

# Analyzing the state of Data Integrity Compliance in the Indian pharmaceutical industry

A survey by Fraud Investigation & Dispute Services



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# Introduction



Arpinder Singh



Rajiv Joshi

The pharmaceutical industry is currently one of the most dynamic industries in India. Its compliance structure is more complex, given that several regulatory watchdogs such as the Indian Food and Drug Administration, the United States Food and Drug Administration, the United Kingdom Medicines and Healthcare Products Regulatory Agency, and other regulators guard it. Currently, the pharmaceutical industry is grappling with various compliance challenges like never before – increased regulation, mergers and acquisitions, push toward harmonization and the endemic – data integrity concern.

Our country has also been subject to increasing inspections by global regulatory bodies in recent times. There has been an upsurge in enforcement actions taken by regulatory bodies for cases related to data integrity. This issue has tainted the pharmaceutical industry in India and has forced companies to rethink their methods of ensuring quality and compliance, and sustaining business.

In line with this, EY Fraud Investigation & Dispute Services team conducted a survey to study the state of data integrity compliance in the pharmaceutical industry in India. As the report details, our findings suggest that while most industry professionals are aware of Good Manufacturing Practices (GMP) guidelines, more than 30% had still received inspectional observations from regulators in the last three years.

We feel that there is a strong need for companies to realign their quality and manufacturing compliance framework in line with regulatory guidelines. Companies need to undertake regular data integrity assessments to identify potential gaps. This also applies to the growing contract manufacturing units and small and medium enterprises (SMEs), with both segments now keen to upgrade their computer systems and facilities to meet regulatory guidelines.

We would like to thank all the respondents and business leaders for their contributions, observations and insights without whom, this report would not have been as successful.

We hope this report will be a useful read for you and help in contributing to meaningful conversations within your organization, among senior executives, boards and other stakeholders.

Handwritten signature of Arpinder Singh in black ink.

**Arpinder Singh**  
Partner and National Leader  
Fraud Investigation & Dispute Services

Handwritten signature of Rajiv Joshi in black ink.

**Rajiv Joshi**  
Partner  
Fraud Investigation & Dispute Services

# Foreword



Ajaz S. Hussain

Integrity of data is the foundation upon which we make decisions of quality, safety and efficacy. When we use medicine at home or in a hospital it is very difficult to judge its quality. Many symptoms of diseases and side-effects from medicine can appear to be similar. Recording of data and information with integrity protects life. Without it we cannot differentiate between a counterfeit and authentic medicine.

Under the US laws and regulation making false claims and not following Current Good Manufacturing Practices (CGMPs) can be criminal offence. When a company is supplying medicines to the USA it has agreed to abide by US laws and regulations. Deviating from these - can cause the product to be considered Adulterated. Testing the product is not sufficient to remove this 'Adulteration' charge. Many do not understand why this is so. Take for example the failure incident which occurred in 2007; it is commonly referred to as the Heparin Disaster. In this incident, established testing methods did not detect the contaminant. More than 100 patients died and many more injured. Unfortunately, history reminds us of many similar incidents. How many such incidents are not detected - is always a serious concern in the minds of the regulators.

Following CGMPs, is a commitment, it saves lives. We make medicines - our first promise is - 'Do No Harm'. With our skills, awareness, and commitment to a culture of quality - we work to provide the 'healing touch' - Confidence and Authenticity. Our medicine must be better than placebos.

I am extremely happy that EY Fraud Investigation & Dispute Services has conducted a survey on a topical subject like data integrity. This survey should help to improve awareness of data integrity issues as these issues need attention. Awareness is the first step, and companies should reflect on this and consider what may be relevant to their situation. The most optimal approach to ensuring reliable compliance is to be proactive - a company's quality system can and should correct and improve; and not wait for a regulatory inspection.

I am confident that this message is being recognized by more and more leaders of the pharmaceutical industry. This survey is a reminder - a means to improve awareness and to communicate this important message.

For the past two years several pharmaceutical companies have requested my advice on how to strengthen their culture of quality. In most cases, unfortunately, such requests come following a serious CGMP deviations which is noted by inspectors from US FDA or other authorities. Lapses in the assurance of data integrity is one of the most serious deviation. Recovering the lost trust is very difficult. The path to recovery requires commitment to transparency and thorough analysis of the potential impact on patient safety, thorough investigation to get to the root cause, effective corrective actions and evidence that such observations will not repeat.

On several such assignments I have worked with EY - their expertise in auditing and data forensics provides the rigor and sufficiency needed to get to the root cause of data integrity issues. Their observations help client to evaluate CGMP relevance of observations they noted and to bring forward an effective plan for remediation. EY data forensics team is world renowned, with their assistance a company can identify, categorize and prioritize necessary corrections.

I congratulate EY on publishing such a relevant report and hope they continue to create awareness and share insights with more of these thought leaderships and initiatives.

Sincerely,

**Ajaz S. Hussain**

Ph.D., Founder Insight Advice & Solutions LLC. Frederick, MD, USA. Former Deputy Director, Office of Pharmaceutical Science, US FDA.

