

Using IT to Improve Data Integrity

The IT Factor

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Communicating with IT leaders about IT's role in data integrity compliance

Establishing SOPs: Getting IT, QA, Supply Chain and R&D on the same page

IT, Quality management and regulatory affairs: Scaling for speed and efficiency under the Final Guidance on Data Integrity and Compliance with Drug cGMP

Mock FDA data integrity Inspection

Creating an “FDA audit IT SWAT team” for continuous improvement

About the Presenter



- Israel Heskiel
- CEO
- DI Advisors
- Over 25 Years in IT Leadership
- Have held the following roles:
 - Program Lead for major Data Integrity IT Program
 - Solution Architect
 - Program Lead for Global IT Programs
 - Sr Program and Project Manager
 - IT Engineer and Infrastructure architect
 - Collaboration and Messaging architect
- Have always worked closely with Legal, Compliance and IT Risk Management
- Clients have included:
 - Investment Banks
 - Pharmaceutical companies
 - Beauty and Cosmetics companies
 - Insurance companies
 - Law Firms

Getting IT Involved

- Most typically, when IT hears FDA, they tune out. (“That’s not my area”)
- Ensure that the CIO, CTO & CISO are fully briefed and onboard
- Ensure the IT leadership communicates
- IT must be trained on Data Integrity – cGXP and Data Integrity may be obvious to you, but not to most in IT and the folks on the ground
 - Some phrases that can get the message across to IT
 - The FDA Inspector is part of Law Enforcement
 - An FDA Inspection is not a Paid Audit, like SOX, Rather an investigation
 - Not being honest with the inspector is a Felony crime in the US
 - Data Integrity is like “SOX on Steroids”
 - When the FDA guidance states “Systems”, it doesn't just mean computers..

Translating for IT, the FDA's "Systems" Stance

Communicate to IT the magnitude of the FDA's latest Guidance document (Dec.2018), which asks :

***What are the "systems" in "computer or related systems" in § 211.68?**

Answers:

The American National Standards Institute (ANSI) defines systems as people, machines, and methods organized to accomplish a set of specific functions. Computer or related systems can refer to computer hardware, software, peripheral devices, networks, cloud infrastructure, personnel, and associated documents (e.g., user manuals and standard operating procedures).

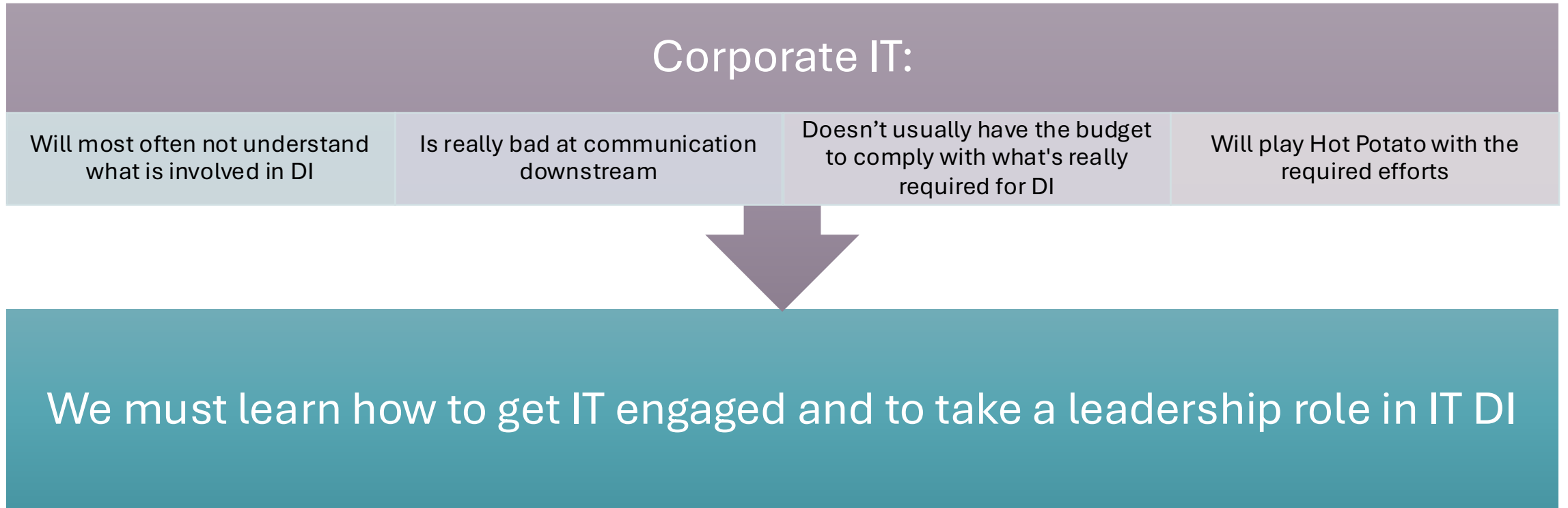
(so basically.... Just about everything!)

