

Presented by
henricigroup

Practical Data Governance ||| Case Studies in Enabling Data Integrity Assurance by-Design

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HG



PDA Aseptic Processing of Biopharmaceuticals Conference 2024

CONNECTING
PEOPLE
SCIENCE AND
REGULATION®

Agenda

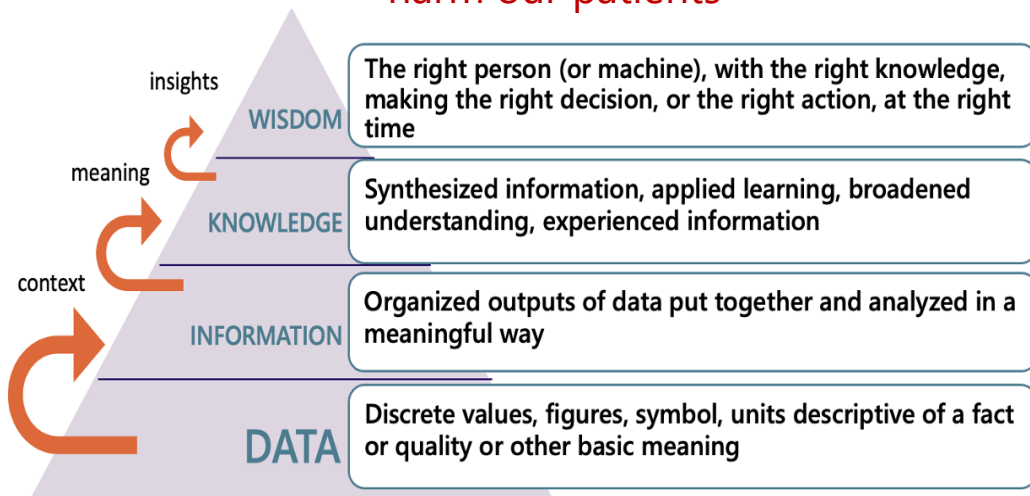
- 1 **Data integrity & the Information Value Chain**
- 2 **Reality Check: Health Authority Trends**
- 3 **Data Governance Journey: From Data Integrity to Data Integrity Assurance by-Design**
- 4 **Practical Data Governance: Planning, Implementing, and Enabling Data Integrity Assurance by-Design**

In this session we will explore practical Data Governance measures to enable data integrity assurance by-design. Through real-world examples, participants will gain insight into the application of data governance principles across organizational cultures, manual processes, computerized systems, and complex, hybrid environments in support of effective risk-based data integrity strategies.

Data integrity & the Information Value Chain

Our Data is our Product

In the worst-case unreliable data impacts product quality and may harm our patients



