The Iby and Aladar Fleischman
Faculty of Engineering
Tel Aviv University

Medical Device Development in Compliance with the Current Regulatory Requirements

[Tuesday 16:30-19:30 starting 24.04.18]

Instructor: Gadi Ginot [gadi@physio-logic.co.il, 050-8317449]
Certification: [Certificate of Attendance]

I. Rationale:

The goal of this basic course is to introduce professionals that are already working in the field of medical devices as well as those who are interested to join the highly regulated medical device space. The course "demystifies" medical device regulation, and enable its attendants to develop, produce and commercialize medical devices in compliance with local and global regulatory requirements. The course provides a comprehensive review of the regulatory requirements throughout the medical device lifecycle.

II. Course Aims and Outcomes:

Aims

Course graduates will understand how medical device regulation affects their micro (day-to-day practice) and macro (organization wide) space. The course provides a comprehensive review of the regulatory requirements throughout the medical device lifecycle. The knowledge gained is expected to enable course graduates to perform more effectively and efficiently reducing compliance risk.

Specific Learning Outcomes:

Specifically, course graduates will benefit from:

- Understanding the role of regulatory compliance, quality assurance and control and clinical research in medical device lifecycle
- Gaining an in-depth understanding of the CE marking classification paradigm, pre-market and post market requirements under the current Directive (MDD) as compared to the future Regulation (MDR)
- Gaining an in-depth understanding of the US FDA regulatory classifications, requirements from Class I, II and III devices and the pre-market registration process (510k, PMA, HDE, De-novo) and post market requirements.
- Familiarizing with the regulatory framework in China, Canada. and Israeli AMAR medical device approval process
- Understanding the role and requirements of the US FDA GMP (QSR) regulation and ISO13485:2016 standard as well as MDSAP.

- Gaining an in-depth understanding of the role and application of design control, risk management (ISO14971), usability (IEC62366-1) and the qualification of the design and the production process.
- Familiarizing with regulatory requirements applicable to implants, sterile (biocompatibility, cleaning and sterilization, package), active (IEC60601-1), software (IEC62304) measuring and digital devices.
- Familiarization with clinical evaluation and investigations.

III. Format and Procedures:

The course is based on frontal lectures, in class exercises and homework. The students are expected to read the recommended reading material prior to the lectures. The lectures will encourage interactions and questions from the audience will be addressed.

IV. Target audience and prerequisites:

The course is open for professionals that are already engaged in the medical device industry as well as for those that are considering a career in that sector. The course does not assume previous knowledge in medical device regulation.

V. Course Requirements:

1. Lecture attendance (85% minimum).

2. Recommended readings:

1. ISO 13485:2016
2. 93/42/EE EU Directive (MDD) and 2017/745 Regulation EU (MDR)
3. FDA QSR regulation according to 21 CFR part 820
4. ISO 14971:2012
5. IEC62304
6. IEC62366
7. MEDEDEV Guidance documents
8. FDA 510(k) & PMA regulations and guidance documents
9. Israeli (AMAR) Law and Regulation

VI. Tentative Course Schedule and agenda

The course will commence on Tuesday starting April 24th,2018 and will take place every Thuesday between 16:30-19:30 for a total of 14 classroom sessions.

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Class #/Date	Topics Assignment
1/ 24.04.18	Introduction to basic terms, concepts and the pre-market regulatory framework in the US
2/ 01.05.18	The US FDA pre-market pathways and requirements
3/ 08.05.18	CE marking under the current MDD
4/ 15.05.18	CE Marking under the future MDR
5-6/ 22.05.18 29.05.18	Israel, China and Canada The role of GMP (FDA QSR & ISO13485:2016)
7/ 05.06.18	Design control, and Process Validation
8/ 12.06.18	Risk Management
9/ 19.06.18	Clinical evaluation and investigations
10/ 26.06.18	Post-market Requirements – the UE
11/ 03.07.18	Post-market requirements – the US The Regulatory requirements concerning Usability Engineering
12/ 10.07.18	Regulatory consideration concerning active medical devices (electrical safety, and software)
13/ 17.07.18	Regulatory consideration concerning sterile medical Device (cleaning, sterilization, biocompatibility, package, shelf life)
14/ 24.07.18	Regulatory compliance, audits and inspections

VII. About the instructor: Gadi Ginot

Gadi (M.Sc, M.B.A), the CEO and founder of Physio-Logic, brings forward over 23 years 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 is a full-service organization that offers accelerated medical device approval, certification and compliance solutions. Physio-Logic's carefully selected multi-disciplinary expert team addresses international registration, quality assurance, software QA, and clinical trials. Our synergistic solution paved the path to market for over 100 devices. Physio-Logic is the vendor of choice of global medical device manufacturers as well as start-ups, VCs and entrepreneurs.

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