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
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