# Data integrity - Current landscape in India

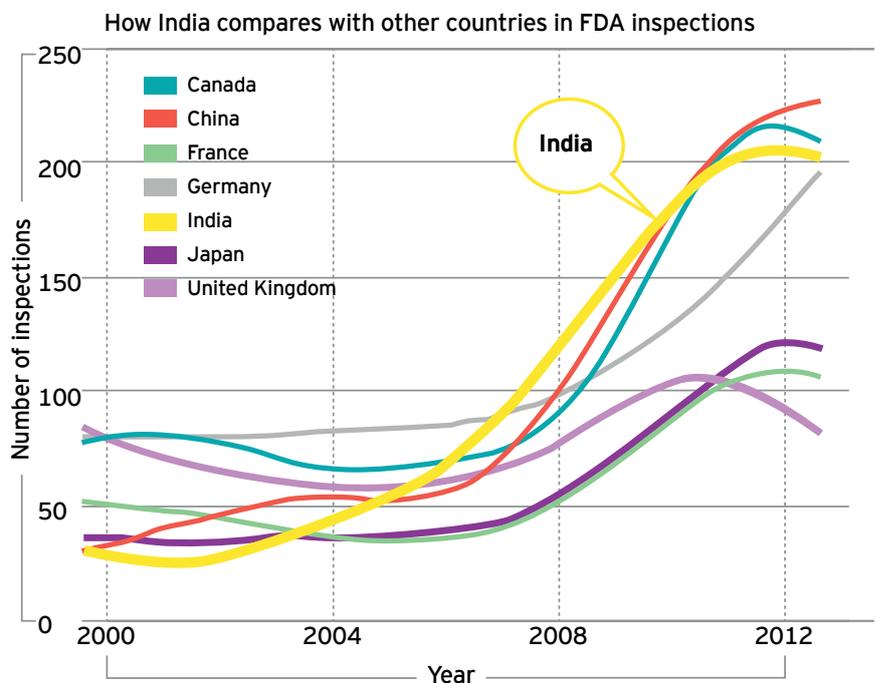
## Did you know?

The CDSCO has urged the Indian health ministry to release the US\$2.9 billion allocated to the department of pharmaceuticals under the Twelfth Five Year Plan, to strengthen its regulatory mechanism at the Central and State level regulatory bodies.<sup>4</sup>

Each consumer expects that drugs they consume to be safe and effective. To ensure this, regulatory bodies such as the United States Food and Drug Administration (US FDA), the United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA) and the Indian Food & Drug Administration (FDA) have set regulatory standards, typically referred to as Good Manufacturing Practices (GMP). GMP assures proper design, monitoring and control of manufacturing processes and facilities for various systems. This is supported by underlying data to trace manufacturing processes, which can prove evidence that the drugs have been manufactured as per agreed protocols.

According to the Indian Ministry of Commerce, India has the second-largest number of manufacturing facilities outside of the US (523 as of March 2014) registered with the US FDA.<sup>1</sup> Furthermore, India's drug exports to the US have risen from US\$1.25 billion in FY10 to US\$3.45 billion in FY14.<sup>2</sup> With the growing importance of the Indian pharmaceutical industry in the global market, the number of foreign regulatory inspections has also increased considerably. According to the US FDA Deputy Commissioner for Global Regulatory Operations and Policy, Mr. Howard Sklamberg, the increase in the number of inspections in India is a reflection of the increasing size of the Indian pharmaceutical industry.<sup>3</sup>

## The most watched nations in FDA inspections<sup>5</sup>



<sup>1</sup>"Impact of 2013 US FDA Actions on Indian Pharma", India Ratings and Research, May 2014, p. 3

<sup>2</sup>"USFDA plans to shift to an incentive based from a penalty based audits," Economic Times, 18 March 2015, via Factiva, © 2015 Bennett, Coleman & Co. Ltd.

<sup>3</sup>"Indian companies not singled out for inspections, says USFDA," Economic Times, 18 March 2015, via Factiva, © 2015 Bennett, Coleman & Co. Ltd.

<sup>4</sup>"CDSCO asks health ministry to release Rs. 1600 cr under 12th Plan for strengthening regulatory apparatus," 4 April 2015, Pharmabiz.com, via Factiva, © 2015 Saffron Media Pvt. Ltd

