Medical Device Development
in Compliance with the Current Regulatory Requirements

[Wednesday 16:30-19:30 starting 22.11.17]

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

I. Rationale:

The goal of this 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.

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 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, US FDA registration and Israeli AMAR medical device approval process
- Familiarizing with the regulatory framework in the Rest of the World (ROW) including China, Brazil, India etc.
- Familiarizing with the new requirements imposed by the new EU Medical Device Regulation to become effective in 2020
- Understanding the role and requirements of the US FDA GMP regulation and ISO13485:2016 standard
- Gaining an in-depth understanding of the role and application of design control, risk management and the qualification of the design and the production process
- Familiarizing with regulatory requirements applicable to implants, sterile, active, measuring and digital devices

III. Format and Procedures:
The course is based on frontal lectures. 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. MEDEDEV Guidance documents
6. FDA 510(k) & PMA regulations and guidance documents
7. Israeli (AMAR) Law and Regulation

VI. Tentative Course Schedule and agenda

The course will commence on Wednesday November 22nd and will take place in the following dates between 16:30-19:30 for a total of 14 classroom sessions.
(November 22nd. 29th, December 6th, 20th, 27th, January 3rd, 10th, 17th, 24th, 31st, Febraury 7th, 14th , 21st, March 7th).

Class #	Topics Assignment	Readings to be discussed
1-2 22.11.17 29.11.17	Introduction to basic terms, concepts and the pre-market regulatory framework in the US, EU, Israel and the ROW	93/42/EE EU Directive (MDD) and 98/79/EC EU Directive (IVD MDD), 2017/745 Regulation EU (MDR), 2017/746 Regulation EU (IVDR) MEDDEV 2. 4/1 Rev. 9, FDA Product Classification
3-4 06.12.17 20.12.17	The GMP (FDA QSR & ISO13485)	EN ISO 13485: 2012, ISO 13485:2016, FDA QSR
5 27.12.17	The US FDA 510(k) and PMA programs	FDA 510(k) & PMA regulations and guidance's

6 03.01.18	CE marking and AMAR registration process	AMAR law and regulations
7 10.01.18	Design control, design and process qualification	
8 17.01.18	Risk Management	ISO 14971
9 24.01.18	Clinical evaluation and investigations	MEDDEV 2.7/1 revision 4; FDA GCP regulations
10-11 31.01.18 07.02.18	Post-market regulatory controls including post marketing surveillance (PMS), vigilance, medical device reporting, Post-marketing clinical follow-up (PMCF)	MEDDEV 2.12/1 rev.8; FDA medical device reporting regulation
12 14.02.18	Regulatory consideration concerning active medical devices (electrical safety, usability, software)	
13 21.02.18	Regulatory consideration concerning sterile medical Device (cleaning, sterilization, biocompatibility, package, shelf life)	
14 07.03.18	Regulatory compliance, audits and inspections	

About the instructor - Gadi Ginot (M.Sc, M.B.A)

Gadi is CEO and founder of Physio-Logic Accelerated Medical Device approval, certification and compliance solutions. Physio-Logic is the largest vendor in Israel serving global medical device manufacturers as well as start-ups, VCs and entrepreneurs. Gadi brings forward over 20 years of international experience in the development and flawless execution of innovative and aggressive regulatory strategies that paved the path to market for breakthrough medical technologies. Gadi is internationally renowned for his outstanding proficiency in regulatory science as well as clinical development and quality assurance of medical device and he is a popular guest speaker in international conferences and meetings.