M. PHARM. (Regulatory Affairs) SEM - II (CBCS -2019 COURSE): Winter - 2021
SUBJECT: REGULATORY ASPECTS OF MEDICAL DEVICES

Day: Wednesday
Date: 01-12-2021

Time 02:00 PM-05:00 PM
Max. Marks: 75

W-20790-2021

N.B.:

1) Q. No. **1** and **Q. No. 5** are **COMPULSORY**. Out of the remaining attempt any **TWO** questions from each section.
2) Figures to the right indicate **FULL** marks.
3) Answers to both the sections should be written in **SEPARATE** answer book.

Q.1 Discuss audit program of Multiple Sites of a Medical Device. **(08)**

Q.2 Describe good clinical practices for clinical investigation of medical devices according to ISO 14155:2020. **(15)**

Q.3 Discuss highlights of Unique Device Identification (UDI) and harmonization according to IMDRF guideline. **(15)**

Q.4 Write short notes on any **TWO** of the following: **(15)**

a) Initiating and closing a CAPA

b) Historical development of medical device regulations

c) Adverse event reporting of medical devices

SECTION-II

Q.5 Give salient points of Medical Device Directives of European Union. **(07)**

Q.6 Describe registration pathway for approval of a Medical Device in US. **(15)**

Q.7 Discuss regulatory approval pathway in Japan. **(15)**

Q.8 Write short notes on any **TWO** of the following: **(15)**

a) CE certification

b) Labelling requirements for OTC devices

c) Medical Device approval process in China

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