

6

Ways Quality Data Can Drive Performance

In a 2019 survey of pharmaceutical industry professionals, 40% cited economic performance as their top quality goal, while those naming compliance as their top goal fell from 74 percent in 2018, down to 66 percent in 2019.¹ Facing increased cost pressures, pharmaceutical executives expect far more from their quality management teams than checking the compliance box. They are investing in people, processes and technologies to build performance-based quality operations that can have a meaningful and measurable impact on their companies' bottom lines.

The key to driving performance is access to complete, accurate and meaningful data. Quality departments that can structure relevant data to create meaningful insights can directly impact operational efficiency, speed to market and many other areas.

1



Limit Risk and Recalls

Pharmaceutical manufacturers that take a more proactive approach to quality can reduce risks, including the risk of recalls. Many leading manufacturers accomplish this by closely monitoring first time right percentage—the ability to complete every step of their processes right the first time. This approach extends out to their suppliers and other business partners as well.

2



Improve Product Quality and Customer Satisfaction

The benefits of a culture of quality are far reaching. When a product functions as intended, outcomes are improved and satisfaction among customers (clinicians, consumers) is higher. When questioned on their driver for quality improvement initiatives, two-thirds of senior executives and quality professionals report that it is customer demand for quality.² A quality culture requires a continuous loop whereby quality data is relayed back to R&D and manufacturing teams to help drive continuous improvements.

3



Drive Operational Excellence

The infusion of quality throughout people, processes, products and technologies drives company-wide operational excellence. It can result in reduced cycle times, cost savings, increased margins and additional performance-oriented outcomes. Research from McKinsey & Company reveals that pharmaceutical manufacturers leveraging advanced analytics could improve Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) by 45-75 percent.³

37 percent of senior executives and quality professionals state that more than 10 percent of employees' time is consumed by addressing yet-to-be-resolved quality issues each week. And this problem isn't going away. Nearly half of those surveyed (44%) said the amount of time employees spend addressing unresolved or ongoing quality issues has increased over the past three years.⁴

4



Accelerate Time-to-Market

Access to actionable quality data can reduce errors and related setbacks during the drug development cycle, enabling a manufacturer to deliver its product to market sooner. Cutting the cycle down by even a month could potentially pay for any quality improvement costs - and more.

5



Meet Compliance Standards

Even though the FDA and other regulators have placed an increased emphasis on pharmaceutical quality, manufacturers still have to ensure compliance with new and emerging regulations. Compliance is no longer the end game; rather, it is a byproduct of a company's efforts to improve product quality, product safety, product efficacy and continuity of supply (both current and new products). Manufacturers can leverage highly efficient quality management systems and quality metrics to achieve proactive compliance and thereby reduce regulatory scrutiny.

6



Drive Greater Supplier Quality

The quality of a pharmaceutical manufacturer's value chain has a direct impact on the quality of its processes and products. McKinsey & Company examined 40 quality incidents across eight different industry sectors and found over 40 percent were due to supplier quality issues.⁵ Manufacturers that implement rigorous and thorough quality management programs that extend out to their suppliers can not only improve product quality but also save time and money by minimizing risk and errors related to their business partners.

¹2019 Pharma Quality Outlook: Performance Becomes Priority Sparta Systems

²Forbes Insights: The Rising Economic Power of Quality, Forbes Magazine, 2017 https://www.forbes.com/forbesinsights/asq_economics_of_quality/

³How pharma can accelerate business impact from advanced analytics, McKinsey & Company, January 2018, <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-pharma-can-accelerate-business-impact-from-advanced-analytics>

⁴The Rising Economic Power of Quality: How Quality Ensures Growth and Enhances Profitability, Forbes Insights, May 2017 https://www.forbes.com/forbesinsights/asq_economics_of_quality/

⁵Supplier quality management: A proactive and collaborative approach, McKinsey & Company, December 2012, <http://www.mckinsey.com/practice-clients/operations/supplier-quality-management-a-proactive-and-collaborative-approach>