PHARMA & BIOPHARMA
OUTSOURCING ASSOCIATION

Pharma & Biopharma Outsourcing Association
10 Alta Vista Dr.
Ringwood, NJ 07456
Tel: 201-788-7994
www.pharma-bio.org

To: Division of Dockets Management (HFA-305)

From: Pharma & Biopharma Outsourcing Association

Subject: Comments for Docket #: FDA-2016-D-1594:
Quality Metrics Technical Conformance Guide, Version 1.0

Date: September 26, 2016

The Pharma & Biopharma Outsourcing Association (PBOA), a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations (collectively described as CDMOs for purposes of this letter), appreciates the Food and Drug Administration's (FDA) efforts and goals to encourage continuous improvement within the pharmaceutical industry and supports initiatives that possess potential benefits for industry, for patients, and for the FDA. The comments below represent a majority view of participating PBOA members who share a unique perspective as organizations providing critical services and solutions within the pharmaceutical industry. Specific or differing views may be separately presented by individual member companies in their own docket submissions.

Our position is that the Quality Technical Conformance Guide would not apply to CDMOs who are not license holders of products. As such, we request that the Technical Conformance Guide be clarified as to the source of the data being from the reporting establishment i.e., license holder/contract giver. The contract giver (reporting establishment) would specify the technical reporting requirements with the contract acceptor (CDMO) in the applicable Quality Agreement. Under these Quality Agreements, reporting establishments and CDMOs consider metrics data to be Confidential Commercial Information per 21 CFR 20.61(b) and would expect FDA to follow existing protections for this category of information as well as implement reasonable protections against electronic theft or unauthorized access. We feel strongly that data security is paramount to the success of this program. Data security should be prominently addressed in FDA's guide, along with assurances for how data security will be maintained.

As an active participant in the Cross-Industry Quality Metrics Collaboration Group -- a broad informal group of trade and technical organizations across the pharmaceutical industry -- we support the Cross-Industry Quality Metrics Collaboration Group's approach on the Quality Metrics Technical Conformance Guide.

In addition, our organizations continue to support the points made in our November 25, 2015 letter to the docket on FDA's Draft Guidance Request for Quality Metrics ("Draft Guidance"), including but not limited to the following:

- Need clarification on the roles and responsibilities for reporting the metrics
- Consideration for the ramifications associated with site-specific versus product-specific metrics

- Underestimation of the burden on the CDMO industry as it relates to the technical implementation, and the alignment effort with various contract givers' specifications and the on-going reporting resources

- Alignment of the reporting timelines as much as possible with existing reporting timeline requirements (e.g., annual reporting)

- Security and confidentiality of the data provided as well as the contractual relationship between the CDMO and the license holder

- Phased approach to allow for the successful implementation by the license holders and evaluation by both FDA and industry as to effectiveness and any needed adjustments

The Pharma & Biopharma Outsourcing Association appreciates this opportunity to submit our comments. We understand that the development of a quality metrics program has been a multi-year process involving many stakeholders and viewpoints, and we hope that the comments above help illuminate the specific areas of interest for CDMOs and other providers of development and manufacturing services for the pharmaceutical industry. We thank you in advance for your consideration of our requests and concerns during the finalization of the Request for Quality Metrics guidance and the Quality Metrics Technical Guide.

Sincerely,

Gil Roth
President
Pharma & Biopharma Outsourcing Association

PBOA

MEMBER COMPANIES

3M Drug Delivery Systems
Afton Scientific
Alcami
Baxter BioPharma Solutions
Catalent Pharma Solutions
Coating Place, Inc.
Coldstream Laboratories
Confab Laboratories
Cook Pharmica
DPT Laboratories
Ei, a Pharmaceutical Solutionworks
Groupe PARIMA
Halo Pharma
IDT Biologika
Jubilant HollisterStier
Metrics Contract Services
Mission Pharmacal / ProSolus Pharmaceuticals
Patheon Inc.
Pfizer CentreOne
Piramal Pharma Solutions
Therapure Biomanufacturing
WellSpring Pharma Services

AFFILIATE MEMBERS

Houlihan Lokey
INTERPHEX
Millrock Technology
PharmSource
TraceLink