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Pharmaceutical Data Integrity Analytics

A Big Data Approach

PROTECT, CREATE, & RECOVER VALUE

Background

The life sciences and pharmaceutical industry has been evolving continuously to deal with newer healthcare-related challenges. The industry consistently races against time to come up with groundbreaking drugs, and works round the clock to evaluate, create and bring to the market a wide range of drugs for the prevention and treatment of any disease.

With the advancement in technology, the pharma industry has also upscaled their technology equipment, expanded their manufacturing facilities to make good quality products and safeguard public health. With this huge responsibility, pharma companies are also under tremendous pressure due to the audit conducted by regulatory bodies, namely, the United States Food and Drug Administration (US FDA), World Health Organisation (WHO), Indian Food and Drug Administration (FDA), the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) and other regulatory agencies.

With heavy involvement of digital technologies in the equipment for manufacturing, testing or any other task involved, terabytes of data get generated on a daily basis on systems across locations. It is the responsibility of the pharma companies to review each data point to ensure compliance with Current Good Manufacturing Practice (CGMP) guidelines as laid out by the regulators. Compliance with CGMP has always been a challenge as many processes remain manual that raises the possibility of human error impacting quality checks. Further, most of the companies still follow the traditional manual or sample-based approach to review data which doesn't cover the entire data population, thus increasing the risk of Data Integrity non-compliance. This area has always been a focus area for the regulators as we can notice from various actions taken by the regulator in the form of 'Form 483' and 'Warning Letter'.

As the world gravitates more and more towards scientific and technological advancements in the pharmaceutical industry, the importance of Data Integrity will continue to remain on the rise. The issues get compounded due to negligence, lack of training, data entry errors, lack of regulatory awareness, poor documentation etc. The cost of rectifying Data Integrity gaps is huge, hence a need for pharmaceutical companies to implement proactive and corrective measures to mitigate Data Integrity risks.

Dealing With the Pandemic

A new pandemic tests the capabilities of the pharmaceutical industry to new extremes. The industry faces several challenges when dealing with a pandemic situation such as:

Shortage of resources onsite / remote working

Restrictions on importing Active Pharmaceutical Ingredient (API)

Social distancing at facilities

Access to data due to travel restrictions

Lack of complete access to documents/ data remotely

Despite the above challenges, pharma companies need to remain compliant.

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Repercussions of Being Non-compliant With Data Integrity Practices

The regulators have been issuing warning letters consistently over the past several years. This trend is concerning as there has been no real dip in the number of warning letters where the regulator could have resolved the issue with minor feedback. A warning letter is a serious cause for concern for the company and the industry at large.

"Data Integrity refers to the completeness, consistency, and accuracy of data, which should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate" (FDA) [1]

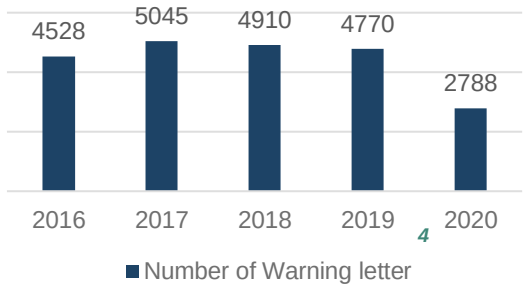
Preventing Data Integrity issues is a worthwhile investment in the company, because recovering from them, when discovered, is far worse than the costs associated with prevention. Data Integrity failures have led to companies losing their manufacturing licenses, consent decrees, warning letters, import alerts, invocation of the application integrity policy, bad publicity when issues become newsworthy, and more.

Drugmaker to pay $50mn in fine for destroying records .[2]

Global manufacturer received warning letters and import bans, resulting in exports dropping $48 million from previous year, after growing 39% over previous 4 years. EBIT dropped $41 million. [3]

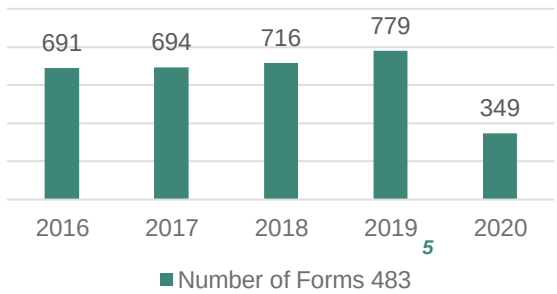
The FDA sent over 2,700 Form 483 observation letters in 2020, compared with more than 4,700 in 2019, a 42% decrease. The trend is essentially the result of fewer inspections by the regulators due to COVID-19 related challenges but as inspection resumes, Data Integrity Compliance is likely to be the focus area of the regulators to ensure reliability and accuracy of the data.

FDA Warning letter



[4]

Numbers of Forms 483



[5]

Leveraging Digitization

The heightened scrutiny by regulatory agencies is the new normal and thus investing in upgrading quality systems through automation and various other digital intervention is the way to reduce human error. As we understand more about the different features of data, both electronic and paper-based, we realize that some of the methods implemented by pharma companies in the past to verify Data Integrity might be outdated.

