AJEENKYA
D Y PATIL UNIVERSITY

Summer Term Examinations (2019)

School : SOM-ICRI **Program:** M.Sc Clinical research

Course: PHARMA REGULATORY AFFAIRS **Course Code**: MGT554

Semester: II **Max Marks:** 70 **Duration (mins):** 2 ½ hrs.

Note : 1. Figures to the right indicates full marks.
2. Answer all the questions.

Q 1. What are the necessary requirements for premarket notification 510K submission for medical device? (5)

Q 2. Explain functions of DGCI and central government for medical device regulation? (5)

Q 3. Describe the safety issues for designing of medical device with appropriate case study. (10)

Q 4. Write a short note on medical device regulatory in India (10)

Q 5. Whether Registration and import license is required for import of non- notified medical device in India? Justify the answer? (10)

Q 6. Draw regulatory process chart for Class I EU medical devices. (10)

Q 7.Describe the regulatory process of Class II & Class III US-FDA Medical devices with the help of flowchart? (10)

Or

Classify medical devices as per SFDA china medical device Regulation?

Q 8. What is transient time duration, short term and long term duration as per medical device regulatory? (10)

Or

Explain the main eight principles of Quality Management Systems for Medical Devices (ISO 14155:2011) with the help of diagram?

All the best