

CPIP Practice Exam

1 _____

Which of the following phases of a clinical trial may be conducted with normal volunteer subjects?

- A Phase 1**
- B Phase 2**
- C Phase 3**
- D Phase 4**

2 _____

Which of the following government regulations specifically defines the safe interaction of pharmaceutical employees with the materials they process?

- A USFDA 21 CFR Part 211**
- B USRCRA 40 CFR Parts 260-281**
- C USOSHA 29 CFR Part 1910**
- D USFDA CFR Part 820**

3 _____

Which of the following best describes the role of a laboratory information management system (LIMS) in a pharmaceutical company?

- A Ordering of laboratory supplies**
- B Managing project timelines for laboratory equipment upgrades**
- C Providing access to scientific reference materials for laboratory personnel**
- D Managing the various laboratory data from sample log-in to reporting the results**

4 _____

Which of the following terms is defined as the planning, directing, monitoring and controlling of the processes related to customer orders, manufacturing orders and purchase orders?

- A Order management**
- B Inventory management**
- C Just In Time (JIT) warehouse management**
- D Just In Time (JIT) ordering**

5 _____

When preparing a New Drug Application, which of the following excipient approaches is most relevant?

- A Documenting supplier/manufacturer location and Drug Master File (DMF)**
- B Obtaining test results for the excipient prior to receipt**
- C Clearly stating excipient specifications and/or grade**
- D Using different lots of ingredients**

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6 _____

The primary role of regulatory authorities around the world is to ensure that prescribed drugs for ailments are manufactured by pharmaceutical companies in accordance with regulations and are:

- A** safe and effective.
- B** available to the patient.
- C** marketed before release to the public.
- D** provided at low cost to the patient.

7 _____

An aspect of the implementation of a robust Quality Management System at a drug product manufacturing facility is that:

- A** it does not require significant costs in either time or resources to implement.
- B** it can provide the controls needed to consistently produce a product of acceptable quality.
- C** it replaces the requirements under the current good manufacturing practice (cGMP) regulations for the manufacture of drug products.
- D** it gives manufacturing personnel the authorization to make changes to a process when they perceive a need for continuous improvement.

8 _____

Which of the following ingredients are increased in a tablet formulation in order to increase the rate at which the tablet breaks up in solution?

- A** Disintegrant
- B** Lubricant
- C** Dessicant
- D** Dilutant

9 _____

For aseptic processing the nature of activities in a supporting clean area determines its:

- A** personnel capacity.
- B** personnel training.
- C** classification.
- D** room size.

10 _____

The traceability matrix should be designed to:

- A** minimise duplication of testing.
- B** aid in the planning of the validation schedule.
- C** be included and approved in the validation master plan.
- D** provide a framework for the planning of design documents.

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11 _____

According to the United States Food and Drug Administration Code of Federal Regulations Part 211, drug products must be quarantined before release by the:

- A** USFDA.
- B** Quality Assurance unit.
- C** Quality Control unit.
- D** manufacturing unit.

12 _____

A drug product processing design must:

- A** avoid additional training requirements.
- B** accommodate existing personnel schedules.
- C** adhere to established or required processing time limits.
- D** achieve maximum overall output based on the final processing step.

13 _____

A MedWatch form is used to inform the U.S. Food and Drug Administration (USFDA) about:

- A** adverse events.
- B** product recalls.
- C** warning letter responses.
- D** changes in product specifications.

14 _____

An organisation's self-assessment is a comprehensive and systematic:

- A** discussion about the organisation's comprehensive quality goals and objectives.
- B** review of the organisation's activities and results against the quality management system.
- C** audit of the interfaces of the organisation's quality management system with other functional business units.
- D** process to define the organisation's quality objectives consistent With the strategy of the organisation.

15 _____

Foreign particulate matter specifications are required for which of the following dosage forms?

- A** Gel
- B** Suspension
- C** Parenteral
- D** Effervescent tablet

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16 _____

Which of the following most appropriately describes materials/finishes for aseptic production?

- A Materials/finishes should provide soft, porous surfaces.**
- B Surfaces should be accessible for cleaning.**
- C Fixtures should have sufficient horizontal surfaces.**
- D Surfaces should have rounded joints.**

17 _____

Electronic signatures that are not based on biometrics should be administered and executed to ensure that the attempted use of an individual's electronic signature by anyone other than its genuine owner requires the:

- A collaboration of two people.**
- B approval of the system owner only.**
- C approval of the Quality Assurance manager only.**
- D collaboration of the Quality Assurance manager and the system owner.**

18 _____

Most firms express inventory turnover by using which of the following calculations?

