Enrolment No.: .....

IITHMR UNIVERSITY

School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-15th (2023-2025)

Second Year, Term 5 End Term Examination, February 2025

PHRM-746 Quality Management

Time - 3 Hours **Maximum Marks: 50 (Minimum Marks: 20)**

Instructions to students:

- **This question paper contains 3 printed page/s.**
- **Don't write anything on the Question Paper except writing your Enrolment No.**

Part A

(Maximum Marks: 5)

Q1. State True or False for the following questions (1 mark each):

a) Kaizen is a Japanese philosophy that encourages continuous improvement by making small, incremental changes over time. The term translates to "good change" or "improvement"

b) Pharmaceutical Quality Assurance is the process concerned with medicine sampling, specifications, and testing, and with the organization's release procedures that ensure that the necessary tests are carried out and that the materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory

c) Quality by Defibration (QbD) is a strategic approach employed in various industries, including pharmaceuticals, manufacturing, and product development, to ensure the consistent delivery of high-quality products

d) The GMP system was first incorporated in India in 1998 in Schedule H of the Drugs and Cosmetics Rules, 1945, and the last amendment was done in June 2005.

e) Deming is best known for his 12 Points for quality and his system of thought called the System of imbecilic Knowledge.

Part B

(Maximum Marks: 15)

Answer the following questions (5 marks each):

Q2. Discuss in brief the concept of Quality and the factors affecting medicines quality. Cite relevant examples in support of your answer.

Q3. Enlist the Deming's 14 Points for Total Quality Management.

Q4. Briefly explain the core components of Quality Risk Management. Cite relevant examples to illustrate your answer

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Enrolment No.: .....

Part C

(Maximum Marks: 30)

Answer the following questions in detail (10 marks each):

Q5. You have been appointed as a consultant for improving the quality standard of a pharmaceutical industry which is facing extreme compliance deficiency in implementing quality concept in the organization. How would you implement the ISO 9001:2015 QUALITY MANAGEMENT SYSTEM in the Pharma Organization.

Q6. Case Study

Maiden Pharmaceuticals Ltd., the Haryana-based company that manufactured and exported the cough syrup that took the lives of 66 children in the Gambia, is a repeat offender and has also lied about being WHO-certified on its website.

Twenty-four hours ago, the WHO issued an alert against four products made by Maiden because they contained diethylene glycol and ethylene glycol. The metabolism of these two compounds in the human body leads to significant liver and kidney damage.

This is why the US has a tight limit of just 0.2% of diethylene glycol in polyethylene glycol when polyethylene glycol is used as a food additive. Maiden's cough syrups themselves required polyethylene glycol.

The company has claimed in the past on its website that its manufacturing facility in the Kundli district of Haryana had been certified by the WHO as complying with 'good manufacturing practices' (GMP).

Reports indicate that Maiden Pharmaceuticals has repeatedly produced substandard drugs in the past yet was allowed to continue to operate. According to the eXtended Licensing, Laboratory and Legal Node (XLN) database maintained by the Government of India, at least two state governments – Kerala and Gujarat – have repeatedly warned of the company's illegal practices.

Kerala authorities found Maiden's products to be of substandard quality at least five times in 2021 and 2022. All of these units had been manufactured in Haryana.

Health department officials had picked up tablets of metformin – used to treat type-2 diabetes – from a taluk headquarter hospital in Palakkad in March 2022 and from a primary health centre in Ernakulam in September 2022. Both sets failed the dissolution test: the drug wasn't able to dissolve properly in a given amount of time, thus failing to release the active ingredient into the body.

So, the officials labelled the samples "not of standard quality".

Another tranche of the same tablets failed the same test in Kerala in December 2021.

You have been appointed as special investigating officer by CDSCO to submit a report on the above incident and suggest corrective actions. What should be the main central points of your report.

Q7. State the principles of Good Laboratory Practices citing relevant examples.

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