Rajiv Gandhi University of Health Sciences

II Semester M.Sc [Clinical Research] Degree Examination – SEP-2019

[Time: 3 Hours] [Max. Marks: 100]

REGULATORY AFFAIRS PHARMACOVIGILANCE AND PHARMACOECONOMICS – PAPER I

Q.P. CODE: 9684

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

LONG ESSAY **2 X 20 = 40 Marks**

1. How do we monitor adverse drug reaction in India? What is the name of the national program. How does anyone report an adverse drug reaction?
2. What is definition of a Serious Adverse Event as per Schedule Y of the Indian D&C Act. What are the timelines and responsibilities of sponsor in reporting SAE in any clinical trial

SHORT ESSAY **5 X 10 = 50 Marks**

3. What is a Standard Operating Procedure (SOP)? What is the importance of an SOP? Write in short, a SOP for measuring blood pressure.
4. Responsibilities of sponsor in a clinical trial
5. Audit in Clinical Trial Brief the difference between Inspection and Audit
6. How is causality assessment done in a suspected adverse drug reaction. Mention some scales and tools used for causality assessment with examples.
7. What is direct cost and indirect costs? Describe this in the context of a pharmacoeconomic study.

SHORT NOTES **2 X 5 =10 Marks**

8. Periodic Safety Update of reports (PSUR)
9. CTRI and its importance

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