



Data Integrity – Importance of Audit Trails

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What is Data Integrity???

What is Data Integrity

- The extent to which all data are complete, consistent and accurate throughout the data lifecycle
- A fundamental part of information security
- Often used as a proxy for “data quality”



Data Integrity – Why Do We Collect Data



❖ Data helps us to make decisions



❖ Good data helps us to make better decisions



❖ Consistently good data helps us to make better decisions that we can trust

Regulatory Expectations



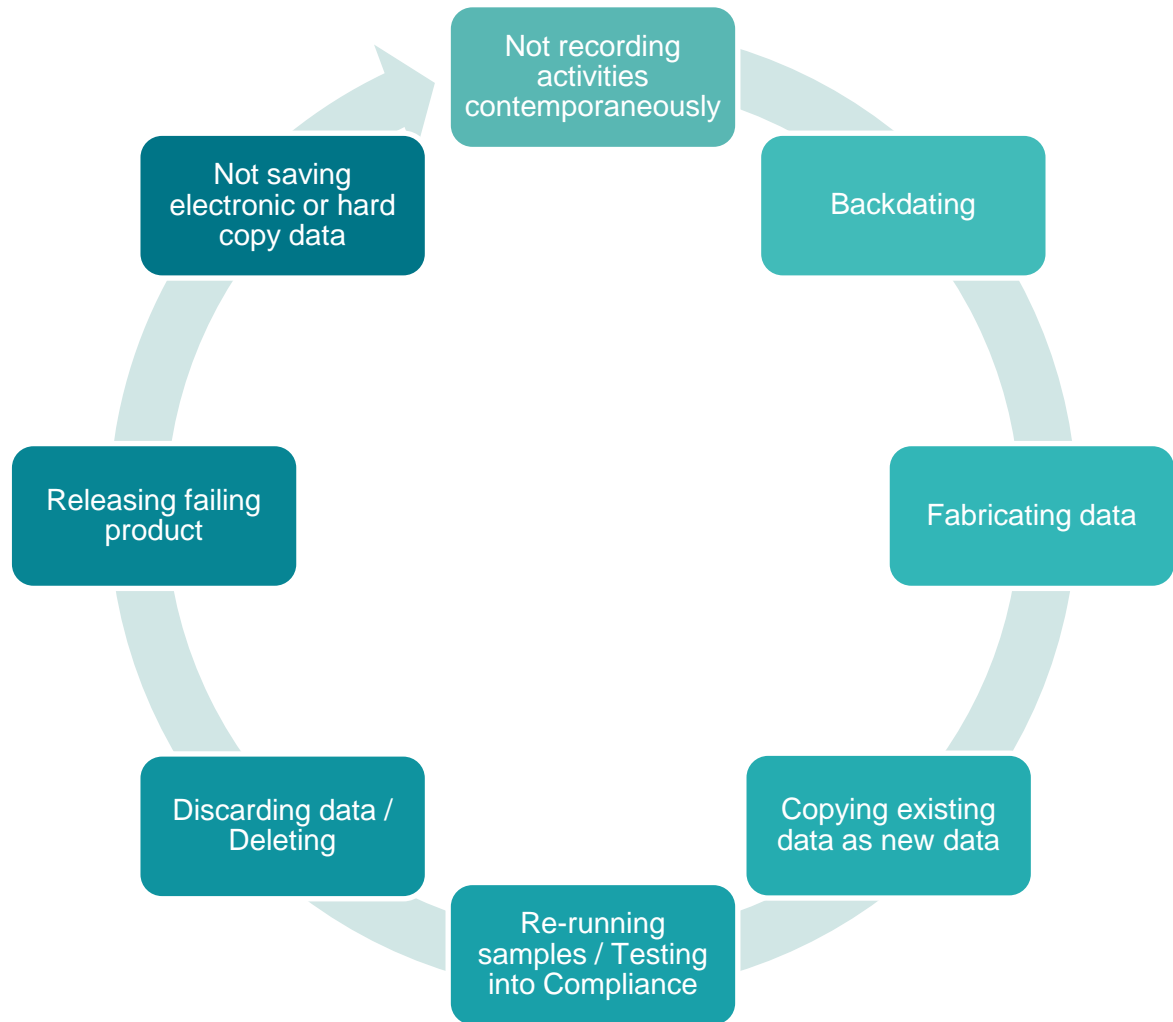
Data Integrity – Regulatory Guidelines





Data Integrity
Concerns

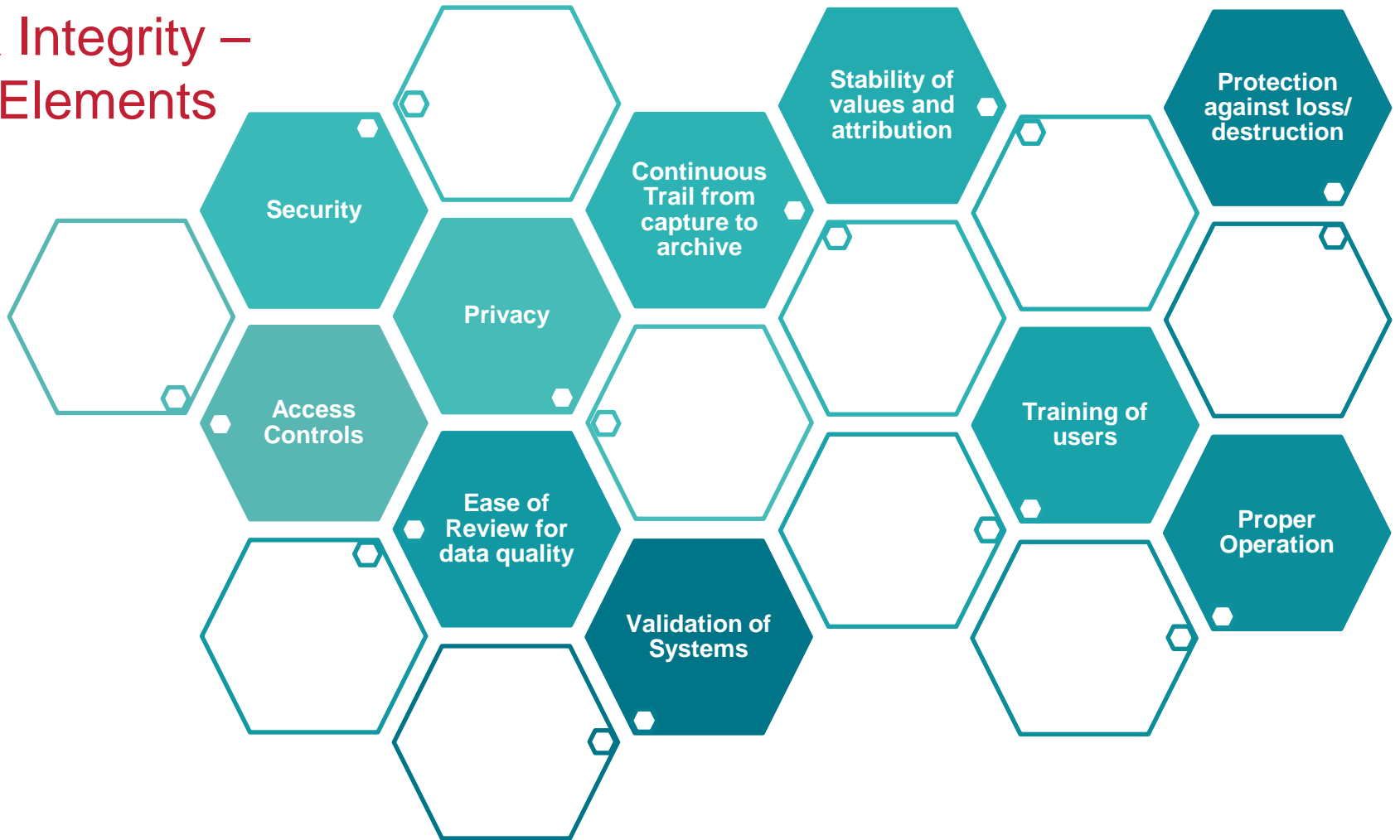
Data Integrity – Concerns



Data Integrity – Key Elements



Data Integrity – Key Elements



DATA INTEGRITY

A hand holding a red marker is shown underlining the text 'DATA INTEGRITY' on a white background. The text is written in a bold, black, hand-drawn font. The red line is drawn horizontally across the bottom of the letters.