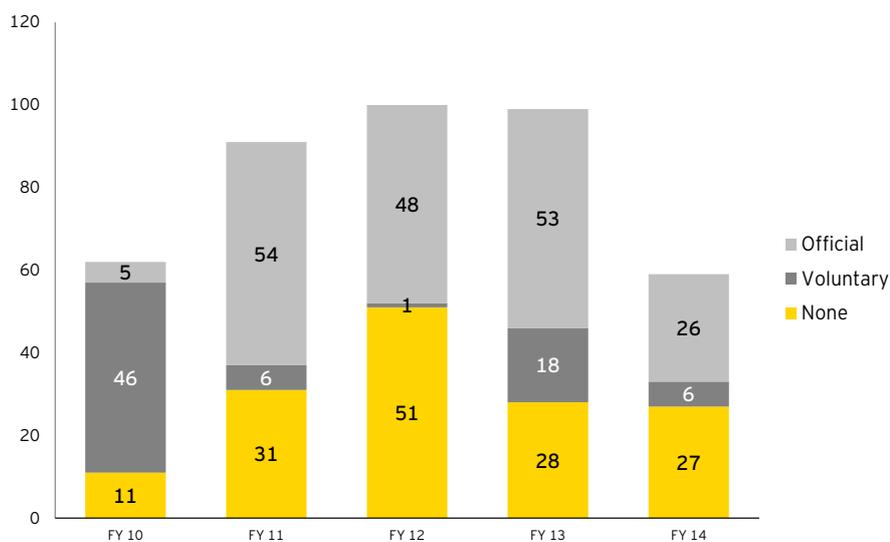
<sup>5</sup>"Intensive Score," Business Today, 16 March 2014, p.51.

<sup>6</sup>"USFDA's warning letters reason to worry for Indian drug makers," Business Today, 3 February 2015, via Factiva, © 2015 Living Media India Limited

At the same time, the increase in foreign regulatory inspections has marred the image of the Indian pharmaceutical industry, with 8 out of the 19 US FDA warning letters issued to companies in India in 2014.<sup>6</sup>



## FDA inspections on Indian pharmaceutical industries<sup>7</sup>



Note: FDA's fiscal year ends on 30 September. None = no inspection found or very minor inspections, voluntary means violations found but regulatory action not recommended and official means regulatory action has been recommended.

There has been a subsequent rise in inspections by local regulatory bodies in India. In December 2014, Maharashtra FDA inspected more than 50 facilities to assess compliance with GMP requirements. It has been reported that representatives of the State FDA have identified 250 companies certified by the Central Drugs Standards Control Organisation (CDSCO) for conducting surprise checks.<sup>8</sup>

The US FDA has invited Indian officials, both at Central and State Government levels, to accompany its team while inspecting pharmaceutical units within the country. This will help Indian regulators mature with respect to conducting inspections, liaise with international regulators, and communicate GMP compliance expectations of international regulators to the Indian pharmaceutical industry.

## Case study

### Repercussions of GMP non-compliance

A leading company received a warning letter from a regulator for one of its plants. Soon after, inspections were conducted on other plants owned by the company. The result was the issuance of another warning letter for CGMP non-compliance to the company.

An import alert was issued on select sites after the company failed to implement corrective measures satisfactory to the regulator. The approval of pending Abbreviated New Drug Applications (ANDAs) was also jeopardized, thereby weakening its future business estimates. Other domestic and international regulators also followed suit, and eventually the company's drugs were recalled from multiple nations.

<sup>7</sup>"Drug firms remain in US FDA cross hairs," Mint, 30 March 2015, via Factiva, © 2015 HT Media

<sup>8</sup>"Pharmexcil to meet Maharashtra State FDA commissioner on Dec 11 Pharmexcil to meet Maharashtra State FDA commissioner on Dec 11," Express Pharma, 5 December 2015, via Factiva, © 2014 The Indian Express Limited

# Violations of GMP

## Did you know?

Import alerts issued against Indian plants in 2013 accounted for 49% of the total 43 imports alerts issued by the US FDA worldwide.<sup>9</sup>

Most regulatory bodies such as the US FDA, the UK MHRA, the India FDA and others conduct inspections on pharmaceutical manufacturing sites or facilities to check if they comply with the defined GMP standards. Inspection observations such as Form 483 are issued if the drug is manufactured under conditions that are non-compliant with GMP standards. If a manufacturer fails to take satisfactory corrective action, the company may be hit by a warning letter, import alert, or any other regulatory action. These regulatory actions not only impact the revenue stream of the company, but also affect the drug maker's ability to get approval for new drug applications.

### Probable Implications of violating GMPs

-  **Business loss** >> Issuance of warning letters can lead to product recalls or import alerts, as well as a fall in the stock prices of listed companies
-  **Reputational damage** >> List of companies violating guidelines are posted on a regulator's website, making the information publicly available, which can be further picked up by the media, thereby tarnishing the company's reputation
-  **Regulatory influence** >> Additional inspections can be carried by other regulatory bodies or customers tarnishing the company's reputation
-  **Competitive disadvantage** >> Competitors can leverage this opportunity to enhance their market share
-  **Diversion to remediation and increase in attrition rate** >> Diversion of management and employees' attention from their daily activities, to focus on Corrective Action and Preventive Actions. The lengthy remediation process tends to cost time, money and often loss of talent



<sup>9</sup> "Impact of 2013 US FDA Actions on Indian Pharma," India Ratings and Research, May 2014, p. 3



## Warning letter extract<sup>10</sup>

“There was incomplete raw data to support the test method validation/ verification activities for the test methods used for your APIs.”

“Our investigators identified calibration and media preparation records that were not authentic in that the persons that signed each record as having performed the activity were not at work on the day the work was accomplished.”

