

Exam Date & Time: 27-Mar-2021 (01:30 PM - 04:30 PM)



MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

Quality Management Systems [PQA-MQA102T - S2]

Marks: 75

Duration: 180 mins.

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) Explain certification process of ISO 9001 in detail. (10)
- 2) Discuss in detail about pharmaceutical quality management (10)
- 3) Discuss in detail about the concept of quality by design and explain its advantages towards the betterment of process development (10)
- 4) Discuss in detail about scope of statistical process control in pharma industry (10)
- 5) a. What is Annual Product Quality Review? (2M)
b. Explain the objective of Annual Product Quality Review as per FDA. 211.180. (e) and product grouping strategy. (8M) (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

- 6) Write a note on quality metrics (5)
- 7) Discuss the importance of PDCA cycle (5)
- 8) Explain the role of descriptive statistics in pharmaceutical process control (5)
- 9) a. What is the difference between incidence and deviation? (1 M)
b. Explain the roles and responsibilities of IPQC personnel in the pharmaceutical industry. (4 M) (5)
- 10) a. Explain the change control procedure for relaxation of water content specification of an API. (3 M)
b. Write in brief the testing and approval of raw materials in Quality Control. (2 M) (5)

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