From: OC GCP Questions
To: [redacted]
Subject: FDA Inspections at sites with eRegulatory systems
Date: Wednesday, June 20, 2018 1:51:00 PM
Attachments: [redacted]

Good afternoon –

Thank you for your patience. Please see the response below from FDA's Office of Regulatory Affairs (ORA). This office performs inspections for FDA.

Here are some examples of what an FDA Investigator is looking for when a firm has an e-Regulatory system. When an FDA Investigator is looking at the e-Regulatory system they will be reviewing SOPs, Work Instructions and meeting notes. Those are the types of documents that also may be printed. We will be reviewing roles and responsibilities of key staff, who has access to each area of the system, access levels established within the system and examining who is conducting QA checks of the system, (audit trail), who is changing data in the system and who is signing off/approving changes to data in the system. We are also looking at how the system is validated, implemented at the site and how staff is trained.

For further information, you can refer to FDA's study data standard research web page https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm. It might answer some of your questions.

Kind regards,

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

From: [redacted]
Sent: Monday, June 18, 2018 1:45 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA Inspections at sites with eRegulatory systems

Does the FDA have a guidance to help sites prepare for FDA inspections at their site if they have transitioned to an eRegulatory system? Are there additional resources the inspector will want to see? Are there common things sites forget to implement during their transition to

electronic? Will all investigators be willing to look solely at electronic or will some require the site to print off records?

Thanks,

[redacted]

[redacted]