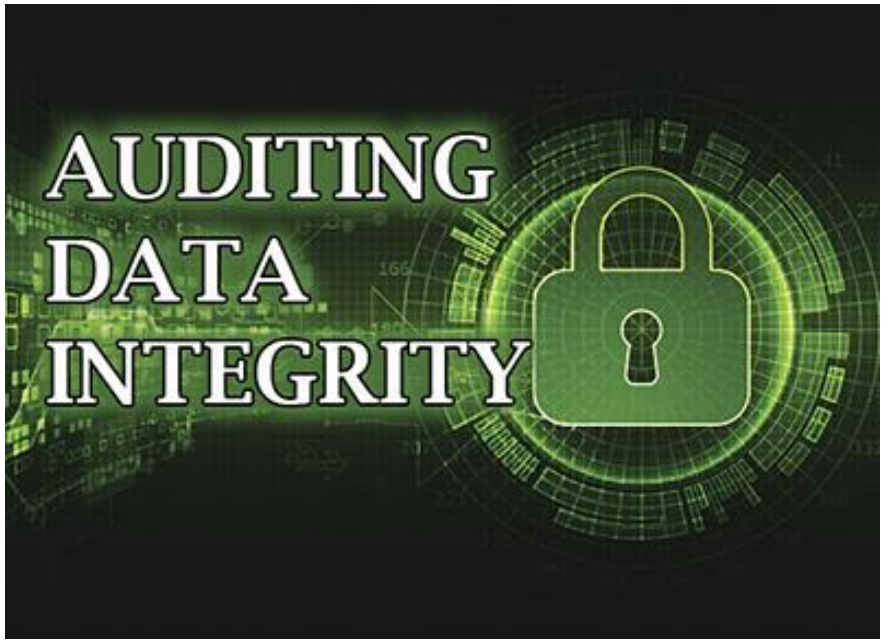
Data integrity is the result of the **combination of many different factors** such as strong quality culture, technology, people and procedures. These are some of the elements expected from an environment concerned about Data Integrity:

- Unique User ID
- Electronic Signatures
- Computerized Systems Validation (CSV)
- User Training
- Periodic Reviews of Critical Data
- Audit Trails
- Well Defined Paper-Based Procedures

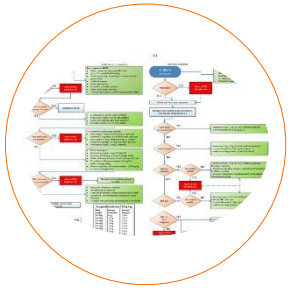
DATA INTEGRITY ASSESSMENT

- A **risk-based assessment** conducted by internal staff and/or an independent third party, focused on detecting weak spots on data integrity and helping to build a remediation plan whenever applicable. Sometimes this assessment can also be described under the acronym DIRA (Data Integrity Risk Assessment).

- This assessment serves to verify company processes, both computerized and paper based, certifying that data is consistent, complete and accurate **throughout the entire data lifecycle**.



WHAT PARTS OF MY SYSTEM A DI ASSESSMENT NEEDS TO COVER?



- **Hardware**
  - Servers
  - Instruments
  - Network Qualification
  - User PCs
  - Disaster Recovery Plan
  - Backup/Restore Processes
  - Archiving of Electronic Data
- **Software**
  - Computerized System Validation (CSV)
  - Applications
  - Integration between applications
  - Traceability
  - Periodic Review
  - Built-in data integrity controls
- **Personnel**
  - Training
  - Mechanisms to report a DI issue
  - Implementation of a "Quality Culture"
  - Safeguards against fraud
  - Governance and data review
- **Procedures**
  - SOP
  - Training material
  - Deviation records
  - CAPA
  - Instrument calibration and maintenance

WHAT ARE THE BEST PRACTICES FOR CONDUCTING A DATA INTEGRITY ASSESSMENT?

BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

- An effective data integrity assessment will contain at least the following activities:
  - Kick-Off Meeting
  - Operational Review
  - Project Plan
  - Data Integrity Assessment
  - GAP Analysis
  - Risk Assessment
  - Remediation Plan

BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

- **Kick-Off Meeting**
  - Important to connect team members and stakeholders.
  - Used to **manage expectations** and to **align team objectives**.
  - Good to stablish effective coordination with any other initiatives as needed.
  - Can be the starter to the creation of a project plan or agenda

