

# MASTER OF SCIENCE IN BIOMEDICAL ENGINEERING

## BIOMEDICAL RESEARCH AND INNOVATION MANAGEMENT AND ASSESSMENT

SSD ING-IND/35, 6 CFU

### Objectives

To provide the student with basic knowledge about:

- the process of research and development of a new product, with particular reference to the biomedical sector;
- the technological innovation, with particular reference to the biomedical sector;
- the planning and management of research projects;
- the protection of intellectual property;
- the procedures for clinical trials and CE mark of a new technology in the biomedical field.

The gained knowledge will allow the student to develop basic and applied understanding skills of the main issues related to the management of research and innovation in the health and biomedical field. This will help the students to mature an autonomy of judgement of different case studies and, through the learning capacity developed, the students will be able to conduct and expose, during special exercises, the analysis of problems assigned to them during the course.

This knowledge will also be preparatory to the introduction to the discipline of Health Technology Assessment (HTA). HTA methods and tools aim at analyzing and evaluating not only the medical and clinical impact of new solution, but also the social, organizational, economic, ethical and legal implications of the introduction of a new biomedical technology. This is carried out through the evaluation of various factors such as efficacy, safety, costs and social impact.

### Prerequisites

No specific prerequisites except those required for the access to the Laurea programme.

### Contents

The course, through frontal lessons and exercises, is focused on learning:

- the main definitions and classifications in the field of research and technological innovation, with particular reference to the biomedical sector;
- the development phases and life cycle of a product, with particular reference to the biomedical sector;
- the basic methods and tools for planning and managing research and innovation programmes, including in the clinical field;
- the methodologies that, from the prototype, allow the product to be placed on the market and also used in clinical practice, including intellectual property protection policies, current regulations, procedures for the approval of clinical trials and for the subsequent CE mark of the biomedical device, other aspects relating to the technology to be analysed in order to increase the probability of success on the market (for example in terms of dependability, safety/security, integrity, confidentiality, availability of use).

During the course, the study of elements of health economics and management and methodologies for the economic analysis of biomedical technologies will be addressed, both from a microeconomic point of view (e.g. cost-benefit, cost-utility, cost-effectiveness) and from a macroeconomic point of view (e.g. systems of financing and reimbursement of health services, policies for controlling health expenditure). Finally, during the course, case studies presented by representatives of: i) public bodies with expertise in biomedical technologies (AGENAS- Agenzia Nazionale per i Servizi Sanitari Regionali, Istituto Superiore

di Sanità); ii) companies, including, for example, Siemens, Johnsons&Johnsons, MASMEC and others; iii) spin-offs UCBM and other start-up companies in the biomedical sector.

At the end of the course there will be the possibility of internships in the companies and it will be proposed experimental degree theses to be carried out in close collaboration with companies or at the Polyclinic of the University Campus Bio-Medico.

## Teaching Methods

Frontal classes (4.5 CFU = 36 hours) presenting the topics of the course. Exercises and seminars, presented by experts in the biomedical field (1.5 CFU = 12 hours) during which students have the possibility to analyze case studies and carry out simple projects in order to apply the theoretical knowledge illustrated in frontal classes.

## Verification of learning

Knowledge acquired during the course will be assessed through a written test followed by an oral test which will be possible only in case of success of the written test (minimum score: 15/30). The oral test may also include the presentation of simple projects performed during course exercises or the discussion of a paper or a case study on the course topics selected by the student and preliminarily approved by the teacher.

The written exam lasts 45 minutes and will be characterized by one open question and 9 closed questions with multiple answers on the course program. The vote is defined considering: 3 points for each correct answer, 0 points for each missing answer or for each wrong answer. The written exam is passed if the achieved mark is greater than or equal to 15/30. The open question will be evaluated assigning a vote between 0 and 3 on the basis of the correctness, completeness and ability to synthesize. The oral exam will allow to modify the written exam vote of  $\pm 5$  points. The oral exams will consist of one question and of the discussion on the answers provided in the written exam. Moreover, the students can choose to analyze in-depth a course argument.

The laude is assigned to students who provide: i) correct and exhaustive answers to all the questions of the written and oral exams and ii) correct, synthetic and exhaustive answer to the open question of the written exam.

## Texts

Textbooks and other materials:

Slides, papers and other materials and handouts provided by the teacher and available on the UCBM e-Learning web platform.

Further reading:

- ) Kotler P., Shalowitz J., Sevens R. J., Turchetti G., "Marketing per la Sanità, logiche e strumenti", Mc Graw Hill, 2010.
- ) Turchetti G., "La Politica degli Acquisti di Beni e Servizi in Ambito Pubblico: le Tendenze in atto nel Settore Sanitario", Franco Angeli, Milano, 2005.
- ) Turchetti G., "L'Health Technology Assessment. Riflessioni sulla dimensione e sulle implicazioni organizzative", in L. Mantovani (a cura di), "L'Health Technology Assessment. Principi, Concetti, Strumenti Operativi", Il Sole 24ore Libri, Milano, 2011.
- ) Ricciardi W., La Torre G., "Health Technology Assessment: principi, dimensioni e strumenti", SEED srl, 2010.
- ) Turchetti G., Labella B., "L'innovazione nelle tecnologie biomediche tra rischio, incertezza, precauzione e gestione", in Comandè, G. (a cura di) "Gli strumenti della precauzione: nuovi rischi, assicurazione e responsabilità", Giuffrè 2006.
- ) Health Technology Assessment (AA.VV. I quaderni di monitor 4° supplemento al n. 23 – 2009 – ed. Agenas.
- ) Turchetti G., I. Palla, F. Pierotti, A. Cuschieri, "Economic evaluation of da Vinci-assisted robotic surgery: a systematic review", Surgical Endoscopy, Vol. 26, pp. 598-606, 2012.

- ) Turchetti G., E. Spadoni, E. Geisler, “Health technology assessment. Evaluation of biomedical innovative technologies”, *IEEE Engineering in Medicine and Biology Magazine*, May/June, vol. 29, n. 3, pp. 70-76, 2010.
- ) Turchetti G., B. Labella, S. Bellelli, S. Cannizzo, I. Palla, S. Mazzoleni, S. Petroni, S. Sterzi, E. Guglielmelli, “Innovation in rehabilitation technology: technological opportunities and socio-economic implications”, *International Journal of Healthcare Technology and Management*, Vol. 10. Nos. 4/5, pp. 245-261, 2009.
- ) Goodman C., “Introduction to health care technology assessment”, National Library of Medicine: National Information Center on Health Services Research & Health Care Technology (NICHSR), 1998.
- ) Velasco Garrido M., Busse R., “Health technology assessment. An introduction to objectives, role of evidence, and structure in Europe”, WHO regional office for Europe 2005. European observatory on health system and policies, 2005.
- ) Kristensen F.B., Sigmund H., *Health Technology Assessment Handbook* Copenhagen: Danish Centre for Health Technology Assessment, National Board of Health, 2007.
- ) Battista R.N., Hodge MJ. The development of health care technology assessment. An international perspective. *Int J Technol Assess. Health Care*, Spring;11(2):287-300, 1995.
- ) Battista R.N., Expanding the scientific basis of health technology assessment: A research agenda for the next decade. *International Journal of Technology Assessment in Health Care*, 22, pp. 275-280, 2006.

