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Quality Metrics and the Link to Operational Excellence

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Executive Summary

The FDA is driving the development of a culture of quality across the pharmaceutical industry. Currently, they request the voluntary submission of summary 'Quality Metrics' (QMs). This request is likely to become a requirement in 2018.

Linking QMs to performance indicators across an organisation will drive focused improvement initiatives, delivering process and supply chain robustness. As a result, this will lead to reduced quality issues, reduced costs and increased profitability. In addition, Quality and Operations executives will have more time to work on strategy rather than day-to-day problem solving.

THE SITUATION

The pharmaceutical industry's 'Quality Metrics' journey has been a slow, continuous process of growth, but it is clear that this development is accelerating. Evidence for this comes with the development of new regulatory requirements designed to summarise process performance and provide an ability to assess the need for inspection according to risk. It helps to consider a little recent regulatory history and some perspectives on the reaction of the industry.

In 2011 the FDA released guidance describing their expectations related to process verification [1]. The industry's response to this guidance is commonly referred to as 'Continued Process Verification' (CPV) [3, 4]. This was soon followed by the EMA who use the phrase 'Ongoing Process Verification' to describe the same concept [2]. The purpose of CPV is essentially to ensure the production process remains in a state of control throughout the manufactured life of the product. It can also be used to drive process improvement.

CPV reports are expected to feed into the Annual Product Quality Review process, alongside other sources of data like the complaints and deviation management systems. Inspectors are more likely to ask how process verification works in an organisation rather than to ask for CPV reports, but requests to see charts and reports are increasingly being made, to substantiate that processes and procedures are actually being used.

Recently, the FDA launched its 'Quality Metrics Initiative', proposing a requirement to submit a data set. The industry reacted strongly, taking their objections to the proposal and the specific data set in it directly to the regulators, and collaborating through a number of associations to present their case in writing and at conference. Subsequently, the FDA 'softened' their position, asking the industry to voluntarily submit a specific data set and stating they will publish a list of the companies going through the process [5].

Discussion in the industry continues, and 'side-bar' conversations suggest most major companies and a number of medium sized enterprises intend to take part in the scheme. They are less willing to talk about how they will do this at the product, site and network levels as, almost certainly, they are seeing difficulty in harmonising and linking data sets internally.

Despite the challenges, it seems inevitable that the FDA will make the submission of a set of Quality Metrics a regulatory requirement. Perhaps in a drive for excellence and efficiency in their inspections process, other authorities are starting to follow suit, as exemplified by Mexico's COFEPRIS who are proposing a process validation data submission program.

Roll on the global harmonisation of the regulatory submissions process, but that seems a long way off and in the meantime, companies are likely to be increasingly pressurised to put good quality metrics in place, and provide them to the agencies. In reality, it makes sense to embrace the direction the FDA is taking and support the development and externalisation of Quality Metrics as an extension of an internal quality culture [6, 7].

Given the level of challenge the FDA has received to its chosen data set; it has engaged academics to substantiate its approach [8]. Already, these academics have seen and written about the link between Quality Metrics and Operational Excellence [9].

The FDA's drive for a culture of quality can be seen as an opportunity for companies to realise the benefits of linking quality metrics into their existing quality systems. To do this, they will need to invest in operational excellence initiatives that connect across their supply chain and into the Quality function. Done well, this will allow executives to lift their line of sight above day-to-day problem solving, and reduce the burden of regulatory inspections.

IN SUMMARY

The FDA's request for Quality Metrics is an opportunity for companies to develop their culture of quality and link measures to more meaningful improvement efforts, through Operational Excellence activities.

Volt Pharma Associates (VPA) has assembled a team of experts to help you deliver on this opportunity. The VPA team consists of a pool of experts in quality assurance, process improvement, equipment performance improvement, supply chain excellence, statistical analysis and overall Operational Excellence.

With the expertise of world-class BioPharmaceutical industry subject matter professionals, VPA put best practice to work for their clients, designing integrated innovative solutions for the complexities of a constantly changing life sciences ecosystem.

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ABOUT THE AUTHORS

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