Data integrity inspections: Fear of the unknown

Risk Consulting

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Introduction

With stricter compliance mandates set by the global food and drug regulators, the pharmaceutical industry faces intense pressure to meet regulatory expectations on product quality and compliance norms.

Regulators such as the U.S. Food and Drugs Administration (U.S. FDA), U.K. Medicines and Healthcare Products Regulatory Agency (U.K. MHRA), Health Canada, World Health Organization (WHO) and Drug Controller General of India (DCGI) cite growing concerns around 'data integrity' non-compliance globally. Any data compromise is perceived as a risk to patient safety. Therefore, it needs to be investigated thoroughly for future rollout.

Do you fear the unknown?

As a Promoter, CXO or a leader heading the quality function of an organisation, if one or more of the following are major concern areas in your manufacturing plant, it is time to act.

While this graphic contains an indicative list of what might singularly or collectively lead to observations by regulators, there is an untouched bucket of susceptible areas under the function of quality assurance that your organisation may be exposed to.

As part of your organisation's management, do you perceive that your 'position of knowledge' can help you deliver quality products and help ensure that your organisation is not impacted by data integrity challenges? It is vital that you protect your organisation against significant risks that may exist, by adopting an effective data integrity review approach.

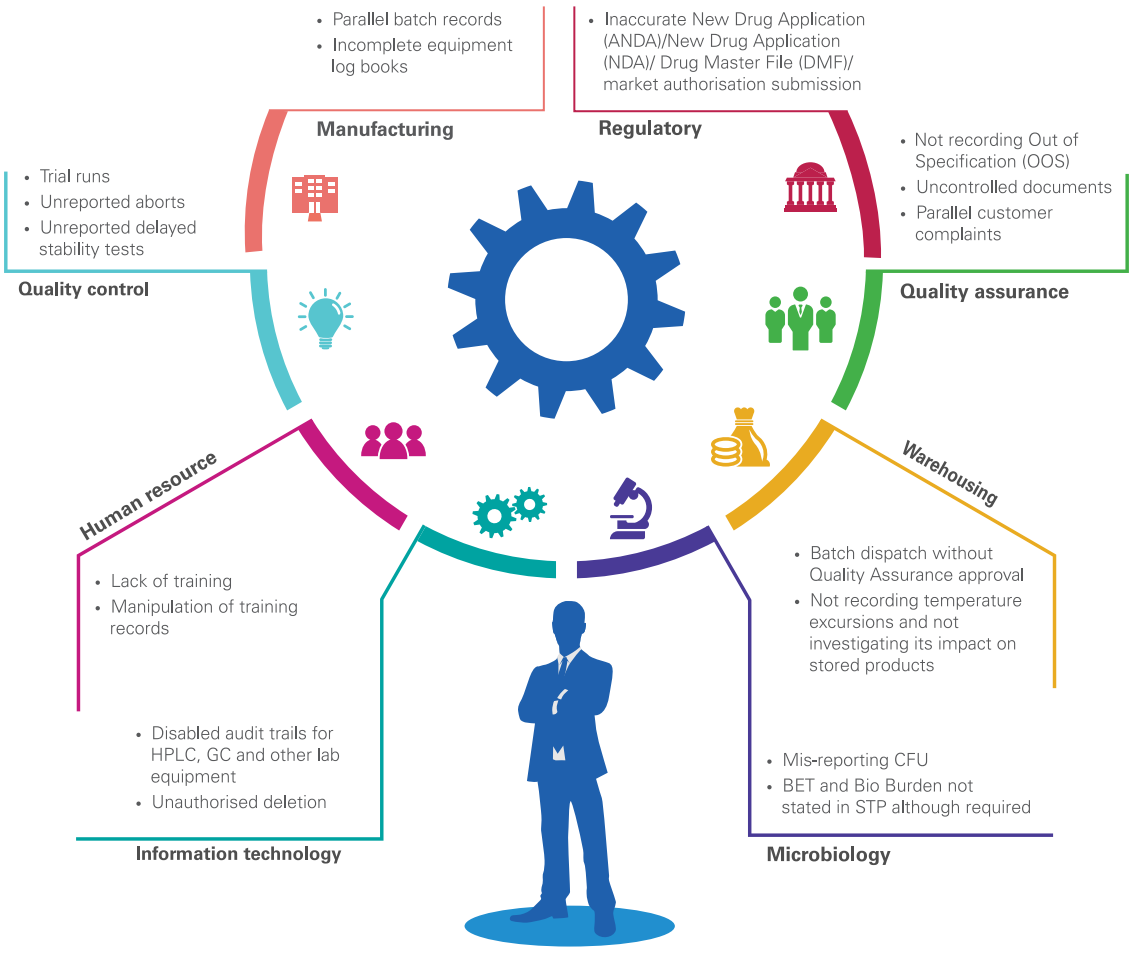


Illustration of KPMG in India's observation of key/typical data integrity observations

Impact of non-compliance to data integrity

A great incentive to give importance to data integrity compliance is the potential risk that non- compliance brings upon the organisation. Depicted below are some indicative perils which should not be ignored.

