


QUALITY ASSURANCE
SOCIETY OF QUALITY ASSURANCE

The Premier Research Quality Assurance Professional Organization

22 October 2004

via E-mail and First Class mail

Dockets Management Branch
Food and Drug Administration
HFA-305
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 2004P-0429/CP1

Dear Sir/Madam:

The Society of Quality Assurance Computer Validation Initiative Committee (hereinafter "CVIC") is pleased to submit the attached response to the Industry Coalition Citizen Petition to the Food and Drug Administration, docket number **2004P-0429/CP1**, for consideration.

The Society of Quality Assurance (hereinafter "SQA") is an international organization made up of nearly 2,000 research quality assurance professionals. We are tasked within our organizations with representing the regulatory and compliance point of view. SQA CVIC members specialize in assuring consumer safety, product quality, and data integrity when these goals are managed via computer systems.

CVIC disagrees with the Industry Coalition's conclusion that the Electronic Records; Electronic Signatures Rule (21 CFR Part 11) should be rescinded. CVIC feels that Part 11 does add value and is not redundant with other regulations. The Industry Coalition has only cited references taken from manufacturing and quality systems regulations, although Part 11 is also applicable to laboratory and clinical regulations. The data submitted from the research and development process are a significant and critical part of the submission and product evaluation process performed by FDA to approve new medicines. These areas must not be ignored in any debate concerning the future of Part 11.

Rescission of Part 11 is not consistent with the FDA's initiative on Pharmaceutical cGMPs for the 21st Century. The initiative embodies a quality systems orientation, international cooperation, and FDA's overall commitment to public health in addition to the concept of a risk-based approach. The concepts set forth in Part 11 are central to implementing this initiative in a scientifically sound way.

The Industry Coalition's Citizen Petition argues two points for rescinding Part 11:

- Part 11 is unnecessarily burdensome and inhibits technological innovation.
- The Government Paperwork Elimination Act (GPEA) has superceded Part 11.

As with any pioneering regulation, there are sections and definitions in Part 11 that could be improved and updated. Ongoing FDA guidance about how to apply the regulation to the specific predicate rules has helped clarify much of the uncertainty of implementation. In addition to highlighting core expectations regarding the implementation and application of Part 11, guidance documents provide a sound basis for understanding and extrapolating Part 11 principles into new technologies and situations.

CVIC is not aware of any evidence that Part 11 is unduly burdensome or that it has inhibited technological innovation. On the contrary, since the enactment of Part 11, there have been many advances in the implementation of digitized bio-imaging technology and electronic data capture technologies, as examples. The ever-increasing number of IND and BLA submissions indicates that Part 11 has not impeded novel approaches to discovery, development, and manufacture of new medicines. System vendors have continued to respond to industry requests for better development practices and added software controls.

It is the opinion of CVIC that the Government Paperwork Elimination Act (hereinafter "GPEA") does not supersede Part 11. There is no evidence of such legislative intent. The agency responsible for implementing the act (Office of Management and Budget – hereinafter "OMB") has not interpreted GPEA in such a fashion. In fact, there is evidence to the contrary:

The Department of Justice commented on the need for each agency to consider the broad range of legal risks involved in electronic transactions. ... We are not, therefore, prescribing specific "one size fits all" requirements applicable to transactions regardless of sensitivity.

[A]gencies should consider whether their policies or programmatic regulations support the use and enforceability of electronic signature alternatives to handwritten signatures as well as to electronic record keeping under Federal programs. [OMB goes on to cite Part 11 as an example of such consideration].

See OMB Memorandum M-00-10, Implementation of the Government Paperwork Elimination Act, 65 Fed. Reg. 25,508, 25,512 (May 2, 2000) (OMB GPEA Procedures).

As evident in the preamble to Part 11, and as demonstrated in subsequent Part 11 guidance, the FDA has done exactly what has been requested by OMB: FDA has considered the broad range of legal risks unique to the types of electronic records and signatures that fall within the scope of the regulation. Rescission of the regulation would be tantamount to abandoning this duty and counter to the intended OMB implementation strategy for GPEA.

In the same vein, the Industry Coalition's classification of electronic records and signatures subject to Part 11 as "low risk" is a flawed application of OMB's GPEA Implementation Guidelines (*infra*). This assertion is based on the following statement:

[T]ransactions between a regulatory agency and publicly traded corporation or other known entity regulated by that agency can bear a relatively low risk of repudiation or fraud, particularly where the regulatory agency has an ongoing relationship with, and enforcement authority over, the entity.

This is, however, only one of three factors to be considered when determining risk, some of which directly relate to the FDA's ability to carry out its enforcement mandate. In advising agencies how to implement GPEA, OMB further advised:

Consider what risks may arise from the use of electronic transactions or documents. This evaluation should take into account the relationships of the parties, the value of the transactions, and the later need for the documents.

With respect to electronic records and signatures within the scope of Part 11, there is a high likelihood FDA will need “accessible, persuasive information regarding the transaction at a later point.” (infra) This is particularly relevant where such information may later be needed as proof in court and meet standards of both admissibility and trustworthiness. The validity and integrity of data provided to the reviewers at FDA directly impacts the health and safety of the public. Regardless of the financial implications, the general public would likely consider transactions affecting their health and safety to be high-risk transmissions. The enormous financial implications to be considered around the business confidentiality of the submittal, the potential lost revenues should the submittal be lost or delayed, and the future liability of the company in assuring that they provided full and complete disclosure of information implies a very high-risk transaction.

The scope of the GPEA focuses on the submission and maintenance of records after they are transmitted to a federal agency. The scope of Part 11 includes the creation, modification, maintenance, archival, and retrieval of those records prior to submission to the agency.

Another argument in the Industry Coalition’s Citizen’s Petition is the assertion that Part 11 requirements are duplicative of predicate regulations. CVIC disagrees with this assertion. Our review indicates that only five (5) of the 29 Part 11 record and signature requirements are duplicative of predicate regulations. The other 24 requirements address requirements that would allow electronic records and signatures to be acceptable under predicate rules. Moreover, there are no clinical practices predicate regulations (GCPs) that overlap with any of the Part 11 considerations.

In the seven years since Part 11 was enacted, many companies and organizations have invested time and resources in developing and upgrading their systems to meet those requirements. Many of these companies have taken this work and expanded the scope of their upgraded systems to include compliance with HIPAA, Sarbanes-Oxley, ICH, EMEA, and other regulations, both US and international. We question the effect that the rescission of Part 11 would have on these companies that have worked and invested so much already – will we move to a lower quality and data integrity standard for health and safety data than financial data? Also, would our international counterparts question health and safety data generated or maintained or submitted electronically in the US?

CVIC respectfully requests the FDA’s full consideration of these issues raised in this response to the Industry Coalition’s Citizen’s Petition and is available to answer any questions that may arise during review.

Sincerely,



Paul Bork, RQAP-GLP
SQA President



Pat Miller
CVIC Chair