BME1101

Introduction to Biomedical Engineering

Ethics and Bioethics

- **Ethics:** Ethics is based on well-founded standards of right and wrong that prescribe what humans ought to do, usually in terms of rights, obligations, benefits to society, fairness, or specific virtues.

- **Bioethics:** Bioethics is a field of study that explores the ethical, moral, and societal implications of advances in biology, medicine, and healthcare. It involves examining and addressing the ethical dilemmas and questions that arise from developments in areas such as genetics, reproductive technology, organ transplantation, end-of-life care, and biomedical research.

- Bioethics deals with many concepts:

➢ Autonomy

➢ Beneficence and Non-maleficence

➢ Justice

➢ Privacy and Confidentiality

➢ Truth-telling and Honesty

➢ End-of-life Issues

- McCormick, T. R., & Min, D. (2013). Principles of bioethics. Ethics in Medicine.

The Statement of Ethical Principles

In 2005 the Royal Academy of Engineering and the Engineering Council jointly created a statement of ethical principles to guide engineering practice and behaviour. The Statement of Ethical Principles is supported by 4 main principles:

- **1. Honesty and integrity:** act in a reliable and trustworthy manner

- **2. Respect for life, law, the environment and public good:** hold paramount the health and safety of others and draw attention to hazards; ensure their work is lawful and justified; respect and protect personal information, intellectual property and also security

- **3. Accuracy and rigour:** always act with care; keep their knowledge and skills up to date

- **4. Leadership and communication:** be aware of the issues that engineering and technology raise for society, and listen to the aspirations and concerns of others; promote public awareness

- Fried, J. (2003). Ethical standards and principles. Student services: A handbook for the profession, 4, 107-127.

- **Example Scenario Related with «Privacy» and «Confidentiality» :** A patient is receiving medical treatment and has medical files maintained by healthcare professionals. It is important that these files are stored while protecting patient privacy and confidentiality. It is an ethical responsibility to share this information only with authorized healthcare professionals for treatment purposes and not to disclose it outside without permission.

- **Example Scenario Related with «Leadership» and «Justice»** A hospital administrator faces a situation where resources are limited due to the pandemic. The number of intensive care beds, ventilators and other critical equipment is decreasing. The manager meets with the healthcare team and decides to determine a fair resource allocation strategy. In accordance with the principle of leadership, the manager focuses on considering all healthcare professionals working in the hospital and their patients equally and fairly. It evaluates the urgency and likelihood of recovery of each patient, without distinguishing between them. As a result, the administrator develops a plan that focuses on saving the most lives by using resources most effectively. This plan prioritizes justice, equality and the general health of the society in accordance with the principle of leadership.

- Amado, E. D. (2024). Critical Bioethical Approach to Health Crisis Scenarios. In Bioethics (pp. 165-182). CRC Press.

Concepts of Standardization

Standardization is any process used to develop and apply criteria (i.e., "standards") that specify the essential characteristics of something for which control and uniformity are desired. In simple terms, in a business environment, the process creates a framework and set of guidelines for entities to follow and deliver products and services with a consistent standard and quality. Therefore, standardization can be applied to almost anything, such as rules/laws, technologies, products, services, behaviors, measurements.

Standardization can provide businesses with countless competitive advantages such as

➤ Ensure uniformity

➤ Improve quality and safety

➤ Increases productivity and overall efficiency

➤ Gain competitive advantages

➤ Attract customers

• Spivak, S. M., & Brenner, F. C. (2018). *Standardization essentials: Principles and practice*. CRC Press

International Standards Organizations

International Organization for Standardization (ISO): ISO is a global body

that develops and publishes international standards. It brings together experts

from different countries to create consensus-based standards in various fields.

Website: https://www.iso.org/home.html

- ➢ **ISO 13485 Medical devices** - Quality management systems - Requirements for regulatory purposes that specifies the requirements for a quality management system (QMS) specifically designed for the medical device industry.

- ➢ **ISO 9001 Quality Management System**, which will enable them to work more efficiently and reduce product defects.

- ➢ **ISO 14001 Environmental Management System**, which will reduce environmental impacts, waste rate and be more sustainable.

- ➢ **ISO 45001 Occupational Health and Safety Management System** to help reduce accidents in the workplace.

