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Janet Woodcock, M.D., Director
Center for Drug Evaluation & Research
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

November 8, 2004

Dear Dr. Woodcock:

After reviewing the "FDA Guidance for Industry – Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations," we agree with the FDA's current direction toward bridging the gap between CGMPs and the FDA's current understanding of modern quality systems.

One observation that we would make is that the draft guidance does not mention the concept of third party audit and certification to a defined quality standard (either FDA's own standard or recognized international standards such as ISO 9001) – a key element in the successful implementation of quality systems in other industries. Adding to the guidance a recommendation for third party audit and certification by an accredited independent body is an issue we would like to explore further with the FDA.

Lloyd's Register Serentec is a member of the Lloyd's Register Group of companies – an organization with a 230 year history of defining performance standards for safety critical processes and assets, and verifying compliance. Lloyd's Register Quality Assurance (LRQA) has been involved with compliance certification for quality management systems since the earliest days of formalized quality management systems.

LRQA has grown rapidly over the past 20 years and is now one of the world's leading certification bodies. LRQA has a global client base that encompasses many of the world's largest companies and helps to ensure that tangible improvements are achieved and demonstrated to regulatory bodies. LRQA has become a Notified Body with European Community Product Directives, acting on behalf of the governments of many member states. Two such directives of direct relevance to the FDA, and in which LRQA has significant experience, are the Medical Devices and In-vitro Diagnostics Directives. LRQA's fundamental understanding of how continual quality improvements can be achieved has resulted in direct involvement in the ISO standards-making process and the creation of industry sector-specific standards.

Lloyd's Register Serentec has provided validation and regulatory compliance services on a global basis to large and small pharmaceutical companies since 1996. Lloyd's Register Serentec specializes in providing validation services for computer systems, automation, equipment and process and assisting clients in 21 CFR Part 11 compliance. More recently, we've been involved in Process Analytical Technology consulting and have developed a four-step methodology to assist pharmaceutical companies in implementing and realizing the benefits of PAT.

The knowledge of effective application of quality management systems across a wide range of industries, combined with the very specific knowledge of the pharmaceutical industry and FDA regulations, makes the combination of Lloyd's Register Quality Assurance and Lloyd's Register Serentec a unique voice. We strongly encourage the FDA to incorporate third party audit and certification in the guidance as a means of helping to achieve the quality improvements enjoyed by other industries and sought by FDA.



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We would like to schedule an exploratory discussion of quality systems and the contribution a third party certification process could make in helping FDA achieve its objectives. We would also appreciate gaining some insight into the direction FDA is considering as the agency moves forward with this initiative.

Thank you for your attention, and we look forward to meeting with you.

Sincerely,



John R. Davis, PE, President
Lloyd's Register Serentec, Inc.



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