So now, apply ALCOA + to the above and this is likely where their mind will be blown...

IT may start to push back and relinquish responsibility, so this is where the Business IT partnership occurs

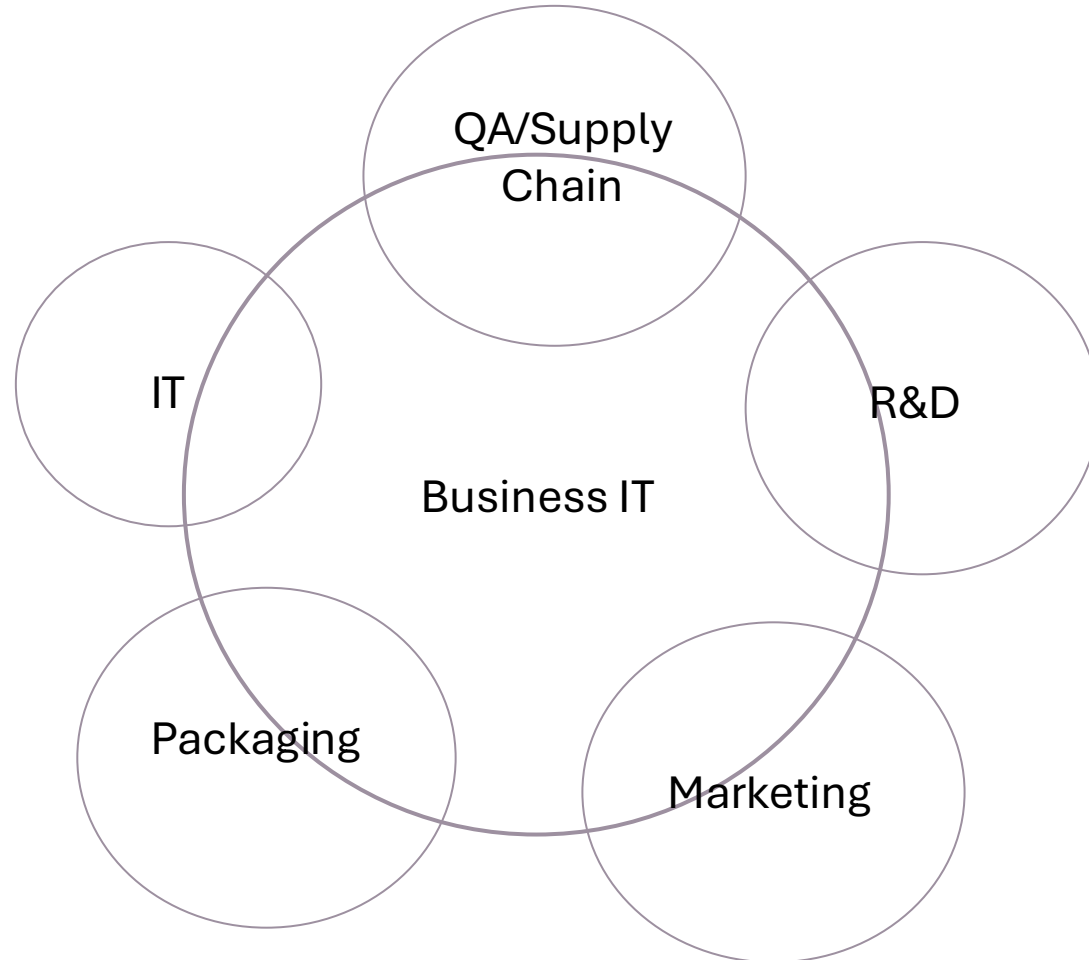
[*Data Integrity and Compliance With Drug CGMP Questions and Answers Guidance for Industry](#)

Understanding IT Relevant to Data Integrity (DI)



Getting IT & Business on the Same Page

Data Integrity Business IT Dynamic



- ❖ All these units have the common thread of “Business IT”
- ❖ Processes that involve technology to some degree
- ❖ IT can no longer be its own silo with Data Integrity

“Business IT”

Business IT = A Business Process that has a significant technology component

Why is communicating the effort as “Business IT” for Corporate IT so important?

