From: OC GCP Questions
To: [redacted]
Subject: GCP Predicate rules
Date: Wednesday, March 28, 2018 10:56:00 AM
Attachments: [redacted]

Good morning –

There is no true listing of predicate rules. See below.

What might be the most relevant reference about which you should become familiar is the part 11 guidance entitled "Guidance for Industry Part 11, Electronic Records, Electronic Signatures- Scope and Application" (http://www.fda.gov/ohrms/dockets/98fr/5667fnl.pdf) . This guidance explains the agency's current thinking on the application of part 11 to FDA regulated activities that involve the creation, modification, maintenance, archiving, retrieving or transmission of records.. Persons must comply with all applicable predicate rule requirements (**where predicate rules mean the underlying requirements set forth in the FD& C Act, the PHS Act, and FDA regulations published in the Title 21 Code of Federal Regulations [Emphasis added)**

Kind regards,

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

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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: Monday, March 26, 2018 4:21 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: GCP Predicate rules

Hello,

I work at a CRO, and we use 21 CFR Part 11 as our guide for compliance. We are a clinical research partner to the pharmaceutical, biotech, and medical device industries, offering biostatistical and data management services (protocol dev, SAPs, analysis and reporting, data mgt.)

I have been training on Part11 and have noticed many references to “following your industry’s predicate rules”, but I don’t know where to find the specific predicate rules for a CRO. On the GCP page, your contact info was listed. Can you help? In a nutshell, what rae the predicate rules for a CRO in GCP?

In the FDA website information, it doesn’t specify, it says:

> “Understanding the predicate rules that apply to your company is key to being compliant with 21 CFR 11 because those rules will determine the corresponding Part 11 controls that apply to your company”

[redacted]

[redacted]