RAPS WEBINAR TRANSCRIPT:

Virtual Audits

celegence

celegence.com

Dr. Sophie Vaillot
Global Head of Regulatory Affairs, Nobel Biocare

Dr. Sophie Vaillot on Best Practices for Virtual Audits

EU MDR

Well, maybe I can just share some insights because we have actually gone through several virtual audits very recently. And the answer is something that I can relate to right to right now due to my web camera not working (laughing), but it is making sure that all the IT portions of the Audit are taken care of. That is, knowing which system you're going to use, making sure that you can test it with the auditors, and doing all of this a couple of days before the audit to make sure there are no issues. What we have found to be very helpful is making sure we have shared folders which are available to the auditors. And also that we prepare as much information as we can ahead of time so it doesn't take ages to download or retrieve. This is also so the information can be easily accessible with clear organization, like for the chat communication of the different teams. Virtual Audits are not much different I would say, compared to a regular audit in terms of preparations, but the I.T. side and managing the availability of all the different participants can be a bit more challenging. So far, it has worked well from all sides, and the NBs have provided us with some good feedback about how it was organized. So, now Dr. Royth might have some perspective from the notified bodies point of view.

Dr. Royth von Hahn

Global Head of TUV SUD's Business Unit - Medical and Health Services (MHS)

Dr. Royth von Hahn on Best Practices for Virtual Audits

EU MDR

Yeah, I share the same experience here. Preparation is one of the most important things, not only for the technical side, also for the documents that are to be reviewed or discussed. It definitely makes sense to prepare that in advance. It is also important to have a good understanding of the scheduling, especially for larger manufacturers, who typically have teams of two or three auditors doing things in parallel. So, availability of the right people needs to be lined up in preparation for the precise scheduling, and it is even more important if you have time zone challenges. For most aspects of virtual audits, we do not see much difference, especially if there is a well-established system already in place. There are limitations of course, when it comes to production, especially like clean room audits, or various specific aspects of production where it is limited what we can do remotely. But other than that, so far it has been quite smooth with the remote audits we have performed. However, it's important to understand that one of the major obstacles for the MDR transition currently, is that we are not allowed to do initial MDR audits in a remote setup. That, at least from our perspective, is the biggest obstacle in really managing the transition into the MDR. Since we cannot rely on previous assessments, and we have to do everything on site for the initial audit, this basically where the current MDR projects get to a full stop.

Helping You With
The New EU MDR Challenges

Celegence has a wealth of knowledge to help you navigate through the complex regulatory challenges that the new EU MDR bring.

We can assist you throughout the entire process to ensure that you and your business are compliant with all of the EU MDR requirements.

For more information, reach out to us at

info@celegence.com

or contact us online at

celegence.com

celegence