1. IT and the business need to understand that it's a partnership
2. IT and the business need to understand who is driving the requirements
3. IT needs to know they must lead the technology aspects

IT will most often, throw the ball over the fence, putting the responsibility back on the Business in a game of ping pong

So why does IT need to lead it?

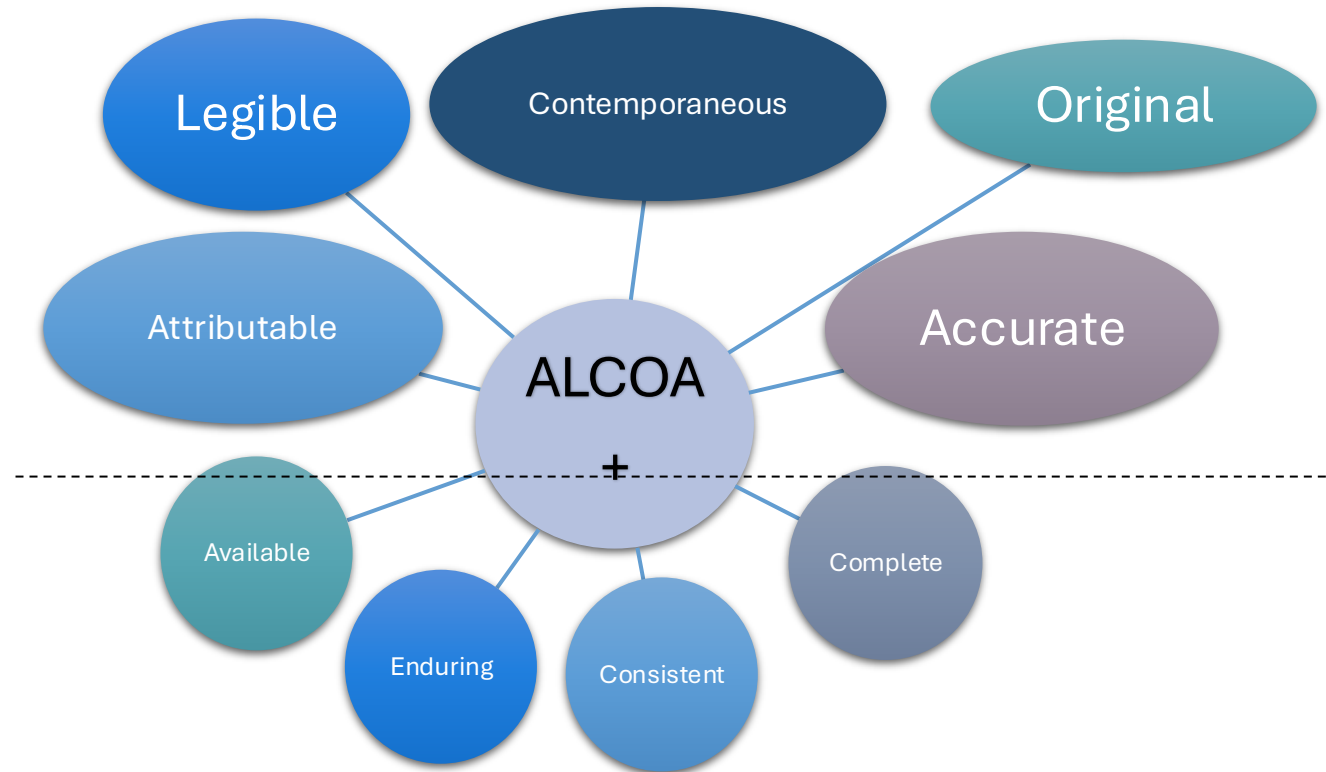
A process that heavily relies on technology, will need IT to lead the solutioning and guide the business