“Our investigators found that laboratory analysts did not document the balance weights at the time of sample weighing. Specifically, sample weights used in calculations were created after the chromatographic runs. The analyst admitted that the sample weights that were represented as raw data from the analysis actually were backdated balance weight printouts produced after the analysis and generated for the notebooks. These sample weights were used to calculate related compounds and impurities used in support of method validations submitted in FDA drug applications.”

Q: Do your employees have a sign off to confirm their understanding and compliance with cGXP such as current good manufacturing practices (CGMPs) and current good laboratory practices (cGLPs)?



Q: In the last three years, has your organization received any letter from a regulatory body entailing their observations from their inspection of your facility (e.g. Form 483, Warning letter)?



The survey states that although **87%** respondents signed off their understanding and compliance with GMP norms, it was noted that **30%** still responded to have received inspection observations from a regulatory body over the last three years. This could raise questions on the effective implementation of GMP norms. It is also critical to understand if prevalent GMPs in the companies are effective enough to have invited inspectional observations by these regulatory bodies.

<sup>10</sup> US FDA, Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters, 2014

# Getting a stamp of reliability through data integrity

## Did you know?

Karnataka Drug Controller mandated companies to adhere to data integrity as prescribed in Schedule L1 of the Drugs & Cosmetic Rule 1945.

“US FDA has been noticing that especially with Indian companies, it did not rely on their capability to resolve the data integrity problems without external support. Now it expects Indian pharma to seek the expertise of third party auditors and consultants to resolve data integrity issues and ensure total compliance.”<sup>13</sup>

Manufacturing drugs for patient well-being is the most important responsibility of a pharma company; and so is maintaining data to ensure traceability of a batch to its origin. Data integrity asserts that data records are accurate, complete, attributable, legible, and intact and maintained within their original context, including their relationship to secondary data records. This definition applies to the data recorded in electronic and paper formats or a hybrid of both.

Considering that raw data acts as an evidence that drugs are safe, efficacious and manufactured as per appropriate quality standards required, violation of data integrity is considered to be grave by leading regulators such as the US FDA, the UK MHRA, Health Canada, Therapeutic Drugs Administration (TGA) and the Indian FDA, all of which mandate data integrity.

Recently, the drug controller in Karnataka, a state in Southern India has insisted on pharmaceutical companies in India adhering to data integrity and security mandated in Schedule L1 of the Drug & Cosmetic Rule 1945.<sup>11</sup> In March 2015, the UK MHRA released a fresh guidance document stating their expectations from companies on data integrity.<sup>12</sup> In fact, the US FDA, in its warning letter to companies, typically recommends that the company undertake comprehensive and global assessment measures and hire a third party auditor experienced in detecting data integrity problems. Hiring a third party auditor provides greater assurance to the agency of the independence and reliability of findings. These expectations of regulators highlight the growing criticality of data integrity.

**Q: To address the data integrity observations, has your organization done an audit or a review to assess potential gaps in assurance of data integrity?**



