

Workshop on clinical evaluations and investigations with medical devices

This seminar is arranged by Medicoindustrien's Expert group for clinical investigations and kindly hosted by Coloplast.

The aim of the day is to see what is in the future of the clinical area for medical devices and also meet peers working with clinical evaluations, clinical investigations and post market clinical follow-up and exchange experience.

Thursday 21 September 2023, 9.00 – 15.00. at

Coloplast A/S, Høltedam 3, 3050 Humlebæk

(Entrance at Høltedam 3, the reception, we are in the auditorium)

Agenda

9.00 – 9.30	Check in & breakfast
9.30 – 9.40	Welcome & introduction, Pernille Trøjgaard, Coloplast
9.40 – 9.55	Back and the Future. “Has anything happened with the outcome of our discussions from last year?” Yes. Update from Lene Laursen, Medtech Denmark
9.55 – 10.10	Future Life Science strategy in Denmark, Lene Laursen, Medtech Denmark
10.10 - 10.20	Update on the development of the new ISO ISO/AWI 18969 ‘Clinical evaluation of medical devices’, Birgitte Berg, Novo Nordisk.
10.20 – 10.40	Coffee break
10.40 – 11.30	Clinical investigations in Denmark & update on European activities, including EUDAMED, DKMA brings their Crystal ball, Kristin Jøranli Astrup og Rasmus Øhrstrøm, DKMA
11.30- 12.30	Lunch & networking
12.30– 13.00	Audit of clinical trials and clinical evaluation including software, René Bombien, TÜV Süd Germany <i>Confirmed – not sure if virtual or in person</i>
13.00 – 13.30	Presentation of the 2023 Clinical Benchmark Report, Veeva.
13.30 – 14.15	Group discussions
14.15 - 14.30	Coffee & cake
14.30 – 15.00	Wrap up of group discussions & conclusion of the day