Terminology Differences

Term	QA/R&D Definition	IT Definition
Data Integrity	Data integrity refers applying ALCOA+ principles with regard to paper, process and technology providing a chain of data custody through out its lifecycle	Computer Data that is complete or whole in structure.
API	Active Pharmaceutical Ingredient	Application Programming Interface
Systems	A Formalized Process.. (And all included in that process)	Computer/Server/Application
FDA/MHRA, etc	Governmental regulatory agency, Law Enforcement	Not our responsibility/tell me what you want me to do/In country X?
CMO/CDMO/TPM	Outside Contract Manufacturing Organization	Not our responsibility or tell me what you want me to do
Backup	Backing up data and keeping it for as long as required	Backup – The process and schedule by which the data is copied or moved from the source to a secondary destination
Retention	Backup	Retention – The length of time the data is kept
Archive	Backup or Offsite storage	Archive – Long term storage of data that is retained, can either be easily accessible or offsite storage of a backup requiring longer retrieval time

What Is the FDA Looking For?

ALCOA+



How Does ALCOA Translate to IT for Data Integrity?

- Process -
 - SOPs
 - Are the IT cGxP related processes defined and documented?
 - How well does the process integrate with IT or are the processes disjointed?
 - Are people trained? Is IT?
- Controls –
 - Double verification or LIMS
 - Tamper Proof logs & audit trails
 - Permissions (application, network and computer security)
 - Chain of custody for data
 - Change control – Is the IT change control system, that involves GxP involved users, validated?
 - WI-FI or network access – otherwise data cant be saved, how to access current SOPs?
 - Door security and its logs, etc.
 - Training logs for IT
 - Packaging/Advertising text is approved, attributable and linked to R&D data

ALCOA +

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Available
- Consistent
- Enduring
- Complete

How Does ALCOA Translate to IT for Data Integrity? (cont.)

ALCOA +

Attributable

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Retention- (Retention/Backup/Ar chive)

Retention of GXP and GXP related Data (such as the permissions & history of permissions on a network folder) retention of Backups, archive retention, metadata retention, etc.)

Laptops, computers, is the data saved when turned in?



Accessibility of Documents –

Are SOPs easily accessible on the network or locally?

How long does it take for people to open them?



Oversight –

Is Quality and management going back to do periodic reviews? Such as reviewing permissions

Is IT validating that backups are readable

How Does ALCOA Translate to IT for Data Integrity? (cont.)



Accountability –

Ensuring every controlled document is signed or attributable, any document that has pertinent data is saved and attributable?

Does every computer that is part of the GXP process have its own unique user login?

Does the Application also have unique credentials?



Backup Availability –

Is the data restorable? If yes, anyone ever try or anyone know how?

How quickly can you get the data restored?

How often is it backed up and for how long? – Don't Assume!



Proper destruction –

Data that has exceeded its lifecycle, how is destroyed (deleted?)

Are computers properly wiped clean when repurposed?

- **ALCOA +**
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A Data Integrity Program

Scaling for Speed and Efficiency

- ❖ This WILL be larger than you think it is & This will be larger than IT thinks it is
- ❖ Each tower must work cross-functionally – Setup cross-functional updates
- ❖ Manage your efforts in Parallel. Do not manage them sequentially
- ❖ Create a cross-functional core team
- ❖ Create a cross functional Steering Committee of Senior Executives
- ❖ Create a Tower based steering committee
- ❖ Ensure your Leadership communicates the priority level of these efforts downstream

The Core Team

1. Create a core team to scale, based on your organizational structure
 1. Data Integrity Program Director
 1. QA Program Lead
 2. IT Program Lead
 3. Marketing/Packaging Program Lead
 4. R&D Program Lead
 5. Supply Chain Program Lead
 2. For each major effort, assign a Project Manager (under the relative program lead)
 3. Assign one Project Manager to manage multiple smaller efforts (under the relative program lead)
 4. Each Tower (represented by Program Lead) should have a compliance lead
 5. Each Tower should have 1 or more technical writers (depending on how many new or updated SOPs are needed)
 - Take note of Cross functional SOPs and don't duplicate
 6. Ensure the IT Tower has a Solution Architect as part of the team
 7. Compliance Lead must track all changes and store all evidence of changes

So Where Do You Begin?

