Data integrity problems a growing risk to global pharma companies

More pharmaceutical companies than ever before are being warned by regulators for falsifying, altering or failing to protect essential quality data about how their drugs are made and tested, posing business risks to cited companies.

At issue are so-called “data integrity” violations of the FDA’s manufacturing regulations, which are collectively meant to ensure drugs are safe, effective and without impurities or defects that might harm patients. The FDA requires companies to maintain manufacturing and drug testing data, and ensure that this information is attributed to specific people, recorded at the time the activity took place, and be original, legible, and accurate. Deviations from these five standards are known data integrity violations. Problems can arise from human error – intentional or unintentional – or machine error such as data recording failures.

Since 2010, the FDA has issued warning letters to an increasing number of companies for these violations, according to an analysis by HRI. From 2010 to 2012, just five drug manufacturers were cited for data integrity violations. From 2013 to 2015, 24 were during. During this time period, the three most common issues cited were a lack of controls to prevent alterations of data by staff, a failure to maintain records of accurate data, and delayed reporting of data.

Violations have been disproportionately found in facilities located outside of the US. Of the 29 warning letters sent to drug manufacturers for data integrity problems, 18 were to companies with facilities based in India and six in China. US-based facilities saw just one violation despite receiving 68.8% of all FDA global drug quality inspections between 2010 and 2015. Based on the increasing rate of violations, the FDA is planning to release a new guidance document on data integrity in 2016.

Warnings may be increasing in the wake of new authority and financial resources given to the FDA by Congress in 2012. These resources were meant to increase inspections of foreign facilities. As of 2012, an FDA regulator can demand access to specific records contained at a manufacturing facility. If records are not provided, the agency can ban the relevant drug from being sold in the US. Flush with half a billion dollars in new generic drug user fees, the FDA has increased foreign drug quality inspections, which are comparatively costly. Foreign drug quality inspections increased from 20.6% in 2010 to 39.2% in 2015.

Industry implications

1) Regulatory reach is now global. As the FDA expands its global presence, more companies may find their foreign manufacturing operations being scrutinized. Companies should audit global subsidiaries and partners to ensure their supply chains adhere to data integrity principles and practices. To date, several companies cited by the FDA have been drug ingredient manufacturers for large companies. If the FDA is able to successfully increase its presence in countries such as China, data integrity findings may increase for companies located overseas.

2) Data integrity violations can shut down facilities. Data integrity issues can lead to import bans, recalls, public warnings, detained products, delayed or denied drug approvals, lawsuits, lost business and costly remediation efforts. Companies should ensure workers value integrity and have effective incentives to meet data integrity standards.

3) Focus on technology to defend against problems. Unique log-in information for each user, a data audit trail and technological defences against unauthorized changes can help companies avoid some of the most common data integrity problems. Technology solutions should be user-friendly to ensure workers don’t circumvent them. Unusual data – for example, the same employee always recording the same result, or batch acceptance rates peaking just before a shift change – from unexpected sources can indicate problems. Approaches used by the financial services community to identify fraud and money-laundering can help companies identify signals before they become problems.