

Data Integrity And Documentation Controls:

Challenges & Best Practices

Maintaining Trustworthy Records

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Disclaimer: The views and opinions expressed by the presenter are solely those of the presenter and do not necessarily reflect the official views, policies, or positions of the organization.

Challenges visible through Inspection Trends

Statistical analysis

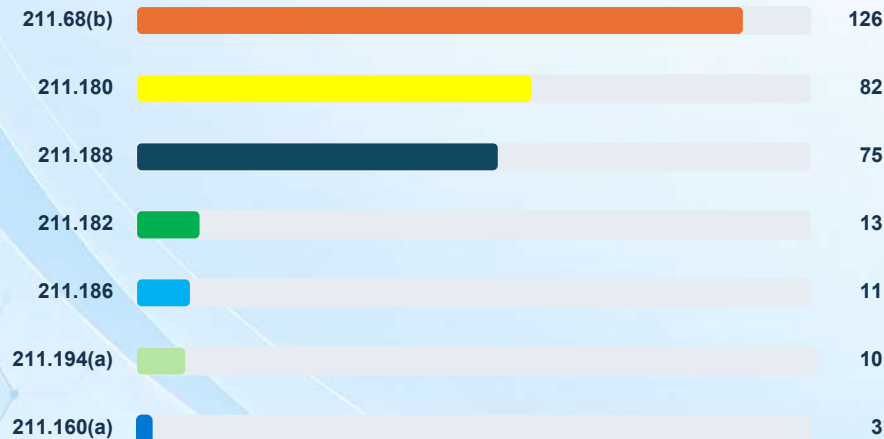
256 inspections

253 companies

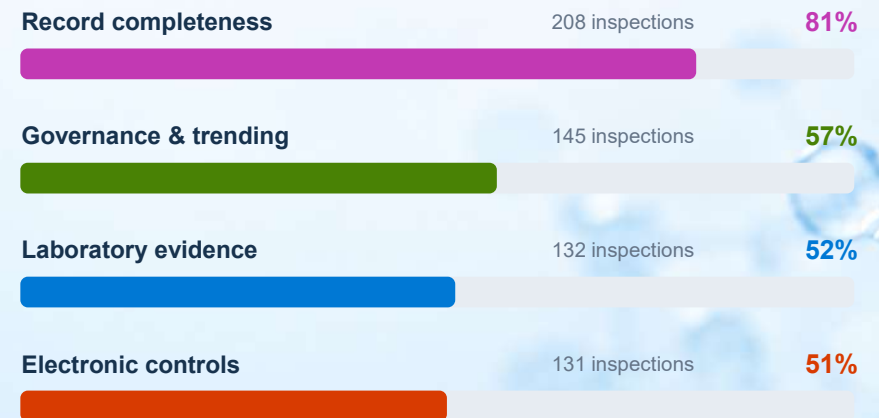
20 countries

320 Citation records
(Jan'25-Jul'26)

CITATION RECORDS BY REGULATORY AREA



INSPECTION THEMES



The dominant signal is incomplete evidence, reinforced by weak governance and electronic controls.

Method note: Citation records were filtered to the seven selected CFR families. Theme percentages are non-exclusive keyword flags at unique-inspection level; one inspection may appear in multiple themes.
Inspection and Form 483 Data source: Courtesy Atlas Compliance www.atlas-compliance.ai

Challenges – Inspection Trends, Expected Controls

Where pharma systems break, and what strong control looks like

01 Electronic controls

- Shared or over-privileged access
- Conflict of Interest
- Data can be changed or deleted
- Audit trails not effectively reviewed
- Backups or electronic records missing

Key reference: 211.68(b)

02 Record completeness

- Missing pages, values or signatures
- Uncontrolled forms and worksheets
- Incomplete equipment and cleaning logs
- Actual events cannot be reconstructed

Key reference: 211.182 / 211.188

03 Laboratory evidence

- Raw data or metadata incomplete
- Calculations or tools not verified
- Second-person review not evident
- Results lack complete traceability

Key reference: 211.160(a) / 211.194(a)

04 Governance & trending

- Annual reviews late or incomplete
- Signals not trended or acted upon
- Procedures omit clear requirements
- Quality oversight fails to close loops

Key reference: 211.180 / 211.186

WHAT STRONG CONTROL LOOKS LIKE

01 Controlled access

- Unique user IDs; roles based on job need
- Privileged access approved and reviewed
- Periodic SOD Assessment

02 Complete records

- Paper and electronic evidence reviewed together
- Missing data, exceptions and corrections resolved

03 Timely verification

- Entries made when the work is performed
- Critical steps and calculations independently checked

04 Learning system

- Signals trended across batches and systems
- CAPA effectiveness confirmed and sustained

Key takeaway: A record is trusted only when the full event can be reconstructed.

