

1) How many modules does the ICH CTD contain

- a) 3 modules
- b) 5 modules
- c) 2 modules

2) What is the main difference between the ICH CTD and the ASEAN CTD

- a) The ICH CTD contains more detailed information
- b) The ASEAN CTD lacks module 2
- c) The ASEAN CTD has six modules while the ICH CTD has only 5
- d) None of the above is correct

3) What does the term prequalification mean?

- a) Assessment of quality and pricing of a product for purchase
- b) Qualify a product based on price
- c) Pre-select certain products from a wider population of options based on standards of quality, safety and efficacy
- d) a) and c) are correct

4) What are the steps of WHO prequalification process for vaccines?

- a) Assessment of file, testing of samples, inspection of facilities and consultation with producing country NRA
- b) Review of quality, pre-clinical, clinical and safety data presented in a dossier
- c) Inspecting the manufacturing site and consulting with the NRA in the producing country
- d) None of the above

5) What is the difference between NRA registration and WHO PQ? In what ways does PQ offer an added value?

- a) PQ focuses on ability of the vaccine to be co-administered with other vaccines?
- b) PQ focuses on the programmatic suitability of the vaccine
- c) PQ ensures that the vaccine is safe and effective and meets the needs of immunization programmes in LMICs and LICs
- d) All of the above are correct
- e) None of the above are correct

6) What is the objective of the WHO site-inspection?

- a) To look at the facilities, how good they are
- b) To ensure that the product is manufactured in compliance with GMP
- c) To ensure that the UN tender specifications are met
- d) To ensure that the product meets WHO-recommended requirements for quality, safety and efficacy
- e) a), b) and c) are correct

- f) b) c) and d) are correct
- g) None of the above are correct

7) What is WHO position regarding use of wP or aP in national immunization programmes?

- a) Use of aP containing vaccines is preferred being a less reactogenic vaccine
- b) Use of wP containing vaccines is preferred because of its higher efficacy
- c) Protection against severe pertussis can be obtained after vaccination with either wP or aP vaccine.
- d) None of the above is correct

8) What is the WHO recommendation for countries that are currently using wP containing vaccines for infants?

- a) To immediately switch to aP containing vaccines due to the high reactogenicity of wP containing vaccines
- b) To continue to use wP containing vaccines with a booster dose with aP containing vaccines
- c) To continue to use wP containing vaccines for primary immunization since the use of aP containing vaccines may lead to resurgence of pertussis after a number of years

9) Which are the regulatory functions expected to be exercised by UN supplied countries?

- a) MA and licensing, PMS and lot release
- b) Lot release, inspections and testing
- c) MA and licensing and PMS
- d) A) and b) are correct
- e) None of the above is correct

10) What are the main constraints faced by manufacturers the timely registration of vaccines in receiving countries?

- a) Heterogeneity of requirements that makes the preparation of submissions difficult?
- b) Lack of clear guidance about the requirements and process to be followed
- c) Outrageous fees charged
- d) a) and b) are correct
- e) b) and c) are correct
- f) None of the above are correct

11. Why is process development important for vaccine production?

- a) vaccines are cheap to produce, so purification is flexible
- b) All vaccines are easy to characterize, so process is important
- c) vaccines are difficult to characterize, therefore the process determines quality
- d) Market demands are high, so quality must be secondary

12. What factor will **NOT** affect process economy for vaccine production?
- a) **market selling price**
 - b) scale of production
 - c) facility utilization rate
 - d) equipment selection
13. What words can relate to microcarriers:
- a) scalable, suspension cells, large surface area
 - b) scalable, adherent cells, T-flasks
 - c) **scalable, adherent cells, large surface area**
 - d) low productivity, adherent cells, large surface area
14. What is the purpose of vaccine purification?
- a) High vaccine efficacy, good safety profile, with more side effects
 - b) Increase impurity profile, good safety profile, process robustness
 - c) **High vaccine efficacy, good safety profile, meet regulatory requirements**
 - d) High vaccine efficacy, less side effects, increase host cell DNA concentration
15. QbD stands for:
- a) Quality by Definition
 - b) **Quality by Design**
 - c) Questions by Design
 - d) Quality by Determination
16. Analytics for vaccines:
- a) **Are usually time consuming and with low precision**
 - b) Are usually fast and accurate
 - c) Are never limited by detection level
 - d) Are cheap and automated
17. Single-use equipment for vaccine production are usually considered to:
- a) Require a lot of fixed piping in the facility
 - b) Require extensive cleaning validation
 - c) Increase turnover time between batches
 - d) **Lead to flexibility and increased production capacity at a given scale**