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 **PRESIDENCY UNIVERSITY**

  **Bengaluru**

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| **Ph.D. Course Work End Term Examinations – JAN-FEB 2025** |
| **Date:** 06 – 02- 2025 **Time:** 09:30 am – 12:30 pm |

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| **School:** SOM | **Program:** Ph. D |
| **Course Code:** MGT916 | **Course Name:** Operations Management in Pharma |
| **Semester**: | **Max Marks:** 100 | **Weightage**: 50% |

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| **CO - Levels** | **CO1** | **CO2** | **CO3** | **CO4** | **CO5** |
| **Marks** | **20** | **30** | **30** | **20** |  |

**Instructions:**

1. *Read all questions carefully and answer accordingly.*
2. *Do not write anything on the question paper other than roll number.*

**Part A**

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| **Answer ALL the Questions. Each question carries 10 marks. 6Q x 10M=60Marks** |
| **1** | The pharmaceutical industry is one of the most complex and regulated industries in the world. With new drugs and treatments constantly being developed, companies must ensure that they can manufacture these [products](https://salvavidaspharma.com/product/) in a cost-effective and efficient manner. Analyze the concept of Lean Manufacturing and its significance in pharmaceutical operations.  | **10 Marks** | **[Analysis]**  | **CO1** |
| **2** | As the complexity and testing requirements of pharmaceutical manufacturing increase, QC laboratories face growing pressure to improve operational efficiency, better manage and allocate resources, and ensure they deliver real business value. Demonstrate the importance of quality control in the pharmaceutical production process.  | **10 Marks** | **[Application]** | **CO4** |
| **3** | The Medicines and Healthcare products Regulatory Agency (MHRA) carries out inspections to check if manufacturing and distribution sites comply with GMP or GDP. You will be inspected when you apply for a manufacturer or wholesaler dealer license and then periodically based on risk assessments. Compare the core differences between GMP and GDP in pharmaceutical operations.  | **10 Marks** | **[Evaluation]** | **CO2** |
| **4** | The FDA drug approval process involves multiple stages to ensure safety and efficacy. Drugs undergo laboratory and animal testing to answer basic questions about safety. FDA review teams thoroughly examine all the submitted data related to the drug or device and decide to approve or not to approve it. Categorize the stages involved in a pharmaceutical drug approval process by the FDA.  | **10 Marks** | **[Analysis]**  | **CO2** |
| **5** | Pharmaceutical continuous manufacturing (PCM) is a cutting-edge approach that enables the production of pharmaceuticals in a continuous, uninterrupted process. Interpret the challenges associated with implementing continuous manufacturing in the pharmaceutical industry.  | **10 Marks** | **[Application]**  | **CO4** |
| **6** | Track-and-trace systems prevent medicine counterfeiting and verify product authenticity. Medication tracking systems track pharmaceuticals from manufacture to patients. Technology plays a vital role in a track and trace of a pharma product. Outline the key steps in ensuring traceability within the pharmaceutical supply chain. | **10 Marks** | . **[Analysis]**  | **CO3** |

 **Part B**

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| **Answer the Questions. Each question carries 20 marks 2Q x 20 = 40 Marks** |
| **7.** | Supply chain disruptions, such as those caused by the COVID-19 pandemic, highlighted the importance of inventory management in ensuring the availability of pharmaceutical products. Healthcare cost constitutes a significant expenditure for any government, and a considerable part of it is accounted for pharmaceuticals. In the United States, $4.1 trillion was spent on healthcare in 2020 ([Hartman et al., 2022](https://www.sciencedirect.com/science/article/pii/S036083522300267X%22%20%5Cl%20%22b24)), and 9.2% of all national healthcare expenditures in 2018 accounted for prescription medicines ([National Center for Health Statistics, 2018](https://www.sciencedirect.com/science/article/pii/S036083522300267X%22%20%5Cl%20%22b34)). Recognizing these facts, an objective of any pharmaceutical [supply chain](https://www.sciencedirect.com/topics/social-sciences/supply-chain-management) is to minimize the cost of timely delivery of medicines to customers, where timely delivery refers to delivering products with acceptable standards, considering the perishable nature of drugs. Choose a pharmaceutical product of your elucidate how the supply chain disruptions can be minimized through effective inventory management**.**  | **20 Marks** | **[Evaluation]** | **CO3** |
|  |
| **8.** | **Intas Pharmaceuticals Limited** has launched “Mabtas” in India. Mabtas is a biosimilar version of Rituximab competent in treating diseases characterized by excessive numbers of B cells, overactive B cells, or dysfunctional B cells like Chronic Lymphocytic Leukemia (CLL) and Rheumatoid Arthritis apart from NHL. Mabtas is manufactured in the state of the art, Asia’s only EU GMP facility of Intas Biopharmaceuticals, Ahmedabad. With the launch of this product, Intas now is the only company to have indigenously developed 6 biosimilars in the domestic market. Intas Biopharmaceuticals is India's first and only biopharmaceutical companies to receive European Union - Good Manufacturing Practice (EU-GMP) certification for its microbial manufacturing facility and only company having product under-registration with EMA. Assess how the regulatory compliance impacts the design and implementation of cold chain logistics in the Intas Pharmaceutical Limited. | **20 Marks** | **Evaluation** | **CO2** |

**\*\*\*\*\* BEST WISHES \*\*\*\*\***