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**Comments on "Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations" [Docket No. 2004D-0443]**

We as a company agree with and commend FDA on this draft guidance, and are impressed with the direction the agency is taking toward harmonizing GMPs with modern quality systems, resulting in standardization of quality management principles.

In line 71 of the guidance, you state, "This guidance describes a comprehensive quality system model..." To meet the definition of the word "comprehensive," a quality system should be all-inclusive, encompassing a key element that is present in all modern, robust quality systems: independent, third party audit and certification. Many other industries (e.g. automotive, aerospace, electronics and food) have embraced the concept of third party independent audit and certification to a particular standard such as ISO9001 as part of their comprehensive quality systems.

To best convey FDA's desire to harmonize GMPs with these modern quality systems, we would like to suggest that you include the concept of third party audit and certification under "Evaluation Activities" in the final guidance.

A certified quality system clearly shows a commitment by the manufacturer to produce reliable, quality products, creating confidence and enhancing its reputation in the marketplace. FDA has already moved in this direction successfully in the medical device industry, starting with Class 1 devices and now extending to Class 2 that go through third party certification.

Some of the specific benefits of third party audit and certification to FDA and industry are:

- Standardizing quality management principles
- Giving companies a tangible method to measure and substantiate their claim that they have a quality management system in place
- Providing FDA with another tool other than their own resources to ensure quality

We believe the inclusion of third party audit and certification in the final guidance will serve to further the goals of the FDA in the area of quality improvement in the pharmaceutical manufacturing industry, and give manufacturers a method of substantiating their implementations of quality systems.

Respectfully submitted,



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