ארגון בוגרי.ות הנדסה
הפקולטה להנדסה
ע"ש איבי ואלדר פליישמן
אוניברסיטת תל אביב

PHYSIO-LOGIC
Accelerated Medical Device Approval

Basic Course on Medical Device Regulations – Virtual (Zoom)

14 Classes | Tuesdays 17:00-20:00 | starting 25.10.22

Total of 42 academic hours

Instructors: **Gadi Ginot, Dr. Tamar Katzav, Yael Goldbrenner, Yoav Galil**

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BACKGROUND:

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 in order 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, CE Marking and Israeli regulatory 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 (high level) 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.

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FORMAT AND PROCEDURES:

Virtual (via zoom)

TARGET AUDIENCE AND PREREQUISITES:

This is an entry level course. It is open for individuals that are considering a career in the medical device field or medical device professionals that are already working in the medical device industry but lack knowhow on medical device regulations. This 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 25.10.22

Date	Topics	Lecturer
25.10.22	Introduction - terms, definitions, and framework of medical device regulations	Gadi
08.11.22	The US FDA pre-market	Gadi
15.11.22	The US FDA pre-market	Yoav
22.11.22	GMP (FDA QSR & ISO13485:2016)	Yael
29.11.22	GMP (FDA QSR & ISO13485:2016)	Yael
06.12.22	Risk Management & Active medical device standards	Tamar
13.12.22	Design Control & Process Validation	Revital
20.12.22 (Hanuka)	The EU MDR pre-market	Tamar
27.12.23	The EU MDR pre-market	Tamar
03.01.23	Clinical evaluation & Investigations	Gadi
10.01.23	Medical software	Gadi
17.01.23	Post-market Requirements & Medical Device Regulations in Israel, China and Canada	Tamar/Yael
24.01.23	Regulatory consideration concerning sterile medical Device (cleaning, sterilization, biocompatibility, package, shelf life)	Ari
31.01.23	Regulatory compliance, audits and inspections	Yael

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ABOUT THE INSTRUCTORS:

Gadi Ginot (M.Sc, M.B.A)

The CEO and founder of Physio-Logic, brings forward nearly 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.