- *ISO - International Organization for Standardization*. (n.d.). ISO. https://www.iso.org/home.html

International Standards Organizations

➢ **ISO 10993 - Biological evaluation of medical devices** is a series of international standards that provide guidance on the biological evaluation of medical devices. These standards are designed to assess the potential risks associated with the use of medical devices in contact with the human body.

• *ISO 10993-1:2018*. (2018, October 1). ISO. https://www.iso.org/standard/68936.html
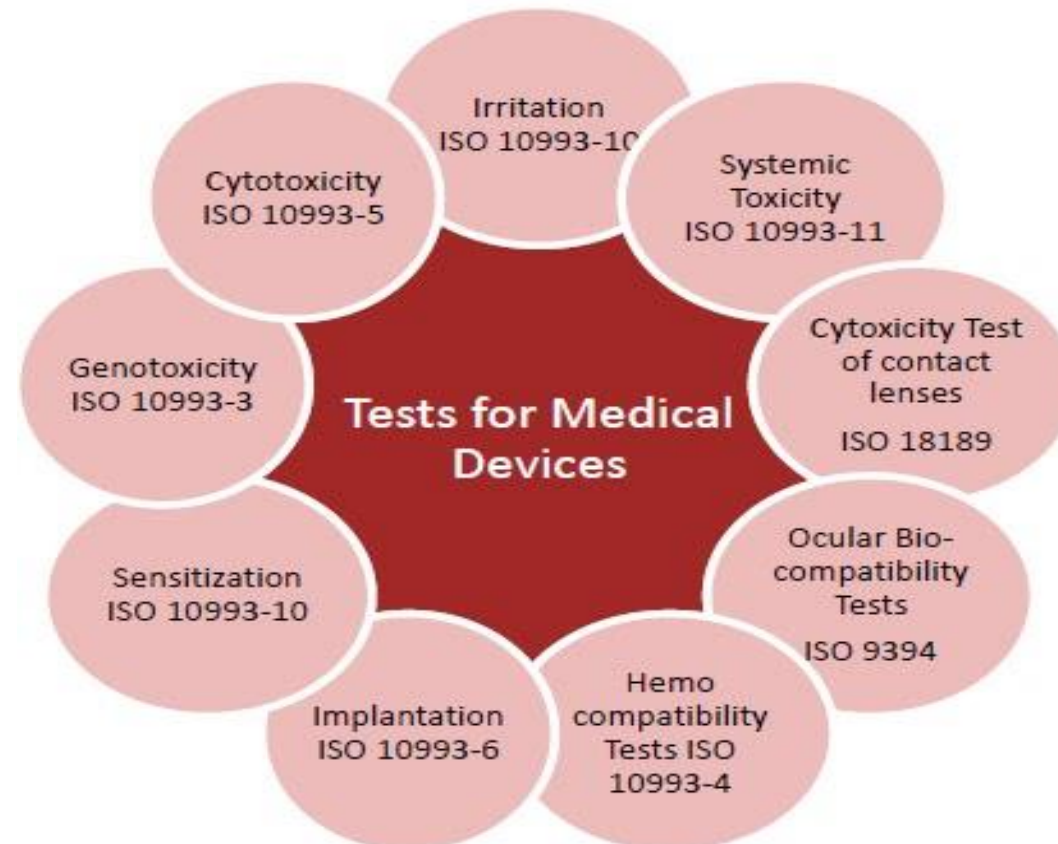
Industry-Specific Standards Organizations

American Society for Testing and Materials (ASTM) International: ASTM develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services[*].

Website: https://www.astm.org

Institute of Electrical and Electronics Engineers (IEEE): IEEE develops standards in the electrical and electronics engineering fields. It covers areas such as communications, power systems, and information technology [**].

Website: https://standards.ieee.org

[*]*ASTM International - Standards Worldwide*. (n.d.). https://www.astm.org

[**]*Home - IEEE Standards Association*. (2023, December 27). IEEE Standards Association. https://standards.ieee.org

Regional Standards Organization and Government Agencies

European Committee for Standardization (CEN) and European Committee for Electrotechnical Standardization (CENELEC): CEN and CENELEC develop standards for the European market, covering various industries and sectors [*].

Website: https://www.cencenelec.eu

National Institute of Standards and Technology (NIST): In the United States, NIST works on developing and promoting measurement standards [**].

