From: OC GCP Questions
To: [redacted].
Subject: Question about the SMO
Date: Monday, January 23, 2017 8:58:00 AM
Attachments: [redacted]

Good morning –

It depends on the contract between the sponsor and the CRO or SMO so I can't specifically answer your question. As stated preciously SMO is not addressed in FDA regulations but CRO is. Please see the citation below.

Sec. 312.52 Transfer of obligations to a contract research organization.
(a) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be described in writing. If not all obligations are transferred, the writing is required to describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred.

(b) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to "sponsor" in this part apply to a contract research organization to the extent that it assumes one or more obligations of the sponsor.

Since the sponsor has regulatory responsibilities and CROs have regulatory responsibility transferred to them for drug studies (21 CFR 312.52) (above) when a contract is written, both the sponsor and the CRO should have specific job descriptions for various positions that include requirements regarding the training and experience of those whom they employ for a role in the conduct of clinical studies.

the sponsor who hires a CRO determines the parameters for the work that CRO is to accomplish. Both the sponsor and the CRO therefore have a responsibility to understand what is required and to ensure that they are compliant with the regulations that pertain. A CRO cannot blame a sponsor if they are found to be noncompliant during a BIMO inspection. Both parties have the responsibility to comply with the pertinent regulations independent of each other.

The contact between the sponsor and the CRO/SMO would explain the responsivities for all parties.

Kind regards,

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

From: [redacted]
Sent: Friday, January 20, 2017 4:00 AM
To: OC GCP Questions
Subject: Re: Question about the SMO

Dear Doreen M.Kezer,

Thank you for your kind response,

I have one further question which needs your advice: the scope of work of SMO seems to be overlapped with CRO's one and more expanding than CRO. Isn't it? And therefore, any activities that SMO cannot do but CRO can?

Thank you in advance for your kind answer
Regards,
[redacted]