TO: U.S. Food And Drug Administration (FDA)
FROM: Louis Garguilo, Executive Editor, Executive Member, Outsourced Pharma

DATE: November 9, 2015

RE: Request for Quality Metrics Guidance for Industry DRAFT GUIDANCE

Outsourced Pharma West is a conference and exhibition for members of the biotechnology, pharmaceutical, and outsourcing service provider industries involved in global drug discovery, development and manufacturing. Our August 25-26, 2015, conference held at the Hyatt Regency in La Jolla, California, included a panel and audience discussion, titled "What are the impacts of FDA quality initiatives on your relationship with your CROs/CMOs?" Here is the published description of that panel:

> "In support of the move toward risk-based inspection schedules, the FDA has started to develop quality metrics as objective measures of the overall quality of pharmaceutical manufacturing sites, their products, processes, and systems. As a sponsor who outsources to development and manufacturing suppliers, how will these initiatives impact your product and the relationship with your suppliers? This panel will discuss details of the FDA's quality metrics initiative as well as best practices around supplier selection, qualification, and evaluation."

Panel attendees were:

- Suketu Desai, Principal & Founder | Biotech CMQR Consulting
- Marlene García Swider, Regulatory Specialist
- Julia O'Neill, Principal | Tunnell Consulting
- Moderated by Timothy Scott, President | Pharmatek

Based on panel/attendee discussions during and after that panel (and also including further discussion at a subsequent Outsourced Pharm West conference, Nov 3-4 in San Francisco), it was suggested that we submit to FDA comments regarding the Request For Quality Metrics Guidance for Industry DRAFT GUIDANCE. Please accept the two comments below for consideration as you draft final guidance, and for future developments on this and related topics.

1. It is recommended that the FDA make available – even if in an abbreviated or abridged format – information the FDA obtains directly as a consequence of any new reporting guidelines for manufacturers, including contract service providers (CMOs), regarding the development and manufacture of drug substance and drug product at their facilities as it relates to quality metrics. We are aware that FDA's Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research (CDER), has made some public

comment about the intention to not make (at least initially) this new "quantitative information" available to the public, but we hope that stance may be open for adjustment.

2. In the case where the FDA adheres to a policy of keeping internal the submitted quantitative and qualitative information from manufacturers and CMOs, since the agency has implied it intends to assign "grades" to each individual manufacturing plant or facility, that at least those grades – or any other rating – along with a scale and description of those grades, be made public.

Both or either 1. or 2. directly above would:

(a) Enhance the ability of all drug discovery and development organizations and sponsors (e.g., academia-based investigators; virtual and start-up companies; established biotechs; Specialty and Big Pharma) to select the most "quality reliable" contact manufacturing locations. This would help increase quality standards for projects at all sponsors, and reinforce the need for obtaining the highest – and measurable – "culture of quality" at all manufacturers and other service providers, and ultimately and positively affect patients.

(b) Further bring CMOs and all third-party drug discovery, development and manufacturing organizations into the public awareness, aiding an already growing understanding of the increased utilization and importance of these organizations in all facets of production of medicines, and again promote higher quality standards throughout the industry and for patients.

Thank you for accepting these comments for consideration.

Sincerely,

Louis Garguilo
Executive Editor/Executive Member, Outsourced Pharma
5340 Fryling Road Erie, PA 16510
Direct phone: 518-618-8478
Email: Louis.Garguilo@LifeScienceConnect.com