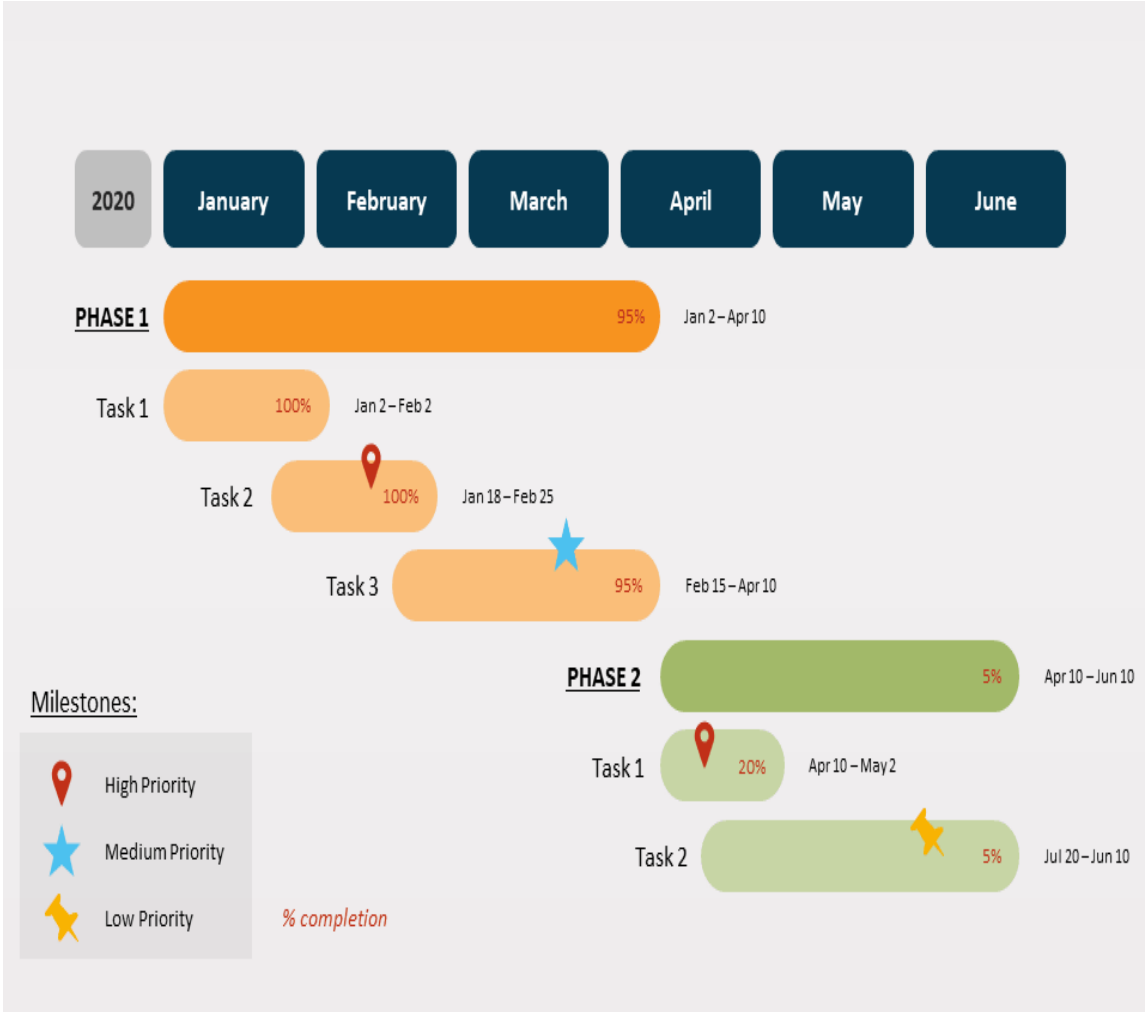
BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

- **Operational Review**
  - Used to bring the assessment team up to speed with the organizational environment, processes, systems and procedures.
  - Recommended to occur before any actual on-site visit.
  - This review can generate extra questions and the need for more documents.

BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

Project Plan

- Must be built based on the agreed-upon information collected during the kick-off meeting.
- Depending on project coverage and scope, it can be replaced by a more informal and streamlined agenda.



BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

- **Data Integrity Assessment**
  - In depth investigation over the topics studied during the Operational Review step.
  - Best when done **following the workflow** of the company vs. an evaluation of separate data silos.
  - Must include a review of organization records and recording practices, with a focus on completeness, consistency and accuracy of data collected, maintained, stored, analyzed and reported by computerized systems and/or written procedures.
  - Must **not** be restricted to computerized systems, as human interaction is generally the root cause of the majority of DI issues.

BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

Gap Analysis

- Made to stipulate the necessary steps to correct/improve data integrity points and get closer to a "desired state".
- The outputs of these analyzes will be later used in the remediation plan to outline the next steps needed.

BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

Risk Assessment

- Made to help prioritize the risks that must be addressed first and foremost, based on the risk they impose to the process, system and customer safety.
- The results of these assessments are later used to define the need for technical/procedural changes, and the extent of periodic reviews needed throughout the data lifecycle.

BEST PRACTICES FOR DATA INTEGRITY ASSESSMENTS

- **Remediation Plan**
  - Developed to remediate data integrity regulatory gaps.
  - Built over the considerations made upon risk assessment.
  - Once implemented, reviews should occur periodically based on the level of risk imposed to the evaluated systems, processes and data.

