From: OC GCP Questions
To: [redacted]
Subject: Source doc / email question
Date: Friday, April 03, 2015 1:16:35 PM

Good afternoon [redacted]--

I checked with the IT specialists in the Center for Drugs (CDER) and this what they said.

They would be hesitant to say her use of email is consistent. It depends on the type of file the email is saved as. Some email is just text that can be easily changed. It really depends what they are using – also identifying who the email came from if it's not secure is a concern. How do you identify the source creator if you don't know who sent the email?

I hope this additional information is somewhat helpful.

Kind regards,

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

From: [redacted]
Sent: Wednesday, [redacted]arch 25, 2015 9:08 PM
To: OC GCP Questions
Subject: RE: Source doc / email question

Wonderful, thank you!

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Wednesday, March 25, 2015 12:20 PM
To: [redacted]
Subject: Source doc / email question

Good afternoon [redacted] –

I am going to check with some IT specialists in the Center for Drugs (CDER). It might take a couple of days for them to respond. As soon as I hear from them, I will send you a second email. Thanks for your patience.

Sincerely,

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

From: [redacted]
Sent: Wednesday, March 25, 2015 1:45 PM
To: OC GCP Questions
Subject: RE: Source doc / email question

Thank you very much, Doreen. I am familiar with the materials you provided (thanks!) – we are very involved right now in our digitization efforts and are becoming very acquainted with the related regs and guidance. That's one reason I'm somewhat fixated on this issue. Another reason is that we are providing the primary endpoint on a Phase 3 trial; hence my extreme caution prior to making changes to a time-tested/audited process.

So in follow-up – just to clarify –the email correspondence from the site, containing source data to respond to queries, would be considered by FDA to comply with Part 11 requirements for electronic records? Or, stated differently, NOT to be non-compliant?

Assume for now that we will print the email and retain the printed copy with the source docs, but I'm mainly asking whether the FDA generally considers the generation and transmission of an email from one center to another to be a trusted and reliable electronic source data record with a clearly identifiable author and an adequate time stamp / audit trail. My concern is that our center would not be able to provide assurances that the site sender's email account is secure and not subject to unauthorized use. On the other hand, if the use of email as a trusted electronic data source has not historically been out of the ordinary, and/or would not raise the eyebrow of an inspector in an audit of a Phase 3 trial, that would give me much more of a degree of comfort in authorizing the change I described to our process and SOP (as long as we always adhere to specific the protocol requirements when different).

Thank you again, I really appreciate your assistance. I know you are busy and I don't mean to take so much time from you – I just want to make sure I understand your comments.

Kind regards,
[redacted]