Website: https://www.nist.gov

[*]*CEN-CENELEC*. (n.d.). CEN-CENELEC. https://www.cencenelec.eu
[**]*NIST*. (2024, January 4). NIST. https://www.nist.gov

National Standards Organizations

Turkish Standards Institution (TSE): It is known as "Türk Standardları Enstitüsü" in Turkish and abbreviated as TSE, is the national standards organization in Turkey. TSE is responsible for the development, publication, and promotion of standards within the country. It operates under the Ministry of Industry and Technology and plays a crucial role in supporting the standardization efforts across various industries in Turkey [*].

Website: https://www.tse.org.tr

American National Standards Institute (ANSI): Oversees the development of voluntary consensus standards in the United States [**].

Website: https://www.ansi.org

Deutsches Institut für Normung (DIN): The German Institute for Standardization, which develops standards used in Germany and internationally [***].

Website: https://www.din.de/en

[*]*TSE - Türk Standartları Enstitüsü*. (2023, December 27). Türk Standartları Enstitüsü. https://www.tse.org.tr
[**] ANSI- American National Standards. (n.d.). https://www.ansi.org
[***] *DIN - German Institute for Standardization*. (n.d.). Din-en. https://www.din.de/en

KNOWLEDGE ABOUT SUSTAINABLE DEVELOPMENT

- Birleşmiş Milletler. (n.d.). Küresel Amaçlar. Kuresel Amaçlar. https://www.kureselamaclar.org/

➤ **Good Health and Well-being:** Biomedical engineers play a pivotal role in promoting universal access to quality healthcare, utilizing cutting-edge technologies to enhance overall well-being and advance global health.

➤ **Quality Education:** Biomedical engineering education is a cornerstone for unlocking a healthier future, empowering individuals with the knowledge and skills needed to make impactful contributions to global health.

➤ **Industry, Innovation, and Infrastructure:** Biomedical engineering drives innovation in healthcare infrastructure, contributing to sustainable solutions that advance the industry and improve global health outcomes.

➤ **Affordable and Clean Energy:** Biomedical engineering research and innovation contribute to the development of sustainable and affordable energy solutions, powering a healthier and greener future for all.

- **Decent Work and Economic Growth:** The field of biomedical engineering fosters decent work and economic growth by creating opportunities for innovation, research, and development in the healthcare industry.

- **Responsible Consumption and Production:** Biomedical engineering emphasizes responsible consumption and production, ensuring that medical technologies are developed sustainably and ethically, contributing to a healthier planet.

- **Peace, Justice, and Strong Institutions:** Biomedical engineers support the establishment of strong healthcare institutions, contributing to a world where health serves as a foundation for peace and justice.

- **Partnerships for the Goals:** Biomedical engineering thrives on collaboration, and partnerships across disciplines are essential for achieving the shared goal of a healthier, more sustainable world.

Knowledge about the effects of engineering practices on health, environment and safety in the universal and social aspects and the problems of the age reflected in the field of engineering.

➤ The impacts of engineering applications on universal and societal aspects of health, environment, and safety are highly comprehensive. These effects manifest throughout various stages of engineering projects, starting from design to construction and operation.

➤ Here are some universal and societal issues encountered in these areas:

• Milic, M. (2018, March 9). Health, Safety & Environmental (HSE) management in engineering practice. LinkedIn. https://www.linkedin.com/pulse/health-safety-environmental-hse-management-practice-mladen-milic

➢ **Health**: Engineering projects, environmental factors, industrial activities, and infrastructure developments can lead to various health issues such as air and water pollution. Construction projects and industrial facilities can negatively affect the health of workers through factors like dust, noise, and vibration. Biomedical engineering applications contribute significantly to patient treatment and care through medical technology and devices.

➢ **Environment**: Infrastructure projects can impact natural habitats, and the use of natural resources, water, and energy consumption can contribute to environmental issues. Industrial wastes, carbon emissions, and other pollutants can degrade air, water, and soil quality. Sustainable engineering practices are crucial to minimize environmental impacts and use natural resources more efficiently.

➢ **Safety**: Insufficient safety measures in construction projects and industrial facilities can pose hazards to workers and the community. Non-compliance with safety standards in structural engineering applications can lead to issues concerning building resilience and user safety. Cybersecurity concerns have become increasingly relevant in engineering applications involving automation and digitization.

