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1st Course on Translational Research and Commercialization of Medical Devices
24 - 26 April 2019 | Leuven, Belgium

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Course organizers and co-chairs:
Prof. Amit Gefen and Assoc. Prof. Daphne Weihs, Israel

"The course is designed to teach the key steps in the process of commercialization with an internationally relevant context, emphasizing both European and US regulatory and other aspects."

TRANS COMET PROGRAMME HIGHLIGHTS

Regulation of medical devices

Jeffrey N. Gibbs, Hyman, Phelps & McNamara FDA Law Firm, United States

US regulation of devices, their impact on commercialization, and tools for expediting entry into the US market. The course will help device companies better understand the multiple pathways to the US market, highlight difference between US and European regulatory systems, explain some of FDA's new approaches, e.g., benefit/risk analyses, Breakthrough Designations, and the de novo pathway, and teach how to maximize chances for successful, timely entry into that market.

The Global Clinical Trial Crisis

James Nolan, InClinica, United States

The CRO market is expected to reach more than $45 billion by 2022. The CRO industry is growing at a rapid rate, affecting the pharma industry, biotech companies and academic arenas.
Clinical trials are being conducted on virtually every clinical condition, but some conditions are receiving overwhelmingly more attention. For example, there are less than 9,000 medical device clinical trials currently recruiting, according to ClinicalTrials.Gov. Compare that to oncology, which currently has more than 15,000 recruiting studies.
This lecture will delve into the general industry perspective on clinical trials, with a focus on medical device trials, as well as the key approaches that companies must have in order to succeed in their clinical trials and the importance of labeling.

Developing of scientific evidence based narrative

Amit Gefen, Tel Aviv University, Israel

All fields of medicine are rapidly becoming evidence-based, and while some fields are progressing slower than others, evidence-based practice will become the only acceptable practice in the next decade. Evidence can roughly be divided into scientific/laboratory/pre-clinical versus clinical evidence. The session will describe effective strategies for companies to develop a solid evidence-based portfolio with adequate balance between scientific and clinical research, showing the biophysical, bioengineering and physiological scientific foundations and highlighting the mechanisms of action that ultimately facilitate the clinical efficacy

Read more about the programme

Admission fees

Early registration fees:
Non-industry: 1 300 EUR
Industry: 2 500 EUR

Late registration fees:
Non-industry: 1 900 EUR
Industry: 3 000 EUR

Important dates

Early registration deadline: **15 January 2019**
Application deadline: **28 February 2019**

Entitlements: access to lectures, course materials, social event

Download application form HERE

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