



How confident are you in your data collection practices for regulators?

Guide

Cisco Lifecycle Services

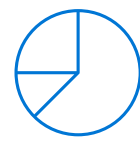
Manual data collection puts your manufacturing production at risk of quality issues, delays, and potential product recalls.

Production decisions rely on data integrity – which is heavily dependent upon manual data collection process often fraught with errors.



FDA's Alcoa+ Data Integrity Principles

- | | | |
|--------------------------|---|------------|
| A Attribute | + | Complete |
| L Legible | | Consistent |
| C Contemporaneous | | Enduring |
| O Original | | Available |
| A Accurate | | |



State of Manual Data Collection

48%
of manufacturing companies still collect data manually



Common Manual Data Collection Errors

- Delayed or incomplete data recorded
- Illegible, missing, or illegal values
- Lack of data ownership
- Missing documentation

Few manufacturing sites are maximizing their use of technology or have the infrastructure needed to deliver real-time, consistent data collection to ensure regulatory compliance.



Typical Manual Data Collection for Air Samplers¹

180 air samplers
430 samples/day
14 employees

Lab daily process

- Log into each air sampler
- Scroll/review each record
- Verify each electronic record matches paper record 1:1

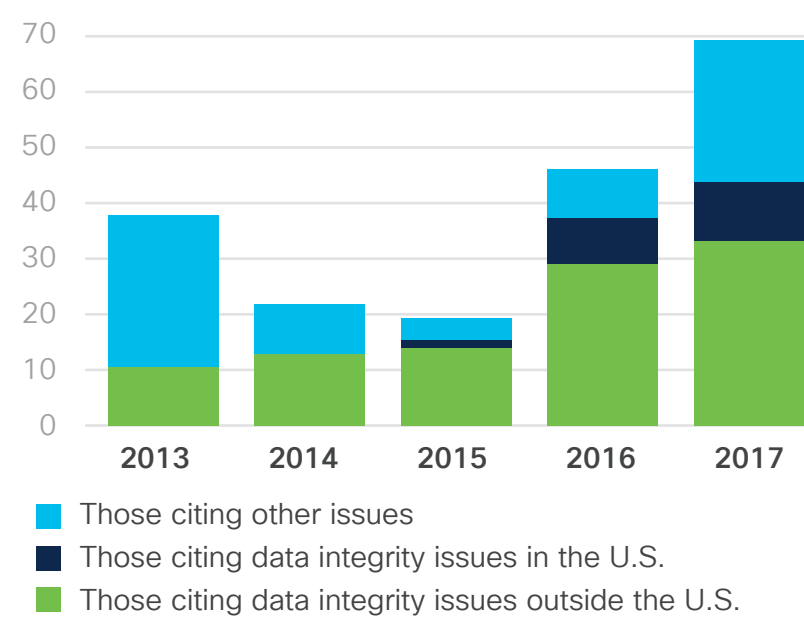
QA weekly process

- Retrieve thermal paper record and digital records
- V&V data and e-sign record
- Save thermal printout for future



Quality Alert

Number of warning letters to drugmakers



FDA's warning letters especially in the U.S., increasing cite data integrity issues. Source: Unger Consulting



Common Site-Level Roadblocks

- Limited onsite regulatory expertise
- Technology cobbled together by experts from different vendors

The cost of non-compliance is too high to risk a manufacturer's reputation and financial health.



FDA Warning Letter Excerpt

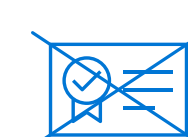
“Your quality system has not adequately ensured the accuracy and integrity of the data to support the safety, effectiveness, and quality of the drugs you manufacture.”



Short Term: Business Disruption

- Implement remediation program; including corrective action plan
- Complete retrospective review
- Comprehensive assessment of products released to market

Result: Decreased productivity and Increased OpEx

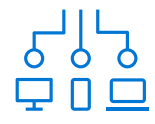


Long Term: Financial and Reputational Damage

- Court Fight Looms as Alpha Co. Drops \$4.3 Billion Beta Co. Deal, Apr 23, 2018
- Beta Co. Plunges After Judge Backs Alpha Co. Exit From Deal, Oct 1, 2018
- Beta Co. CEO Steps Down After Loss of \$4.3 Billion Alpha Co. Deal, Dec 8, 2018
- Alpha Co. Seeks \$76 Million From Beta Co. in Buyout Dispute, Apr 23, 2020

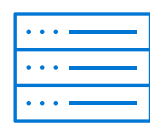
The foundation of a smart manufacturing automated data collection process is a secure operational technology (OT) network that is integrated with the IT network.