The focus should be on adopting new advanced technological approaches, by implementing proactive solutions to ensure Data Integrity over its entire life cycle in compliance with applicable regulations.

1. https://www.fda.gov/media/97005/download
2. https://timesofindia.indiatimes.com/business/india-business/indian-drugmaker-to-pay-50mn-in-fine-for-destroying-records-before-fda-inspection/articleshow/80782989.cms?utm_source=contentofinterest&utm_source=contentofinterest&utm_medium=text&utm_medium=text&utm_campaign=cppst&utm_campaign=cppst
3. https://www.lachmanconsultants.com/wp-content/uploads/2016/05/data-integrity-whitepaper.pdf
4. https://www.assurx.com/are-fda-warning-letters-and-483-observations-about-to-spike/
5. https://www.pharmaceuticalonline.com/doc/fda-fy-drug-inspection-observations-and-trends-0002

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Our Solutions –
Lookback Data Integrity Analytics

Using Big Data approach, our team conduct a Data Integrity lookback on both electronic and paper-based information sources to identify the gaps and prepare a remediation plan.

Our lookback approach includes:

Risk Assessment

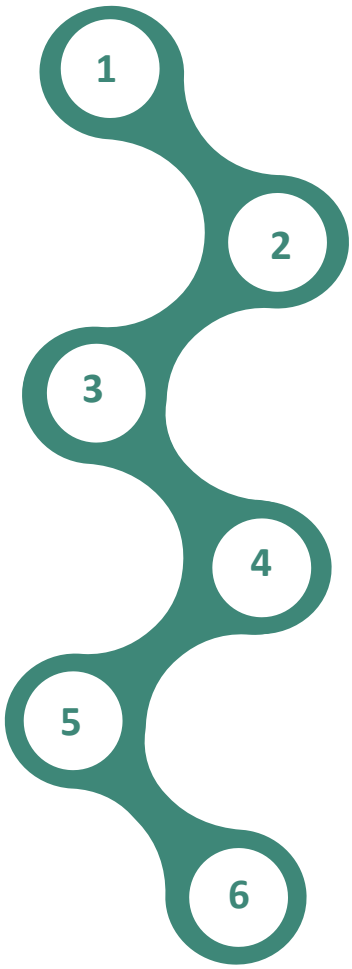
Working with the stakeholders to understand the current situation, the risk they are exposed to and create an initial response to the regulators.

Data Collection

Collect 100% of the data from the identified system (CDS/Non CDS/ LIMS) or hardcopy documents in a forensically sound manner to maintain the authenticity of the data.

Remediation-CAPA

Following the scenarios tests result, we help the company develop and execute a Corrective and Prevention Action (CAPA) to remediate the risk and ensure future compliance.



Requirement Gathering

Determine what systems, data, people and processes are required to be looked at. Identify If any root cause can be easily fixed for moving forward.

Data Analysis

Process data, develop algorithms and test Data Integrity scenarios to identify the scope of the problem and identify if there is any compromise on the quality of the product. Categorize the anomalies into low, medium and high Data Integrity risk.

Regulatory Reporting

To satisfy the regulators, we will deliver a detailed Data Integrity report with evidence covering technical and functional aspects.

As the FDA 2018 Data Integrity and Compliance with Drug cGMP Guidance states:

"FDA encourages you to demonstrate that you have effectively remediated your problems by investigating to determine the problem's scope and root causes, conducting a scientifically sound risk assessment of its potential effects (including impact on data used to support submissions to FDA), and implementing a management strategy, including a global corrective action plan that addresses the root causes." [6]

It's all about trust… Once trust is lost with regulators & customers, it can be difficult to gain back but not impossible

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Our Solutions –

Proactive Data Integrity – Early Warning System (EWS)

Our team offers an advanced analytics solution connected to the client's existing systems- a seamless Data Integrity compliance monitoring feature. It identifies Data Integrity anomalies in real-time from electronically generated data, highlighting the alerts, showcasing meaningful insights through dashboard reports.

The solution is flexible enough to fit into the existing framework of manufacturing and Quality Control (QC) labs, catering to the needs of all types of users, be it testing analysts or board of committee members.

Key Feature -

Advanced Analytics
for identifying Data Integrity anomalies with their risk projection.

Data Under One Roof
centralized access to data, spread across various manufacturing facilities.

Flexibility
to customize the DI scenarios and workflows as per your business needs and data.

Handle High Data Volumes
from all systems namely CDS and Non-CDS.

Security Control
on user access, with read and write rights restricted as per requirement.

Customized Case Management
workflows designed for review of the DI anomalies.

Audit Trail Management
for review and evaluation of data, ensuring compliance with 21 CFR part 11.

Dashboard & Reports
for performance monitoring covering MIS reports for stakeholders, testing analyst, and facilities wise DI anomalies report etc.

