Biotek Salon #23

February 2nd, 2022, from 15:00-17:30
COBIS, M10, Ole Maaløes Vej 3, 2200 Copenhagen N

EU Clinical Trials Regulation: On your marks, get set, go!

DANSK BIOTEK & **OZACK** invite you to a workshop on the implications of the (not really) new EU Clinical Trials Regulation No 536/2014 (CTR) to smaller players in the world of pharma.

The CTR will finally become applicable on January 31st, 2022 - even though it has been in force since 2014, the Go-Live date has been postponed multiple times due to the complexities of the Clinical Trials Information System (CTIS). Fortunately, the CTR allows for a three-year transition period for the sponsors to fully prepare for the future of clinical research in the EU.

In this workshop, with the support from Lene Grejs Petersen from the Danish Medicines Agency (DKMA), we will summarize the key changes the CTR brings, demystify the complexities of the CTIS, and provide practical tips on how to tackle the challenges ahead.

Agenda:

14:30 Registration and networking

15:00 Welcome by DANSK BIOTEK

15:15 The following speakers

- Lene Grejs Petersen, Senior Adviser, DKMA
- Ann Christine Korsgaard, Regulatory Affairs Executive, Ozack
- Ivana Glatzova, Regulatory Affairs Manager, Ozack

will go through and facilitate discussions on:

- Changes the CTR brings and how different life will be after January 2022
- Benefits and pitfalls of the CTR
- Options and responsibilities of the sponsor in the CTIS
- Transparency requirements and how to protect your confidential information

16:30 Questions and discussions

17:00 Networking, snacks, and refreshments

To accommodate covid-19 restrictions, max. 50 people will be allowed at the event on a first come first served basis. Furthermore, face masks and sanitizer will be available to everybody.

Register here

The event is free of charge for members; however, non-members will be charged a fee of 500 DKK