DATA INTEGRITY ASSESSMENT DELIVERABLES

- An effective data integrity assessment will contain at least the following deliverables, which must be built in mutual collaboration between team members and reviewed by stakeholders for completeness and acceptance.
  - Finalized Project Plan
  - On-site Assessment Notes
  - Data Integrity Assessment Final Report

WHY SHOULD I CARE ABOUT PERIODIC REVIEWS OF DATA INTEGRITY?

BENEFITS OF DATA INTEGRITY ASSESSMENTS

- **Strengthens You Organization's Data Integrity Focus**
  - Helps reinforce to all company collaborators that the organization is committed to data integrity.
  - Promotes an environment in which collaborators are able and **encouraged** to help identify and alert for DI issues.
  - Gives regulatory agencies a **degree of confidence** that your company knows how to address data integrity issues properly.

- **Key Definitions**
  - Quality Culture vs. Witch Hunt
  - Teamwork

BENEFITS OF DATA INTEGRITY ASSESSMENTS

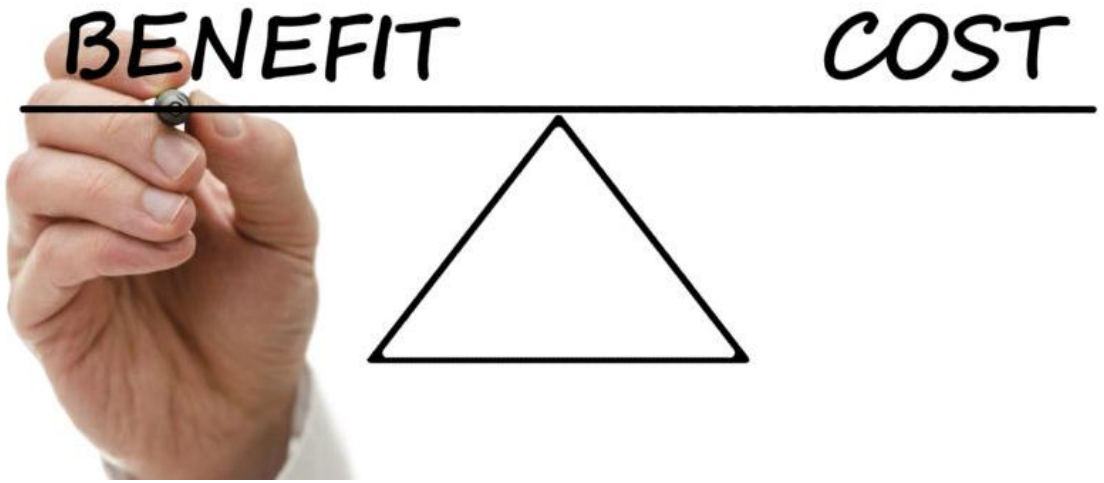
- **Provides Peace of Mind**
  - Robust review processes give you the peace of mind that identified issues will be properly addressed.
  - Regulatory agencies know that problems happen. What they expect from you is demonstrated capabilities to address such issues with **sound technical and scientific accuracy and details** in an organized, streamlined and properly documented procedural way.

- **Key Definitions**
  - Proactive vs. Reactive
  - Well Defined Procedures

BENEFITS OF DATA INTEGRITY ASSESSMENTS

- **Reduces Costs**
  - Costs to remediate DI issues identified by a regulatory agency are significantly higher than if they were identified proactively by your company.
  - Costs can be significant: warning letters, import alerts, facility shutdown, remediation costs, delayed/denied drug approvals, damaged reputation, recalls, consent decrees.

- **Key Definitions**
  - Direct Costs
  - Indirect Costs



BENEFITS OF DATA INTEGRITY ASSESSMENTS

- **Stay Focused on Your Core Business**
  - Less time spent on running after compliance issues as they occur means more time spent on your core business.

- **Key Definitions**
  - Planned Periodic Reviews
  - Incremental Improvements

CONCLUSIONS

- Data Integrity violations are a result of multiple factors.
- Company executives and senior management are responsible for creating a quality culture within the organization.
- Having an external consultant is beneficial, as a fresh set of unbiased eyes can help identify DI breaches.
- Focus on Data Integrity must ALWAYS be directed to making better and safer products for customers, and not only to satisfy regulatory compliance.

ASTRIX DATA INTEGRITY ASSESSMENT SERVICES

- **Experienced Professionals** – our consultants are knowledgeable about FDA regulations.

- **Thorough Assessment** – Our experts assess your laboratory informatics environment to identify data integrity risks:

  - Data origination
  - Data traceability
  - Data backup, archive, restore and recovery processes
  - Data review and approval
  - Electronic signatures
  - Audit trails
  - User access/roles/permissions
  - Instrument integration
  - Documentation related to system(s) operation
  - Quality culture

- **Deliverable:** ***Data Integrity Assessment Final Report***
  - Documents gaps and issues related to data integrity
  - Documents recommended remediation activities and improvements

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