# Deviations

## Plan

- Pre-approved Deviations
- Covering a specified period of time or number of batches
- Shall be approved before execution
- Shall be handled through Change Control Procedures
- Evaluated for product impact
- Need re-qualification
  & re-validation

## **Un-Plan**

- · Also call as incident
- Non compliance from the designed system or procedures
- Examples of unplanned deviations include:
  - Human error.
  - Malfunction or breakdown of equipment or instrumentation
  - Utility or service failure
  - Yield deviation.

# **Deviations Deviations**

**CL Gary** 

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