• Foy, D. (2023, November 29). Managing Health and Safety Risks in engineering. HSE Network. https://www.hse-network.com/managing-health-and-safety-risks-in-engineering/

➢ **Social Issues:** Infrastructure developments and urban planning directly influence the daily lives of communities. Proper planning of transportation, housing, and energy infrastructure is essential. Projects carried out without considering socio-economic balances can contribute to social inequalities. Technological Developments and

➢ **Ethics:** Innovations in technologies such as artificial intelligence and biotechnology shape engineering applications and bring along ethical concerns. To address these issues and make engineering applications more sustainable and community-focused, it is crucial for engineers to adhere to ethical principles, engage in interdisciplinary collaborations, and develop projects with a consideration for societal needs. Additionally, awareness and continuous education are necessary to respond to new challenges emerging with technological advancements.

• Foy, D. (2023, November 29). Managing Health and Safety Risks in engineering. HSE Network. https://www.hse-network.com/managing-health-and-safety-risks-in-engineering/

Legal Awareness in Engineering

The legal aspects of biomedical engineering involve a range of issues related to the development, use, and regulation of medical technologies, devices, and procedures.

Some key legal considerations ;

➢ **Intellectual Property (IP)**

Engineers often work on innovative technologies and inventions. Protecting intellectual property through patents, trademarks, and copyrights is crucial. This involves navigating the patent application process, ensuring freedom to operate, and addressing issues related to infringement.

➢ **Liability**

Biomedical engineers must consider liability issues associated with the use of medical devices or technologies. This includes ensuring that their designs and products comply with safety standards and regulations. Liability concerns may also extend to issues such as product defects, inadequate warnings, and failure to meet industry standards.

➢ **Regulatory Compliance**

Medical devices and procedures are subject to regulatory oversight by agencies such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe. Compliance with regulatory requirements is essential to ensure the safety and efficacy of biomedical products. This includes adherence to Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).

- Robert J Borns, "THE LEGAL ASPECTS OF ENGINEERING EDUCATION ," Session F1H, 2002, 18–23.
- Rosa Mayelin Guerra-Bretaña and Andrea Lucía Flórez-Rendón, "Impact of Regulations on Innovation in the Field of Medical Devices," Research on Biomedical Engineering, 34.4 (2018), 356–67 <https://doi.org/10.1590/2446-4740.180054>

Legal Awareness in Engineering

➢ Ethical Considerations

Biomedical engineers often deal with sensitive issues related to human health and life. Ethical considerations may include patient privacy, informed consent, and the responsible use of emerging technologies such as genetic engineering or artificial intelligence in healthcare. Ethical guidelines, institutional review boards (IRBs), and ethical review processes play a significant role in ensuring responsible conduct.

➢ International Law and Standards

Biomedical engineering is a global field, and products may be developed, tested, and marketed internationally. Understanding and complying with international laws and standards, such as ISO standards for medical devices, is crucial for ensuring a seamless and lawful global presence.

➢ Health and Safety Regulations

Engineering projects often have significant health and safety implications. Legal awareness includes understanding and adhering to regulations that promote workplace safety, risk management, and the well-being of individuals affected by engineering activities.

- Robert J Borns, "THE LEGAL ASPECTS OF ENGINEERING EDUCATION ," Session F1H, 2002, 18–23.
- Rosa Mayelin Guerra-Bretaña and Andrea Lucía Flórez-Rendón, "Impact of Regulations on Innovation in the Field of Medical Devices," Research on Biomedical Engineering, 34.4 (2018), 356–67 <https://doi.org/10.1590/2446-4740.180054>.
- Toader Elena, Damir Daniela, and Toader Ionut Alexandru, "Ethical and Legal Aspects in Biomedical Research Involving Human Beings," Proceedings - 2nd Advanced Technologies for Enhanced Quality of Life, ATEQUAL 2010, 2010, 79–82 <https://doi.org/10.1109/ATEQUAL.2010.29>.

Legal Awareness in Engineering

➤ Environmental Laws and Sustainability

With increasing emphasis on sustainability, engineers must be aware of environmental laws and regulations. Legal awareness in this context involves integrating environmentally friendly practices into engineering projects and ensuring compliance with sustainability standards.

➤ Risk Management

Legal awareness helps engineers identify and manage legal risks associated with their work. This includes anticipating potential legal challenges, implementing preventive measures, and having contingency plans in place.

➤ Continuous Education

Given the dynamic nature of laws and regulations, legal awareness in engineering requires a commitment to continuous education. Engineers should stay informed about updates, changes, and new developments in the legal landscape relevant to their field.

- Robert J Borns, "THE LEGAL ASPECTS OF ENGINEERING EDUCATION ," Session F1H, 2002, 18–23.

