



GlaxoSmithKline

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20-Dec-2001

Dear Sir/Madam

Re: Comments on; "Draft FDA Guidance for Industry; Electronic Records; Electronic Signatures, Validation" Docket No. 00N-1538

GlaxoSmithKline a research-based pharmaceutical company is engaged in the discovery, development, manufacture, and sale of pharmaceutical products. We welcome the opportunity to submit comments on aspects of the Draft Guidance.

General Comments:

- 1) It is suggested that rather than publish a separate document the computer validation guidance covered in this Draft document might be better positioned as an update to the FDAs existing 'Inspection of Computerised Systems Used in Drug Processing' published in 1983. There appears to be no changes to basic FDA computer validation requirements whether or not Part 11 is involved. A single source of reference for FDA computer validation guidance would promote consistency and avoid those seeking advice on computer validation having to search multiple FDA guidance documents.
- 2) The current Draft Guidance seems to place emphasis on initial validation of computer systems. It is suggested the description of validation requirements be extended to provide details of expected operational controls to maintain validation during use of a computer system. Topics to cover might include security access, change control, backups, archiving, and training.
- 3) It is suggested that the topic of validating hybrid solutions (the integration of procedural controls and electronic records, such as print and sign) should be included for legacy systems. This is key guidance because current technical limitations will prevent full electronic compliance with Part 11 for many systems. It may take a number of years until suitable system upgrades become available from vendors to facilitate full electronic compliance with Part 11 requirements.

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Specific Comments:

- 1) Dynamic Testing as presented in Section 5.4 is not routinely used nomenclature in our experience and it is suggested that perhaps unit testing, integration testing, and systems testing would be better used. It should be recognised however that the terms unit testing and integration testing may not be readily applicable to some Programmable Logic Controllers (PLCs) and laboratory instrumentation where there are no units of code to test or integrate rather the software exists as single entity. In addition it is not clear whether the lack of any reference to the role of Installation Qualification, Operation Qualification, and Performance Qualification for computer systems is intentional or not.
- 2) In Section 5.4.3 further definition and examples of what is meant by "quantifiable test results" would also be useful. It is suggested that tests results can be based on discrete and repeatable observations as well as definitive data values and physical system outputs.
- 3) Section 6.1 Commercial, Off-The-Shelf Software tackles a very important aspect of modern computer systems. Bespoke/custom development is much less common now compared to integrating configurable COTS products. There is a built in dependency on supplier documentation and practices for COTS products some of the suppliers of which will only have a small percentage of sales into the pharmaceutical industry. It may not be feasible in some instances to access all life cycle documents for standard COTS software products. It is suggested that the differences for user validation of custom (bespoke) software and COTS software be described in more detail perhaps with reference to supplier audits. Specific opportunities to reduce user validation such as not duplicating supplier functional testing of unaltered standard functionality could be discussed where reliance can be placed in supplier practices and documentation.
- 4) Further review of web-based applications in Section 6.2 to include the intranet as well as the internet would be useful especially if FDA have any different expectations regarding validation of such applications. It is not clear whether the lack of any reference to the role of Open and Closed Systems is intentional or not.

We appreciate the opportunity to comment. Thank you for your consideration.

Sincerely



Dr Guy Wingate
Director, Global Computer Validation