QUALITY ASSURANCE™
SOCIETY OF QUALITY ASSURANCE
The Premier Research Quality Assurance Professional Organization

1 July 2004 Via First Class mail and E-mail

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Attn: Docket Number 2004N-0133 (Electronic Record; Electronic Signatures; Public Meeting)

Dear Dockets Manager:

The Computer Validation Initiative Committee (CVIC) of the Society of Quality Assurance (SQA) wishes to thank the FDA for the opportunity to comment on potential revisions to 21 CFR 11 (Part 11), the Electronic Records/Electronic Signatures Regulation.

SQA is an international organization made up of over 1,700 individuals who are primarily quality assurance and regulatory compliance professionals, across GMP, GLP and GCP (GXPs). The CVIC has been in existence since 1996 and is a key committee within SQA. Our group has focused on computer system validation and Part 11, and has played a key role in assisting our own organizations and SQA in understanding regulatory expectations and requirements surrounding the use of computerized systems in regulated environments. We are the people who have interpreted Part 11 in our workplaces. Although implementation of Part 11 has been a challenge, the benefits have outweighed the burdens. Part 11 has encouraged industry to adopt quality standards that have improved the way the regulated information technology organizations manage their applications, systems and infrastructures. It has forced computerized system vendors to become more accountable for their development and support practices. It has improved the reliability, repeatability, trustworthiness and integrity of the data submitted to the FDA. Software vendors *have* responded to the controls we have requested to support data integrity. Portions of the rule have pushed industry and suppliers to change processes and systems, which has factored into improving the quality of products and data.

In recent years, there has been an increased reliance on electronic records and computerized systems for research data collection and analysis, process control, data analysis leading to product claims, safety reporting and tracking, and problem resolution (corrective action). The increased reliance, combined with anticipated increased regulatory scrutiny of electronic data integrity and predicate rules that do not clearly and consistently address computerized system compliance requirements, has generated concern among quality professionals regarding any significant reduction in the requirements or a complete repeal of Part 11. Please note that not all predicate rules require validation of computerized systems. Part 11 has done much to help the QA professionals and the pharmaceutical businesses in providing a common cross GXP expectation for computerized system compliance. If the Agency relied solely on the wide variability of the predicate rules (as was the case pre-Part 11) there is the requirement of having to address countless interpretations and variations across industry with the potential of wasting resources on approaches that may be found unacceptable by the FDA. We would like to continue to see clarity and consistency across the regulations regarding computerized system compliance in order to best support the quality and integrity of electronic data.

2365 Hunters Way, Charlottesville, VA 22911 · Telephone 434/297-4772 · Facsimile 434/977-0899
Website: www.sqa.org · E-mail: sqa@sqa.org

Some degree of validation is required for any computerized system creating or handling regulated records, regardless of the medium of the record (electronic or paper) or the predicate rule governing the work. Given the number of FDA regulations impacted by computerized systems, amending all of the predicate rules would be a daunting task. This goal is much more effectively achieved through the promulgation of a cross-predicate rule such as Part 11.

We would like to thank the Agency for providing a risk-based approach to computerized system compliance. We would ask the Agency to refrain (as you have done in the past) from prescribing a methodology or endorsing any given methodology. Given the extreme variability of needs across the regulated industry due to predicate rule and business requirements, we ask that each company be permitted to develop and document its own approach to compliance with the regulatory requirements.

We are very pleased to see re-enforcement in the Scope and Application Guidance regarding the ability to migrate electronic records to other formats or media for long-term regulatory retention periods. Long-term retention of electronic records in original format becomes problematic as years go by, due to the need to retain a strategy for accessing minimal hardware if needed (which will no longer be available at some point), older software (which may become unsupported), and staff expertise on the outdated system. We agree that it is acceptable to migrate records at some point, as long as they are accurately and completely copied, with no reduction in meaning and context.

We are encouraged to see the Scope and Application Part 11 Guidance reinforce electronic copies of records to be supplied to the Agency in generic formats. This allows industry standard options for providing the FDA with the needed electronic records.

In conclusion, we are pleased to see clarification in certain system-related areas within the Scope and Application Part 11 Guidance and the provision for a risk based approach. Since the use of computerized systems has increased considerably over the past 10 years, and will continue to increase, it is appropriate for the FDA to have regulations that are specific to computerized systems. We are confident that the FDA will rely on its own investigative experience in the field, and the historical data from 483s and warning letters to conclude that the need for clear, consistent cross-GXP requirements for computerized systems compliance still exists and is best achieved through a single cross-predicate rule such as Part 11.

CVIC and SQA thank the FDA for the opportunity to comment at this very important juncture of proposed regulation revision.

Sincerely,

Patricia Miller

Patricia Miller, Chair
Society of Quality Assurance Computer Validation Initiative Committee

Paul Bork

Paul Edward Bork, RQAP-GLP, President
Society of Quality Assurance