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Second Semester M. Pharm Degree Examination - JUNE-2019

[Time: 3 Hours] **[Max. Marks: 75]**

Medical Device Regulations

Q.P. CODE: 5148

Your answers should be specific to the questions asked.
Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any Three) **3 X 10 = 30 Marks**

1. Define and classify Medical Devices with examples. Describe the Medial Devices product life cycle management. (7+3)
2. Explain the Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011)
3. Classify Medical devices as per US-FDA. Discuss about Unique Device Identification of medical devices. Add a note on its implementation. (2+5+3)
4. Describe in detail the process of CE certification in EU with timelines. (7+3)

SHORT ESSAY (Answer any Nine) **9 X 5 = 45 Marks**

5. Discuss the organizational structure, purpose and working of IMDRF. (1+2+2)
6. What is STED format? Write about the salient features of STED format. (2+3)
7. Describe the adverse event reporting of medical devices. Add a note on its importance. (4+1)
8. Discuss the process and importance of clinical investigation of Medical devices. (3+2)
9. What is premarket notification (510k)? Write the regulatory approval process of premarket notification. (1+4)
10. What are In vitro diagnostics directives? Write in brief about the approval process of in vitro diagnostics directives in EU. (1+4)
11. Classify medical devices as per European Union directive. Discuss the important regulations of Active implantable medical device directive. (2+3)
12. Describe the regulatory approval process of Medical devices in European Union.
13. Discuss the clinical Trial Regulations specific for Medical Devices in Asia.
14. Describe the Quality System requirements for medical devices in Japan.

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