

01 November 2001

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

0088 01 NOV 14 P1:46

Re: Docket No. 00D-1538
21 CFR Part 11:
Validation

My thoughts on the Validation Guide, #00D-1538:

- Section 5.1, 2nd sentence

The sentence does not read very clearly to me. If one does not have user needs or intended uses written down, then how can one say anything about them (... consistently meet them.)?

I suggest rewording the sentence to be something like:

"One must always first establish in writing the end-user requirements (needs), including the intended uses. Only that way, will one be able to then methodically, thoroughly and accurately confirm that the system performs as desired."

I'd suggest that they add something to the affect of:

"Generally, but especially for complex systems, end-user requirements established by a cross-functional team are more complete than if created by an individual. The final requirements document should be approved by a system 'champion' or oversight committee or as stated in the Validation Plan."

- Section 5.1, 2nd paragraph

I would suggest that the word "reliability" be substituted for the word "performance" in all cases where the phrase "system performance" is currently used. I feel that "reliability" is more appropriate and is more descriptive of what I feel is desired - maintaining data integrity & trustworthiness. The term "reliability" is defined in the draft Glossary of Terms; "performance" is not. "Performance" implies to me such things as the speed of the system, which I wouldn't think would be a regulatory issue.

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I'm not sure what point is trying to be made with the 2nd bullet, Scalability. I'd suggest this one be dropped. It doesn't seem to me that bandwidth or # of workstations would be a regulatory issue, unless they somehow impact the reliability of a system. In my experience, those factors may impact how quickly, or not, as system responds to input but usually doesn't have any direct impact on the integrity of the data. This is to me a "customer satisfaction" issue, not a regulatory one. In my opinion, the rest of the paragraph speaks to reliability satisfactorily.

- Section 5.4.1, 1st bullet, 2nd sentence:

Instead of the phrase "unexpected data entries", I'd suggest something like "non-standard data entries". I just don't feel comfortable that the word "unexpected" will communicate what the Guide intends.

- Section 5.4.1, 2nd bullet

I'd suggest dropping this bullet. Whether one does or does not use simulation testing does not seem like a regulatory issue to me. This bullet strikes me as more of a definition (of the fairly obvious), instead of any form of guidance.

- Section 5.6, 1st bullet

I'd suggest that the phrase "product safety, efficacy, and quality" be replaced with "product identity, strength, quality and purity", as referred to in the GMPs, 211.22 (c).

- Section 5.4.1, 2nd bullet

I'd suggest replacing the word "confidentiality" with some other term like "security". I don't see that "confidentiality" is generally a regulatory issue, although it's certainly important from a company's competitive standpoint. Or, note that "confidentiality" pertains only to patient medical records in clinical trials.

- Section 6.1.2

I'd prefer the word "or" instead of "all" toward the end of the 1st sentence. I don't feel that conducting an audit of every single vendor we use is reasonable, and certainly isn't practical. For software in "wide use" (the 1st bullet) like EXCEL, an audit isn't necessary I don't feel. The software quickly gets tested & major 'bugs' fixed in the field. Also, the structural integrity of software for a 'small' (a few thousand dollars) system could reasonably be established through "wide use" (1st bullet), I feel. One needs to factor in the 'risk' (as is pointed out elsewhere in the Guide) and assess whether or not an audit is appropriate (i.e., worth the cost of doing it).

- Section 6.2

I'd like to see the term "internet" defined for us. While many people/companies probably use the internet for their system data transfer, I'd guess more companies use 'closed' systems that communicate over a wide area network (WAN). Do their comments apply to WANs (& LANs) or to just the internet or both?

Thank you for the opportunity to comment on the draft guidance. I hope that these comments will be informative and useful as finalization of the guidance proceeds.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce L. Hogle". The signature is stylized with a large initial "B" and a long horizontal stroke at the end.

Bruce L. Hogle
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