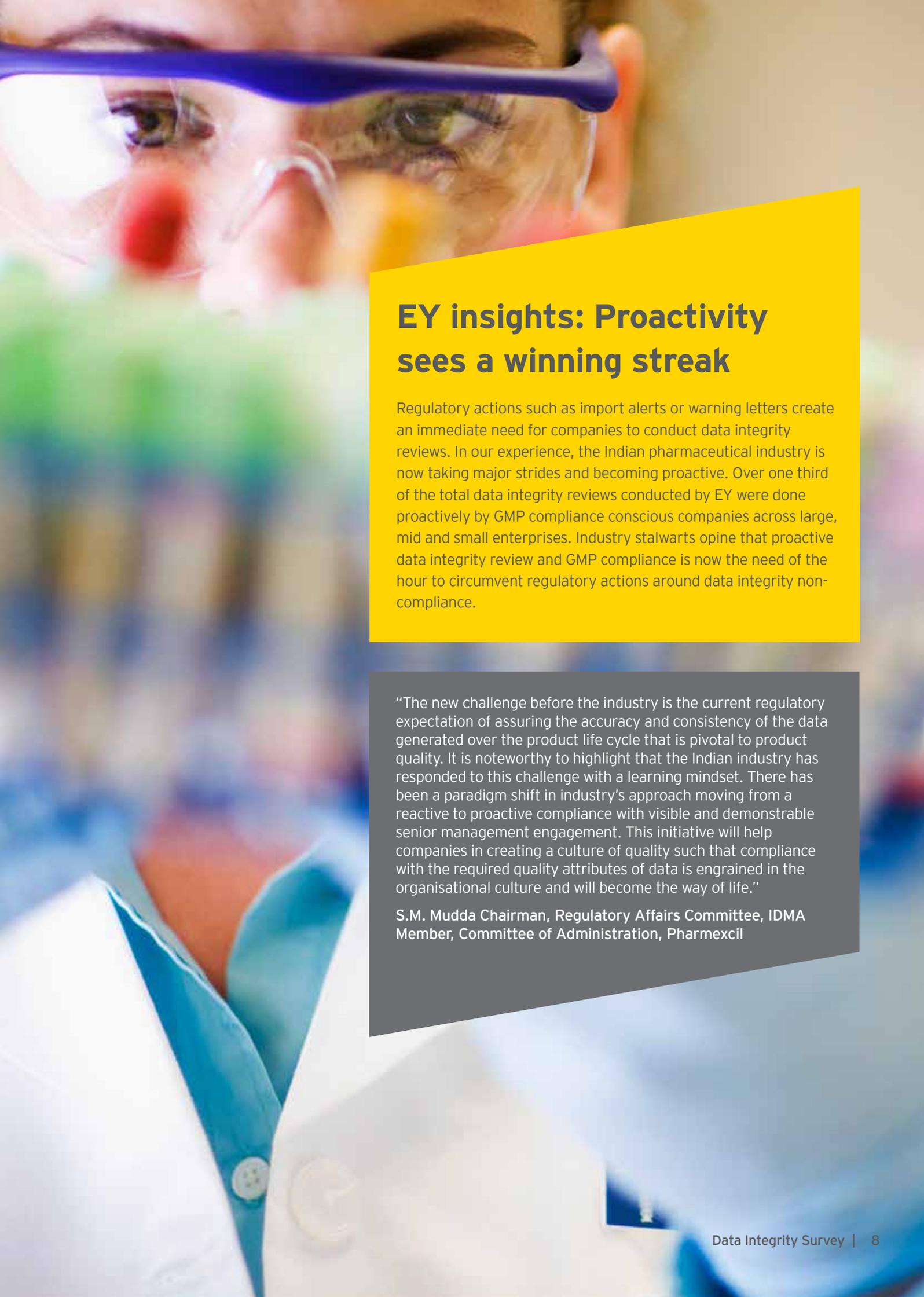
67%

**67%** respondents have conducted an audit or a review to assess potential gaps in the assurance of data integrity, while **33%** have not conducted a data integrity review.

<sup>11</sup> “Karnataka DC insists on adherence to Para 15 C of Sch L1 in D&C Rule for data integrity compliance,” 20 January 2015, Pharmabiz.com, via Factiva, © 2015 Saffron Media Pvt. Ltd

<sup>12</sup> “MHRA issues GMP data integrity definitions & guidance document for pharma cos,” 31 January 2015, Pharmabiz.com, via Factiva, © 2015 Saffron Media Pvt. Ltd

<sup>13</sup> “US FDA expects Indian pharma to seek third party audits to resolve data integrity issues”, 23 March 2015, Pharmabiz.com, via Factiva, © 2015 Saffron Media Pvt. Ltd



## EY insights: Proactivity sees a winning streak

Regulatory actions such as import alerts or warning letters create an immediate need for companies to conduct data integrity reviews. In our experience, the Indian pharmaceutical industry is now taking major strides and becoming proactive. Over one third of the total data integrity reviews conducted by EY were done proactively by GMP compliance conscious companies across large, mid and small enterprises. Industry stalwarts opine that proactive data integrity review and GMP compliance is now the need of the hour to circumvent regulatory actions around data integrity non-compliance.

“The new challenge before the industry is the current regulatory expectation of assuring the accuracy and consistency of the data generated over the product life cycle that is pivotal to product quality. It is noteworthy to highlight that the Indian industry has responded to this challenge with a learning mindset. There has been a paradigm shift in industry’s approach moving from a reactive to proactive compliance with visible and demonstrable senior management engagement. This initiative will help companies in creating a culture of quality such that compliance with the required quality attributes of data is engrained in the organisational culture and will become the way of life.”

**S.M. Mudda** Chairman, Regulatory Affairs Committee, IDMA  
Member, Committee of Administration, Pharmexcil

### Did you know?

The UK MHRA recently released guidance in March 2015 emphasising on data integrity.

Q: Is there work pressure on the manufacturing personnel to meet Key Performance Indicators (KPI) such as volume of output, low rejection ratio, overall equipment effectiveness?



Our survey indicated that over **57%** of the employees agreed to have seen work pressure on the manufacturing personnel to meet Key Performance Indicators such as volume of output, low rejection ratio, overall equipment effectiveness.

### Warning letter extract<sup>14</sup>

"Your firm lacked accurate raw laboratory data records for API batches shipped by your firm. The inspection revealed that batch samples were retested until acceptable results were obtained. In addition, your quality control (QC) laboratory failed to include complete data on QC testing sheets. Failing or otherwise atypical results were not included in the official laboratory control records, not reported, and not investigated."

Q: Does your organization have a clearly documented Standards Operation Procedures (SOP) on backup and Deletion of Laboratory data such as files generated by HPLC/GC/UV/IR?



**13%** do not have clearly documented Standards Operation Procedures (SOP) on backup and Deletion of Laboratory data such as files generated by HPLC/GC/UV/IR.

Q: Is Quality Assurance (QA) adequately staffed to witness and review the manufacturing and testing of all the products independently?



**18%** do not have adequately staffed to witness and review the manufacturing and testing of all the products independently.

