



Eindhoven MedTech Innovation Center

## Program 2023

### Clinical regulatory (Susan Hommerson)

Thursday, September 14, 2023, 14.00-17.00

Room: FLUX 0.150

This course is an initiative by e/MTIC (Eindhoven MedTech Innovation Center) and organized by SMPE/e (School of Medical Physics and Engineering). The course is obligatory for all e/MTIC related PhD's and PostDocs. In this half day course, the ethical and regulatory framework for clinical trials will be presented.

#### Course contents

The fundamentals of Good Clinical Practice (GCP) and the Dutch regulatory framework including the role and the responsibilities of the researchers involved will be discussed.

Furthermore, the process workflow within e/MTIC studies and the respective institutes and where to find support documentation (templates) will be highlighted.

The course will consist of an introduction in GCP and legislation mandatory for all PhDs, post-docs and master students involved in clinical research.

#### Course objective

After the course, you will have an understanding of the regulatory framework and basic knowledge of the first steps to set-up a clinical trial. In addition, you will know where to find the necessary required information and support within TU/e and e/MTIC related institutions.

#### Course information

- Date: Thursday, September 14, 2023
- Time: 14-17 hrs
- Location: TU/e, FLUX building, room FLUX 0.150 (30 pers.)
- Costs: free of charge, with a no show, € 50 will be charged (a presentation list will be circulated)
- This course is obligatory for all e/MTIC PhD's and PostDocs.

#### Course coordination

- Course contents: Susan Hommerson, Coordinator medical & medical device research at TU/e, [s.m.hommerson@tue.nl](mailto:s.m.hommerson@tue.nl)
- Course registration: Annebee Langenhuizen, Course coordinator SMPE/e courses, [smpee@tue.nl](mailto:smpee@tue.nl)