Best Practices: Proactive & Efficient Management of Data & Controls

Simple working principle, practical example and representative market solutions

01

Identity & Privileged Access

HOW IT WORKS Unique IDs and role-based permissions restrict what each user can do. Sensitive administrator access requires approval, is time-limited and is periodically recertified.

EXAMPLE A QC analyst can enter results but cannot change user rights. Temporary administrator access expires automatically after the approved task.

MARKET EXAMPLES Microsoft Entra® ID Governance | CyberArk® | Okta® | GxP Digitize™

02

Digital Records & Connected Evidence

HOW IT WORKS Electronic batch records, laboratory systems, equipment data and controlled documents are connected to create one complete, traceable evidence package.

EXAMPLE Equipment readings are captured directly, laboratory results are linked to the batch, missing attachments are flagged and only the current procedure is displayed.

MARKET EXAMPLES Körber PAS-X® | Siemens Opcenter® | Veeva® QualityDocs | LabWare® LIMS | E-log

03

Continuous Verification & Exception Review

HOW IT WORKS Predefined rules continuously detect missing entries, late changes, unusual values, calculation errors and significant audit-trail events. Reviewers focus on exceptions.

EXAMPLE A result changed after initial entry, a late critical entry or a missing attachment is automatically routed to QA for independent review.

MARKET EXAMPLES Veeva® Vault QMS | TrackWise® Digital | Kneat Gx® | Audit-trail analytics

04

AI-Enabled Learning & Assurance

HOW IT WORKS Validated analytics combine data across batches, systems, users, deviations and CAPAs to identify recurring patterns and emerging risks.

EXAMPLE A dashboard identifies repeated late entries in one process, recurring equipment deviations or CAPAs that did not prevent recurrence.

MARKET EXAMPLES Veeva® Vault Training | Microsoft Power BI® | SAS® | Seeq®

PREVENT access misuse • **CAPTURE** complete evidence • **DETECT** exceptions automatically • **LEARN** from recurring trends

- Market examples are representative examples only, not an exclusive/exhaustive list.
- Vendor qualification and validated implementation required.

Best Practices: Proactive & Efficient Management of Data & Controls

Automate high-volume reviews, convert fragmented data into trends and identify risk before product impact

05

Automated Laboratory Data Review

HOW IT WORKS

Connects with CDS, FTIR, UV, KF, LIMS and other laboratory systems. Predefined rules review results, metadata and audit trails, then present only exceptions.

EXAMPLE

Pro-DRE detects a reprocessed chromatography sequence, manual integration, deleted injection or result change and routes the event for documented review.

MARKET EXAMPLES ProvenTech Pro-DRE™ | Automated Audit Trail Review | LIMS/CDS connectors

06

Digital Product Quality Review

HOW IT WORKS

Automatically gathers batch, laboratory, deviation, complaint, change, stability and CAPA data, creates statistical trends and builds a traceable PQR draft.

EXAMPLE

The system calculates yield and assay trends, Cpk/Ppk and recurring deviations, then highlights adverse trends and open commitments for QA assessment.

MARKET EXAMPLES Caliber AnytimePQR® | AmpleLogic® APQR | Light Pharma® APQR | APQRSmart™

07

Continued Process Verification

HOW IT WORKS

Continuously collects critical process parameters and quality attributes from MES, LIMS, ERP and equipment, then applies control charts, capability analysis and alert rules.

EXAMPLE

A gradual shift in granulation time, compression force or assay is detected across batches before a specification failure, enabling early investigation.

MARKET EXAMPLES CaliberCPV® | AmpleLogic® CPV | Light Pharma® CPV | Seeq® | BatchSmart

08

Predictive Quality & Process Intelligence

HOW IT WORKS

Combines process, equipment and quality-system data to identify multivariable patterns, forecast drift and prioritize the conditions most associated with deviations.

EXAMPLE

Analytics links rising equipment vibration, longer cycle time and moisture variation with increased rejection risk, allowing maintenance or process adjustment.

MARKET EXAMPLES Seeq® | SAS® | Microsoft Fabric® | Power BI® | validated ML platforms | BatchAccel

IMPLEMENTATION PRINCIPLE

Validate data interfaces and algorithms, approve exception rules, retain source-data traceability, and require qualified-person review of alerts, trends and AI-generated conclusions.

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Best Practices: Back to Basics in dynamic world

Reliable decisions require controlled data across its full lifecycle of paper, hybrid & electronic data .



ALCOA evolved to ALCOA+ through expanded data-lifecycle expectations; the term ALCOA++ has been used in industry to further emphasize the “traceability”.
Sources: IPA Data Reliability Guideline (2017); IP[®] A Best Practices on Digital Data Management, 21 CFR Part 11 Compliance (2022).

Backup: Market Solutions for Data & Quality Controls

Microsoft® Entra® ID Governance

Identity lifecycle, entitlement management and access reviews for controlled user access.

[Website >](#)

CyberArk®

Privileged access management for securing, monitoring and governing administrator credentials and sessions.