<sup>14</sup> US FDA, Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters, 2014

## Key root causes of data integrity issues as per EY's experience:

**Shortage of manpower:** Shortage of staff and excessive work pressure can lead to inaccurate and incomplete documentation.

**Quantity over quality:** Employees may be forced to compromise the acceptable quality levels in order to meet production targets or dispatch timelines.

**Lack of awareness:** Often, employees are not trained or inadequately trained to understand GMPs. This causes employees to consider activities as a chore rather than understanding their relevance in light of GMP.

**Effectiveness of trainings:** While the company may hire the best international trainers, employees mentioned that there were language and accent barriers, which prevented the employees from understanding the content, thereby making the training redundant.

# Requirements under 21 CFR Part 11

## Did you know?

- ▶ The UK MHRA stated in the guidance note dated March 2015, that companies should focus on the lab when examining the data integrity of contract manufacturers as most of them reintegrate the data to save time and money.
- ▶ The guidance note also directs that full retention of audit trails should be implemented to show all the changes made to the data from previous to original. The details of the person making the changes should be recorded with the time and reason.

A company's standard operating procedures (SOPs) describes how processes are to be performed while manufacturing a particular drug or formulation. During implementation of these processes, the US FDA registered company needs to comply with Title 21 of the Code of Federal Regulations (CFR) - Part 11, commonly known as "21 CFR 11". 21 CFR Part 11 establishes the criteria under which electronic records and signatures are stored and is considered trustworthy, reliable and equivalent to paper records by the US FDA.

According to the US FDA 21 CFR 11.10e, "Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period of at least as long as that required for the subject electronic records and shall be available for agency review and copying." This indicates US FDA's expectation that audit trails are enabled.

Q: Are you aware of 21 Code of Federal Regulations (CFR) Part 11 compliance requirements?

Q: Are audit trails on laboratory equipment always enabled in your organization?



25%

**25%** of the respondents indicated that they were not aware of 21 CFR Part 11 compliance requirements.



21%

**21%** stated that audit trails on lab equipment are not always enabled in their organizations.

## Case study

### Advantage - Proactive review

A pharmaceutical major approached EY to conduct a proactive data integrity assessment at multiple sites. The scope was focused on the review of data associated with laboratory testing, such as test data of High Performance Liquid Chromatography (HPLC), Gas Chromatography.

Basis on the extensive forensic data analysis exercise, EY managed to pull out data files that were deleted, re-processed, re-run, and potential trial runs. The company is now investigating and assessing the root cause of the improper data files, and putting Corrective Action and Preventive Action (CAPA) in place.



Q: Are the employee login ids and passwords for laboratory systems such as HPLC, GC's shared in your organizations?

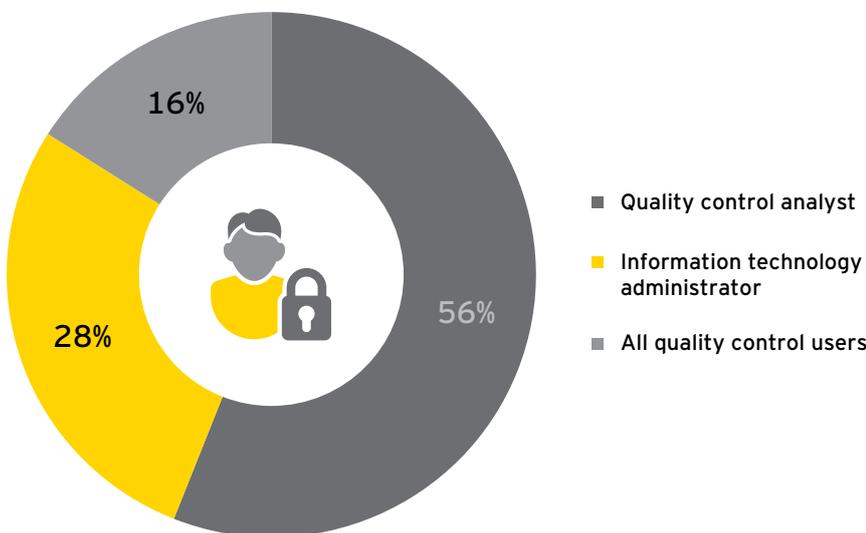


33% mentioned to have shared employee login ids and passwords for laboratory systems such as HPLC, GCs. These numbers indicate that organizations still need to make a significant headway in terms of being compliant with 21 CFR 11 standards.

It is important that the management pays more attention to these requirements, as failure to do so can invite regulatory and/or penal actions on the company.

“Good manufacturing practice (GMP) deviations detected during inspections related to electronic data submissions was elementary and urgently recommended companies to get a third party auditor or pharma consultant. These experts could first perform an in-depth GMP review and ensure data integrity deficits are removed.”<sup>15</sup>

Q: Who has administration rights for laboratory systems such as HPLC, GC's. in your organization?



Nearly 72% users in the quality control department have IT administration rights for laboratory systems such as HPLC, GC.

### Warning letter extract<sup>16</sup>

“Your firm did not have proper controls in place to prevent the unauthorized manipulation of your electronic raw data.”

