دانشگاه علوم پزشکی تبریز

دانشکده علوم نوین پزشکی

Course Guide: Principles of Commercialization and Standardization of Tissue Engineering Products

Instructor / Instructors: Dr. Azizeh Rahmani Del Bakhshayesh, Dr. Payam Keyhanvar

Prerequisite or Corequisite: Principles of Tissue Engineering

Number of Units: 2 Type of Units: 2 Theoretical and . Practical Units Level: Ph.D. in Tissue Engineering

Number of Sessions: 17

Start and End Dates of Sessions:

Weekly Session Time: Wednesdays, 10:00 AM - 12:00 PM

Location of In-Person Sessions: Site, Faculty of New Medical Sciences

Overall Goal and Introduction to the Course:

The significant growth of research activities in universities and research centers across the country is undeniable. However, it should be noted that currently, the knowledge cycle remains incomplete at the end of the research stage. Research achievements, if they do not lead to addressing societal needs through the generation of intellectual property and the added value from the sale and commercialization of these assets, cannot be considered a vital factor in the development of the country's economy. Academic research and commercialized products are concepts of two different natures, essences, and phases. Therefore, the results of academic research must be transformed into commercial products through a phase conversion process. Although the framework or indicators of an ideal model for such a process can be defined, there is a gap between a general qualitative model and a specific quantitative one. Commercialization is the process of transforming

science, technology, new research, or an invention into products, industrial processes, or services that are deliverable and marketable.

Hence, the overall goal of this course is to familiarize students with commercialization and to create a suitable platform for establishing a strong connection between university and industry.

Learning Domains: Cognitive

Course Learning Objectives

It is expected that learners, after completing this course, will be able to:

1. Define the concepts in the field of commercialization.
2. Describe the characteristics of advanced businesses and the business plan of technology-based firms.
3. Explain the value chain.
4. Describe the financing methods for technology companies and types of investments.
5. Explain business models.
6. Elaborate on intellectual property rights in technology business and its numerous examples.
7. Describe methods for protecting intellectual property, especially patent registration and its stages.
8. Know and discuss the various stages of establishing and financially managing technology businesses.
9. Explain commercialization models.
10. Describe the necessary actions for commercializing research achievements.
11. Describe the stages of company registration.
12. State the stages of registering a knowledge-based company.
13. Outline the stages of clinical translation of a tissue construct.
14. Discuss the social challenges of commercialization in the field of tissue engineering.
15. Explain the research phases from *in vitro* to clinic.

16. State the governing regulations for FDA approval of a tissue construct.

Teaching Methodology

Verbal teaching and lectures, Q&A, discussion, conference, small groups

Student Assessment Method

Continuous Assessment: Class activities including seminar presentations, group work, and quizzes, participation in class discussions, assignments (Score)

Final Assessment: Written exam (16 points)

Attendance and Absence: (2 points)

Total Points: 20

Minimum Passing Score for this Course: 14

Permitted Absence Hours for this Course: 8 hours

Educational Resources

- Resources from which exam questions will be designed:

✓ Entrepreneurship and Technology Commercialization: Hosseini, Aghajani, Seyed Ali Akbar Hosseinzadeh, Pejvak Mahdipour Kardesht
✓ Commercialization and Financing of Technology: Jarooni and Wanglimparat
✓ Commercialization of Innovation: Madhavan Ramanojam
✓ Monetizing Innovation: Madhavan Ramanojam
✓ Laws and Regulations of Company Registration, Authors: Sharif Zeisi, Zahra Arab
✓ Practical Guide to Company Registration: Specific Joint Stock Company, Limited Liability Company, General Partnership, Non-Commercial Institutions, and Cooperative Companies, Author: Javad Sadeghi
✓ Property and Ownership Law: Seyed Ahmad Ali Hashemi, Ebrahim Taghizadeh

✓ National Commercialization Workshops Held
✓ Lanza R, Langer R, Vacanti J. Principles of Tissue Engineering. San Diego: Academic Press (Latest edition)
✓ Internet Websites

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Educational Resources for Further Study

✓ J Cribb, Hartomo TS. Sharing Knowledge: A Guide to Effective Science Communication. Australia: CSIRO Publishing (Latest edition)
✓ Gascoigne T, Metcalf J. Incentives and Impediments to Scientists Communicating through the Media. Australia: CSIRO (Latest edition)
✓ Gray G. Engaging Politicians and the Community in a Dialogue for Science. Federation of Australian Scientific and Technological Societies (Latest edition)
✓ Roederer JG. Communicating with the Public, Politicians, and the Media, COSTED Occasional Paper No.1, July 1998, UNESCO
✓ Rola, A. C., J.PT Liguton and D.D.Elazegui. 2005. How Can Community-based Research Influence National Level Policy? Water Management in the Philippines. Public Policy. UPCIDS, forthcoming.
✓ Tollini, H. 1998. Policy and Research: Loops of a Spiral? In. Tabor, Sand D. Faber. (Eds). Closing the Loop: From Research on Natural Resources to Policy Change. Policy Management Report# 8, European Centre for Development Policy Management (ECDPM)/ International Service for National Agricultural Research (ISNAR). The Netherlands. pp 22-24.

Learning Opportunities

Possibility of visiting incubators, science and technology parks, accelerators, and chambers of commerce

Holding business and commercialization workshops at the university and faculty level

Opportunity to participate in events of the University's Health Innovation and Acceleration Center and EDC

Contact Information

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Session Titles for 2 Units of Principles of Commercialization and Standardization of Tissue Engineering Products

Session	Title	Instructor	Date
1	Concepts of Commercialization and Standardization	Dr. K / Dr. R	
2	Concepts of Commercialization and Standardization	Dr. K / Dr. R	
3	Business Plan and Value Chain	Dr. K / Dr. R	
4	Business Plan and Needs Assessment	Dr. K / Dr. R	

Session	Title	Instructor	Date
5	Intellectual Property Rights, Types of Research, Technology Transfer	Dr. K / Dr. R	
6	Research and Development Management, Knowledge-Based Companies, Types of Intellectual Property	Dr. K / Dr. R	
7	Providing a Suitable Platform for Interaction between Industry and University, Regulations and Agreements	Dr. K / Dr. R	
8	Clinical Translation Pathway for Tissue Constructs	Dr. K / Dr. R	
9	Research phases from *in vitro* to FDA approved, Regulations for FDA approval of a tissue construct	Dr. K / Dr. R	
10	Principles of GMP, GLP, Quarantine, Standards (ASTM, CBER), Principles of Aseptic Production and Sterilization	Dr. K / Dr. R	
12	Familiarity with National and International Laws and Regulations in the Field of Tissue Engineering Products	Dr. K / Dr. R	
13	Information Management System in Business Plan and Needs Assessment	Expert from Industry	
14	Consultation Sessions and Group Guidance	Expert from Industry	
15	Challenges and Pitfalls in Technology Commercialization Standardization	Expert from Industry	
16	Different Models of Business Management and Financial Analysis	Expert from Industry	

Session Conduct Method: In-person in the classroom, at the Site location

Educational Media Aid: Computer and Whiteboard