Data integrity inspections: Fear of the unknown

Risk Consulting

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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.

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.

Management’s position of knowledge?

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

‘It did not happen if it was not documented’ is the stand many taken by many regulators. Recent interviews and 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 20151 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.)

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/

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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 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.

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. Responsibility to customers, employees, business partners, regulators and shareholders.

Key differentiators
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**

[Diagram showing various forensic service offerings for life sciences, including:
- Financial statement misappropriation
- Embezzlement
- Kickbacks
- Conflict of interest
- Expense frauds
- Data theft
- Payment to HCPs and KOLs
- Payment to TPA
- IP monetisation
- Corruption in public tendering
- Use or third party liaising agents to obtain licenses/custom clearance etc.

Key areas of focus include:
- Unreported deviations and complaints
- 21 CFR Part 11
- Trial run
- Counterfeit
- Channel stuffing
- Distributor investigations triggered by whistleblowing suspicion or proactively
- Contract manufacturing unit investigations/reviews
- Expensive gifts, five star entertainment
- Foreign travel sponsorship in gulf of CME
- Ghost patients in PAP, leakage or samples
- IP assessment
- Fraud risk assessment
- Anti bribery and corruption
- Supply chain leakage
- Data integrity investigations
- Marketing and promotion reviews
- Employee frauds
- Due diligence
- Revenue
- Procurement
- Fee for service
- Fair market value
- Non-compliance
- Sales promotion
- CME
- Events
- Regulatory
- Scrape
- Patents
- Intellectual property (IP) Protection
- Use or third party liaising agents to obtain licenses/custom clearance etc.]

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The views and opinions expressed herein are those of the interviewees and do not necessarily represent the views of KPMG in India.

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