From: OC GCP Questions
To: [redacted]
Subject: 21CFR11 question regarding electronic training records
Date: Thursday, February 22, 2018 3:33:00 PM
Attachments: [redacted]

Good afternoon –

Thank you for your patience. There is the cleared response from FDA's Office of Medical Policy (OMP).

Response: Your process/procedure for documenting employee training is acceptable.

For validation of electronic systems used in clinical investigations, FDA recommends using a risk-based approach when deciding to validate electronic systems. You should consider (1) the nature of the electronic system (e.g., commercial off the shelf systems, customized systems), (2) the intended use of the electronic system (e.g., used to create, modify, maintain, archive, retrieve, or transmit records that are essential to the clinical investigation), and (3) potential risks to study participant safety, data security, and data integrity. For example, validation would not be important for electronic systems used only to generate SOPs.

We recommend that you that you document your risk assessment and your determination of the potential of the system to affect the security and integrity of the record. For more information on using a risk-based approach, please see FDA guidance for industry, use of electronic records and electronic signatures in clinical investigations under 21 CFR Part 11 (available at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm563785.pdf).

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Tuesday, February 20, 2018 10:56 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Cc: [redacted]
Subject: 21CFR11 question regarding electronic training records

Hello,

We are currently evaluating some electronic learning management systems to assist us in managing our training. These systems require user names and passwords to enter the systems

and have an audit trail to confirm the correct user name and password was used to acknowledge training. The system would record who assigned the training and when it was assigned.

We would like to know if the FDA would have any concerns if an employee electronically acknowledged their training through this system by answering a question that asked them to confirm they read the assigned document. There would be no actual signature.

Also, do these learning systems require validation in your opinion?

Thank you so much for your assistance!

Take care,

[redacted]