

# Case Study CSV

## Restoring Data Integrity in Chromeleon 7.2 for a Pharma Manufacturer

### Client Overview

A leading pharmaceutical manufacturing company using Chromeleon 7.2 for chromatographic analysis faced **critical data integrity concerns** during an internal GMP audit—putting regulatory compliance at risk ahead of inspection.

### Our Approach

Our CSV experts conducted a deep-dive technical and compliance assessment:

- System architecture & configuration review
- Network performance and storage analysis
- Audit trail gap identification
- User access & privilege validation

### Solution Delivered

#### Technical Remediation

- Reconfigured data vaults, folder security & communication channels
- Implemented dedicated service accounts
- Stabilized and validated backup/restore processes

#### Validation Execution

- Completed IQ, OQ, PQ protocols
- Validated:
  1. Audit trail generation
  2. Sequence execution
  3. Processing methods
  4. Reporting & archival
- Established full traceability matrix
- Performed network stress testing

#### Compliance Strengthening

- Improved audit trail review mechanisms
- Conducted user training on ALCOA+ principles
- Standardized Chromeleon workflows

### Business Impact

- Zero audit observations during inspection
- 100% data integrity restored before scheduled USFDA inspection
- Increased user confidence & compliance readiness
- Streamlined QC operations
- Improved system performance under high load

### Key Challenges

- **With an USFDA inspection scheduled within 8 weeks, resolution was time-critical.**
- Data synchronization failures between clients and central server
- Missing sequence events in audit trails
- Backup and restore inconsistencies
- Use of unvalidated processing methods in QC
- High risk of observations from USFDA / WHO / MHRA

### Root Cause Identified

**Within 72 hours**, High network load + misconfigured batch archival tasks led to audit trail gaps and partial data synchronization.

### Conclusion

With a structured CSV approach, the client transformed a high-risk compliance scenario into a **fully validated, audit-ready environment**—ensuring long-term reliability and regulatory assurance.