

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Do signatures on documents such as monitoring reports and SOPs need to be Part 11 compliant
Date: Monday, August 31, 2020 1:20:00 PM
Attachments: [REDACTED]

Good afternoon –

Thank you for your email. OMP generally takes longer to respond than OGCP does. OMP is very good about responding to outside stakeholders. I believe that the answer I gave in the previous response (PDF you provided) is accurate. However, as you see I referred to OMP.

As you wait for OMP's response, please see a few FDA guidance documents that will be helpful to you. These guidances were developed by OMP.

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers - <https://www.fda.gov/media/105557/download> Please review each question in this guidance.

Part 11, Electronic Records; Electronic Signatures — Scope and Application - <https://www.fda.gov/media/75414/download>

Computerized Systems Used in Clinical Trials - <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/guidance-industry-computerized-systems-used-clinical-trials>

Kind regards,

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Office of Clinical Policy and Programs
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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, August 28, 2020 2:45 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Do signatures on documents such as monitoring reports and SOPs need to be Part 11 compliant

Good afternoon,

I sent this inquiry to the OMP, however have not received a response. In thinking on it further, it's more of a GCP question anyway.

In addition to the below I wish to reference one of the Q&A responses that I found to be most closely related to my questions (please see attached; note that I renamed the document when I saved it as part of my research). As this Q&A speaks to the signing of documents by site staff and my question pertains to documents signed by a sponsor company/ CRO, I'd like confirmation that the same line of thinking applies.

My understanding is that the regulations and guidance are intended to offer sponsors and their designees the necessary flexibility to carry out clinical trials. The digital signature solution used by company X is home-grown and built under the "spirit" of 21 CFR Part 11. There is an SOP on validation which was followed and an SOP for users of the digital signature. A risk assessment was performed and for those minor items in which the digital signature fails to 100% comply with Part 11, it was determined, by a group of qualified personnel, that those risks were acceptable.

Again, the document types that the company would sign with the digital signature include: monitoring visit reports, company SOPs, training on sponsor protocols, SOPs, etc.; UAT documents, database "go live" approval, etc. These documents are not submitted to the agency.

An expeditious reply would be greatly appreciated!

Kindest regards,

██████

From: ██████████

Sent: Sunday, August 23, 2020 2:56 PM

To: CDEROMP@fda.hhs.gov <CDEROMP@fda.hhs.gov>

Subject: Do signatures on documents such as monitoring reports and SOPs need to be Part 11 compliant

To OMP,

Per the regulations:

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records

requirements set forth in agency regulations.

To my knowledge there are no regulations that specifically require that a sponsor (or CRO acting on the sponsor's behalf) that is conducting clinical research studies create standard operating procedures (example SOPs used by industry cover Monitoring, Project Management, Training, Data Management activities, etc) nor for those SOPs to be signed. Similarly, I am not aware of a specific regulation that requires documentation of monitoring activities in a monitoring visit report format, nor that those reports be signed.

However, it is my experience that the industry standard is that the above document types (and others) are commonly used and that they are signified as "official/ final" by a signature.

My question is- if a company chooses to generate, maintain, etc these types of documents and use a digital signature, must that digital signature be 21 CFR Part 11 compliant? Or is it sufficient to use a risk-based approach to develop a digital signature that the company considers to be "validated" against pre-defined specifications (certainly this would all be documented)?

If this is indeed acceptable for the document types mentioned, are there any documents associated with clinical trial development (this does not include GMP or any records that would be submitted to the agency) that must be Part 11 compliant?

Kindest regards,

A solid black rectangular box used to redact a signature.