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LIFE SCIENCE PROFESSIONALS

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

RE: Comments on "Draft Guidance for Industry – Computerized Systems Used in Clinical Trials"; Docket No. 2004D-0440

Dear Sir/Madam:

ISPE welcomes the opportunity to submit comments in response to FDA request for feedback to the above draft document. ISPE is an international society promoting the integration of industry professionals and regulatory agencies worldwide to improve the Life Sciences.

The ISPE technical sub-committee known as GAMP Forum has prepared the comments submitted here. GAMP Forum is an international organization with active regional steering committees for USA, Europe, and Japan. Membership includes pharmaceutical companies, suppliers, and consultants. The GAMP Forum is responsible for the GAMP4 Guide and is currently working on several new Good Practice guidances, including risk-based Electronic Record/Signature Guidance.

ISPE/GAMP appreciate the significant rewrite that this draft guidance represents, and in particular the adoption of a risk-based approach to the use of computerized systems in clinical trials. This is viewed as allowing a greater level of pragmatism in the application of validation principles in the clinical trials area. The overwhelming consensus of those who commented was that this draft is viewed as a very positive move forward in removing the barriers to the use of new technology in this sector of the industry.

The following points represent a high level summary of the many comments submitted by our membership:

- 1) The scope of the document clearly excludes computerized medical devices, such as sphygmomanometers, peristaltic pumps, glucose monitors etc, as well as equipment such as incubators. We suggest that these pieces of equipment can be used to generate and process GxP critical data locally within the instrument. Can the scope of the guidance be clarified by providing a clearer definition of analytical instrumentation in relation to its data processing capability?
- 2) GAMP Forum applauds the positive steps to bring the Clinical Trials guidance into line with the position outlined in the Part 11 Guidance on Scope and Application, but as this is also subject to change, it is suggested that specific, detailed references to Part 11 and related guidance are kept to a minimum and that discussion should focus on



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either predicate rule expectations or the general concepts behind the current FDA position on Part 11.

- 3) Can the respective responsibilities of Investigator Sites, CRO's and Sponsors in relation to validation and electronic records controls be clarified? Some systems are used by one party but managed by another organization (e.g. web-based applications used to collect data, systems operated by third party organizations).
- 4) There is general concern regarding the agency's expectation for document availability. This applies to not only documentation associated with 'commercial off the shelf' applications, but also to documentation related to the implementation of systems within the public sector, where many Clinical Trial investigator sites are based. In fact at many points in the guidance, concern was expressed as to exactly whom it should be applied as particular problems may be experienced in the public sector of the Clinical Trial industry that could preclude many organizations from taking part in clinical trials.
- 5) How much detail is required to fulfill the recommendation for each study protocol to identify the steps used in a computerized system for data handling? GAMP Forum would recommend that such detail could remain at a high level and indicate a reference to more detailed systems descriptions held elsewhere rather than repeat information for the sake of doing so. This may specifically be the case where trials are supported by external partners, particularly those in the public sector.
- 6) Restrictions on the use of external applications for browsing, querying or reporting seem too far-reaching. This should be accepted if these external applications or protection systems are validated. In fact, over time it may be preferable to allow such an activity as data becomes archived and may no longer reside in the original application.

ISPE hopes that the above comments provide useful feedback in what is seen as an important initiative by our membership.

Thank you for the opportunity to comment.

Yours Sincerely,



Bob Best