Data Integrity –
Audit Trail

Audit Trail

*The audit trail is a form of **metadata** containing information associated with actions that relate to the **creation**, **modification** or **deletion** of GXP records. An audit trail provides for secure recording of life-cycle details such as creation, additions, deletions or alterations of information in a record, either paper or electronic, without obscuring or overwriting the original record. An audit trail facilitates the reconstruction of the history of such events relating to the record regardless of its medium, including the “who, what, when and why” of the action.*



Audit Trail

audit trail means a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record.

For example, the audit trail for a high performance liquid chromatography (HPLC) run should include the user name, date/time of the run, the integration parameters used, and details of a reprocessing, if any. Documentation should include change justification for the reprocessing.



Data Governance, Life Cycle & Audit Trails

Creation /
Collection

Processing

Reporting

Disposition

Retrieval

Retention



Collection

- Manual entry by authorized individuals
- Time & Date Stamp
- Specified Format
- Second Verification
- Procedures for Change record
- Validation
- System controls against manipulation



Processing

- Manual Vs. Technology platform
- Validated Process
- Electronic / Print / Hand Written Data
- Access Permissions for data processing



Reporting

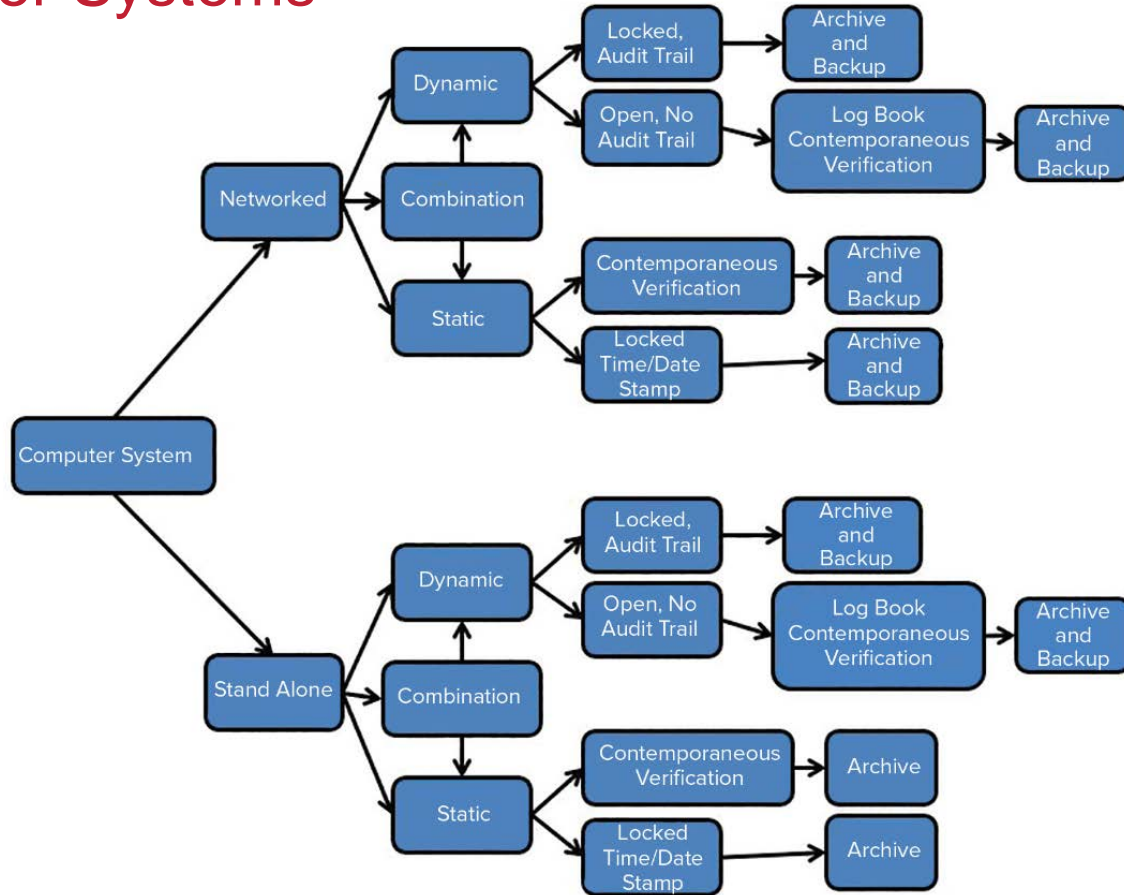
- All Data including meta data
- Executed Batch Manufacturing Record.
- Equipment log book.
- Line clearance checklist.
- In-process control recording formats.
- Batch Report and its electronic data.