One of the biggest risks of over looking data integrity is compromising with patient's safety and lives, which is an irreparable damage.

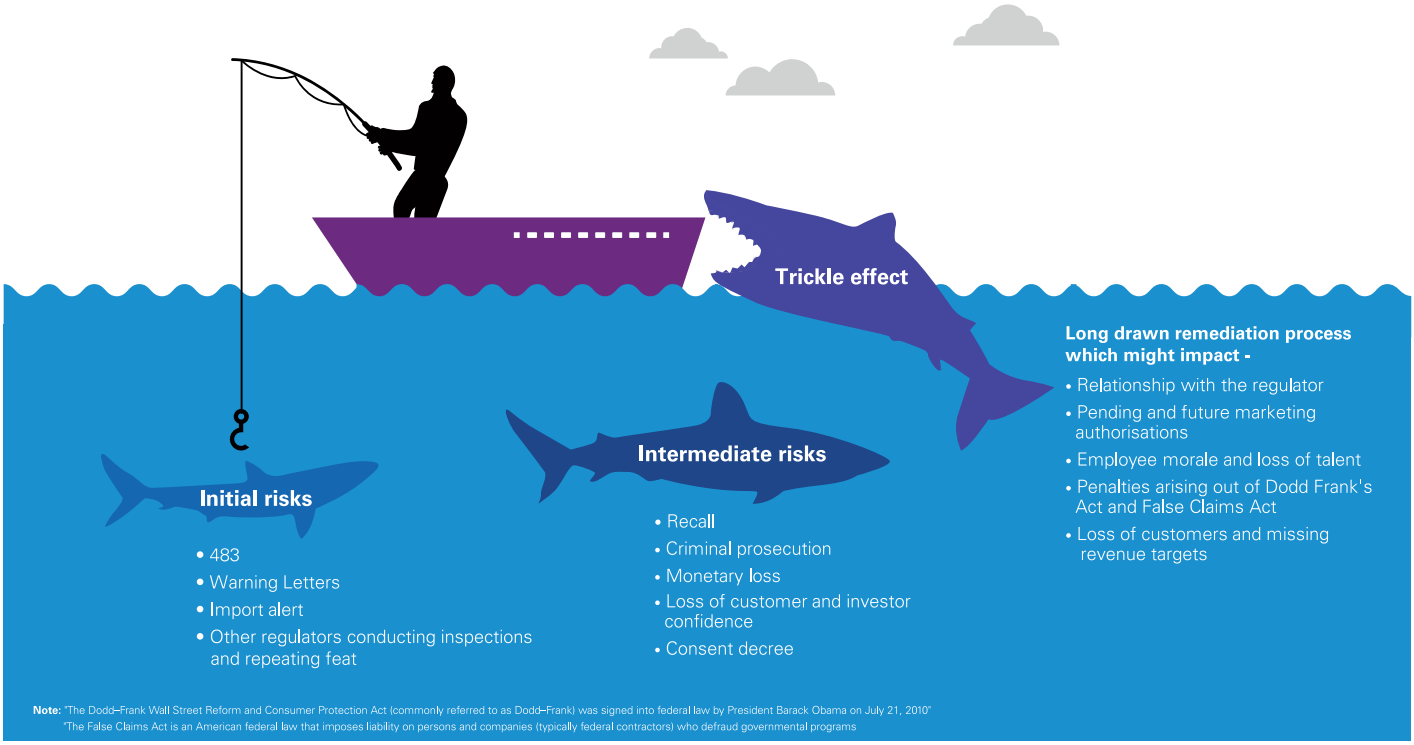


Illustration of KPMG in India's depiction of typical risks of non-compliance to data integrity that a company may face

'It did not happen if it was not documented' is the stand many taken by many regulators. Recent interviews news articles point towards a rise in inspections in India and China on Good Manufacturing Practices (GMP) and data integrity. More than 200 warning letters were issued by the U.S. FDA in 2014 through 2015[1] to organisations, including those in India. From administrative actions, these have escalated into enforcement actions (such as warning letters, Form 483 observations, civil judicial actions, product recalls, seizures, consent decrees, civil penalties and possible criminal prosecution.)

Our Electronic Good Manufacturing Practices (e-GMP) approach

India has the second highest number of the U.S.[2] FDA approved sites outside the U.S. There is a well-adopted approach to inspections, which is an eye-opener for many in the industry. This approach is now being explored by regulators of several countries and the result of this goes beyond sales. Resolving cases of breach of data integrity is an enormous task and takes months of dedicated staff, consultants and voluminous records of information.

