FDA, Machine learning, GMP
HIPAA, GDPR, Wearable, IEC62304, Agile,
EU MDR, CE Marking
ISO13485, Clinical Validation, Apps,
Telehealth, COVID-19

בעקבות ההצלחה נפתחה ההרשמה למחזור שני בקורס בסיסי אונליין (זום) בנושא רגולציה של רפואה דיגיטלית

15 מפגשים שבועיים בהנחייתו של גדי גינות, החל ב-20.04.2021

קורס ייחודי מסוגו בישראל, מספר המקומות מוגבל, הקדימו להירשם!

Syllabus
Digital Health Regulation Basic Course

Instructor: Gadi Ginot, (M.Sc, M.B.A)
Certification: [Certificate of Attendance]

I. Objectives

Course graduates will understand how digital health devices (software, hardware, wearable) are regulated in the US, EU (CE mark) and Israel.

Specific Learning Objectives:

- Key terms and definitions.
- Pre-market US FDA requirements.
- Pre-market EU CE Marking requirements (the new EU Medical Device Regulation).
- Pre-Market Israeli (MoH) requirements.
- Medical device software EU and FDA regulations and quality practices.
- Quality Management System for Software products to EU, ISO13485 and FDA requirements.
- Regulatory requirements from machine learning.
- Clinical validations of standalone software medical devices to EU and FDA requirements.

II. Agenda

Virtual Classroom ID	Date	Topics
1	20.04.21	Pre-Market US FDA requirements
2	27.04.21	
3	04.05.21	Pre-market EU MDR requirements
4	11.05.21	
5	18.05.21	Medical device software EU and FDA regulations and quality practices
6	25.05.21	
7	01.06.21	Quality Management System for Software products to EU, ISO13485 and FDA requirements.
8	08.06.21	
9	15.06.21	Privacy and security regulations and standards in the US, EU and Israel
10	22.06.21	
11	29.06.21	Clinical validation of stand-alone software and medical digital products
12	06.07.21	
13	13.07.21	Regulatory requirements from machine learning.
14	20.07.21	Israeli pre-market requirements
15	27.07.21	Digital health regulatory pathways during COVID-19 pandemic