**Case Study 1: Deviation in Manufacturing Process**

Scenario:

You work in a pharmaceutical manufacturing company, and your team is responsible for producing a critical medication. During routine quality checks, it’s discovered that the temperature in one of the manufacturing rooms deviated from the specified range during the weekend. This room is crucial for maintaining the stability of the product.

Questions:

      1.    Identify the Deviation:

      •     What is the deviation in this case?

      •     How might the temperature deviation impact the product?

      2.    Root Cause Analysis:

      •     What could be the possible reasons for the temperature deviation?

      •     How would you conduct a root cause analysis?

      3.    Corrective Actions:

      •     What immediate actions would you take to address this deviation?

      •     What long-term corrective actions might be necessary to prevent a similar deviation in the future?

      4.    Communication:

      •     How would you communicate this deviation to relevant stakeholders, including regulatory bodies if necessary?

**Case Study 2: Missing Entries in Laboratory Logbook**

Scenario:

You work in a research laboratory responsible for testing and analyzing samples for a variety of projects. During a routine audit, it is discovered that several entries are missing from the laboratory logbook for a specific experiment conducted last month. The missing entries include details on sample preparation, equipment calibration, and observations made during the experiment.

Questions:

      1.    Identify the Deviation:

      •     What is the deviation in this case?

      •     How might missing entries in the logbook impact the validity of the experiment?

      2.    Root Cause Analysis:

      •     What could be the reasons for the missing entries?

      •     How would you conduct a root cause analysis to understand why the entries are missing?

      3.    Corrective Actions:

      •     What immediate actions would you take to address this deviation?

      •     What measures might be implemented to prevent missing logbook entries in the future?

      4.    Communication:

      •     How would you communicate this deviation to the laboratory team?

      •     What steps would you take to ensure that everyone is aware of the importance of maintaining accurate logbook records?