From: OC GCP Questions
To: [redacted]
Subject: Electronic Document Management System
Date: Friday, January 24, 2014 11:34:06 AM

Good morning –

I cannot specifically answer your question. You will have to determine whether your eDMS SOPs for training etc. fall within this scope of Part 11 definition below.

FDA's regulations for electronic records and electronic signature can be found at 21 CFR Part 11 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11). Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations, as well as electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

I've listed below a few FDA guidance documents that you may find helpful in answering your question:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additonal questions.

Kind regards,

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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.

-----Original Message-----
From: [Redacted]
Sent: Thursday, January 23, 2014 7:27 PM
To: OC GCP Questions
Subject: Electronic Document Management System

Dear Sir/Madam,

I work for a clinical trial site and we use an electronic document management system (eDMS) for our SOPs and SOP training records. Does our eDMS required to be 21 CFR Part 11 compliant? Please advise.

Thanks and best regards,

[Redacted]