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NOVEMBER 30TH 2016

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Inside This Issue

FDA's Quality Metrics Reporting Program: Submission of Quality Metrics Data

Continuous improvement and innovation in the pharmaceutical manufacturing industry are an important part of FDA's mission to protect and promote public health. Industry currently uses quality metrics to drive improvement and monitor quality systems and processes.

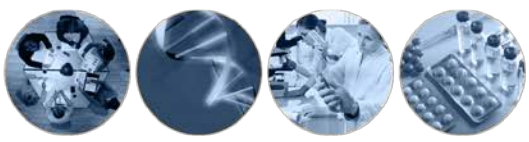
FDA can use quality metrics data from industry to develop improved compliance and inspection policies and practices, improve the ability to predict and mitigate future drug shortages, and encourage innovation in the pharmaceutical manufacturing industry. To help achieve these goals, FDA is initiating a voluntary quality metrics reporting program to address common quality issues in the pharmaceutical industry and permit participants to submit data in the initial phase of the program. The reporting program is described in the new draft guidance, *Submission of Quality Metrics Data*, which has been significantly revised from the 2015 draft guidance, *Request for Quality Metrics,* in response to stakeholder feedback. FDA is requesting additional comments prior to issuing a final guidance.

Quality Metrics Data Reporting: This reporting program will help FDA to segment and support high performers, address product shortage issues, and advance operational excellence and quality practices. We expect that most of the quality metrics data are being collected and evaluated by establishments already as part of their ongoing monitoring programs. Manufacturers should routinely use additional quality metrics beyond the metrics described in this guidance to improve their products, processes, and quality systems.

Under this program, FDA anticipates that most of the submitted reports will be for a covered drug product or an active pharmaceutical ingredient (API) used in the manufacture of a covered drug product. Generally, a "covered drug product" is one that is subject to a new drug application, abbreviated new drug application, biologics license application, a drug marketed pursuant to an over-the-counter monograph, or a marketed unapproved drug product. Also, owners and operators of establishments engaged in the manufacturing of a covered drug product are considered "covered establishments." Other types of establishments may also choose to submit quality metrics data as explained in the guidance.

FDA will accept both product reports and site reports. However, we prefer a product report for a single product that includes data from all covered establishments. Compilation of data into a single product report will facilitate data analysis and identification of product specific issues. A site report can also be submitted by any covered establishment and would individually list all of the data associated with each covered drug product or API used in a covered drug product.

Reporting establishments may submit quality metrics data reports where the data is segmented on a quarterly basis throughout a single calendar year. FDA intends to open the electronic gateway in January 2018 to receive voluntary submissions of data generated in 2017. We expect to begin the data analysis when the portal is closed and then publish initial findings on *fda.gov*. After evaluating the results of the voluntary phase of the program, FDA intends to initiate notice and comment rulemaking under existing statutory authority to develop a mandatory quality metrics reporting program.



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How Will FDA Use Quality Metrics Data? FDA envisions information collected from a fully implemented quality metrics reporting program will be important in focusing the use of FDA resources on the areas of highest risk to public health. Activities include:

- establishing a signal detection program to identify establishments and products that may pose significant risk;
- identifying situations in which there may be a risk for drug supply disruption;
- improving the effectiveness of establishment inspections; and
- improving FDA's evaluation of drug manufacturing and control operations.

The metrics described in the guidance do not strictly determine the quality of the establishment or its products. Therefore, FDA intends to use quality metrics information with other knowledge available to FDA in order to achieve these goals.

Why Voluntary? This voluntary phase will allow FDA to use information about participating establishments in our risk-based decision making as we further develop the quality metrics reporting program. It will also allow all types of drug manufacturing establishments to report information. Note that FDA does not intend to take enforcement action based on errors in a quality metrics data submission made to this voluntary phase, provided the submission is made in good faith.

Why Participate? Participation in the voluntary phase shows commitment to increasing transparency between industry and FDA, and contributes to improving quality monitoring. Use of the information generated in this phase may be limited if FDA does not receive a large body of data, as it may not be representative of the industry. Thus, FDA intends to:

- work with establishments towards early resolution of potential quality problems when we identify a signal.
- include the reporting of quality metrics as a tool in our surveillance inspection risk-based model to improve our inspection effectiveness.
- publish on *fda.gov* the names of establishments that voluntarily report quality metrics data per the guidance. This list will provide information about *whether* an establishment voluntarily submitted quality metrics data to the Agency, and how much data was submitted. Inclusion on the list is not an indication of FDA's *evaluation* of the submitted data.
- share how quality metrics data have affected the frequency of current good manufacturing practice inspections.
- obtain feedback from participating establishments.
- consider the use of calculated metrics as an element of the post-approval manufacturing change reporting program.
- continue to support the adoption and implementation of new technology by manufacturers.

FDA does not intend to publicly disclose information submitted during the program's voluntary phase since that is considered confidential commercial information under the Freedom of Information Act.

With the publication of this revised draft guidance on the *Submission of Quality Metrics Data*, FDA continues to encourage the implementation of a modern, risk-based pharmaceutical quality assessment system and the modernization of pharmaceutical manufacturing as part of the Agency's mission to protect and promote public health.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

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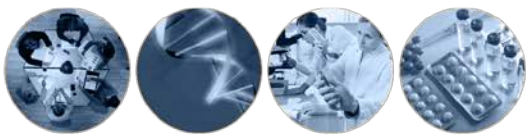

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