16BM769 MEDICAL DEVICE LIFE-CYCLE MANAGEMENT 3-0-0-3

Objectives:

- To understand Medical Device Life Cycle
- To understand the various phases, requirements and deliverables of the device life cycle
- To understand regulatory processes

Medical Device Development Process - Customer Requirements, Proof of Concept, Design Control, Design Verification and Validation; Clinical trials – Process, SAC, IEC approvals; Safety Testing; Design Transfer; Product Launch; Risk Management; Regulatory strategy; Intellectual Property management; Project Management; Start-up company experiences, Support ecosystem, Time to market; Medical Device Standards, Regulatory approval processes – FDA / CE; Medical Devices Rules 2016.

TEXTBOOKS / REFERENCES:

1. T. R. Kucklick (Ed.), *The Medical Device R&D Handbook*, 2nd ed., Boca Raton, Fla.: CRC Press, 2013.
2. E. Whitmore, *Development of FDA-regulated medical products: A translational approach*, 2nd ed. Milwaukee, Wis: ASQ Quality Press, 2012.
3. N. F. Kerr and T. Recupero, *Product Launch: Practical Guide to Launching Medical Device Products*. Kerr Consulting Group Llc, 2015.
4. S. S. Mehta, *Commercializing successful biomedical technologies: basic principles for the development of drugs, diagnostics and devices*, Cambridge: Cambridge University Press, 2008.
5. B. Burge et al., *A Manual Introducing Intellectual Property to Scientists – Patents*, World Scientific Pub Co Inc, 2010.
6. IEC Standards 60601-X, ISO 13485, ISO 14971, ISO 14133, Relevant FDA / CE Regulatory protocols

Outcomes:

- Better understanding of the challenges in medical device development
- Better understanding of regulatory approval
- Better understanding of the process of device transition from laboratory to market.