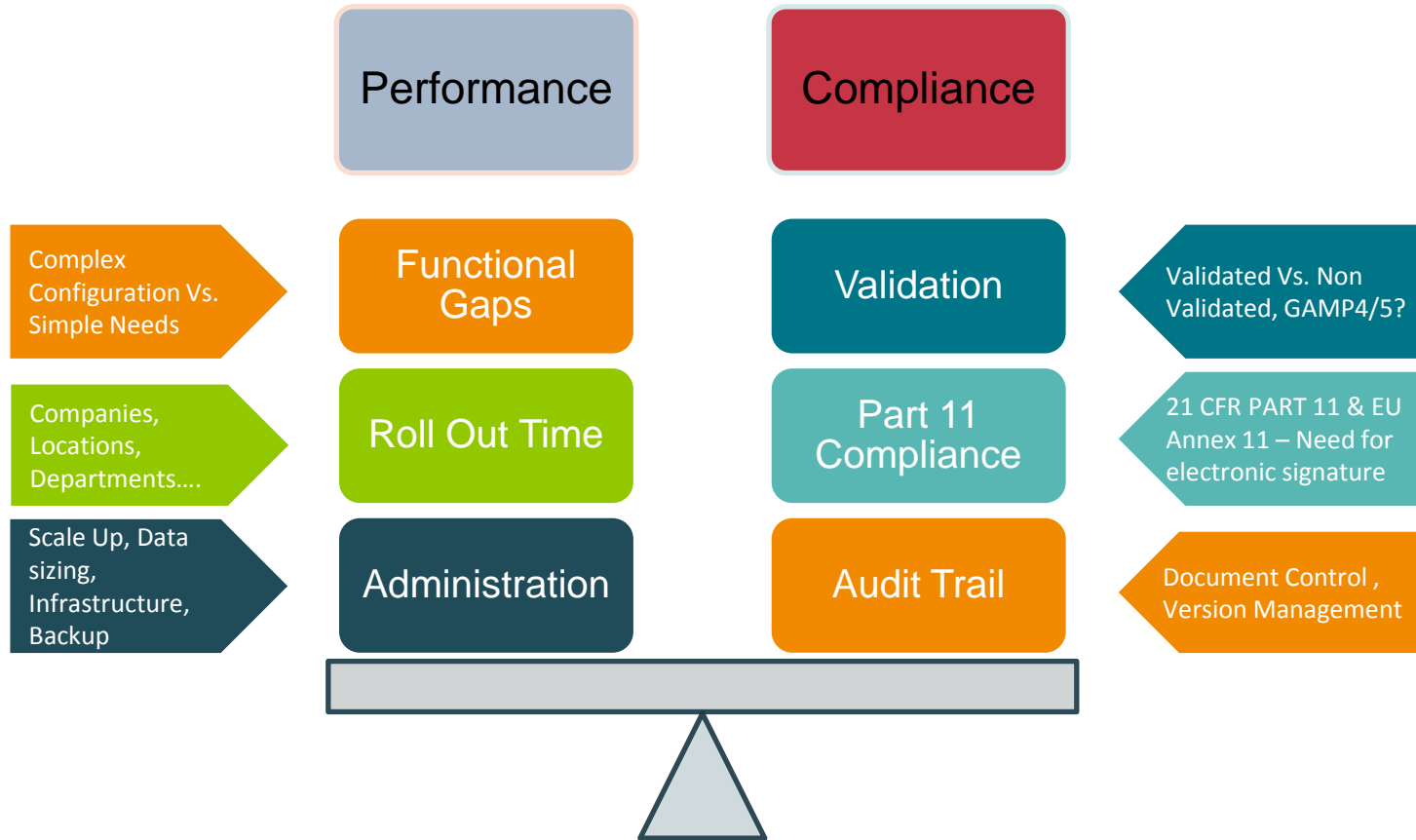
Retention

- Archival
- Back up – Disaster recovery

Use of Computer Systems



Use of Computer Systems





- Compliance
- Competitiveness
- Continuous improvement
- Confidence

The Bottom Line

UL OPERATES IN
MORE THAN
143
COUNTRIES



AND ACROSS
MORE THAN
20
INDUSTRIES

UL MARKS APPEAR on more than
22 BILLION
PRODUCTS GLOBALLY



UL has helped to set
MORE THAN
1600

standards defining safety,
security, quality and sustainability



**SCIENCE & GLOBAL
EXPERTISE**

UL SOFTWARE IS USED BY

10,000+



**ORGANIZATIONS IN
OVER 10 INDUSTRIES**