“There was no written explanation for deletion events observed on audit trails for your standalone HPLC units.”

“Our investigators identified the practice of performing trial injections for HPLC analyses prior to running the release and stability tests that are then reported.”

<sup>15</sup> US FDA, Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters, February 2014

<sup>16</sup> US FDA, Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters, 2014

# Whistle-blowing, the next big wave

## Case study

### A bounty-ful reward

An employee of a leading company blew the whistle on the company's questionable manufacturing practices. This was corroborated by providing evidence to the regulatory authorities on the company falsifying drug data and violating good manufacturing practices. The investigation resulted in the drug maker pleading guilty to the wrongdoing and paying a hefty sum in settlement. The whistle-blower was awarded a significant sum from the regulator.

Over the last few years, corporate India has seen the rise of a new kind of crusader - the whistle-blower. These champions have tried to uncover many corporate scams related to financial fraud, bribery and corruption. In the pharmaceutical sector, there have been instances when issues around drug adulteration and misrepresentation have been unearthed due to whistle blowing. With the growing maturity of global regulations, protection offered to whistle-blowers and the possibility of being awarded bounties, the revolution of whistle-blowing has gained significant momentum.

## Reviewing the legalities

### India

The Companies Act 2013 has made it mandatory for listed companies or such class of companies to establish vigil mechanisms for their directors and employees, in order to report genuine concerns in the recommended manner. Clause 49 of the SEBI listing agreement also lays down similar provisions.

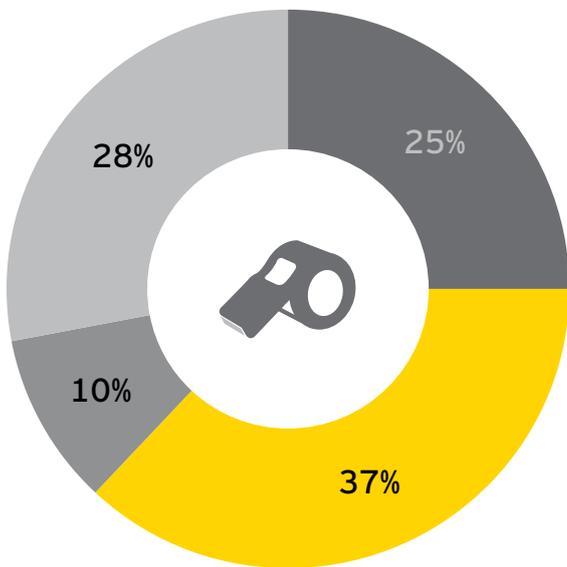
Since drugs relate to patient safety, a sensitive subject, the CDSCO has devised a reward scheme for blowing the whistle on spurious or fake drugs.

### USA

Under the Dodd-Frank Wall Street and the False Claims Act, an individual with knowledge of fraud committed by a business may blow the whistle to defined regulatory bodies. If the claim is proven valid, the whistle-blower is entitled to a percentage, or "bounty", of the sum recovered. Additionally, the Department of Justice (DoJ) has enforced CGMP violations under the False Claims Act.



Q: Does your organization have a whistle-blowing mechanism to report and investigate quality concerns, if any?



- My organisation has a whistle-blowing policy
- My organisation has a whistle-blowing policy and a mechanism
- My organisation has a whistle-blowing policy and a mechanism outsourced to a third party service provider
- My organisation does not have a formal whistle-blowing policy

### Did you know?

- ▶ The CDSCO has implemented a reward scheme for individuals who report companies manufacturing fake or spurious drugs.
- ▶ Association of Certified Fraud Examiners reports that whistle-blowing is the most powerful method of identifying fraud in organizations.

## Whistle-blowing, a salvage opportunity

Our survey revealed that while **47%** of the respondents had whistleblowing policies and mechanisms implemented internally, **28%** indicated that their organizations did not have such frameworks in place. This means that while a lot of the stakeholders may genuinely want to help companies by flagging any unethical acts or wrongdoing, the lack of whistle blowing mechanisms offered by the companies could force them to report the potential fraud externally.

In fact, there has been an uptick in whistle blowing complaints in India over the last two years. According to the last released data from the Central Vigilance Commission (CVC), India received close to 450 complaints in just the first half of 2014, while the annual number stood at 698 complaints in 2013.<sup>17</sup>

<sup>17</sup>"More disclosures of corruption in the govt?," Hindustan Times, 10 August 2014, via Factiva, © 2015 HT Media Limited

## Looking ahead

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“Running away from any problem only increases the distance from the solution. The easiest way to escape from the problem is to solve it.

I believe and practice the above statement. With the huge opportunity and growth potential that the pharmaceutical contract manufacturing space has in India, I think the time has come for the industry to become more proactive by doing detailed data integrity self-assessments.