- A Cost of goods sold during a time period divided by average inventory value during the time period**
- B Units sold during a time period divided by average units in inventory during the time period**
- C Sales revenue during a time period divided by average inventory value at selling price**
- D Cost of goods sold during a time period divided by sales revenue during the time period**

19 _____

Conveyor systems for automated pharmaceutical packaging operations should be:

- A designed for a single application.**
- B sized to maximise the equipment footprint.**
- C specified independent of line integration requirements.**
- D designed to allow for transport through successive process steps.**

20 _____

Which of the following is recognised by the U.S. Food and Drug Administration (USFDA) as an official compendium?

- A United States Pharmacopeia (USP)**
- B The Merck Index**
- C Association of Official Analytical Chemists**
- D ISPE Baseline Guides**

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21 _____

The evaluation of the risk to quality must be:

- A performed in a way that yields quantitative results.
- B based on the use of a formal risk assessment tool.
- C linked to the protection of the patient.
- D approved by the quality control unit.

22 _____

Tablet weight variation outside specifications is most likely due to:

- A blend moisture concept.
- B poor or erratic powder flow.
- C release pressure adjustment.
- D inadequate pre-compression.

23 _____

In cleaning validation, rinse water is considered advantageous over surface swab sampling in some instances such as:

- A Rinse water analytical methods are superior to methods that can be developed For analysis of swab samples.
- B Rinse water sampling allows for sampling and evaluation of inaccessible systems Or systems that cannot be routinely disassembled.
- C Qualification testing if the rinse water meets compendial requirements to establish acceptability.
- D Solubility in water is not an issue for drug products.

24 _____

Under the current guidance from United States Food and Drug Administration (USFDA) concerning 21 CFR Part 11 Records, the regulations are applicable to all of the following EXCEPT:

- A records that are required to be maintained under predicate rule requirements and that are not maintained in electronic format in place of paper format.
- B records that are required to be maintained under predicate rules, that are maintained in electronic format in addition to paper format, and that are relied on to perform regulated activities
- C records submitted to FDA, under predicate rules in electronic format.
- D electronic signatures that are intended to be the equivalent of handwritten signatures, initials and other general signings required by predicate rules.

25 _____

Which of the following help strategically balance the inventory policy and customer service levels throughout the supply chain?

- A Quality management system
- B Inventory planning system
- C Human resource system
- D Work request system

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26 _____

According to the United States Pharmacopeia/National Formulary (USP/NF), the only acceptable methods for producing water for injection are distillation and:

- A chromatography.
- B reverse osmosis.
- C sterile filtration.
- D ultrafiltration.

27 _____

Which of the following statements is TRUE about regulatory bodies around the world?

- A International Conference on Harmonisation Q7 Guidelines on Good Manufacturing Practice (GMP) requirements are legally binding in the United States, Europe, and Japan.
- B The Food and Drug Administration issues Good Manufacturing Practice (GMP) Compliance Certification to companies following satisfactory GMP Inspection.
- C The State Food and Drug Administration issues Good Manufacturing Practice (GMP) Compliance Certification to companies following satisfactory GMP Inspection.
- D The Japan Pharmaceutical Manufacturers Association issues Good Manufacturing Practice (GMP) Compliance Certification to companies following satisfactory GMP Inspection.

28 _____

When implementing approved changes, measures should be taken to:

- A minimise post-change testing requirements.
- B identify previous batches affected by the change.
- C ensure that all documents affected by the change are revised.
- D apply scientific judgement to determine the end state of the change.

29 _____

Which of the following will always change when a process is transferred?

- A The use of the product.
- B The assays used to test the product.
- C The scale at which the product is made.
- D The location where the product is made.

30 _____

Which of the following is the documented verification process that ensures all aspects of a facility, utility, or equipment that can affect product quality are correctly installed?

- A Site Acceptance Test (SAT)
- B Installation Qualification (IQ)
- C Commissioning Plan Summary Report
- D Performance Qualification (PQ) Summary Report

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31 _____

Which of the following is an attribute of a process excellence programme?

- A Value stream mapping**
- B Mistake-proofing**
- C Process redesign**
- D DMAIC**

32 _____

The International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use has adopted a new standardised format for marketing applications for new medicinal products. This new application format is called a:

- A new drug application (NDA).**
- B common technical document (CTD).**
- C medical product application (MPA).**
- D marketing authorisation application (MAA).**

33 _____

Which of the following terms describes the investigative and data collection activity to forestall the occurrence of manufacturing deviations?

