Quality Metrics Guidance

The FDA's Plan to Transform & Evolve through Data

In the pharmaceutical industry, the volume, value, and focus on quality data continues to expand with nearly every organization striving to optimize data for actionable input that will improve their business. With the release of the quality metrics guidance, the U.S. Food and Drug Administration (FDA) is adopting a similar approach by establishing metrics and data analytics capabilities that would optimize their own processes and procedures, and in turn deliver valuable efficiencies for the industry at large.

High-functioning, quality-centric organizations can use the FDA guidance as an impetus for addressing challenges that plague even the most highly-evolved organizations in life sciences.

Overview

Citing authority granted by the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), the FDA's program aims to develop and implement a set of standardized quality metrics that:

1 Improve the efficiency and effectiveness of risk-based inspection scheduling.

Establishments with highly controlled manufacturing processes have the potential to be inspected less often (as a lower priority for inspection) than similar establishments that demonstrate uncontrolled processes (as a higher priority for inspection).

2 Assist in the evaluation of production quality aimed at predicting and preventing drug shortage issues.

The FDA has found that the majority of drug shortages stem from quality concerns requiring remediation efforts, which in turn, may interrupt production and cause drug shortages.

Evaluation of quality information will enable the FDA to work with establishments towards early resolution of quality problems and to reduce the likelihood that the establishment's operations will be disrupted and impact the drug supply.

3 Promote responsible practices and quality-driven corporate culture.

Industry leaders understand that quality initiatives are more effective in organizations where quality is as much a shared corporate identity as it is a single department. Standardized metrics for demonstrating corporate commitment to quality have been relatively elusive in the past but the FDA guidance takes an important step in measuring the role that quality plays in an organization's identity.

Who Is Affected?

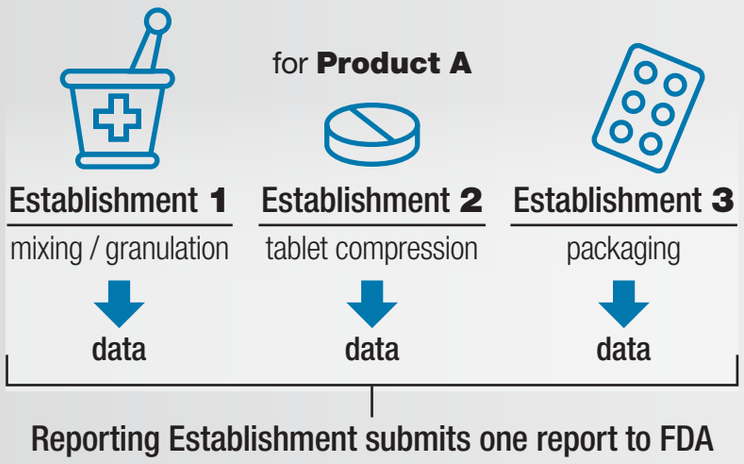
The guidelines mandate reporting for U.S. organizations engaged in the manufacture, preparation, propagation, compounding, or processing of finished dosage forms (FDF) of covered drug products or active pharmaceutical ingredients (API) used in the manufacture of covered drugs products. This includes both owners and operators of establishments in the U.S. and those offering to import into the U.S.

Covered drug products include:

- **Drug products that are the subject of an approved application under section 505 of the Federal Food, Drug, & Cosmetic Act or under section 351 of the Public Health Service Act**
- **Drug products that can be marketed pursuant to an over-the-counter monograph**
- **Marketed unapproved drug products**

Reporting establishments would submit one report for each FDF and one report for each source of API. Where there is more than one source, multiple reports will be required.

Failure to report requested quality data may elevate an establishment's predicted risk, leading to an earlier inspection. Furthermore, products associated with the establishment may be deemed adulterated and subject to enforcement action.



Opportunities Beyond Compliance

Industry commentary on the FDA's quality metrics guidance has largely addressed the challenges associated with alterations to existing data collection and reporting practices. However, this guidance also presents a distinct opportunity for quality leaders to use the requirements as a tool for demonstrable improvements to common obstacles in quality.

Universal, standard metrics for quality give leadership a global view of their product(s) across multiple locations, facilities, and vendors. This harmonization of data allows for a more efficient and cohesive quality system, more effective data analytics capabilities, and improved oversight of third-party contractors. As the industry increasingly relies on the use of contract organizations in the production lifecycle, the ability to synchronize quality management across multiple parties will evolve as a key indicator of a quality-driven organization, especially for virtual organizations that contract out manufacturing, packaging, and distribution.

The risk-based scheduling facilitated through the quality metrics guidance ensures that the FDA's resources are dedicated to those cases with the highest risk and the greatest potential impact to patients. High-performing organizations with robust compliance programs will undergo fewer inspections. In alleviating the burden of frequently disruptive inspections, the guidance not only incentivizes quality but also allows leaders in quality and regulatory to become less reactive and more proactive in their planning.

While the FDA's final guidance is still under development, it is evident that standardized, universal quality metrics are imminent as an industry-wide regulatory requirement. Using this opportunity to enact effective and widespread change to existing quality operations will not only give organizations a head start to regulatory compliance but serve as a competitive differentiator in the future.

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