Proactiveness comes with faith, courage and commitment to the cause, giving the entire initiative a positive energy, whereas reactivity is driven by fear. Support this proactiveness with apt training to employees, technology upgradation, continuous monitoring reviews, and this will lay the foundation for creating and sustaining the highest level of quality and regulatory compliance by any company. “

**Mehul Shah,**  
Head - Contract Manufacturing,  
Indian Drug Manufacturer's  
Association (IDMA)

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### Proactive approach to quality and compliance

With Government of India's focus on the “Make in India” initiative, and commitment to battling fraud and corruption, the pharmaceutical industry is being very closely watched to recoup and lead the initiative. The government is more vigilant and is emphasising on GMP compliance guidelines set by global, central and state regulators. While the pharmaceutical industry is committed to gearing up on quality and compliance, the remedy for the industry now is to get more proactive in its quality compliance drives. The same can be done by **adopting regular internal and external data integrity assessments to identify gaps if any, such as to identify if laboratory test data files have been deleted outside of routine archiving process, monitor data to identify potential trial runs, re-processed files and use of common or shared login id and password.** The company is to then divulge into the root cause of these issues and address the gaps without camouflaging or hiding facts, as data integrity essentially is, “do as you say, and say as you do.”

In fact, even companies with a good track record with regulators and regardless of the existing or anticipated GMP compliance concerns should initiate periodical proactive data integrity assessments to assess their current state of quality compliance. This not only acts as self-assurance, but may also provide comfort to regulators, customers, investors on the management's commitment to quality and compliance.

### Harmonization, the bridge to inclusive growth

Countries are now evolving their individual regulatory frameworks so that they are closely aligned to global standards. Harmonization of regulatory standards will help companies improve efficiency by following a single guidance note or dossier. As such, regulators from the western world are typically seen to lead the way, and hence, compliance with requirements such as 21 CFR Part 11, data integrity, will soon be minimal compliance requirements for the Indian pharmaceutical industry to abide by.

It is then imperative that the Indian pharmaceutical industry do more sooner than later on compliance with **essentials of 21 CFR 11, such as enable audit trail of laboratory systems, respect unique user id and password at all times, ensure administration rights are with the right people and department, that computer systems are validated** and so on. Having an integrated periodical proactive data integrity assessment program, accompanied by upgraded computer systems in line with 21 CFR 11, will not only aid the progress of Indian pharmaceutical companies but also improve the industry's tarnished image.

## Survey methodology

This report is based on the responses received from over 170 respondents from the Pharmaceutical Industry in India during the period January-March 2015. The principal respondents were from Business Management, Corporate quality, and Legal and Compliance domains. They represented a mix of active pharmaceutical ingredients, formulations excipients and others supplying domestically as well as exporting to countries such as the USA, Europe, Japan, Australia, etc.

In addition to the survey results, the report also includes the case studies and insights which are based on EY's experience over a period of time, views of industry personnel and the recent incidents reported in news.

Note: Not all questions were answered by all respondents; hence the total percentage is derived bases the total number of responses received for each question.

# About EY Fraud Investigation & Dispute Services

## Our services

- ▶ Anti-fraud and fraud risk assessment
- ▶ Fraud Investigation
- ▶ Anti-bribery and Anti-corruption Compliance Services
- ▶ Dispute Advisory Services
- ▶ Data Integrity Reviews
- ▶ Competition and Trade Services
- ▶ Ethics and Integrity Due Diligence
- ▶ Third-party Due Diligence
- ▶ Whistle-blowing Services
- ▶ Supply Chain Compliance
- ▶ Forensic Technology & Discovery Services
  - ▶ Computer forensics
  - ▶ Forensic Data Analytics
  - ▶ e-Discovery
  - ▶ Software License and Forensic Disputes Services
  - ▶ Cybercrime Investigation and Intelligence Services

Dealing with complex issues of fraud, regulatory compliance and business disputes can detract from your efforts to achieve your company's potential. Enhanced management of fraud risk and compliance is a critical business priority – whatever the industry sector. With our more than 2,000 fraud investigation and dispute professionals around the world, we will assemble the right multi-disciplinary and culturally aligned team to work with you and your legal advisors. In addition, we will provide you the benefit of our broad sector experience, our deep subject matter knowledge and the latest insights from our global activities.

## FIDS India

- ▶ **Deep competencies:** Our FIDS team has specific domain knowledge along with wide industry experience.
- ▶ **Forensic technology:** We use sophisticated tools and established forensic techniques to provide requisite services to address individual client challenges.
- ▶ **Global exposure:** Our team members have been trained on international engagements and have had global exposure to fraud scenarios.
- ▶ **Market intelligence:** We have dedicated field professionals, who are specifically experienced and trained in corporate intelligence, and are capable of conducting extensive market intelligence and background studies on various subjects, industries, companies and people.
- ▶ **Thought leadership:** We serve a variety of leading clients, which gives us deep insight into a wide range of issues affecting our clients and business globally.
- ▶ **Qualified professionals:** We have a qualified and experienced mix of Chartered Accountants, Certified Fraud Examiners, Lawyers, CIAs, CISAs, engineers, MBAs and Forensic Computer Professionals.

# EY Offices

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+ 91 80 6727 5000  
Fax: + 91 80 2210 6000 (12th floor)  
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Off Western Express Highway  
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Near DLF Golf Course  
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