From: OC GCP Questions
To: [redacted]
Subject: Question on 21 CFR part 11 requirement
Date: Friday, June 01, 2018 9:44:00 AM
Attachments: [redacted]

Good morning –

Thank you for your patience. I had to send your email to the Center for Drugs (CDER), Office of Medical Policy (OMP). Please see their cleared response below.

Response:

Yes, FDA requires that persons using electronic signatures certify to FDA that all electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures (see 21 CFR 11.100(c)). You can submit one document as an organization that describes how you will implement legally binding requirements for use of electronic signatures, as described in 21 CFR 11.100. There is no electronic link for submission. Electronic signatures hardcopy should be sent to: 12420 Parklawn Dr. Element Bldg., Room 2133 Rockville, MD 20857.

FDA does not acknowledge receipt of these certifications, but upon your request, FDA will acknowledge that your hardcopy certification was received. In addition, organizations need not await FDA's response before putting electronic signature systems into effect.

Kind regards,

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

From: [redacted]
Sent: Thursday, May 17, 2018 12:34 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question on 21 CFR part 11 requirement

Hi team,

Good morning..!

Please provide clarification on below points of 21 CFR part 11 requirements.

1. As per 21 CFR part 11, Section no: 11.100 (b), (c) mentioned that,

(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.

(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.

(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.

So, if we are implementing electronic signature in Clinical trial Management software for preparation of monitoring reports and its approval, then, as an organization, we have to provide certification on above mentioned address to comply 21 CFR part 11 requirements. If yes, then FDA is providing acknowledgment of receipt of such certification. Is there any link for electronic submission of such certificate?

Thank you

With Regards

[redacted]