Identify GxP processes & Performing mock inspections

- Start these efforts in parallel
- Do NOT wait for all the cGxP processes do be documented in full
- Navigating IT can be daunting - Bring the right people in
- Do a risk assessment of the processes to determine priorities

Identify GxP Processes

1. Identify High-level GxP and the IT related process with an IT Solution architect
2. Identify and Document existing data flow – within the process
3. Assign accountability for leading the various efforts to departments
4. IT must deep dive with the business into its related process, to identify any possible gaps

So Where to Begin: Inspection

- Inspection

- Conduct your own internal Data Integrity inspection using site managers, compliance managers, Data Integrity leads, IT Data Integrity experts
- You have received a 483 warning letter
- Previous FDA inspections with observations
 - If your inspection results produce observations/483s that involve any technology component, incorporate IT from the onset.
 - Review each observation/483 in detail and define what the prevailing component is.
 - Does an SOP need to be written that may require technology?
 - Is it an SOP that interacts with technology process may need to be refreshed?
 - Such as new hire or termination?
 - User moving from one department to another

So Where to Begin: Inspection

- Is it a process that is highly interactive with technology?
 - Do your PLCs have permissions properly managed and tracked?
 - Batch records
 - Lab Testing
 - Compounding
 - Weighing stations
 - Distribution
 - Automated picking
- Backup of data?
 - What is backed up
 - How is it backed up
 - Where is it backed up
 - Are the backup files validated
 - Are they ever tested for readability
- Procurement
 - List of suppliers for that site
 - Is there a process to categorize approved or disqualified vendors? Is this done electronically?

Don't Presume or Assume anything!!

Mock FDA Inspection: Benefits

One of the most productive efforts to prep for an FDA inspection, is the mock Inspection run-through using NIPP

Benefits:

- Streamline your site team's knowledge of who, what and where
- Identify potential gaps in Data Integrity and other areas
- Communication with Site teams around Data Integrity
- Establish support structure for ensuring Data Integrity

Mock FDA Inspection: Staffing

- Corporate QA/R&D lead (not site QA/R&D lead)
- QA/R&D site Compliance Lead
- IT Compliance Lead
- IT Data Integrity Lead
- Site QA/R&D Data Integrity Lead
- Production Manager
- Site Team

Mock FDA Inspection

- Use the New Inspection Protocol Program (NIPP) method
- Conduct a walk through the entire facility and ask the right questions. Be challenging
- Any ambiguity in an answer, should be delved into further
 - Don't be lenient, the FDA inspector will dig, you should too
- Ask for a run through of the process,
- For each process, ask for the current SOP to be pulled up on the screen in the room
- Identify any anomalies or discrepancies and ask for explanations
- Ensure the appropriate people are available to demonstrate their answers on screen
- Ensure there is clarity and cohesion amongst the staff response and it is verifiable
- Look for gaps in the answers and documentation.

Bring out the deficiencies!

FDA Inspection: IT SWAT Team

➤ **Why is it critical to have an IT SWAT team ready for inspection?**

To streamline your IT related responses and demonstrate proper quality control, inclusive of IT. IT can be a maze to navigate and the NIPP will not provide sufficient time to navigate it.

➤ **SWAT Team Qualifications:**

- The IT SWAT team should be comprised of people that know the systems used by the site, including enterprise systems
- They should know how to work the systems they are qualified for
- They should know the processes related to IT – Global and local
- They should fully understand the questions being asked
- They should answer questions directly, without going on a tangent
- Don't make the AI mistake -They should never guess or from memory.

FDA Inspection: IT SWAT Team

➤ IT SWAT Team Framework

- IT Subject Matter Experts (SME) with the proper qualifications should be on-call during inspection
 - On-call means:
 - Be ready to demonstrate or provide documentation within an hour or so. This could mean via Web conference or on-site
 - Be ready to communicate immediately with acknowledgment
- SMEs should understand what being “on call” means for FDA
- Have alternates in case someone is out
- Train them on the processes and include them in Mock inspections
- Make sure they have the downstream and upstream support that they need

FDA Inspection: IT SWAT Team

➤ Examples of SMEs

- Network Storage
- Backup and retention
- Document management
- Security and Identity management
- Warehouse Management systems
- Production/manufacturing systems
- Weight station
- Local on-site Desktop support



Q&A

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