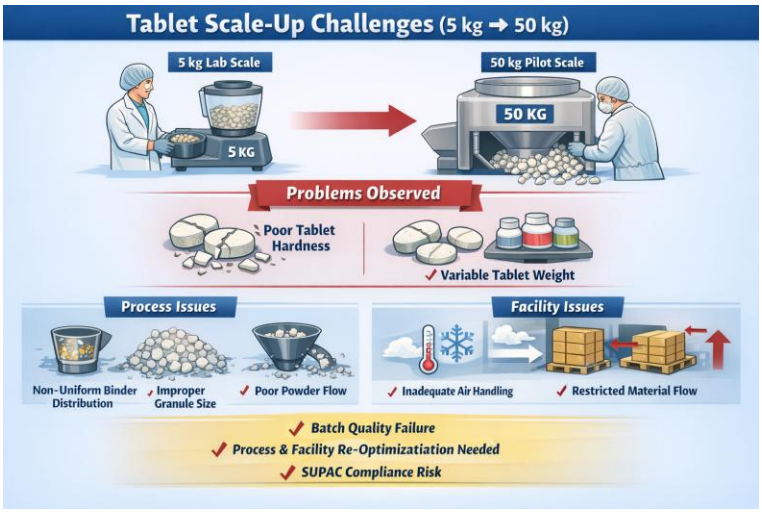
SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES

BP702T – INDUSTRIAL PHARMACY II (PCI Syllabus)

CASE STUDY PUZZLES

Case Study Puzzle 1: The Scale-Up Dilemma *(Unit I – Pilot Plant Scale-Up Techniques)*

Scenario:



A formulation scientist is scaling up a tablet batch from 5 kg laboratory scale to a 50 kg pilot batch. After granulation, the tablets show poor hardness and variable weight. The production area also faces inadequate air-handling and material flow restrictions.

Puzzle Question:
Identify the possible causes of these manufacturing issues. Which factors related to personnel, equipment, and space requirements could have been overlooked? How can the team modify their pilot plant design and documentation to comply with SUPAC guidelines and ensure product quality during scale-up?

Case Study Puzzle 2: Technology Transfer Trouble *(Unit II – Technology Development and Transfer)*

Scenario:
A pharmaceutical company completed R&D for a semisolid formulation and initiated technology transfer to the commercial manufacturing unit. During validation, batch yield

decreases by 8%, and the viscosity varies between batches. The receiver unit claims insufficient documentation from the R&D team.

Puzzle Question:
What are the critical gaps in this technology transfer process? Discuss how WHO's TT protocol and Quality Risk Management principles could have prevented these variations. What specific documents should be shared between the sender and receiver units for successful transfer?

Case Study Puzzle 3: The Regulatory Race *(Unit III – Regulatory Affairs)*

Scenario:
A company developing an anti-diabetic drug plans to file its application for market authorization in both India and the US. The regulatory team prepares a dossier in CTD format but later receives queries from CDSCO about the lack of specific biostatistical data and incomplete Investigator's Brochure (IB).

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Puzzle Question:

Analyze what went wrong in the submission process. Which sections of the CTD and IND documentation might require revision? How should the Regulatory Affairs department coordinate with clinical and biostatistics teams to meet global regulatory requirements?

Case Study Puzzle 4: The Quality Crisis *(Unit IV – Quality Management Systems)*

Scenario:

During routine inspection, a tablet manufacturing plant receives multiple “Out of Specification (OOS)” reports for tablet disintegration time. The investigation reveals inconsistent granule moisture and inadequate blending time. Management also notes that the process validation documents are outdated, and no QbD model is implemented.

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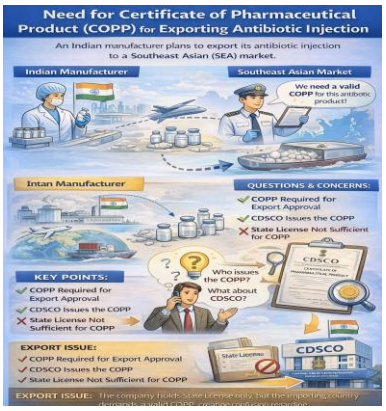
Puzzle Question:

Identify the root causes of the OOS results. How could Quality by Design (QbD) and Six Sigma tools be applied to prevent recurrence? What immediate corrective and preventive actions (CAPA) should be implemented under Total Quality Management (TQM)?

Case Study Puzzle 5: The COPP Confusion ***(Unit V – Indian Regulatory Requirements)***



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Scenario:
An Indian manufacturer plans to export its antibiotic injection to a Southeast Asian market. The importing country requests a valid Certificate of Pharmaceutical Product (COPP), but the company only holds a State License. The firm also lacks clarity about CDSCO's role in export certification.

Puzzle Question:
Explain the regulatory pathway to obtain COPP from CDSCO. What are the responsibilities of the Central and State Licensing Authorities in this process? How does COPP ensure international quality compliance for export products?