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Controlled substances in non-clinical research

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Most people know what controlled substances are, but may not be as familiar with the settings in which they are used. So, what does it mean to use controlled substances in a non-clinical setting? In research, this distinction refers to the fact that human subjects are not involved; instead, the controlled substance is used in bench (wet lab) experiments or for animal research.

The Drug Enforcement Agency (DEA) requires individual researchers to complete an application for a research registration to use controlled substances for research purposes in the non-clinical setting. In this article, these individuals are referred to as registrants. Upon DEA approval, the registrant will receive approval documents called registrations (akin to licensure).

Authorized users are individuals the registrant has granted permission (by way of their registration and DEA Authorized Users Log) to have access to the controlled substances. Many states mimic this process, meaning researchers have to maintain both federal and state registrations. And, last but not least, in the world of controlled substances, a diversion is when controlled substances go purposefully missing by way theft.

Who is responsible?

Last year, I spoke at a conference about the ins and outs of controlled substances, going over the regulations and implementation within my institution. One of the questions I received was, "Who is responsible?" The answer is one that most compliance professionals don't like, but have become accustomed to giving...it depends. It depends on your institutional commitment, infrastructure, internal resources, risk tolerance, etc. I also had one person ask why the institution would be involved at all, given that the registrant is solely responsible for the registration, documentation, and storage of the controlled substances.

I thought this was a very interesting question; however, from my perspective it was a simple answer. For my institution, controlled substance compliance is a partnership between the institution and the registrant. My institution has a role in the process and, therefore, responsibility. The registrant will contact us to order their controlled substances, and then the order is placed and processed through our system, the substance is received by our loading docks, and it is delivered by our personnel. It isn't until the point of delivery that the registrant actually has custody of the controlled substance, but then it is stored in a safe that was installed by our personnel in one of our facilities. Second, it is a good faith investment, as with many of the research regulations, that we provide education to help facilitate compliance. Last, as with all bad deeds that get published for the public eye, reputation is at stake when the headline will read, "Dr. Diversion at Your Hospital investigated in loss of controlled substances" and no one will know whether the hospital was technically responsible or not.