

From: OC GCP Questions
To: [REDACTED]
Subject: Handwritten signature audit trail
Date: Friday, April 28, 2017 9:52:00 AM
Attachments: [REDACTED]

Good morning –

The response below was cleared by the Center for Drugs (CDER), Office of Medical Policy (OMP).

Response: Yes, it is permissible to execute handwritten signatures to electronic records.

Kind regards,

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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.

From: [REDACTED]
Sent: Friday, April 21, 2017 8:59 AM
To: OC GCP Questions
Subject: Handwritten signature audit trail

21CFR Part 11 defines handwritten signatures. Further, in the comments, FDA wrote, "Although the handwritten signature recorded electronically and electronic signatures, as defined in part 11, may both ultimately result in magnetic impulses or other forms of computerized symbol representations, the means of achieving those recordings and, more importantly, the controls needed to ensure their reliability and trustworthiness are quite different."

ref: 13442 Federal Register / Vol. 62, No. 54 / Thursday, March 20, 1997 / Rules and Regulations

Closed systems require login and password for access. Is it permissible for a user to access a document and have another user apply a handwritten signature? The audit trail would show who accessed the document and the handwritten signature documents the person signing.

[REDACTED]

[REDACTED]