AJEENKYA
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End Term Examinations (April/May 2019)

School : SOM-ICRI **Program:** M.Sc Clinical research
Course: Pharmacovigilance I **Course Code**: MGT553
Semester: II **Max Marks:** 50 **Duration (mins) :** 150 mins

Note : 1. Figures to the right indicates full marks.

2. Answer all the questions.

Q 1. Definition of Pharmacovigilance, drug, AE (adverse event), ADR (adverse dug reaction) and side effect. (5)

Q 2. What are the valid case criteria in pharmacovigilance? Also explain de-challenge and re-challenge. (5)

Q 3. What is SUSAR and explain the different Expedited Reporting Criteria based on seriousness. Give timelines for regulatory reporting of SAE for investigator, sponsor etc. (5)

Q 4. What is the aim and importance of pharmacovigilance. (5)

Q 5. What is a suspect drug, concomitant medication, treatment drug, medical history and drug history? (5)

Q 6. What is adverse drug reactions and explain its types? (5)

Q 7. What is SAE, what are seriousness Criteria, briefly describe them and provide examples of each SAE criteria. (10)

Or

Define signal as per WHO, what are the indicators of signal and describe the steps in managing signal and give an example for signal detection. (10)

Q 8. What is PSUR and what are the time lines of reporting PSUR to regulatory authority FDA and EMEA? What is the content of PSUR. (10)

Or

What is causality and describe the WHO causality types? (10)

All the best