

# HIT

## Digital Health Regulation - Bootcamp for Executives

Instructor: Gadi Ginot, (M.Sc, M.B.A) & Physio-Logic's Digital Health Experts  
Certification: [Certificate of Attendance]

### I. Course Objectives

#### *Aims*

Course graduates will understand how medical device regulation affects their digital health products. The course provides a comprehensive overview of the digital health regulatory landscape and up to date requirements. The knowledge gained is expected to enable course graduates to perform more effectively and efficiently reducing compliance risk.

#### *Specific Learning Objectives:*

Specifically, course graduates will be familiar with:

- The role of regulatory compliance, quality assurance and control and clinical research in digital health product development.
- The regulatory requirements of the US FDA, EU and Israeli Ministry of Health pre-market and post-market applicable to digital medical device and wellness products
- The regulatory requirements and standards concerning privacy and security in the US, EU and Israel
- Medical software standards
- Wearable device standards
- Clinical trials of digital health products in compliance to regulations and standard
- Quality system requirements and standards for medical and consumer digital health products

### II. Agenda

Date	Topics
Wed. 06.05.20, 17:00-21:10	The regulatory framework for regulating medical digital health products in the US, Israel and Europe
Fri. 08.05.20, 08:30-12:40	
Wed. 13.05.20, 09:00-17:10	Medical Software regulations and standards, clinical trials
Fri. 15.05.20, 08:30-12:40	Standards concerning Hw medical & consumer electrical equipment (wearables)
Wed. 20.05.20, 09:00-17:10	Privacy and security regulations and standards, regulation of wellness products
Fri. 22.05.20, 09:00-12:40	Quality management system requirements and certification