The MHRA 2018 GXP Data Integrity Guidance and Definitions states :

"Senior management should be accountable for the implementation of systems and procedures to minimize the potential risk to Data Integrity, and for identifying the residual risk, using risk management techniques."[7]

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Representative Engagements

Retrospective Data Integrity Review

FDA Warning Letter – DI review for a global pharmaceutical company based in Japan

Situation

The FDA identified Data Integrity (DI) compliance gaps in a leading drug manufacturing company and issued a warning letter for Site A and import alert for Site B leading to restrictions for selling the product in the market. This resulted in serious financial consequences for the company due to product recalls, delayed drug approvals and loss of customers due to reputational damages.

Solution

Performed a process and system analysis to immediately rectify the gaps for future compliance. Using Big Data approach, we collected and processed electronic data from multiple systems (CDS, NON-CDS, LIMS) into our analytic tools. Data Integrity scenarios were then designed as per the client's business processes and data.

Results

Observations helped the client in identifying DI compliance gaps and the team assisted in effective Corrective and Prevention Action (CAPA) to address these gaps. We delivered a detailed Data Integrity report with evidence covering technical and functional aspects to fulfil the regulators requirements. Potential anomalies identified from electronic review reduced the number of paper-based review of batch records.

Proactive Data Integrity Solution

Data Integrity Review Automation – Realtime monitoring

Situation

The Client required a monitoring mechanism to identify Data Integrity issues continuously and proactively across multiple manufacturing facilities as the company grew rapidly. They also required an automated procedure to review data generated from different systems (CDS, LIMS etc.) and to monitor performance remotely.

Solution

Developed and implemented centralized solutions on client premises to identify Data Integrity issue in real time. We also produced a dashboard reporting review mechanism to check the overall performance. Automated verification and validation checks were implemented in the solution in accordance with USFDA Data Integrity guidelines. Automated more than 70% of the manual review activities.

Results

Positive impact on the business as there were significant improvement in the quality control team performance. Facility head got control of the data with real time insights and information. The client was able to showcase a technology driven Data Integrity compliance program during inspection to gain trust.

** Certain engagements may have been performed by Ankura professionals while at other firms.*

Our Data & Technology Services

Technology, Privacy, and Cyber Risk Advisory

Cyber Risk Advisory
- IT and cyber strategy & governance
- Cyber assessments and compliance
- Cyber resiliency and planning
- Operational cyber functions

Data Privacy Advisory
- Data privacy assessment and readiness programs
- Data inventory and mapping
- Development of policies and procedures
- Fractional privacy manager services
- Technology implementation

Technical Solutions
- Vulnerability and penetration testing
- Solution specific security assessments
- Security Architecture
- Security Solution Implementation
- Cloud Security
- Social Engineering Campaigns

Response Intelligence & Investigations

Incident Response
- Industry leading technique to quickly evaluate and mitigate security incidents
- Crisis handling and response while leveraging endpoint detection, user behavior and threat analytics to contain and eradicate

Investigations
- Support to criminal/civil litigation efforts, regulatory proceedings, and confidential internal investigations
- Legally defensible outcomes that answer our clients' most complex questions

Threat Intelligence
- Multi-sourced technical collections, dark web data, and specialized threat intelligence add context and efficiency to investigations
- Open and closed source collections and analysis that discover and assess exposure risk and threat actor impact to our clients

Expert Witness
- Digital media forensic and cybersecurity practitioners qualified as expert witnesses
- Digital investigative analysis, internet technologies expertise, and computer forensics
- Provide qualified expert opinions on reasonable security practices

Managed Data Protection Services

Threat Detection and Response
- Continuous threat hunting and real-time incident response
- Malicious activity detection and ongoing testing of security controls

Third Party Risk Management
- Design, deployment, and ongoing management of third-party risk assessment and remediation activities

Security Analytics and Data Mining
- On demand data mining services to support identification of sensitive data exposed in a data breach incident
- Advanced log analysis to support security incident root-cause and impact determinations

Data Analytics, Advisory & eDiscovery

Data Analytics And Data Strategy
- Utilizing our data expertise to make sense of structured information to identify trends and patterns in the data in response to fraud, money laundering and investigations

Data Collection & Digital Forensics
- Handling data capture and performing analysis of devices and servers and information systems

eDiscovery Project Management And Hosting
- Using advanced technology to host and manage data in response to Litigation and regulatory requests
- Using machine learning technology to prioritize data

Software License Consulting

Software License Compliance
- Enterprise-wide assessment of software deployment vs. entitlements and reduce risk of non-compliance.

Cost Optimization
- Identify actual requirement vs. deployment and detect license wastage.

Audit Defence
- Responding to audit notifications and assistance in avoiding or preparing for audits.
- Communication with auditors on behalf of the clients and negotiations with software publishers.

Managed SAM
- Enable a continuous monitoring process overseeing the software lifecycle to control, manage and optimize the use of software across an organization.
- Assist clients to build a robust SAM process with focus on Process, Tools, Operations, Team and Training

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