DBY-014-1102003 Seat No. _____

M. Pharm. (Sem. II) (W.E.F. 2017) Examination

July - 2022

MRA-203T : Regulatory Aspects of Medical Devices

Faculty Code : 014
Subject Code : 1102003

Time : **3** Hours] [Total Marks : **75**

1 Answer all the questions, each carry 2 marks. **10×2=20**

(1) Define medical devices.

(2) Classify medical devices as per EU with example.

(3) Give full form of IDE and STED.

(4) Give four examples of Class D medical devices as per India.

(5) What are the scopes of ISO 14155?

(6) Which class of medical devices (As per USA) require clinical trials?

(7) Define quality management system of medical devices.

(8) What is 21 CFR part 820 stand for?

(9) Explain the importance of CE certificaion.

(10) How post marketing surveillance of medical devices is differenet from durgs?

2 Answer any 2 out of 3, each carry 10 marks. **2×10=20**

(1) Write a detailed note on ISO 13485.

(2) Write a detailed note on scope of GHTF and its role in medical device industries.

(3) Write a detailed note on CE certification processes.

3 Answer any 7 out of 9, each carry 5 marks. **7×5=35**

(1) Describe the organizational structure of GHTF.

(2) Write a detailed note on labelling requirement of medical devices as per 21 CFR 801.

(3) Write a detailed note on calssification of In Vitro diagnostics as per USFDA.

(4) Which agencies are responsible for regulation of medical devices in China, Japan and ASEAN countries? Describe regulatory registration process as per Japanese regulation.

(5) Write a note on adverse event reporting of medical device.

(6) Describe the documentation required for Clinical Investigation of medical devices.

(7) Describe lifecycle of medical devices.

(8) Write a note on investigational Device Exemption (IDE)

(9) Describe in detail Regulatory requirements of medical devices as per ASEAN countries.
