Quality Metrics – FDA Public Meeting

Ashley Boam, MSBE
Acting Director
Office of Policy for Pharmaceutical Quality
FDA/CDER

OFFICE OF PHARMACEUTICAL QUALITY

August 25, 2015

Why Quality Metrics?

Industry

- One important element of oversight and controls over the manufacture of drugs to ensure quality (section 501 FD&C Act)
- Enables continual improvement of process performance and product quality
- Supports continual improvement of the pharmaceutical quality system

Why Quality Metrics?

FDA

- Provide insight into the state of quality for product and facility
- More quantitative and objective measure of quality at the product, site, and system levels
- Enhance risk-based surveillance inspection scheduling model
- Improve effectiveness of inspections
- Help to identify factors leading to supply disruption

Why Quality Metrics?

Patients

- More reliable patient access to important therapies
  - Commitment to continual improvement by industry leads to more robust manufacturing processes
  - Fewer recalls
  - Fewer quality-related drug shortages

Request for Quality Metrics

Guidance for Industry

FDA Issues Draft Guidance

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Tara Gooen Bizjak at 301-796-3257 or (CBER) Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

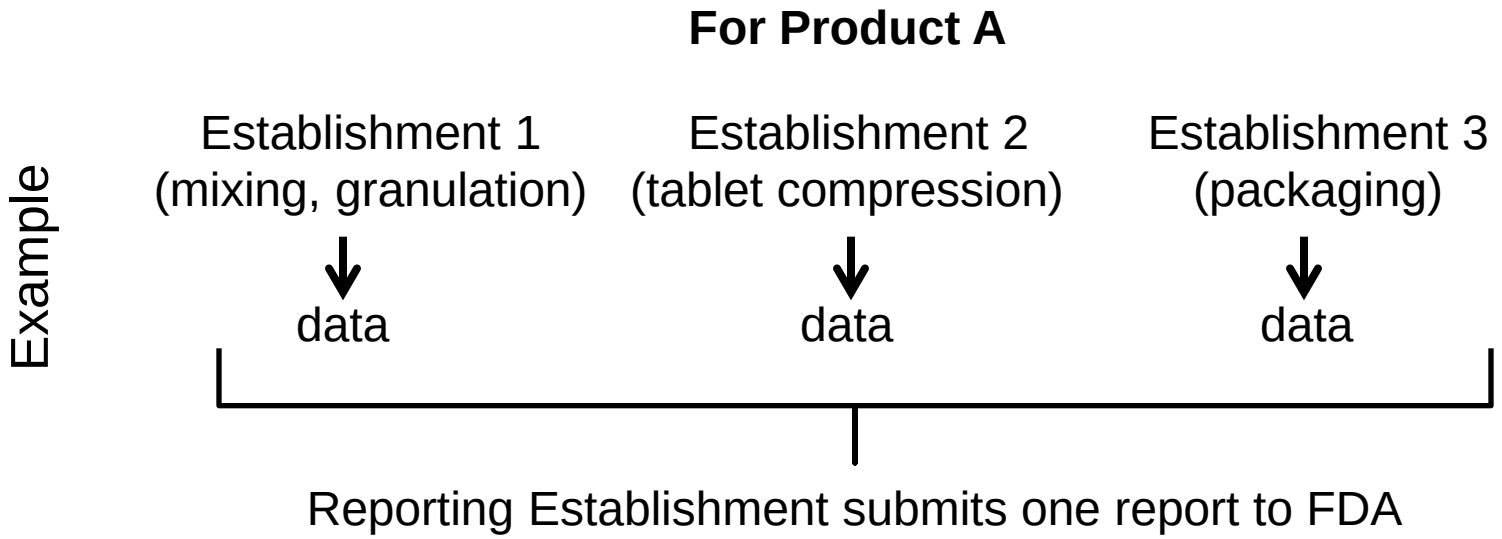
July 2015
Pharmaceutical Quality/CMC
Current Good Manufacturing Practices (CGMPs)

Who would report?

- Owners or operators of establishments that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug, specifically:
  - Finished dosage form (FDF) of a covered drug product, or
  - API used in the manufacture of a covered drug product.
- "Covered drug product"
  - subject to an approved application under section 505 of the FD&C Act or under section 351 of the PHS Act.
  - marketed pursuant to an OTC monograph.
  - a marketed unapproved drug product.

Who would report?

- "Reporting Establishment"
  - Provides one report for each API or for each FDF
  - One establishment should already possess or have access to all of the data needed to submit such reports
  - Generally expect that the Quality Control Unit (Quality Unit) will be best positioned to provide these data



What would be reported?

- Reporting establishments would report data; these data should already be available per CGMPs
  - Number of lots attempted
  - Number of specification-related rejected lots
  - Number of attempt lots pending disposition >30 days
  - Number of OOS results
  - Number of lot release and stability tests
  - Number of OOS results invalidated due to lab error
  - Number of product quality complaints for the product
  - Number of lots attempted which are released for distribution or for the next stage of manufacturing
  - Whether the associated APRs or PQRs were completed within 30 days of annual due date for the product
  - The number of APRs or PQRs required for the product

Data vs. Metrics

- FDA would use the data to calculate metrics:
  - Lot Acceptance rate
  - Product Quality Complaint rate
  - Invalidated Out-of-Specification (OOS) rate
  - Annual Product Review (APR) or Product Quality Review (PQR) On Time rate
- Public comment requested on several optional metrics
  - Senior management engagement
  - CAPA effectiveness
  - Process capability/performance

When/how would data be reported?

- Reporting establishments to submit data for a 1-year period that begins after FDA issues its request
  - Reports due within 60 days of end of the reporting period
  - Public comment sought on frequency of reporting and data collection timeframes
- Reporting through the FDA Electronic Submissions Gateway
  - Separate technical specification guidance with details to follow

How does FDA intend to use quality metrics?

- Develop objective measures for:
  - Quality of a drug product
  - Quality of a site
  - Effectiveness of systems associated with the manufacture of pharmaceutical products
- Analysis of quality metrics – context matters
  - Appropriate comparators may vary
    - Compare same metric, same product, same establishment over time?
    - Compare same metric, different products, same establishment?
    - Compare same metric, establishments performing same unit operation?
    - Compare same metric, products in the same class (e.g., large molecule injectables)?
    - Other?

How does FDA intend to use quality metrics?

- Goals for use of quality metrics:
  - Identify risk-based factors that could impact inspection frequency
  - Improve detection of manufacturing conditions that may lead to a shortage
- Use in conjunction with other sources of information about product and site quality
  - Inspection results
  - Recalls
  - Field Alert Reports/Biological Product Deviation Reports

Thank you for attending!

- For more information on this guidance, please see the CDER SBIA webinar at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm456059.htm

- Please provide your comments on the guidance to the docket:
  - www.regulations.gov docket #FDA-2015-D-2537