From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, February 22, 2005 8:00 AM
To: [redacted]
Cc: [redacted]
Subject: RE: Question about the Use of SAS

Dear [redacted],

Your inquiry was forwarded by George Smith to our office for reply. Please accept my apologies for the delay in responding to your inquiry. After consulting with experts in our biostatistics division, I offer the following information about SAS programs and hope this might still be useful to you.

Here are answers to the questions you submitted below:

1) the agency has officially adopted the SAS program as a standard statistical program and recognizes it as validated software. To ensure that an analytical program coded using SAS accomplishes what the user intends, it would be important to perform functional testing on the coded program. Our Part 11 Scope and Application guidance notes that the agency plans to use enforcement discretion with regards to systems/software validation requirements. Since any coded program will be manipulating critical study data, again for this reason, functional testing of the coded program would be necessary.

2) I would expect an FDA investigator would like to review the records documenting the kind of testing that is to be performed on the coded program, as well as records documenting test results. Because SAS is a COTS program, we appreciate the fact that validation data of the SAS program itself may not be available from the vendor. I would not expect FDA investigators to ask to see validation information on the commercially available SAS program.

Again, my apologies for the delay in replying to your inquiry. I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Monday, January 24, 2005 8:51 AM
To: [redacted
Subject: Question about the Use of SAS

[redacted]:

I work with [redacted], both who speak very highly of you. I am hoping that you might be able to help with a couple of questions. [redacted] about taking a risk-based approach to addressing regulatory concerns with SAS programs. The general point [redacted] is to understand how [redacted] SAS programs are being used in terms of safety, quality and effectiveness, then base the validation effort and integrity controls on that use. I have a couple of questions from and FDA point-of-view and was hoping you could provide some insight.

1. Is FDA concerned about the validation of SAS programs that are used to analyze data in pre-clinical, clinical and manufacturing environments? I am not referring to validating the SAS program itself (i.e. Base SAS and other tools), but the actual SAS programs that are written for data analysis.

2. During FDA inspections, would an investigator ever ask about validation of SAS programs? This would include if programs are validated as well as the procedures used for validation.

Thank you in advance for your help. If you would prefer not to be quoted, just let me know.

Best regards,

[redacted]