

December 12th 2001

U.S. Department of Health and Human Services
Food and Drug Administration 9571 '01 DEC 17 P1:35
Office of Regulatory Affairs

RE: Docket 00D-1538, 21 CFR Part 11 Draft Guidance (Aug 2001 ed.)
(hereinafter "Draft Guidance")

Dear FDA,

I have been employed in FDA-regulated industries for 20 years and was first trained in GMP requirements in 1982. I have also participated in the ISO-9001 and ISO-9002 certifications of three business. I write as an individual to represent the practitioner's point of view, and because my views may not necessarily be those of my current employer.

Overall, the Draft Guidance is a good start, thank you. But I have some distinct concerns it would be helpful if FDA would address.

I

Regarding section 5.1, System Requirements Specifications, FDA says "without first establishing end user needs and intended uses, we believe it is virtually impossible to confirm that the system can consistently meet them." Here's the problem - in real life, users often state "desirements" as if they were "requirements" and in the end, what they get works fine but looks nothing like what they said they wanted. In this world, it is useless to the point of value-subtracting to even try to trace the up-front "desirements" to the actual implementation.

FDA appears to be focusing on an out-dated arms-length software development model as if it were the only way software development and implementation ever happens. With modern iterative development methods, users broadly state their goals and intended uses up front and then the technical implementation occurs with the close cooperation of the intended users, and occurs simultaneously with the development of training materials, test plans and operational procedures.

When predicate regulations require training materials, objective tests and operational procedures (which must be evergreen) and where those regulatory requirements have been met, then the entire set of intended uses of a system can be determined by a review of those materials. What we said we wanted when we started, just doesn't matter.

00D-1538

CY

I would like to see section 5.1 updated to clearly state that when the intended uses of a system can be adequately determined by a review of the current operational procedures, tests and training materials, no separate system requirements specification is needed.

II

Regarding the extent of validation discussion in section 5.6, it would be very helpful if FDA would either expressly adopt or expressly step away from the widely-distributed General Principles of Software Validation (Version 1.1 Draft, June 9, 1997), where FDA says in section IV-G that "Software cannot be partially validated." Section 5.6 appears to say that software can indeed be partially validated, that is, if a (potential) function is determined to pose no risk to product safety, and poses no risk to (controlled) data integrity, then the use of such a function is out of part 11's scope. The section 5.6 guidance leads me to the conclusion that some auxiliary functions such as cost accounting, for example, are exempt from part 11 validation requirements. Please confirm or deny; can a system be partially validated?

III

It appears to me that the reference to the above-quoted draft document "General Principles ... June 1997" in the new Draft Guidance Appendix A, pg 15, is wrong because it violates 21 CFR Part 10, Good Guidance Practices.

General Principles over-reaches its intended target by overstating it's scope and audience, in my humble opinion, and whether you care about that or not the comment period closed 4 years ago and there is no final guidance yet, so there is no avenue for commentary. Part 10 appears to forbid FDA's use (even if only by reference) of a document in this state. The purpose of a draft is to inspire commentary only. So when the comment period is closed on a draft, part 10 seems to say that the draft is no longer useful. I recommend correcting the error by removing the reference, and any other references to drafts that might be in the document.

Thank you for your attention,

 12/12/01
Ray Miller