

Printed Pages: 01

Sub Code: MPM205

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**M PHARM  
(SEM II) THEORY EXAMINATION 2017-18  
MEDICAL DEVICE REGULATIONS**

**Time: 3 Hours**

**Total Marks: 70**

**Note:** Attempt all Sections.

**SECTION A**

- 1. Attempt all questions in brief.** **2 x 7 = 14**
- a) Write difference between medical devices IVDs and pharmaceuticals.
  - b) What is summary technical document (STED)?
  - c) Explain in brief about validation of medical devices.
  - d) What is the meaning of GHTF?
  - e) Mention adverse event reporting of medical device.
  - f) Explain in short premarket notification.
  - g) Write in short about CE certification process.

**SECTION B**

- 2. Attempt any three parts of the following:** **7 x 3 = 21**
- a) Explain in detail about IMDRF structure, functions and regulatory guidelines of IMDRF.
  - b) Discuss Quality system regulations of medical devices: ISO13485
  - c) Write about medical devices and IVDs as well as regulatory registration procedures for Asian.
  - d) Write an illustrative note on regulatory approval process for medical devices with reference to European Union.
  - e) Write a note on good clinical practice for clinical investigation of medical devices.

**SECTION C**

- 3. Attempt any one part of the following:** **7 x 1 = 7**
- a) Write about purpose and functions of summary technical documents.
  - b) Discuss the principles of medical devices and IVDs.
- 4. Attempt any one part of the following:** **7 x 1 = 7**
- a) Write down about clinical investigation plan for medical devices.
  - b) Explain verification of medical device.
- 5. Attempt any one part of the following:** **7 x 1 = 7**
- a) Write classification and regulatory approval process for medical devices.
  - b) Discuss in detail about pre-market approval (PMA) for quality system requirements.
- 6. Attempt any one part of the following:** **7 x 1 = 7**
- a) Write down about CE certification process.
  - b) Explain Basics of *in vitro* diagnostics and approval process with reference to European Union.
- 7. Attempt any one part of the following:** **7 x 1 = 7**
- a) Describe Registration procedures for Medical device regulations in world health organization.
  - b) Write down about the quality system requirements for India in brief.