1. Change Control is a regulated system which ensures all proposed changes are adequately evaluated, planned, and executed with cGMP guidelines.
   1. True
   2. False
2. “Create new material in SAP, Supporting Documents, Test Data Sheet, Specification, for new raw material required for the manufacturing of 4P product”.

Above change control can be classified as

* 1. Critical
  2. Major
  3. Minor
  4. Intermediate

1. All Change Controls require an Impact Assessment to be performed by:
   1. SME (Subject Matter Expert)
   2. RA (Regulatory Affairs)
   3. QA (Quality Assurance)
   4. All of the above
2. Change that Impacts a GMP Product or process, or will be involved in a regulatory filing, will be tracked via
   1. Deviations
   2. Change controls
   3. Periodic review
   4. Continuous improvement process
3. What is considered a “Critical Change”,
   1. Documentation updates or non-critical equipment changes
   2. Changes that severely impacts product/process/equipment
   3. Decommissioning of equipment
   4. None of the above
4. “Engineering, Equipment, Installation of two new Freezers, one new Refrigerator”

Above change control can be classified as

* 1. Critical
  2. Minor
  3. Intermediate
  4. Major

1. What will be the next step after performing Impact Assessment,
   1. Change plan Definition
   2. Final approval
   3. Initiation
   4. Change execution
2. Changes to Facility/Equipment performed through work records in
   1. Salesforce
   2. Veeva Quality system
   3. BMRAM
   4. Microsoft Teams
3. The purpose of Change control system is to access and manage changes to prevent adverse impact on drug product.
   1. True
   2. False
4. In Filling Down time occurs due to
   1. Equipment Malfunction
   2. Maintenance activities
   3. Shift changes
   4. All of the above
5. Scheduled asset maintenance will come under
   1. Unplanned downtime
   2. Planned downtime
   3. None of the above
6. In filling downtime refers to the period When the filling equipment or process not operating as intended
   1. True
   2. False
7. Example for unplanned downtime
   1. Equipment Failure
   2. Documentation check
   3. Shortage of stoppers
   4. All of the above
8. The primary cause for the downtime is,
   1. Material shortage
   2. Human error
   3. Facility issues
   4. Equipment Failure
9. If the downtime is due to issues on Capper, what are may be the expected causes.
   1. Capping station adjustment
   2. Overseal jam
   3. Deformed stoppers
   4. All of the above