From: OC GCP Questions
To: [redacted]
Subject: Electronic signatures
Date: Wednesday, June 27, 2018 9:32:00 AM
Attachments: [redacted]

Good morning –

Please see the regulations on electronic signatures. (Part 11 Subpart C – Electronic Signatures) CFR - Code of Federal Regulations Title 21

The regulation found at 21 CFR 11.100(c) simply requires that persons using electronic signatures certify to FDA that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures.

A separate certification is not needed for each electronic signature, although certification of a particular electronic signature is to be submitted if the agency requests it. The agency does not intend to establish certification as a review and approval function. In addition, organizations need not await FDA's response before putting electronic signature systems into effect, or before continuing to use an existing system.

A single certification may be stated in broad terms that encompass electronic signatures of all current and future employees, thus obviating the need for subsequent certifications submitted on a pre-established schedule.

The agency has revised Sec. 11.100 to clarify where and when certificates are to be submitted.

Sec. 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

(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.

(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

The agency does not agree that the initial certification be provided only upon agency request because FDA believes it is vital to have such certificates, as a matter of record, in advance of any possible litigation. This would clearly establish the intent of organizations to equate the legally binding nature of electronic signatures with traditional handwritten signatures. In addition, the agency believes that having the certification on file ahead of time will have the beneficial effect of reinforcing the gravity of electronic signatures by putting an organization's employees on notice that the organization has gone on record with FDA as equating electronic signatures with handwritten signatures."

As you can see, the regulation leaves the decision as to who submits the certification entirely up to the affected parties. Whether you, the CRO/sponsor plan to submit certification is something your firm should

clarify with and, ideally, obtain in writing from the CRO/sponsor so there is no later misunderstanding about this regulatory responsibility.

Please also see FDA's guidance on Electronic Records – Electronic Signatures.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf

If I have not adequately answered your question, you may contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as they are the experts on Part 11 compliance.

Kind regards,

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

From: [redacted]
Sent: Wednesday, June 27, 2018 5:00 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Electronic signatures

Dear FDA,

Is it allowed to sign multiple documents (audit report and audit certificate) with a single electronic signature in the system that issues both documents? If allowed, are there any requirements to be fulfilled (to be described on the documents themselves or otherwise)? If not, can you provide any reference to the specific FDA requirement that needs to be met and requires each individual document to be signed electronically separately (21 CFR 11)?

[redacted]