- A Corrective Action**
- B Root Cause Analysis**
- C Preventive Action**
- D Trend Analysis**

34 _____

The best way to decrease tangential flow filtration (TFF) process time is to increase the:

- A feed flow rate.**
- B membrane area.**
- C pressure.**
- D hold-up volume.**

35 _____

To maximise uptime on unit operations, what activity needs to be performed on a basis?

- A Relocate the unit operations.**
- B Perform preventative maintenance.**
- C Clean the unit operations.**
- D Replace older equipment.**

36 _____

All production and process control procedures must be reviewed and approved by which of the following?

- A Engineering Department**
- B Production Operators**
- C Quality Control Unit**

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D Chemistry Labs

37 _____

The pharmaceutical industry is most likely to follow which of the following guidances when there are differences between FDA, EMEA and JPMA regulations?

- A ICH
- B GAMP
- C PhRMA
- D ISPE Baseline Guides

38 _____

The current qualification paradigm is focused on the:

- A the project team that should confirm validation by the installation and operational qualification.
- B comprehensive verification of installation and operation against detailed functional requirements and detailed design specifications.
- C the science of the manufacturing process, with an emphasis on the performance and results of the process.
- D Performance Qualification (PQ), because it is the true test of acceptability as defined by a process-based user requirements specifications.

39 _____

Which of the following calculations is used to scale-up a disk stack centrifugation operation for the recovery of biological products?

- A Equivalent Sigma surface ratio and flow rate
- B Shear rate ratio and flow rate
- C Centrifugal force ratio and centrifuge speed ratio
- D Centrifuge speed ratio

40 _____

If an autoclave is used solely for product sterilisation, the minimum requirement for calibration is:

- A once per month.
- B once every three months.
- C on a periodic basis.
- D once per year.

41 _____

Which of the following terms refers to the specific controlled temperature storage system that is used during the transportation of drug products?

- A Temperature tracer control
- B Cold chain storage
- C Refrigerated carriers
- D Contained shipments

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42 _____

Which of the following is responsible for setting potable water standards?

- A U.S. Department of Agriculture
- B U.S. Food and Drug Administration
- C U.S. Pharmacopeia/National Formulary
- D U.S. Environmental Protection Agency

43 _____

A drug product is produced at a facility where the process is well understood, advanced engineering and controls are employed, and the facility has a well-functioning quality system. According to the United States Food and Drug Administration Compliance Practice Guidance, the number of conformance batches necessary for the process validation of this drug product manufacturing process is:

- A at least one research batch.
- B three conformance batches.
- C based on the company's internal policies.
- D based on discussions with regulatory authorities.

44 _____

An oncology drug for oral application is classified at class occupational exposure level (OEL) 3 for occupational exposure risk and is developed as oral solid dosage form. The occupational exposure risk is minimised if the granulation process is developed in which of the following types of process equipment?

- A A high shear mixer plus a fluid bed dryer
- B A high shear mixer plus a tray dryer
- C A fluid bed granulator
- D A one-pot processor

45 _____

Which of the following would be considered a "reprocessed" Active Pharmaceutical Ingredient (API)?

- A As part of the established manufacturing process for the majority of batches, introduce unreacted material back into the process and repeat a chemical reaction
- B Introduce material back into process and clarify using a filtration process that does Not exist in the standard manufacturing process
- C Continue a chemical reaction after an in-process control test has shown that the step is in complete
- D Introduce material back into the process and repeat the filtration step from the established process of a single of batch

CPIP Practice Exam

46 _____

An air-handling unit (AHU) is set to which of the following in order to maintain the supply air temperature among the varying thermal loads in different building zones?

- A** A set-point value for the zone with the largest cooling load
- B** A set-point value for an average cooling load of the effected zones
- C** A fixed differential value between the supply and exhaust air temperatures
- D** A set-point value for the zone that has a cooling load midway between the smallest and largest loads

47 _____

Documentation for significant steps performed in a production batch record include the identification of:

- A** both the person performing the step and the direct supervisor of the step.
- B** the person performing the step.
- C** the direct supervisor of the step.
- D** both the direct supervisor of the step and the Quality Assurance reviewer.

48 _____

An example of a composition analyser or measurement device is a(n):

- A** infrared analyser.
- B** photometric analyser.
- C** conductometric analyser.
- D** refractive-index analyser.

49 _____

The expiry date for a drug product is dependent on the:

- A** clinical trials.
- B** sampling plan .
- C** storage conditions .
- D** number of batches tested .

50 _____

In order to avoid CO₂ accumulation, which of the following methods should be implemented for a bioreactor?

- A** Helium sparging
- B** Pure oxygen supply
- C** Gas exchange enhancement
- D** Operation pressure increase