Test 1 Hanoi workshop 20-24 March 2017

1. What is the required (by WHO guidelines) and the most suitable (by risk assessment) environment for open preparation of buffers and media to be sterilized by filtration?

- Grade D clean room
- Grade D unidirectional airflow unit
- **Grade C clean room**

2. What is one of the reasons why a grade D environment is **not suitable** for open processing of low-bioburden intermediates / products to be sterilized in the end?

- According to the WHO GMP guidelines, minimum a grade C environment is required for open aseptic processing
- **There are no limits for particles in grade D rooms for the status "in operation". Thus, a grade D environment is partially uncontrolled in operation**
- Environmental monitoring in operation is normally not performed for grade D rooms and is also not required by the guidelines
- Grade D rooms are generally not acceptable for the handling of products or intermediates (by guideline definition)

3. For which of the following parameters do GMP guidelines (WHO, US FDA, EU, etc.) **not** give numeric guidance values to be considered?

- Air change rate in clean rooms
- Clean room recovery time from "in operation" to "at rest"
- **Interlock times for air locks**
- Differential pressure between production clean rooms of different grade

4. Which of the following features is absolutely mandatory to be implemented for a biosafety level 2 laboratory (according to the WHO biosafety manual)?

- Use of biosafety cabinets for open handling of hazardous material
- On-site or in-lab autoclave
- Ventilation system with inward airflow (negative pressure)

- **None of the 3 features mentioned above**

5. Particularly regarding the room pressure concept, use of biosafety cabinets and the installation of HEPA filters for room exhaust air, the design for biosafety level 1 and 2 clean room production facilities should follow:

- **A risk based approach, considering GMP requirements, biosafety requirements and the risks related to the biological agents handled**
- Strictly the requirements defined in the WHO biosafety manual
- Only GMP requirements because the WHO biosafety manual does not define strictly mandatory features for biosafety level 1 and 2
- Only GMP requirements because product protection is paramount and features as e.g. UAF units with inward airflow or negative pressure clean rooms are not allowed therefore

6. Which statement is wrong for the operation of a grade A isolator?

- According to GMP guidelines, it is allowed to operate a grade A isolator in a grade D environment
- **If operated in a grade C environment, it is allowed to open the isolator enclosure during processing**
- Grade A isolators can be operated at negative pressure compared to the surrounding room (may be required e.g. for biosafety reasons or for highly active sterile products)
- Isolators should be air-tight if closed, verified by regular leak-tests

7. Which of the following features or requirements does **not** strictly apply for grade A in B areas (as defined by GMP guidelines or risk-based good engineering practices)?

- **A restricted access barrier system is required to prevent operators from entering / reaching into the grade A area**
- Cladding or curtains are required to guide the airflow and assure an unidirectional / laminar airflow
- Monitoring of the air speed is required in operation
- During qualification, smoke studies have to be performed to verify the desired air flow patterns

8. Which of the following points is a mandatory prerequisite for test leveraging (use of commissioning tests for GMP qualification)?

- The commissioning tests must be executed by the system user or owner
- **The commissioning test plans must be reviewed and approved by the system user or owner**
- All tests must be performed at the final installation site / site of system use
- Commissioning tests must be witnessed by the equipment / system supplier

9. Which of the following two activities is / are strictly required by GMP regulations?

- Commissioning (FAT / SAT)
- Design review / design qualification
- Both activities listed above
- **None of the two activities listed above**

10. Which of the following points is **not** a major objective of a quality management system?

- Continuous improvement of procedures and processes
- Customer satisfaction
- **Business growth**
- Maintaining the company in state which can be called “fit for operation”

11. Risk is a combination of ….

- Hazard x Consequence
- **Likelihood x Consequence**
- Consequence x Time
- Frequency of adverse event x Time

12. Something with the potential to cause harm is called:

- **A hazard**
- A risk
- A consequence
- A likelihood

13. Accident / incident reporting is important as it allows us to:

- **Learn from accidents and near misses so we can prevent recurrence**
- Punish those responsible
- Provide jobs for biosafety officers
- Only address issues after they have occurred

14. Vaccination needs will be determined only by:

- Seniority of personnel involved
- Length of time working in institute
- **Risk of exposure to the agents the staff are working with**
- Whether or not the individual is a member of staff or a contractor

15. The item on the lowest level of the hierarchy of control is:

- **PPE**
- Substitution
- Elimination
- Engineering controls

16. During cleanup of a minor spill outside containment, it is essential that:

- Personnel should act as quickly as possible to start pouring disinfectant on the area
- Immediately shut down the laboratory and evacuate the building
- **Take control of the situation, including leaving the room where necessary to prepare for cleanup activities**
- Request other colleagues come to the area immediately to help with the cleanup

17. Containment is an important principle as it:

- Makes sure PPE is the most important aspect of keeping workers safe
- **Prevents exposure to potentially harmful biological organisms**
- Reduces the need for vaccination of potentially exposed personnel
- Means SOPs do not need to be in place to handle spills

18. An effective biorisk management system promotes _____ activities:

- Corrective
- **Preventive**
- Controlled
- Documented

19. Human factors is an important element in the biorisk management programme as it:-

- Places responsibility only on production staff to work safely and securely
- Provides a framework for punishment when things go wrong
- **Addresses the need for measurement and management of human behavior**
- Discourages staff feedback and complaints

20. Emergency exercises and simulations should be:

- As long and challenging as possible
- Carried out randomly, especially at weekends
- **Structured, realistic and conducted in safe and controlled environment**
- Reviewed only when you have time