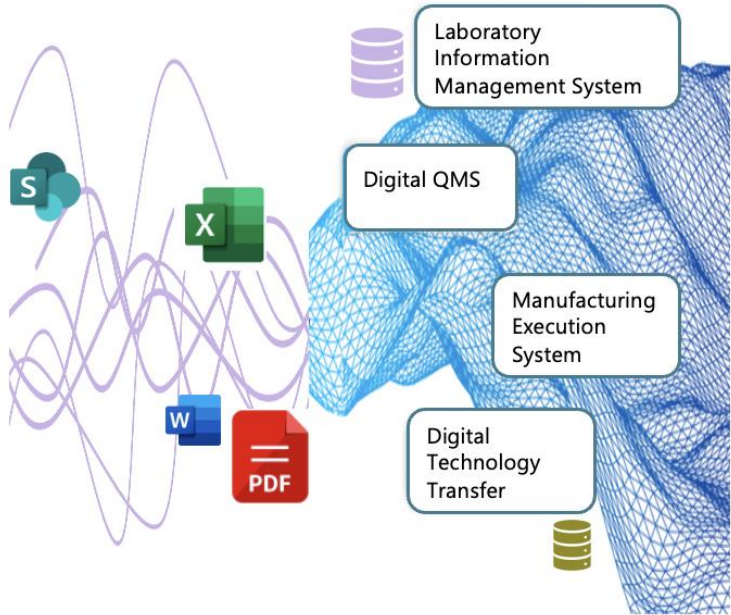
Our Patient



Data Integrity & The “Transforming” Information Value Chain

Data & Digital Transformation

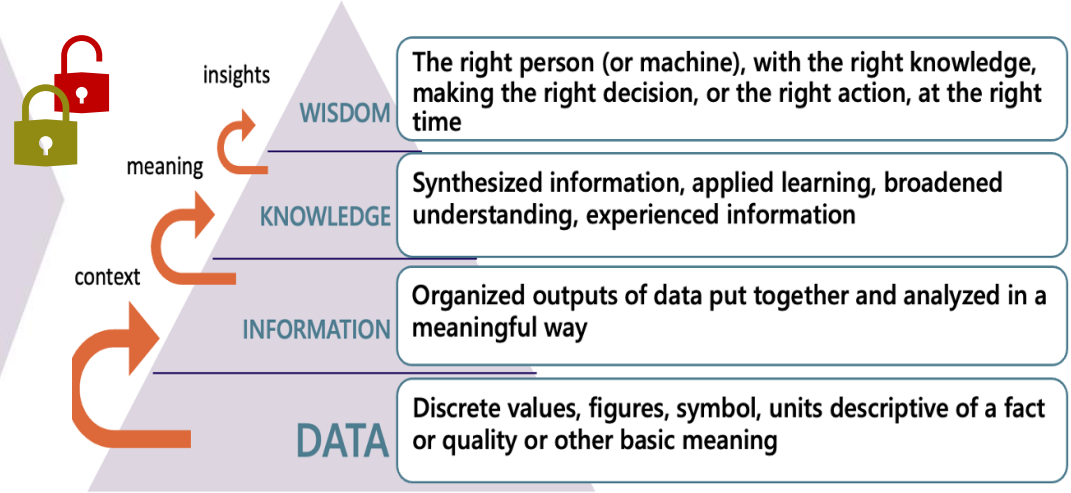
More and more DATA



Adapted with permission from QbDVision, Inc.

The Environment has Changed...

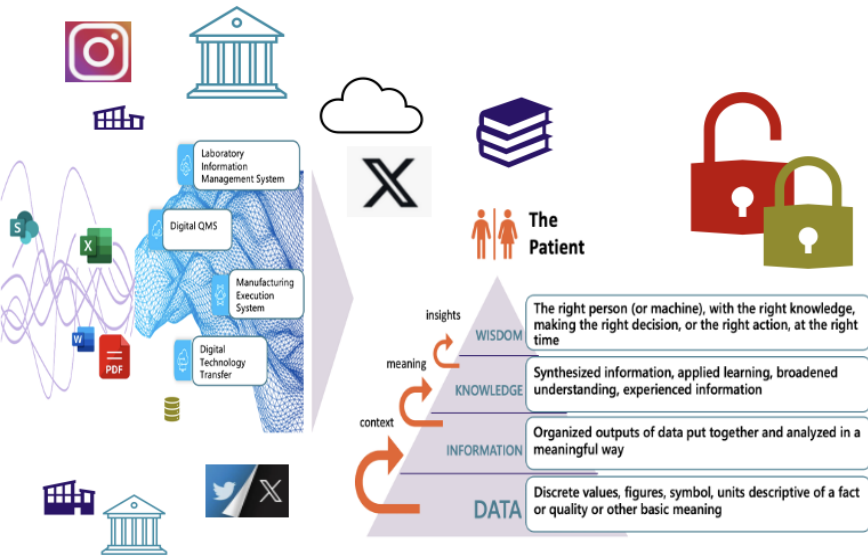
Expectations for data integrity remain the **same**.



