From: OC GCP Questions
To: [redacted]
Subject: Question about internal computer system
Date: Thursday, March 29, 2018 11:35:00 AM
Attachments: [redacted]

Good morning –

I sent your email to the Center for Drugs (CDER), Office of Medical Policy (OMP). See below

Below is OMP's cleared response:

Part 11 requirements are not intended to apply to electronic systems that are used just to create paper printouts that are subsequently maintained in traditional paper-based systems. In such cases, the electronic systems would function essentially the same way that manual typewriters or pens would function, and any signatures would be traditional handwritten signatures. Storage and retrieval of records would be of the traditional file cabinet variety.

Part 11 regulations may apply to your system depending on whether your actual business practices make use of electronic records instead of paper records under § 11.2(a). For example, if a record is required to be maintained under a predicate rule and you use a computer to generate a paper printout of the electronic records, but you nonetheless rely on the electronic record to perform regulated activities, the Agency may consider you to be using the electronic record instead of the paper record. That is, the Agency may take your business practices into account in determining whether part 11 applies".

In addition, complying with the European Union General Data Protection Regulation (GDPR) does not mean that the electronic system also complies with FDA's part 11 regulations.

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: Wednesday, March 28, 2018 1:21 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Re: Question about internal computer system

Thank you for your response,

We are a very small group of 8 CRAs .We provide monitoring services but we collaborate with bigger CROs that manage the entire trial and the CTMS and eTMF. The CRAs are writing up the report on a word document and the

final approved monitoring report is uploaded in the sponsor eTMF.
The CRA would have access within our restricted system to our internal SOPs and their own training records scanned. All those documents are paper at our office. All employee also have a paper copy of our SOPs. Any client documents (protocole, study plans, SOPs..) are accessed through the client's CTMS or collaborating CRO CTMS. Our CRA would have specific access to the CTMS or eTMF.

Any final approved documents generated from our CRAs would be filed in the client CTMS or eTMF that is part 11.

Anything that requires to be audited by a client would be either available in the eTMF or the CTMS or through paper, with regards to our service that is mandated. Like our clients have working documents or portal such as SharePoint with vendors, we have internally a system that we use as a working but any final documents are not filed in there. Any changes to the final documents would be tracked in the eTMF managed by our client or collaborating CRO.

For computer systems that are compliant to European Union General Data Protection Regulation (GDPR), is this comparable to part 11?

Thank you again for your assistance

[redacted]

From: OC GCP Questions <OCGCP.Questions@fda.hhs.gov>
To: [redacted]
Sent: Tuesday, March 20, 2018 3:55 PM
Subject: RE: Question about internal computer system

Hi [redacted],

I have reached out to our subject matter experts (SMEs) on electronic systems and Part 11. They are asking for the following information to assist in addressing your inquiry:

- What study services do you provide for your client?
- What study files do your staff have access to?
- What access privileges (e.g., read only access, read/write access) are given to your staff?
- Does your study staff have the ability to modify data that will form part or all of a required record for the clinical trial?
- Why do you consider your internal system not auditable (and not auditable by whom)?

If you could reply with this additional information, I will forward the details to our SMEs to provide a response.

Many thanks,
Bridget Foltz
Bridget A. Foltz, M.S., MT(ASCP)
Health Scientist Policy Analyst

Office of the Commissioner (OC)
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U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, March 19, 2018 2:40 PM
To: OC GCP Questions <OCGCP.Questions@fda.hhs.gov>
Subject: Question about internal computer system

Good day,

We have a question regarding the computer system that we using internally within our team. During clinical trials, we are always filing everything in our clients or collaborating CRO CTMS. Within our team we have access to our internal restricted shared VPN that is only used as a working file and that may file temporarily study files (agreed as per our contract with our clients). All study documentation are however uploaded in the official study client TMF or CTMS, which our team has access.

Our internal shared VPN is for our team only and used as working study file and is not auditable. From a security aspect, our internal VPN is highly secured and it complies to security requirements that we document and that are auditable but it does not comply to all aspects of the 21 CFR Part 11 (audit trail). Because of the utility of this system within our group, based on the services that we are mandated for and because we are filing all study documents in the clients or CRO official CTMS, our plan is not for us to move forward to modify our internal system for one that would include an audit trail and comply to 21 CFR part 11. We would like to have the FDA's advice on this.

Thank you very much for your assistance

[redacted]