HOWEVER, despite the increased focus on quality in the pharmaceutical industry, there has been a significant increase in the number and severity of quality defects. Food and Drug Administration (FDA) has indicated that for the pharmaceutical industry to “continue to be successful, drug manufacturing must become agile, rapidly scalable, efficient, reliable – and less costly”. These challenges can only be met by making better use of data and knowledge, allowing us to reduce the enormous cost of poor quality and, in parallel, improve data integrity.

How will industry cope with big data?

FDA recently published its guidance on modernising the pharmaceutical manufacturing base. FDA has also highlighted that modernising the manufacturing base needs to be supported by integrated strategies towards product and process understanding, underpinned by real-time monitoring of critical process data, which taken together should support better understanding, monitoring and process control.

The regulatory strategy within the EU is similar. However, all of these novel approaches generate significant volumes of data, ie, information rich, which necessitate enhanced data management solutions and enhanced data infrastructure to collect, process and analyse these data-rich streams.

Therefore, the connectivity of equipment, people, processes, services and supply chains all contribute towards ‘Pharma 4.0’. Industry 4.0 technologies will enable manufacturers to have better visibility of ongoing operations, allowing them to be more responsive to information about changes in raw materials, inventory, assets, quality, waste, output and customer demands, highlighting improvement opportunities and ensuring that actions are taken, saving time, money and resource.

Data integrity

However, at the same time that both industry and regulators want to embrace and embed ‘big data’ into their decision-making process, there are parallel concerns and significant unease about data integrity in general. FDA and European Medicines Agency (EMA) have issued draft guidance on the subject of data integrity, due to the increasing numbers of cGMP violations involving data integrity during routine cGMP inspections. Agencies are increasingly concerned about these trends because data integrity is a critically important element of industry’s responsibility “to ensure the safety, efficacy, and quality of drugs, and of FDA’s ability to protect the public health”. These data integrity related cGMP violations have led to numerous regulatory actions, “including warning letters, import alerts, and consent decrees”.

In parallel, EMA has developed a set of Q&As with guidance for stakeholders on actions that assure data integrity and also minimises data integrity risks at all stages of the data lifecycle in all pharmaceutical quality systems (PQS).

Conclusion

The significant cost of a poor-quality culture is often underestimated by the pharmaceutical industry. For example, consider what would be the organisational outcome if the costs for non-conformity (NC) or out of specification (OOS) outcomes were presented in annual reports? Undoubtedly this would fuel an appetite for significant change. However, these quality challenges can only be addressed by making better use of data and knowledge to facilitate better and quicker decision making. Although there are ongoing concerns about data integrity, compliance could actually improve if better ‘data-driven’ decisions could be made and the human element is removed from the equation.