

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Help with receiving letter from FDA regarding compliance with 21 CFR Part 11
Date: Friday, March 01, 2019 11:11:07 AM
Attachments: [REDACTED]

Good morning –

OGCP is not sure that FDA would send a system “validation letter”. However, this office is not the correct office. You will need to contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov . They respond to Part 11 and electronic records in clinical studies questions.

Kind regards,

The OGCP Group

From: [REDACTED]
Sent: Friday, March 01, 2019 10:47 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Help with receiving letter from FDA regarding compliance with 21 CFR Part 11

Good Morning – I am looking for some assistance in getting a validation letter from the FDA regarding our site's systems that use electronic signatures. In the past we have submitted letters to the FDA stating that our site intends that all electronic signatures are legally binding. The last letter that was sent was in May 2010 and is attached for your review. We had not received a response from the FDA in regards to this letter, and I didn't think that the FDA would send a response.

However, I am working with a study sponsor that states we should have received a validation letter from the FDA that would confirm that the FDA validated that our system(s) are in compliance with FDA 21 CFR part 11. So at this time I am seeking assistance on how I would go about getting a validation letter from the FDA about our systems.

The EMR that we use is Epic, and there are signatures within that system. The system is a COTS product, and is fully compliant with the requirements of 21 CFR part 11.

We use adobe for electronic signatures. Each staff member logs on to our network with an individual username/password. The individual username/password is connected to each person's digital certificate. Users also enter in another password to apply their signature. We have an SOP in place that walks users through the appropriate steps to electronically sign a document. Our SOP states that when we apply a signature, the document must be locked upon signature (this is an option in the signing page within adobe). This ensures that there can be no changes to the document after signing. The digital signature itself includes a date/time stamp and a reason for signing (i.e. I am the author of this document, I have reviewed the document, I am approving the document, I attest to the accuracy and integrity of the document. Etc.). Here is a snippet of what our eSignatures look like: