**From:** Beers Block, Patricia on behalf of OC GCP Questions
**Sent:** Friday, October 28, 2005 7:45 AM
**To:** [redacted]
**Subject:** RE: Electronic signatures

Dear [redacted],

Thank you for your inquiry about electronic signature certification requirements. You raise important issues about which we frequently receive questions. We recently posted the Federal Register publication of 21 CFR Part 11 to our Good Clinical Practice Program's web page (see "Miscellaneous" at www.fda.gov/oc/gcp/preambles/default.htm). This posting includes the preamble and the codified for the Part 11 final rule. I mention this because this publication contains the agency's comments on electronic signature certification procedures. I've copied (immediately below) comment #120 because I believe it best answers your questions.

120. Several comments questioned the procedures necessary for submitting the certification to FDA, including: (1) The scheduling of the certification; (2) whether to submit certificates for each individual or for each electronic signature; (3) the meaning of ``territory'' in the context of wide area networks; (4) whether such certificates could be submitted electronically; and (5) whether organizations, after submitting a certificate, had to wait for a response from FDA before implementing their electronic signature systems. Two comments suggested revising proposed Sec. 11.100(c) to require that all certifications be submitted to FDA only upon agency request. One comment suggested changing ``should'' to ``shall'' in the last sentence of Sec. 11.100(c) if the agency's intent is to require certificates to be submitted to the respective FDA district office.
The agency intends that certificates be submitted once, in the form of a paper letter, bearing a traditional handwritten signature, at the time an organization first establishes an electronic signature system after the effective date of part 11, or, where such systems have been used before the effective date, upon continued use of the electronic signature system.
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 preestablished schedule.
To further simplify the process and to minimize the number of certifications that persons would have to provide, the agency has revised Sec. 11.100(c) to permit submission of a single certification that covers all electronic signatures used by an organization. The

revised rule also simplifies the process by providing a single agency receiving unit. The final rule instructs persons to send certifications to FDA's Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857. Persons outside the United States may send their certifications to the same office.
The agency offers, as guidance, an example of an acceptable Sec. 11.100(c) certification:
Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that [name of organization] intends that all electronic signatures executed by our employees, agents, or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures.

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

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
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-----Original Message-----
**From:** [redacted]
**Sent:** Monday, October 24, 2005 3:43 AM
**To:** gcpquestions@oc.fda.gov
**Subject:** Electronic signatures

Hello!

I have questions related to the way the certification of electronic signatures has to be performed.

We are about to start [redacted] where electronic data capture will be used at the investigative site level. My questions iare the following:

- Do we have to produce a certificate for every person who will be entitled to sign the CRFs? Or do we have to make one certificate per site? Or even one certificate with all the names of the investigators and sub-investigators?
- Do the certificates need to show the handwritten signature of every individual who is authorised to sign the CRFs?
- Do the certificates have to show how the electronic signatures will appear?
- Finally would it be possible to see an exmaple of such a certificate?

Thanks for your early reply,

[redacted]