

FDA Announces Quality Metrics Pilot Programs

July 3, 2018

Key Points

- FDA has announced new quality metrics pilot programs that seek industry stakeholder perspective and feedback.
- FDA's voluntary pilot programs target companies submitting Type C and Pre-ANDA meeting requests, as well as a variety of human drug establishments.
- Eligible companies are invited to submit proposals for participation to FDA by August 28, 2018 for the 2018 Quality Metrics Site Visit Program or by July 29, 2019 for the Quality Metrics Feedback Program.
- There are potential upsides and downsides to participating in these voluntary programs. Companies should carefully consider whether to participate.

On June 28, 2018 the U.S. Food and Drug Administration (FDA) announced its [Quality Metrics Feedback Program](#) and [2018 Quality Metrics Site Visit Program](#), voluntary pilot programs that were initiated to allow industry stakeholders to provide the agency with the feedback for the development of its Quality Metrics Program.

Background

FDA first released [draft guidance for industry](#) regarding quality metrics in July 2015.¹ This draft guidance outlined FDA's intention to require owners and operators of various types of pharmaceutical manufacturing facilities to submit quality measurement data to the agency.² FDA asserted its authority to obtain these records and other information under the Food and Drug Administration Safety and Innovation Action (FDASIA).³ As noted in our [previous analysis](#), FDA intended to use this information to inform its risk-based inspection priorities and scheduling, as well as to identify situations that potentially pose a risk to the drug supply chain.⁴ However, industry feedback strongly indicated that the agency should initiate further studies and discussions prior to the establishment of a mandatory FDA Quality Metrics Program.

FDA revised its [draft guidance](#) in November 2016, proposing instead to establish a voluntary reporting phase of its Quality Metrics Program.⁵ FDA's revised program

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proposed calculating certain quality metrics for products and covered establishments based on the voluntarily provided data.⁶ FDA's quality metrics were (1) Lot Acceptance Rate, (2) Product Quality Complaint Rate and (3) Invalidated Out-of-Specification Rate.⁷

FDA reiterated that it intended to use these quality metrics to help identify products and establishments that pose substantial risks to consumers and the drug supply chain, as well as to improve inspections and FDA's evaluations of drug manufacturing and control operations.⁸

FDA further indicated that it intended to publish a public list of establishments that voluntarily reported quality data to its program.⁹ This Quality Metric Reporters List proposed dividing participants into tiers based on their levels of participation in the voluntary program.¹⁰ Both the brand and generic pharmaceutical industries submitted public comments arguing that FDA lacked legal authority to institute the draft program and that the program was flawed.

FDA has responded to these comments by rolling out new quality metrics pilot programs.

Quality Metrics Feedback Program

New Drug Application applicants or sponsors and pre-Abbreviated New Drug Application applicants or sponsors may voluntarily participate in FDA's Quality Metrics Feedback Program by submitting a written request. In particular, FDA is seeking participants willing to share a variety of information, including detailed information on established quality metrics programs, current and historical product-specific measures and supporting data, process performance and process capability, corrective and preventative actions, quality culture and on-time-in-full fulfillment of orders.

Additionally, FDA will launch a pilot program for establishments with quality metric programs that are involved in the manufacture, preparation, propagation, compounding or processing of certain drug products, or an active pharmaceutical ingredient used in the manufacture of a covered drug product. FDA will select the first nine eligible establishments that submit applications.

2018 Quality Metrics Site Visit Program

This voluntary pilot program is intended to provide FDA with opportunities to observe quality metrics programs within pharmaceutical companies through site visits. FDA is seeking information regarding the benefits and challenges associated with implementing and managing a quality metrics program. A company participating in the pilot program will host 5 to 10 FDA representatives at a site for one to two days so that they can observe how quality metrics data are gathered, collected and reported to company management. The company is also invited to provide FDA with a presentation regarding the development and management of the company quality metrics program.

These new quality programs represent a scaling back of the plans that FDA announced in its 2015 and 2016 draft guidances. The programs also show that FDA continues to view quality metrics as an important part of strong quality systems.

There are potential advantages and disadvantages that firms should consider when weighing whether to participate in FDA's new programs.

On the positive side, firms often benefit from having contact with FDA outside of typical application, inspection or enforcement contexts. FDA values the information that firms provide when the agency is entering a relatively new area, such as quality metrics. Firms would have the opportunity to showcase successful metrics programs and would likely obtain informal feedback from the regulator. These information exchanges can be useful for FDA and firms, and generate goodwill.

However, there are some risks to participating. There is broad agreement about the importance of quality culture, but assessing quality culture can be highly subjective. For example, in its new programs, FDA will examine "the routine assessment and management oversight of quality culture," including "the behaviors, beliefs, values, morals, conventions, goals, and practices that characterize or are associated with manufacturing..."¹¹ FDA does not currently have comprehensive criteria for judging some of these items, beyond forming a general impression, nor does it have comprehensive criteria for the optimal organizational structure to promote product quality. Indeed, relevant decision-makers in FDA could differ on how to assess these items. Thus, before providing this information to FDA, a firm should consider whether agency decision-makers could differ with the firm in some of these areas, which could have some consequences for the firm.

Firms should carefully evaluate whether it is in their advantage to participate in these programs. The best approach will likely vary, depending on the firm's quality metrics program, its track record with FDA and other factors.

¹ FDA, Draft Guidance for Industry, "Request for Quality Metrics" (July 2017), [available here](#).

² *Id.* at 1-2.

³ *Id.* at 2.

⁴ *Id.* at 7-9.

⁵ FDA, Draft Guidance for Industry, "Submission of Quality Metrics Data" (Nov. 2016), [available here](#).

⁶ *Id.* at 7.

⁷ *Id.*

⁸ *Id.* at 12.

⁹ *Id.* at 13-14.

¹⁰ *Id.*

¹¹ *Id.* at 6.