From: OC GCP Questions
To: [redacted]
Subject: Question about study site equipment
Date: Friday, November 06, 2015 6:57:20 AM

Good morning –

This office does not generally handle questions regarding maintenance of equipment and documentation, the guidance document (link below) states –

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070337.pdf

Under a robust quality system, sufficient resources should be allocated for quality system and operational activities. Under the model, senior management, or a designee, should be responsible for providing adequate resources for the following:

To supply and maintain the appropriate facilities and equipment to consistently manufacture a quality product

To acquire and receive materials that are suitable for their intended purpose

For processing the materials to produce the finished drug product

For laboratory analysis of the finished drug product, including collection, storage, and examination of in-process, stability, and reserve samples

Additionally, the protocol and/or sponsor requirements should guide on equipment maintenance and what documentation is needed to provide assurance that the equipment is working properly.

Developing standard operating procedures (SOPs) and quality control/quality assurance units, organizations have the means in place to address problems when they arise. If your sites and you as the sponsor do not already have SOPs, you should definitely consider developing SOPs to ensure that your sites have (and uses) consistent work processes and procedures. You may also wish to consider, if you do not already have one, establishing a quality control unit. Such actions may help your organization prevent occurrences from happening in the future and handle any such problems when they do occur.

If problems do occur with site equipment, your organization should at least do an assessment to determine what caused the problems. For example, what were the "instrumental errors"? Were the errors due to operator error or was the equipment in poor repair? The answers to those questions would provide a direction for you to pursue further action. For example, if the errors were on the part of the operator, why did the operator make them? Was the operator not trained on the proper use of the equipment? Was the operator appropriately supervised? Or did the operator simply make an error in using the equipment (although they had received proper training)? If the equipment was faulty, why? Is it old and in need of replacement, or did it need to be serviced, or was there a problem with the software? Had the equipment been properly calibrated, and/or had the software been properly validated? Is the equipment regularly serviced and maintained? Again, the answers to the questions will help you determine your next possible course(s) of action.

Your questions may also be answered in the FDA regulations under 820 Quality System Regulation - Production and Process Controls.

CFR - Code of Federal Regulations Title 21

Please see other web links below that might be helpful to you.

Guidances (Drugs) > Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance - Equipment

CFR - Code of Federal Regulations Title 21

Inspection Guides > Page 9

http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070336.pdf

I hope this information is helpful to you. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, November 06, 2015 12:47 AM
To: OC GCP Questions
Subject: Question about study site equipment

Dear Sir/Madam:

Regarding the site equipment used in study, such as from CT machine, freezer for storing biological samples, refrigerator for study drugs, to centrifugal machine, thermometer, body thermometer, weighing scale, and etc, as a sponsor, what documents we need to collect from site to demonstrate the equipment are maintained and working well? Do we need to? Sometimes it is very difficult to collect such documentations from site. Though the equipment are maintained, however there may be no certificate for all.

Best regards
[redacted]