FTI CONSULTING™

DATA INTEGRITY SERVICES

RESOLVING DATA INTEGRITY CHALLENGES AND SECURING COMPLIANCE FOR PHARMACEUTICAL COMPANIES

EXPERTS WITH IMPACT™

Data Integrity Audits **by Regulatory Agencies**

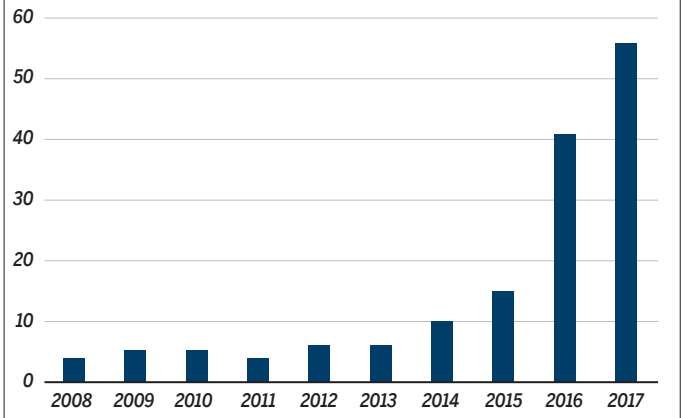
Data integrity audits conducted by regulatory agencies such as the United States Food and Drug Administration (US FDA), Indian Food and Drug Administration (FDA), the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) and other regulatory agencies pose immense challenges for pharmaceutical companies. A globally dispersed supply chain, large and complex data sets, insufficient systems control, a lack of training or appropriate manpower – all of these factors can decrease the company's ability to achieve data integrity compliance and increase the chances of enforcement actions by regulators such as costly fines and penalties.

As the rate of data integrity audits accelerates, pharmaceutical companies need to ensure that data (both electronic and paper-based) is reliable, accurate and managed in accordance with the Current Good Manufacturing Practice (CGMP) regulations. And, to accomplish good data integrity practices, pharma companies need to take necessary measures to identify and implement the correct processes and technology to remedy errors and attain compliance.

Number of Data Integrity Associated Warning Letters by Country, CY 2008-2017[1]

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	TOTAL
China	1	1	3	1			2	2	14	19	43
USA	1	2	1	1	1			0	7	15	28
India	1	1		2		6	7	10	9	12	48
Europe		1					1	2	6	3	13
Brazil								0	3		3
Japan	1							0	2	1	4
Thailand								1			1
Canada			1		1					2	4
Mexico					2					1	3
UAE					1						1
Jamaica					1						1
S. Korea										2	2
Singapore										1	1
TOTAL	4	5	5	4	6	6	10	15	41	56	152

Data Integrity Associated with Warning Letters, CY 2008-2017[1]



[1] Source: *Pharmaceutical Online* article: "An Analysis Of 2017 FDA Warning Letters On Data Integrity" by Barbara Unger, Unger Consulting. https://www.pharmaceuticalonline.com/doc/an-analysis-of-fda-warning-letters-on-data-integrity-0003

For companies found with **data integrity issues** and **non-compliance with CGMP practices**, the monetary and reputational risk can be **severe**.

SOME RECENT EXAMPLES INCLUDE:

A 15% reduction in market capitalization following a US FDA warning on possible violations of manufacturing standards at three plants in India;[2]

A $500 million penalty paid by a pharma company to the US government for a variety of CGMP failures;[3]

A 47% decrease in annual revenues for a pharma company after the US FDA banned imports from two of its Indian-based plants;[4]

In addition, once data integrity audits identify compliance issues, those companies need to correct the faulty systems or risk being added to a debarment list, further limiting the company's ability to develop or sell products. Depending upon the audit findings, these data integrity remediation projects have cost as much as $100 million.[5]

Organizations now seek data integrity experts who have a blend of regulatory, technology, scientific and process knowledge to control or remediate data integrity issues. FTI Consulting provides a full range of proactive and corrective and preventive action (CAPA) data integrity solutions to help pharmaceutical companies better manage risks.

[2] Source: *Live Mint* article: "The Rs1 Trillion FDA Impact on Indian Pharma" by Reghu Balakrishnan, December 2, 2015.

[3] Source: FDA Zilla blog post: "The Story of Three Consent Decrees" by Barbara W. Unger, August 25th, 2016.

[4] Source: *Business Today* article: "Cracking the FDA Code" by P.B. Jayakumar, May 24, 2015.

[5] Source: Lachman Consultants white paper, "The Real Cost of Poor Data Integrity in Pharmaceutical Manufacturing," May 19, 2016.

Proactive Data **Integrity Review**

Leveraging advanced analytics, we provide an on-premise automated solution to proactively identify data integrity issues in real-time for regulatory quality compliance. This includes analyzing electronic data and identifying potential anomalies in data generated by laboratory instruments within the pharma facility's Quality Control (QC) lab.