How to be an entrepreneur and innovator in Biomedical Engineering?

1. **Identifying Problems:** Understanding the healthcare industry's challenges and identifying unmet needs or gaps that can be addressed through innovation is crucial. Students can learn to recognize these problems by engaging with medical professionals, patients, and other stakeholders.

2. **Innovative Solutions:** Biomedical engineering students can learn to apply their technical skills to develop innovative solutions to healthcare problems. This could involve designing medical devices, improving diagnostic tools, creating new therapies, or developing biomedical materials.

3. **Prototyping and Testing:** Entrepreneurship in biomedical engineering involves not just ideation but also prototyping and testing of solutions. Students can learn how to create prototypes of their ideas and conduct rigorous testing to ensure safety, efficacy, and compliance with regulations.

4. **Understanding Regulatory Requirements:** Entrepreneurs in biomedical engineering need to navigate complex regulatory pathways. Learning about FDA regulations, ethics in research, and compliance standards is vital for students planning to bring their innovations to market.

5. **Business Skills:** Students can benefit from learning basic business skills such as market analysis, creating business plans, intellectual property rights, funding strategies, and understanding the economic aspects of the healthcare industry.

6. **Collaboration and Networking:** Entrepreneurship often involves collaboration with multidisciplinary teams. Biomedical engineering students can learn the importance of networking, teamwork, and collaborating with professionals from diverse backgrounds, including healthcare providers, business experts, and investors.

7. **Case Studies and Guest Lectures:** Integrating real-world case studies and inviting successful entrepreneurs or industry professionals as guest lecturers can provide students with practical insights and experiences in the field.

8. **Pitching and Communication:** Effectively communicating ideas is crucial for entrepreneurial success. Students can learn how to pitch their innovations convincingly to investors, stakeholders, and potential customers.

9. **Adaptability and Resilience:** Entrepreneurship can be challenging. Teaching students about adaptability, resilience, and the ability to learn from failures is important in preparing them for the uncertainties and obstacles they might face.

10. **Ethical Considerations:** Understanding the ethical implications of their innovations is crucial for students. They should be aware of the potential impacts of their work on patients, society, and the environment.
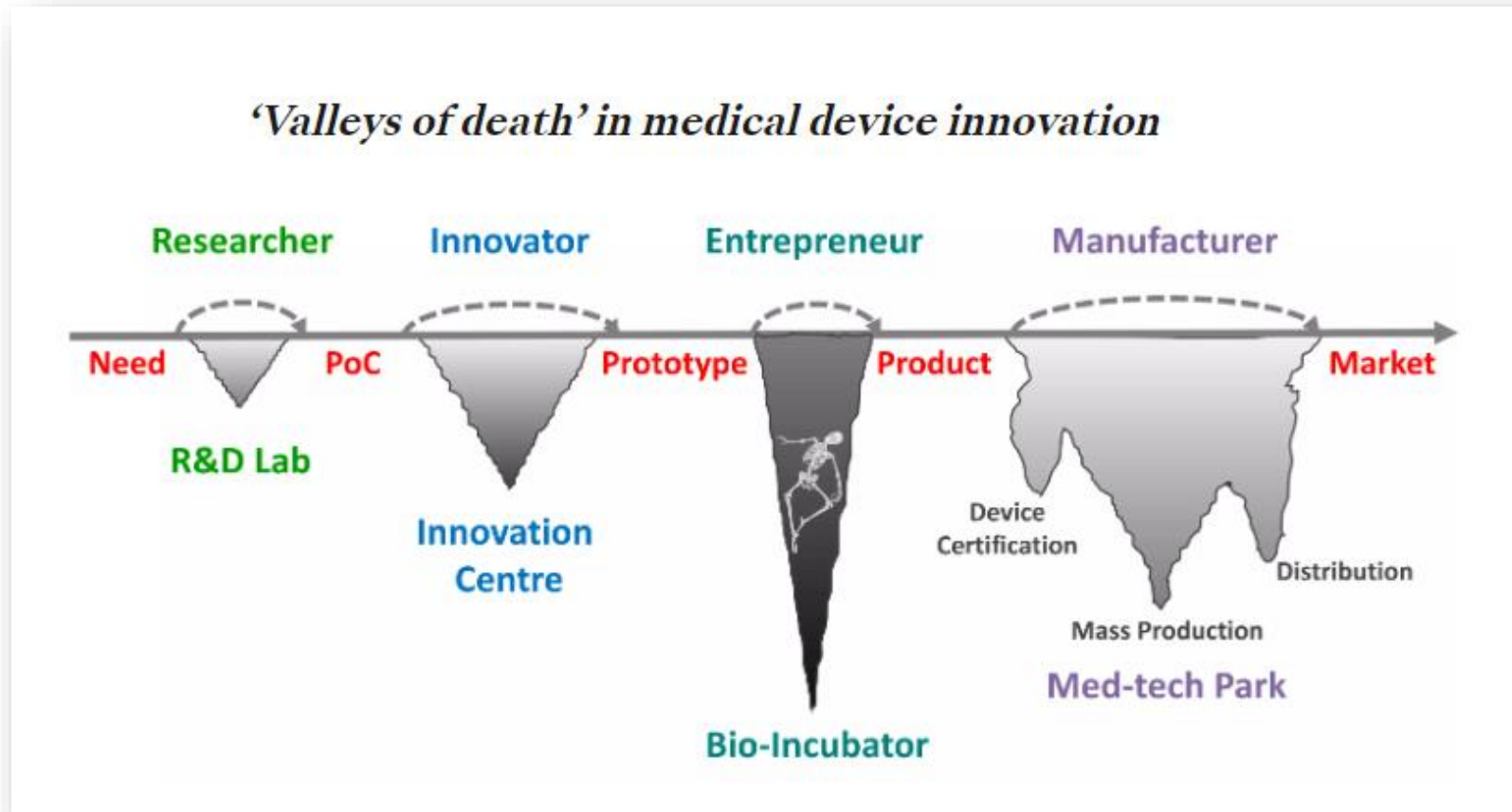
How to be an entrepreneur and innovator in Biomedical Engineering?