[Website >](#)

Okta®

Cloud identity and access management supporting single sign-on, multifactor authentication and lifecycle management.

[Website >](#)

GxP Digitize™

Digitalization solutions for regulated GxP workflows and records; confirm the specific module and validated use case with the vendor.

[Website >](#)

Körber PAS-X™

Manufacturing execution system for electronic batch recording, guided execution and production traceability.

[Website >](#)

Siemens® Opcenter™

Manufacturing operations management portfolio connecting production execution, quality and operational data.

[Website >](#)

Veeva® QualityDocs™

Controlled document management for authoring, approval, distribution and effective-version access within Veeva Quality Cloud.

[Website >](#)

LabWare® LIMS™

Laboratory information management for samples, tests, results, workflows and laboratory data traceability.

[Website >](#)

E-log / electronic logbook

Replaces paper equipment and area logs with time-stamped, searchable and reviewable electronic entries; capabilities vary by vendor.

[Website >](#)

Veeva® Vault® QMS™

Cloud QMS supporting connected quality processes such as deviations, CAPA, change control, audits and complaints.

[Website >](#)

TrackWise® Digital™

Cloud-based quality management system with integrated workflows, reporting and analytics across quality processes.

[Website >](#)

Kneat Gx™

Digital validation lifecycle platform for creating, executing and managing validation documentation and evidence.

[Website >](#)

Veeva® Quality Analytics™

Reporting and analytics across quality content and QMS data to support oversight and trend review.

[Website >](#)

Microsoft® Power BI®

Business analytics platform for connecting data, building interactive dashboards and monitoring trends.

[Website >](#)

SAS® Viya®

Analytics platform supporting statistics, forecasting and machine-learning use cases with governed data and models.

[Website >](#)

Seeq®

Industrial analytics platform for time-series process data, monitoring, investigation and operational insights.

[Website >](#)

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Backup: Market Solutions for Data & Quality Controls

ProvenTech™ Pro-DRE™

Automated laboratory data and audit-trail review that highlights predefined exceptions for documented assessment.

[Website >](#)

Caliber® AnytimePQR™

Digital APQR/PQR solution for collecting source data, generating statistics and producing review-ready reports.

[Website >](#)

AmpleLogic™ APQR™

APQR software for collating quality data, workflow review, statistical analysis and report generation.

[Website >](#)

Light Pharma™ APQR™

Digital product-quality-review offering; confirm current product scope and integration specifications with the vendor.

[Website >](#)

APQRSmart™

Digital APQR solution; confirm current features, interfaces and regulatory documentation directly with the provider.

[Website >](#)

CaliberCPV™

Continued process verification software for ongoing process-data aggregation, statistical monitoring and trend alerts.

[Website >](#)

AmpleLogic™ CPV™

CPV platform for monitoring critical process parameters and quality attributes using statistical trends and dashboards.

[Website >](#)

Light Pharma™ CPV™

CPV software for process monitoring and statistical review across batches.

[Website >](#)

Microsoft® Fabric™ / Power BI®

Data and analytics platform for integrating enterprise data, building governed models and visualizing quality and process trends.

[Website >](#)

BatchSmart™

AI powered Software for review and analysis of paper based manual BMRs

[Website >](#)

LabelSmart™

Ensuring Errors free packing materials by identifying human errors before it is too late.

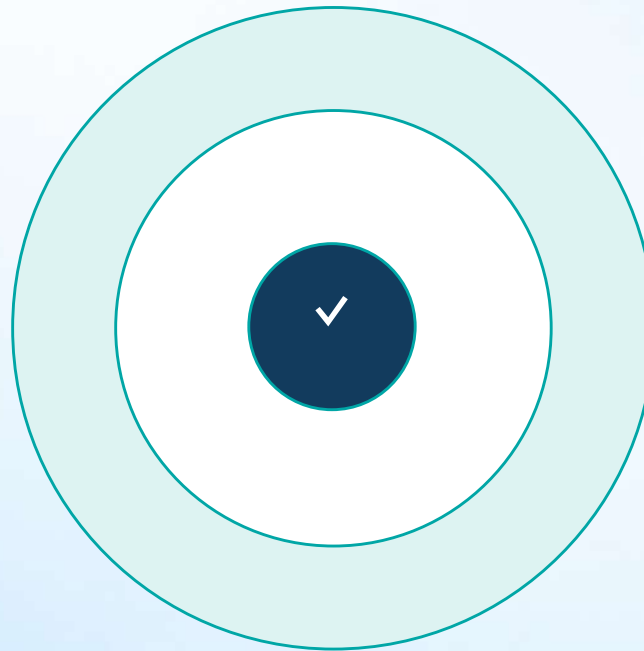
[Website >](#)

CoASmart™

Smart way to digitally capture Certificate of Analysis data, review analyse for error free operation

[Website >](#)

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Thank You

Questions & Discussion

Protect data integrity • Strengthen document control • Enable proactive quality oversight