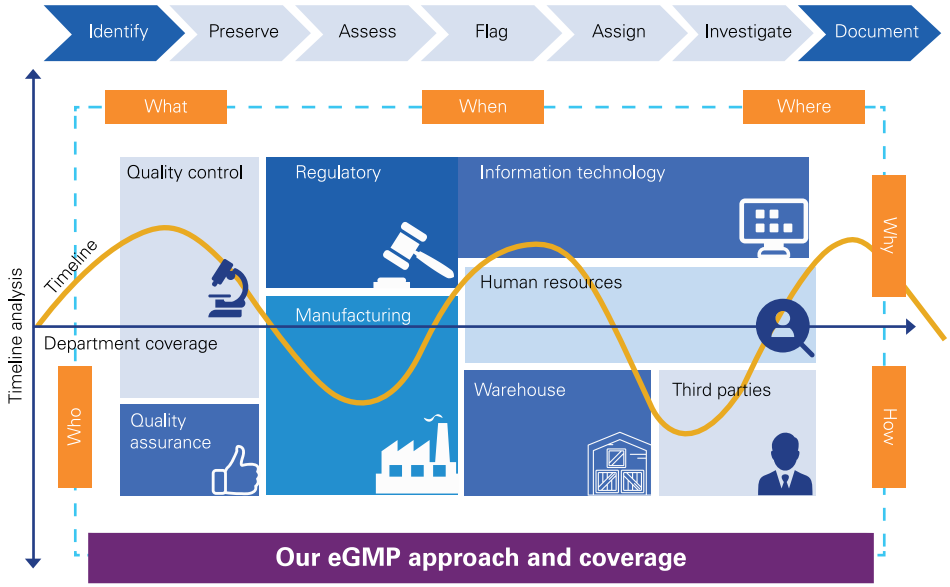
Based on our in-depth knowledge and experience we have developed a detailed approach:

- Our approach encompasses **pre-emptive and reactive measures** to be adopted by clients in the pharmaceutical sector. It involves running diagnostics not only in the impacted manufacturing plant, but **across an organisations plants around the world**
- Has distinctive, **technology-centric approach that uses algorithms** to help organisations identify potential deviations in the data-intensive quality control laboratory
- Is a customised, algorithm driven tool that evolves in accuracy as we understand your IT network environment and quality control processes. The result is a focused group of injections that fall positive on potential deviations such as trial runs, reprocessed injections, deleted injections, aborts. These aspects are the current focus

1. http://www.fda.gov/
2. http://archive.indianexpress.com/news/despite-ranbaxy-laboratories-others-indias-usfda-record-better-than-most-others/1172703/

areas of leading regulators across the Americas, Europe, Canada, Australia, and the WHO

- Provides an inside view to laboratory data across tests, instruments, users and department within a plant and across plants. This approach helps in retrospective analysis of issues and future projections on compliance.

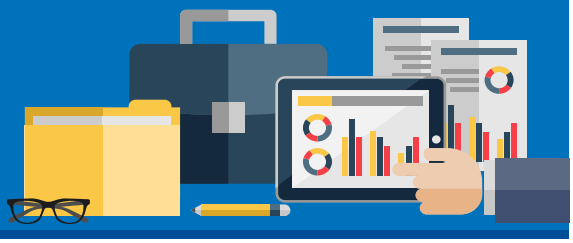


An organisation which takes an initiative to address potential data integrity issues represents the management's commitment to –

A. Safety

B. Quality and compliance

C. Responsibilty to customers, employees, business partners, regulators and shareholders.



Key differentiators

- **Data integrity investigation experience:** The team has experience in working across Active Pharmaceutical Ingredients (API), oral solids, injectable, topical, excipients and the team's work in the past has helped clients put an effective Corrective Action Preventive Action (CAPA) in place in response to Form 483, warning letter, statement of non-compliance, import alert etc.
- **Dedicated and trained resources:** Our team comprises of forensic professionals from varied backgrounds, including former law enforcement officials, former-police officers, former-CBI officials, certified fraud examiners, chartered accountants, management professionals with in depth experience in the Life Science sector, business ethics professionals, technology professionals and analysts. They are supported by our on-site investigation team that verifies facts in person, thereby increasing the credibility of our services.
- **Vast experience:** We have investigated over 1300 cases of economic crime of various kinds including some of the most high profile cases featured in leading financial dailies. We have sector-specific experience across multinational/ domestic firms and regulators.
- **Technology-backed approach:** We can produce accurate and objective reports with fast turnaround time, by using proprietary technology tools. Our dedicated forensic technology laboratory can mine and analyse large volumes of data in paper and electronic formats in minutes and effectively support on-site investigations.

Our service offerings

We offer a host of other forensic services to help life science companies prevent, detect and respond to fraud.

Forensic service:
Life sciences service proposition

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