The Iby and Aladar Fleischman
Faculty of Engineering
Tel Aviv University

Basic Course on Medical Device Development in Compliance with the Current Regulatory Requirements

14 Classes, Tuesdays 17:00-20:00 starting 12.10.21. Total of 42 hours.

Instructors: Gadi Ginot (CEO & Founder Physio-Logic) & Physio-Logic Subject Matter Experts (SMEs)
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- ## Rationale:

The goal of this basic course is to introduce newcomers to the regulated medical device space. The course "demystifies" medical device regulations and enable its attendants to understand what is required inorder to develop, produce and commercialize medical devices in compliance with the up to date regulatory requirements. This basic course provides a structured and comprehensive overview of the regulatory requirements throughout the medical device lifecycle with an emphasize on the pre-market stage and the US FDA and CE Marking requirements.

- ## Aims and objectives:

Aims

Course graduates will understand how medical device regulation affects their micro (day-to-day practice) and macro (organization wide) space. The knowledge gained is expected to drive course graduates to fulfill their roles and obligations in compliance with the regulatory requirements.

Specific Learning Objectives:

Course graduates will understand:

- the role of regulatory compliance, regulatory strategy, quality assurance and control, and clinical research in medical device lifecycle
- the CE marking process under the new EU MDR
- the US FDA regulatory paradigm including classifications, the pre-market registration process (510k, PMA, HDE, De-novo) and post-market requirements.
- the regulatory framework in China, Canada and Israel
- the role and requirements of the US FDA GMP (QSR) regulation and ISO13485:2016
- The objective and process of MDSAP certification
- the role and practice of design control, risk management (ISO14971), usability (IEC62366-1) and the qualification of the design and the production process.
- Key regulatory requirements applicable to implants, sterile (biocompatibility, cleaning and sterilization, package), active (IEC60601-1), and software (IEC62304) digital devices.
- The requirements from clinical evaluation and investigations.

- **Format and Procedures:**

In-class frontal lectures.. **Target audience and prerequisites:**

This is an entry level course. It is open for professionals that are already engaged in the medical device industry and lack formal training and education on medical device regulations as well as for those that are considering a career in that sector. The course is basic and does not assume previous knowledge of medical device regulation.

- **Course Requirements:**

Attendance (85% minimum).

- **Certification**: Certificate of Attendance.

- **Course Schedule**

14 classroom sessions every Tuesday between 17:00-20:00 starting 12.10.21

Date	Topics
12.10.21	Introduction - terms, definitions, and framework of medical device regulations
19.10.21	The US FDA pre-market
26.10.21	The US FDA pre-market
02.11.21	The EU MDR pre-market
09.11.21	The EU MDR pre-market
16.11.21	Design Control & Process Validation
23.11.21	Risk Management & Active medical devices
30.11.21 (Hanuka)	GMP (FDA QSR & ISO13485:2016)
07.12.21	GMP (FDA QSR & ISO13485:2016)
14.12.21	Clinical evaluation & Investigations
21.12.21	Medical software
28.12.21	Post-market Requirements & Medical Device Regulations in Israel, China and Canada
04.01.22	Regulatory consideration concerning sterile medical Device (cleaning, sterilization, biocompatibility, package, shelf life)
11.01.22	Regulatory compliance, audits and inspections

- **About the instructors:**

Gadi Ginot (M.Sc, M.B.A), the CEO and founder of Physio-Logic, brings forward three decades of international experience and leadership in the development and execution of regulatory strategies that paved the path to market for breakthrough medical technologies. Gadi is internationally renowned for his outstanding proficiency in regulatory sciences mastering both the clinical, quality, and regulatory aspects. He is a popular guest speaker in international conferences and meetings. Physio-Logic accelerated medical device approval, certification and compliance solution is the vendor of choice of global medical device manufacturers as well as start-ups, VCs and entrepreneurs.

Tamar Katzav (Ph.D.), VP Project Management at Physio-Logic. Tamar brings forward over 14 years of experience in leading quality assurance, compliance and regulation of medical devices, active substances, and drugs. Tamar managed medical device regulatory teams in global companies including submissions and maintenance of registration in different territories including 510(k), CE Marking and AMAR submissions. Tamar manages the area of In-Vitro -Diagnostics (IVD) regulation in the company and has extensive experience in this field. Tamar is a certified Internal Auditor according to ISO 13485: 2016 and 21 CFR 820.

Yael Goldbrener (B.A) VP Q&R Services at Physio-Logic. Yael has over 18 years of experience the medical device industry in the capacity of Quality and Regulatory Affairs Manager. Yael has a track record of leading a large number of companies to certification of ISO 13485: 2016 and MDSAP, AMAR and CE approvals of medical devices and FDA submissions. Yael is a certified Internal Auditor according to ISO 13485: 2016 and 21 CFR 820.

Yoav Galil (B.Sc, MBA) Head of Digital Health Practice at Physio-Logic. Yoav has over 15 years of experience in the medical device and digital health industry. Yoav has successfully lead various regulatory and clinical strategies, IEC62304, GDPR, HIPPA and IPA compliance projects, FDA submissions and clinical investigations. In Addition, Yoav is a certified auditor for ISO27001 and GCP.