Medical device innovation starts from bedside (need in hospital) to bench (product engineering) to business (commercialization) to bedside (application). Critical steps include clinical need validation, proof-of-concept, detailed product design, rapid prototyping, pilot batch manufacturing, lab testing, human clinical trials, regulatory approvals, mass production and distribution. These require close collaboration among experts from multiple disciplines – medical, biomaterial, mechanical, product design, manufacturing, electronics, software and management.

The total lead time to traverse the above steps can take 3-4 years for even low-risk devices. Take for example the digital stethoscope module developed by Ayu Devices, a start-up from BETIC, IIT Bombay. The need was identified in 2015 by a rural hospital doctor, who wanted to avoid sending his patients to city for second opinion, by recording and sending the stethoscope sounds to expert doctors. The proof-of-concept was developed within four days during a hackathon (Figure 1). It however, took several months (in 2016) to develop a prototype, and two more years to develop a fully functional product, followed by regulatory approvals, regular production, initial distribution and rural medical camps. By early 2020, the device sold more than 1000 units across the country. High-risk devices such as heart valves involve much longer lead time (8-10 years) along with considerably higher level of expertise and funding.

https://health.economictimes.indiatimes.com/news/industry/biomedical-innovation-and-entrepreneurship-in-india/76088267

How to be an entrepreneur and innovator in Biomedical Engineering?

'Valleys of death' in medical device innovation

How to be an entrepreneur and innovator in Biomedical Engineering?

Clinical Need to Proof-of-Concept- Clinical immersion in hospitals is essential to observe the procedures of diagnosis and treatment first-hand to identify unmet clinical needs. Prior art search is carried out to avoid 'reinventing the wheel'. Then research projects are taken up to explore new solutions, such as new biomarkers, sensors and algorithms. Proof-of concepts and lab set-ups are developed to demonstrate the core scientific working principles.

Step 2:

Proof-of-Concept to Prototype:

Major tasks include product engineering (including 3D computer-aided design, simulation and optimization) followed by rapid prototyping (plastic, metal and electronics), and basic testing (mechanical and electrical). Several iterations of design, prototyping, testing and clinician feedback are performed till the desired outcomes are achieved.

Step 3:

Prototype to Product: This involves product design for manufacturability, followed by medical-grade pilot manufacturing of a small batch required for lab tests and human clinical studies. Pilot manufacturing has to be carried out using the same equipment as those for mass production later, such as computer-controlled equipment for machining, sheet metal forming, injection molding and PCB fabrication, with quality management system in accordance with ISO 13485. Medical devices need to be tested for biocompatibility, mechanical safety and electrical safety.