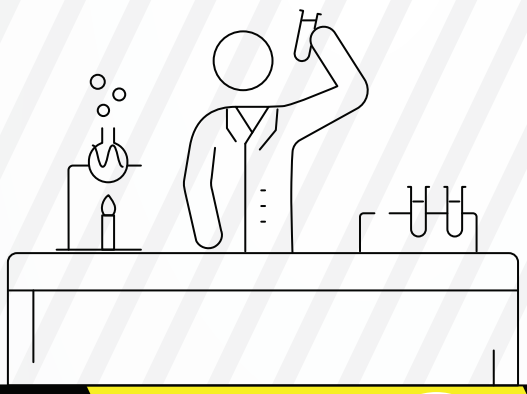
# Modern Laboratory Equipment and the Path to Data Integrity

The digital era is reshaping laboratories operating in regulated environments

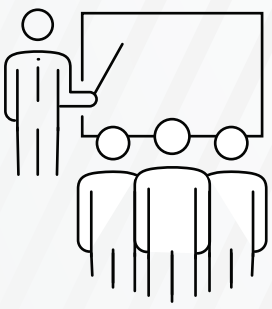


Ensuring electronic data integrity is key to produce reliable, trustworthy results that guarantee user safety, high product quality, and better reproducibility

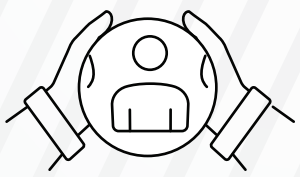
Paper-based records → Electronic data storage (00110011 01011010 10110101) → Laboratory information management systems (LIMS)

## What are the most common data integrity violations?

FDA warning letters often point out data integrity violations, which are common across many labs



### User roles and access management



Sharing administrator accounts causes traceability problems, data manipulation, and unexpected system configuration changes

### Incomplete audit trails

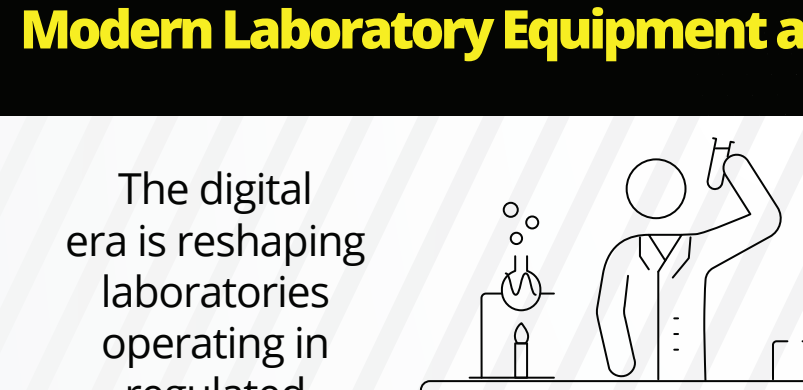
Certain software or instruments do not keep a log of all events, or the audit trail feature can be switched off

### Manual data input

Even simple transcription errors when inputting data into a LIMS can result in nonconformance to audits

## How can we prevent data integrity violations?

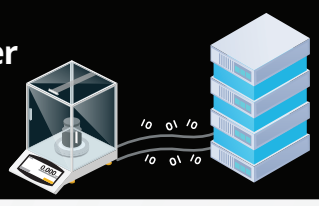
### Data should follow the ALCOA principles




### Comply with the FDA 21 CFR part 11 or the EU GMP Annex 11

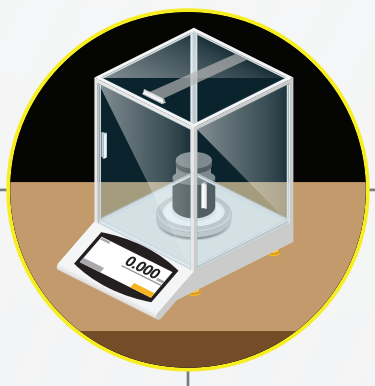
(Audit trail capability, user and role management with personalized accounts, electronic signatures, etc.)

### Ensure safe and seamless data transfer to prevent human input error and manipulation



## What instrument features can bring most of the digital transformation?

Modern lab instruments should allow us to achieve compliance without interrupting the workflow or substantially increasing workload



- Permanent audit trail
- Internal alibi memory
- Versatile user management and access control
- Electronic signatures
- Easy integration into laboratory systems
- Automatic backup
- Time synchronization
- Standard file formats
- High connectivity

**Cubis® II, and other instruments containing all these features, can give companies embarking in the digital journey a competitive edge**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**Editorial article title:** Ensuring Data Integrity: How Audit-Proof Digital Solutions Offer an Easier Route to Lab Digitalization
**Interviewee information:** Sebastian Weber and Mitesh Chhana
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