Data Integrity & The “Emerging” Information Value Chain

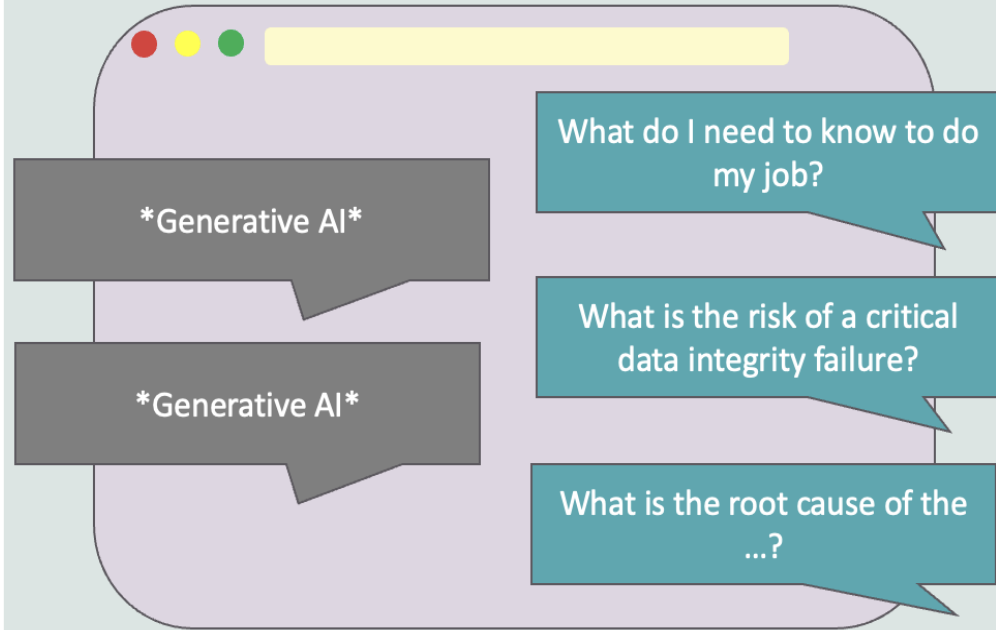
Emerging Technologies, AI/ML

Data NOT generated for YOUR intended use,
NOT subject to GMP/DI



A Vision for Enabled Compliant Applications

Unreliable data also equals missed opportunities of unknown impact



Reality Check: Health Authority Trends

Reality Check: Health Authority Inspection Trends

PDA RAQAB Update,
PDA/FDA Joint Regulatory
Conference
Sept 2024

“With new technology comes a heightened focus on data integrity, integrated quality management systems and risk-based approaches”

Antonella Maggio,
Co-Chair Parenteral Drug
Association (PDA),
Canada Chapter



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration



Reality Check: Health Authority Common Observations

PDA/FDA Joint Regulatory Conference Sept 2024

“Too many data integrity problems,”
Patrizia Cavazzoni, M.D.,
Director, CDER,
US FDA

↑ 17.1%

Baseline deficiencies; not related to Emerging Technologies.

Data Governance &
Data Integrity

Quality Management
System

- Data Integrity policy unavailable or incomplete for Employees
- lack of proper training/outdated training on data integrity principles
- Non-compliance with SOPs
- Insufficient management review process
- Insufficient RCA and CAPA process
- Data Integrity not integrated into computerized systems
- Weakness in internal audits and self assessments

Data Governance Journey: From Data Integrity to Data Integrity Assurance by-Design



"DI by-Design"

