

# **BME317 Biomedical Devices Innovation**

**Level:** 3

**Credit Units:** 5 Credit Units

**Language:** ENGLISH

**Presentation Pattern:** EVERY JAN

## **Synopsis:**

Every commercially viable novel biomedical device is the culmination of years of detailed due diligence, planning and overcoming many different types of hurdles. While it is important to have a great idea, it is often not enough to develop a great biomedical device. Most people lack the knowledge and understanding of the many commercial and regulatory aspects of developing a biomedical device. BME317 Biomedical Device Innovation aims to equip students and future innovators with the important considerations and planning needed to develop a commercially viable and regulatory approved biomedical device.

## **Topics:**

- Introduction to medical technology innovation
- Needs Finding and Needs Screening
- Concept Generation
- Concept Selection
- Intellectual Property Strategy
- Research and Development Strategy
- Clinical and Regulatory Strategy
- Reimbursement Strategy
- Marketing, Sales and Distribution Strategy
- Operating Plan and Financial Model
- Business Plan Development
- Innovative Biomedical Devices

## **Textbooks:**

Paul Yock, Stefanos Zenios, Josh Makower, Todd J. Brinton, etc: Biodesign: The Process of Innovating Medical Technologies 2nd Edition Cambridge University Pres  
ISBN-13: 9781316095843

**Learning Outcome:**

- Discuss biomedical device innovation processes from the medical, engineering, and business perspectives
- Examine the importance of value exploration and recognise the ‘signposts’ that lead to high value needs
- Evaluate the three-phase design process for innovating medical technologies, i.e. identify → invent → implement
- Determine the different types of business models that are used in the medical device fields
- Analyse the thought and due diligence processes involved in conceptualising a biomedical device
- Develop various strategies and plans by using emerging technology to bring innovation from idea to market

**Assessment Strategies (Evening Class):**

<b>Components</b>	<b>Description</b>	<b>Weightage Allocation (%)</b>
Overall Continuous Assessment	QUIZ 1	15
	TUTOR-MARKED ASSIGNMENT 1	15
Overall Examinable Components	ECA	70
<b>Total</b>		<b>100</b>