The critical infrastructure required to process data for the enterprise must be merged with industrial networks to ensure data integrity.



Industrial Systems

- Unified facility network (wired/wireless)
- Connected machines, control systems, and monitoring and diagnostic systems
- Manufacturing applications



IT Systems

- Network management and security
- Business applications
- Virtualization and computing
- Business analytics and data governance



Industrial Security

- Industrial segmentation
- OT visibility and threat detection



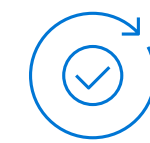
Operational benefits

- OT segmentation and protection
- Secure remote access to critical data



Business benefits

- Lower operational costs due to staffing and manufacturing efficiencies
- Improved compliance to reduce risk of operational slow downs
- Increased analytics to business provide insights to make better decisions
- Improved overall equipment effectiveness (OEE) through better visibility of machine performance



Digital transformation

- A robust connectivity environment is the foundation of all smart factory digital transformation efforts.

A secure OT network isn't enough to be proactive, predictive, and preventative – manufacturers need 3 key components to mitigate risk and ensure regulatory compliance.

Solution

1

Visibility

- Real-time monitoring
- Cross-site aggregation of data
- Identify trends and event triggers
- Compliance readiness

2

Data management and analysis

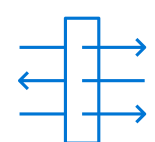
- Operational insights to mitigate risk and downtime
- Automation of tasks to increase speed and decrease errors
- Data security integral throughout operations

3

Specialized expertise

- Smart factory
- OT and IT integration
- Specialized data management processes
- Cloud
- Data management best practices

Results



Transparency

- Grants wider access to critical information and data
- Data that meets the "ALCOA" principles



Accountability

- Data-driven decisions to meet compliance and quality goals
- Electronic audit trails
- Secure back ups to ensure data is always available



Speed

- Faster identification of issues
- Faster problem scoping
- Efficient, targeted corrective actions

Cisco Lifecycle Services

Ensure data completeness and integrity, meet compliance demands, and reduce risk with Cisco Lifecycle Services.

Work with a market leader in cybersecurity and networking with 15+ years of experience digitizing industrial operations.



Cisco and our partner ecosystem

3 million devices delivering analytics

1.7 million certified professionals

62,000 trusted partner ecosystems



IoT/OT Cybersecurity & Networking Leader

Award: Forrester Wave Leader 2021, Industrial Control Systems (ICS) Security Solutions

Award: 2021 Gartner Magic Quadrant™ for WAN Edge Infrastructure



Highly skilled in-county experts

Regulated industry expertise in 23 countries including key manufacturing hubs in China, US, India, Europe, South Korea, Brazil, Japan, Mexico, and more.



Expert advisory services

- Design, deploy, de-risk, and optimize your infrastructure.
- Configure data collection processes according to cGMP
- Expand into Industry 4.0 with Cisco Digital Manufacturing Services (CDMS) framework.



Specialized services to support your business imperatives

Scrum Services: Proactively address your top initiatives throughout the lifecycle with flexible IT engagements that allow you to easily adjust skillsets.

Expert-as-a-Service: Close technology gaps by adding the precise expertise you need to elevate collective knowledge and perform at peak levels.



Outcomes-driven customer experience journey.

Cisco understands your business and your industry, and we know which technologies can help you achieve the business outcomes you want.

Our outcomes-driven customer experience journey will help you align your business priorities with outcomes to ensure your technologies support your business goals. This means we continuously engage at every step to identify, implement, and drive adoption with the right Cisco solutions to deliver measurable business impact.

Next steps

Schedule a workshop with your facility operations team to:



Identify areas of potential risk reduction between your IT and OT environment.



Identify manual data processes for automation consideration.