**UL WORKS TO PROTECT THE MARKET
FROM COUNTERFEIT GOODS**

IN 2015 UL PARTICIPATED IN 506 SEIZURES, ELIMINATING MILLIONS
OF DOLLARS OF COUNTERFEIT PRODUCTS FROM THE MARKET

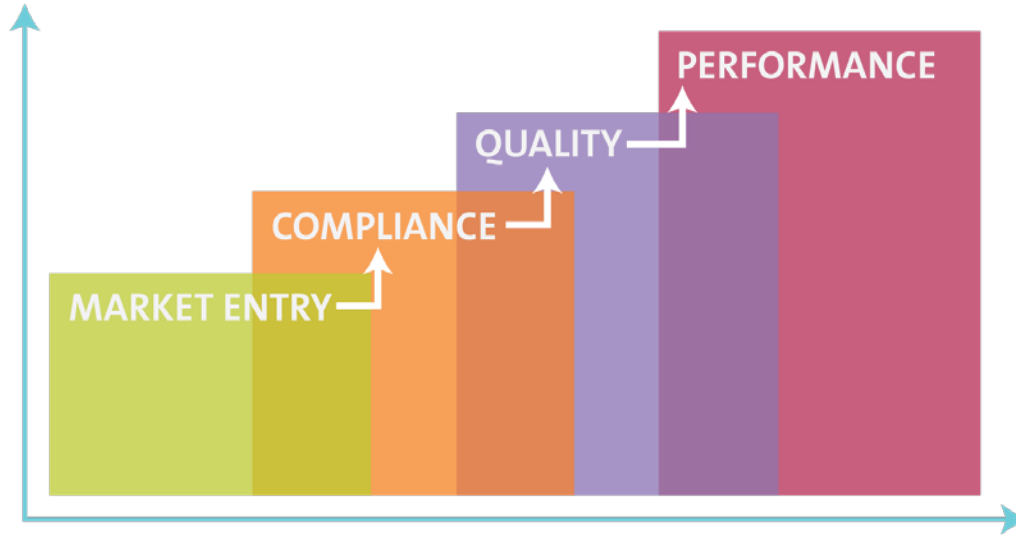
UL SERVES

1 OUT OF 3

FORTUNE 500 COMPANIES



About UL



We are a **strategic partner** that provides people, process, and technology **solutions** that help Life Science companies enter new markets, attain and sustain compliance, improve quality, and optimize business performance



Q&A





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