# Rajiv Gandhi University of Health Sciences



**Second Semester M. Pharm Degree Examination - JUNE-2019**

**Time: Three Hours** **Max. Marks: 75 Marks**

## Regulatory Affairs
## Q.P. CODE: 5166

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. What is intellectual property? Discuss different conditions to be satisfied by an invention to be patentable.
2. What are the principles and elements of TQM? Add a note on tools and techniques of quality.
3. Discuss in detail regulatory requirements for Biosimilars submission.
4. Discuss USFDA regulatory requirements for contract research organization.

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

5. What is the significance of patents in pharmaceutical industry?
6. Explain the role of WIPO.
7. What are regulations in trademark protection?
8. State the objective and function of Central Drugs Standard Control Organization.
9. Discuss Regulatory requirements of EU.
10. Write a short note on concept of total quality management.
11. Write a note on post approval regulatory affairs in Biosimilars.
12. Explain EMEA regulatory requirements.
13. Discuss different parts of patents.
14. Write a note on patent of addition.

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