KEY FEATURES OF OUR PROACTIVE DATA INTEGRITY SOLUTION ARE:

- **Scalability to handle large volumes of data** from various systems such as CDS and non-CDS
- **Advanced case management workflow for review of alerts.** This includes a hierarchical approval workflow to ensure alerts are properly addressed
- **Forensically sound data management and audit trails** to report user activities for accountability and compliance reporting
- **Advanced analytics and predictive models** for log analysis and anomalies identification for efficiency and cost-savings
- **Centralised dashboards and reports** for multiple locations
- **Identity and access management and user access control** for greater security

PROMOTING A CULTURE OF DATA INTEGRITY

We help our clients promote a culture of data integrity within the organization, significantly improving the adoption and success of the solution. This includes partnering with key stakeholders to ensure buy-in and adherence to the program, as well as educating teams on the solution's real-time alerting, case management workflow and dashboards for optimal use and transparency.

Reactive Data **Integrity Review**

Our expert team conducts comprehensive data integrity investigations of historical data – both electronic and paper-based, then creates and implements a remediation plan.

REACTIVE DATA INTEGRITY REVIEWS INCLUDES:

BUSINESS PROCESS AND SYSTEMS ANALYSIS

Understanding business processes, procedures, data flow and technical infrastructure of the company's IT and manufacturing equipment, as well as issue identified by regulators

DATA INTEGRITY ASSESSMENT

Identify weaknesses in the technical controls, gaps in the data and/or processes, and develop scenarios for testing potential future data integrity risk

DATA INTEGRITY ANALYTICS

Develop algorithms and test data integrity scenarios on historic data, identify anomalies and asses the risk

REMEDIATION AND RISK MANAGEMENT

Following the scenario test results, help the company to develop and execute a plan to remediate the risks and implement a go-forward plan to ensure future compliance

Data Integrity **Services at Work**

CASE STUDY

Proactive Data Integrity Review on Quality Control Lab Equipment

Situation: Given the increase in regulatory audits, a large pharmaceutical company wanted to proactively identify data integrity issues and build a continuous monitoring capability in its quality control lab.

Solution: Our expert team collaborated with the client to create an automated solution to identify the data integrity issues within the quality control laboratory equipment. The solution automated scripts of various complex scenarios to continuously monitor and identify data integrity gaps in near real-time. It then identified data anomalies, sent an email alert notification and maintained an audit trail.

Result: Our expertise gave the client an adaptable yet efficient way to analyze the data and monitor the user behavior activity on a continuous basis. The automated solution was implemented at the client network to cover all of the company's manufacturing facilities in one centralized, end-to-end data integrity review of its quality control laboratory.

CASE STUDY

CAPA Data Integrity Review

Situation: The FDA conducted an inspection at the quality control facilities of one of India's leading drug manufacturing companies. Finding compliance gaps, the FDA issued a warning letter that could potentially lead to harmful restrictions for the business.

Solution: The team of experts performed a forensic data integrity review on the electronic data of the quality control lab equipment's to identity anomalies in the laboratory testing data of the Chromatography System (CDS) and Non-Chromatography System (Non-CDS). Using forensic tools, the team identified instances of unauthorized data deletion and misutilization of the computerised system controls. The team extracted terabytes of data across different laboratory instruments using scripting techniques and constructed a consolidated database. Then, the team developed and ran complex data integrity scenarios, including experimenting with duplicate data and data manipulation.

Result: From the results of the scenario tests, the team developed new methodologies to correct the system's failures and go-forward processes for future compliance. The FTI Consulting team's comprehensive review and investigation of the issues enabled the client to put an effective Corrective and Preventive Action (CAPA) plan in response to the warning letter.

Why FTI Consulting **Is Uniquely Qualified**

PHARMA INDUSTRY EXPERTISE

Our global team has deep expertise within the pharmaceutical and medical devices industries. We combine this industry knowledge with a keen understanding of the legal and regulatory landscape, so solutions are on-point and follow defensible processes.

ADVANCED TECHNOLOGY

FTI Consulting can leverage the client's existing infrastructure and enhance it with leading-edge technology, including forensic tools, machine learning, artificial intelligence, visual analytics and robotics, to cost-effectively connect disparate data for critical business needs.

CRITICAL INSIGHTS

With the global team's deep expertise within legal, regulatory and compliance matters as well as within pharma and other highly regulated industries, our solutions cut through the noise to deliver what's important to the client organization, from uncovering hidden warning signs, monitoring risky activities to helping achieve software license compliance.

EXPERT TEAM

Because no two environments are the same, FTI Consulting's data scientists, forensic investigators and software developers combine to gather requirements, problem-solve and develop a wide variety of analytics solutions to deliver concrete improvements with demonstrable value for organizations.

CUSTOM SOLUTIONS

FTI Consulting can develop bespoke solutions that fit any environment. No matter the industry, existing IT infrastructure or client pain point, the FTI Consulting team delivers practical solutions to meet critical business challenges.

Amit Jaju
Senior Managing Director
Mobile: +91.98200.73695
Direct: +91.22.50365016
amit.jaju@fticonsulting.com

EXPERTS WITH IMPACT™

About FTI Consulting

FTI Consulting is an independent global business advisory firm dedicated to helping organizations manage change, mitigate risk and resolve disputes: financial, legal, operational, political & regulatory, reputational and transactional. FTI Consulting professionals, located in all major business centers throughout the world, work closely with clients to anticipate, illuminate and overcome complex business challenges and opportunities. For more information, visit www.fticonsulting.com and connect with us on Twitter (@FTIConsulting), Facebook and LinkedIn.

www.fticonsulting.com

©2018 FTI Consulting, Inc. All rights reserved.

12 11 18