**Data Integrity
"ALCOA +"**

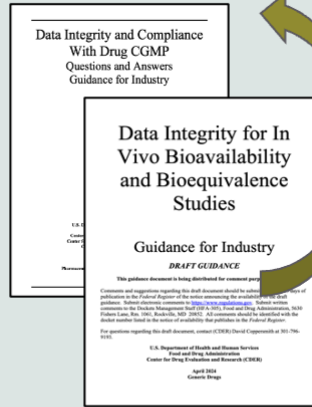


2024



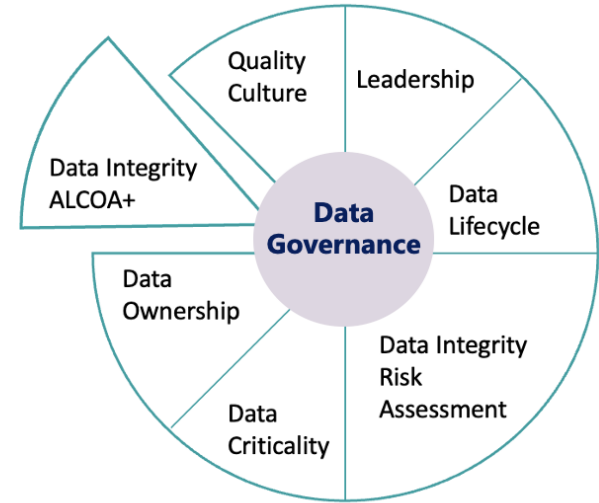
2014

**Data Governance
"Holistic"**



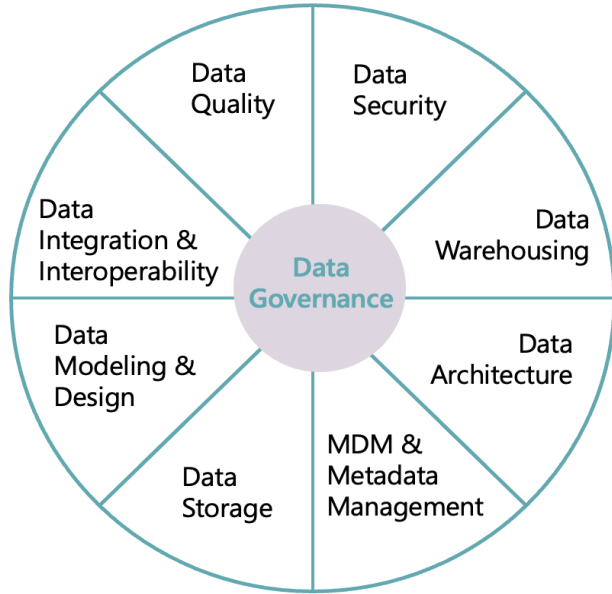
**FDA adopts
"Data Governance"**

Data Governance GXP Model



"Data governance is the sum-total of arrangements which provide assurance of data integrity."

Data Governance Enterprise Model



DAMA-DMBOK

Data Management Body of Knowledge

Digital Transformation & Emerging Technologies

Sept 2024
Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle



2023

Using AI/ML in the Development of Drug and Biological Products



2023

Artificial Intelligence in Drug Manufacturing

2023

Data Quality Framework for EU Medicines Regulation

2021

FDA Office of Digital Transformation

2011-2013

Digital Transformation and Industry 4.0

2017

Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization

Practical Data Governance: Planning, Implementing, and Enabling Data Integrity Assurance by-Design

Data Integrity Assurance by-Design

Digital/Data Strategy & Roadmap:

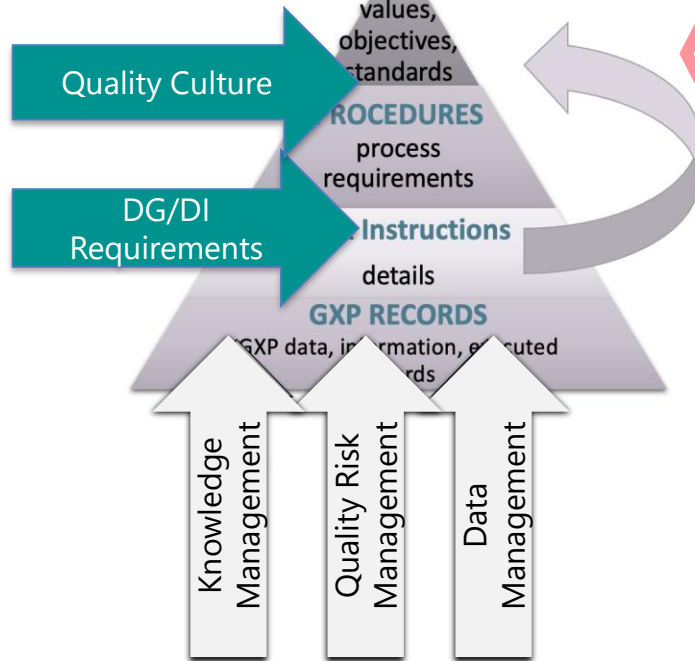
The "Anchor" for successful realization (ALM to Paper: "Can't get there from here.")

Quality Culture & Data Culture:

(LIMS "reason")

Data Governance Master Plan:

Quality "Project" Plan w/Prioritized Implementation Strategy (Why we need a "Plan")



Policies, Procedures & Technical Controls

"Heavy Hitters":

- Glossary of Terms
- Aligned Requirements
- Embedded DI Controls
- Document Management & CSV
- Owners & Inventories
- (Rogue People, Rogue Data & Rogue Systems)

Data Integrity Assurance by-Design

Data Integrity Risk Assessments (DG Risk Assessments):
An E2E Process Approach (Abbreviated BR)



Quality Culture

DG/DI Requirements

POLICY

values, objectives, standards

PROCEDURES

process requirements

Instructions

details

GXP RECORDS

GXP data, information, computer records

Knowledge Management

Quality Risk Management

Data Management



Data Governance System Review: Metrics, Trends & Monitoring
(Culture, Detection, Correction & Prevention)



Data Integrity Risk Assessments:
Outputs & the QMS



Continuous Improvement
From Compliance to Innovation

Thank you!

