ARE YOU AUDIT READY?

Here's what you'll need to know...

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State of the Industry

By the numbers

- Almost 100 FDA warning letters were issued to pharmaceutical companies in 2014
- 645 FDA form 483's were issued in 2014
- 15% The number of FDA inspections is expected to increase by 15% in 2015
- The FDA recalled 1,647 drug products in 2014
- Average cost of failing an audit estimated at $480,000
- 15 Pharmaceutical companies have 15 days to respond to a FDA form 483

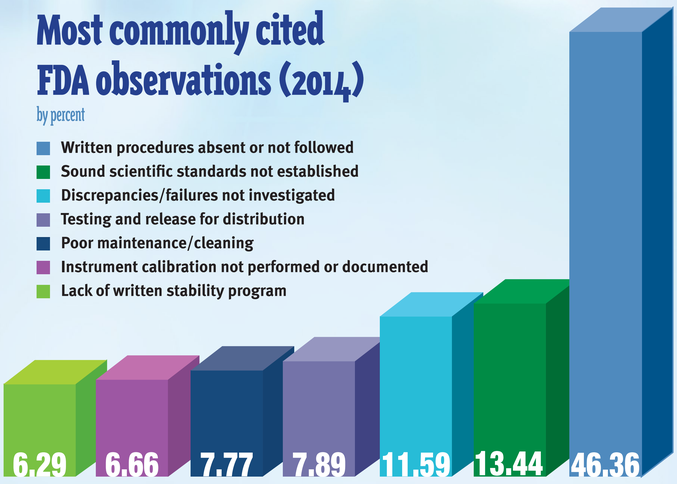
FDA AUDITORS CITE #1 OBSERVATION DURING ONSITE VISITS

Responsibilities and procedures applicable to Quality Control are not being documented or followed correctly.

Most commonly cited FDA observations (2014)

by percent

- Written procedures absent or not followed
- Sound scientific standards not established
- Discrepancies/failures not investigated
- Testing and release for distribution
- Poor maintenance/cleaning
- Instrument calibration not performed or documented
- Lack of written stability program



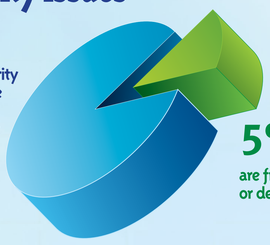
Customer Challenges

DATA INTEGRITY

"The accuracy, consistency and completeness of data over its entire lifecycle in accordance with regulations"

Reasons for data integrity issues

95% of data integrity issues are due to poor data management practice



5% are fraudulent or deliberate

5 Added costs of receiving a warning letter

1. $ DECREASED EFFICIENCY
2. $ DAMAGE TO REPUTATION
3. $ LOSS OF BUSINESS
4. $ COMPETITOR LEVERAGE
5. $ STOCKHOLDER CONFIDENCE

Compliance Solutions

Ensure the following are documented

SUPPLIER RECORDS:
Demonstrate use of suitable vendors with clear selection criteria.

OPERATOR RECORDS:
Define system permissions and access level appropriate to roles.

ALL SOPs:
Any deviations from SOPs

Any out of spec results and resultant corrective action

TRAINING RECORDS:
Detail the instruments, equipment and methods each operator is trained to use.

INSTRUMENT RECORDS:
Show details of calibrations and maintenance.

Use ALCOA+ Criteria for Data Integrity

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

+ Complete + Consistent + Enduring + Available

Audit Do's

- Ensure data is backed up on a secure, centralized server
- Keep metadata to ensure completeness
- Integrate instruments and systems to avoid transcription errors
- Keep access levels to minimum required for role

Audit Don'ts

- Share user identities
- Use test samples for System Suitability Tests

Laboratory Data Management Solutions

- **Laboratory Execution System** — Drives users through methods and SOPs in stepwise fashion
- **Laboratory Information Management System** — Complete sample, test and result workflow management
- **Scientific Data Management System** — Secure, future-proofed data archival and retrieval
- **Chromatography Data System** — Instrument control, data collection and analysis

4 Types of Data Must be Managed

1. Audit trail
2. Visual observations
3. Raw data from instrument or equipment
4. Associated contextual metadata (column used, temperature, operator, time and date, reagent used, etc.)

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