

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Part 11 Question - Important
Date: Wednesday, March 16, 2016 6:07:24 AM

Good morning –

Please see the response to your question from the Office of Medical Policy. Thank you for your patience.

Kind regards,

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

If the individual logs on to an electronic system using a username and password, it's not necessary to re-enter the username when an individual executes a series of signings during a single, continuous period of controlled system access. The signed document must contain information that clearly indicates the printed name of the signer, the date and time when the signature was executed, and the meaning associated with the signature (see 21 CFR 11.50 and 11.200(a)).

In addition, the signing should be done under controlled conditions that prevent another person from impersonating the legitimate signer. Such controlled conditions may include: (1) requiring an individual to remain in close proximity to the workstation throughout the signing session; (2) use of automatic inactivity disconnect measures that would "de-log" the first individual if no entries or actions were taken within a fixed short timeframe; and (3) requiring that the single component needed for subsequent signings be known to, and usable only by, the authorized individual.

In order to make it impractical to falsify records, the electronic signature component executed after the initial signing (e.g., password) must only be used by its genuine owner (see 21 CFR 11.200(a)(2)). The electronic signatures must be administered and executed to ensure that their attempted use by anyone other than their genuine owners requires collaboration of two or more individuals (see 21 CFR 11.200(a)(3)).

From: [REDACTED]
Sent: Friday, February 26, 2016 3:47 PM
To: OC GCP Questions

Cc: [REDACTED]
Subject: FW: Part 11 Question - Important

Greetings,

We have been signing EDC systems electronically since 1999 and our document system for about 8 years. We were recently inspected for a now-cleared de novo 510(k). The way our signature works, the user logs in with his/her username and password and when signs, enters there password again. Example below

I certify that I am the sole owner of a unique combination of username and password. This combination of username and password is to be exclusively used by me to electronically sign documents.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that my electronic signature is the legally binding equivalent of my handwritten signature.

Password:

Comments:

Approve

Return with comments

Can you help on this issue below or put us in the right direction.

We are being told that even if someone logs in to our system with a username and password and then wants to sign, they would have to enter their username and password again for the first signature but not subsequent ones. First of all this makes no sense to me but also makes it very complicated since the system cannot know 1st signature vs. subsequent signature. 2nd, we have never been told by FDA that our signature system is not valid, in fact just the opposite.

Is there any other place written where the work flow is clarified?

Part 11 states that for eSignatures, it requires the entry of two components (typically the user ID in addition to the password), except in cases where multiple signings occur during a single session, in which case subsequent signings may be performed with only one component.

(a) Electronic signatures that are not based upon biometrics shall:

(1) Employ at least two distinct identification components such as an identification code and password.

Comment: [REDACTED]

(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual. **Comment: In order to sign electronically, a signee must have first logged into the system with a username and password. The actual signing then occurs just with entering the password again.**

(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components. **Comment: Once a signee exits a session, he/she must log in again with a username and password.**