



CLEANROOM TECHNOLOGY CERTIFICATION -EXAMINATION

1 April 2009 1730 -1930

Candidates should read the following instructions:

- 1) Candidates should not turn over the page of this examination script until asked to do so by the invigilator.
- 2) Write your answers below or next to the questions in this examination paper. Write neatly, as marks will be lost if answers cannot be read.
- 3) No-one should leave the exam room before the first half hour has passed. All examination scripts must be handed to the invigilator before they leave. If the candidate has completed the exam before the end of the time allocated they should hand in the script and leave quietly.
- 4) Candidates are allowed to bring in and consult, the following standards during the exam:
 - ISO 14644-1,
 - ISO 14644-2,
 - ISO 14644-3
 - Annexe 1 of 'The Rules Governing Medicinal Products in the European Union. Volume 4. (1997). Good manufacturing practices - Medicinal products for human and veterinary use'. Often called the EU GGMP
- 5) Candidates should provide their own standards for consultation during the exam. However, these must be submitted to the invigilator before the exam for inspection. They must be clearly marked with the candidates name and will be returned immediately before the examination.
- 6) If candidates are uncertain as to the meaning of any question, they must interpret it as best they can, and put down on the exam paper what they think the question means. They should then give an answer to what they think the question means.
- 7) Candidates are not allowed to bring into the examination room any electronic equipment, including programmable calculators, or any notebooks, folders or documentation (except the standards for consultation). All such material may be safely stored with the invigilators during the examination.
- 8) The pass mark is 50%.. The number of questions is 73
- 9) The candidate should print their name in the box.

Name =

Exam Questions

Chapter 1 – Introduction

1. What constructional materials should be used to build a cleanroom?
2. By what name are turbulently ventilated cleanrooms also known?
3. What simple and broad steps and would you take to design and construct a cleanroom?

Chapter 2 - History of Cleanrooms

1. Describe an operating theatre in, and around, the 1890s.
2. How effective was Sir John Charnley's work on ventilation of operating room between 1959 and 1970
3. What major advantage has a unidirectional flow in preventing contamination dispersal by a person working in the room?

Chapter 3 - Cleanroom Classification Standards

1. What is the approximate size of a human hair?
2. What is the ISO 14644-1 cleanroom standard called, and when was it published?

3. What is the class limit for airborne particles $\geq 0.1\mu\text{m}$ in an ISO Class 2 cleanroom?
4. What is the size of particle in ISO 14644 - 1 that defines 'macroparticles'?
5. What is the EU GGMP classification grade for a cleanroom where an isolator is placed for aseptic processing?
6. What type and quality of airflow does the FDA require in the critical area?

Chapter 4 -Information Sources

1. What is the name and number of the standard that deals with biocontamination control in cleanrooms?
2. Where can the Guidelines on Sterile Drug Products Produced by a Aseptic Processing be obtained?

Chapter 5 - The Design of Turbulently Ventilated and Ancillary Cleanrooms

1. How do turbulently ventilated cleanrooms differ from ordinary air-conditioned rooms e.g. an office or shop, in terms of air supply and air movement?
2. What percentage of fresh outside air is likely to be introduced to the re-circulated air, and why?
3. Typically, what level of particles $\geq 0.5 \mu\text{m}$ is generated by an operator moving about in a laboratory coat?
4. In lower standards of cleanrooms, where HEPA and ULPA filters are not required, what type and efficiency of air filter is often used?
5. Name any disadvantages of high-level located extract grilles.

Chapter 6 – Design of Unidirectional Cleanrooms and Clean Air Devices

1. What effect do 'obstructions' have on unidirectional airflow?

2. State one reason why unidirectional flow rooms are more expensive to build and run than turbulent flow rooms.
3. Give two examples of clean air devices.
4. Give an example of one type of simple unidirectional air device.

Chapter 7 – Construction Materials and Surface Finishes

1. State two reasons why cleanroom surfaces, particularly floors, should be able to withstand liquids.
2. Why should consideration be given to minimise ‘electrostatic charge’ in cleanroom construction materials?
3. Name two examples of cleanroom floor covering.

Chapter 8 – High Efficiency Air Filtration

1. What efficiency does an ULPA filter have against 0.1 – 0.2 μ m particles?
2. The pressure drop across a filter is dependent on what?
3. Name two types of particle removal mechanisms?
4. What is the MPPS normal size range?

Chapter 9 – Cleanroom Testing and Monitoring

1. List the tests that show a cleanroom works satisfactorily.
2. What characteristics of a cleanroom dictate the type of testing to be carried out?

Chapter 10 - Measurement of Air Quantities and Pressure Differences

1. What does a Pitot-static tube measure?
2. If required, how is pressure inside a room increased?

Chapter 11 - Air movement control between and within cleanrooms

1. How can the direction of airflow through doors be checked?
2. Why is it important to check air movement as part of the test protocol?
3. Give an advantage and a disadvantage of using streamers.

Chapter 12 - Filter Installation Leak Testing

1. How do high efficiency air filters operate?
2. In what situation would filter integrity testing not be necessary?
3. What are the advantage of using hot generated challenge over cold generated challenge?

Chapter 13 - Airborne Particle Counts

1. What is the lowest particle size sensitivity of a standard bench-top particle counter?
2. Which type of particle monitoring system is the most expensive?
3. Which occupancy state would normally have the lowest particle count?
4. From 14644-1, give the formula for the minimum airborne sampling volume.

Chapter 14 - Microbial Counts

1. Name two techniques used by impaction samplers to remove micro-organisms from the air.
2. Explain the principle of inertial impaction.
3. A 9cm Petri dish (64cm^2) is placed close to a filling process and the microbial count on the plate after 4 hours was 2. What is the contamination rate when the container with a neck area of 1cm^2 , is open for an average of 2 minutes?

Chapter 15 - Operating a Cleanroom – Contamination Control

1. What does a risk diagram show?
2. How can contamination from people be reduced?

3. Define the term 'validation'

Chapter 16 - Cleanroom Disciplines

1. Give 5 examples of personal items not allowed into the cleanroom.
2. How should personnel position themselves with regarding to working with the product in the cleanroom?
3. Give an example of a suitable disinfectant for cleaning gloved hands in an aseptic production area

Chapter 17 - Entry and Exit of Personnel

1. Why is it that in some individuals, washing can lead to an increased dispersion of skin and skin bacteria ?
2. Why are watches and rings generally removed before entering the cleanroom ?
3. In the change area, when selecting the new cleanroom garments, what should be checked prior to use?

Chapter 18 – Materials, Equipment and Machinery

1. List four examples of types of materials used in cleanrooms
2. Why is an airlock used to transfer items into the cleanroom?

3. How can large machinery be brought into a cleanroom with no entry provision?

Chapter 19 -Cleanroom Clothing

1. How many skin particles do humans shed in 24 hours?
2. Discuss four points that should be considered in the design and manufacture of cleanroom garments.
3. What type of water is used in the washers of a cleanroom laundry?
4. Give two performance tests carried out on cleanroom fabric
5. Why are antistatic properties of cleanroom clothing important?
6. Describe two methods used to check the antistatic properties of cleanroom garments?

Chapter 20 – Cleanroom Masks and Gloves

1. How does a mask prevent the passage of particles to the environment?
2. Why should operators wear gloves?

3. List three general types of gloves.

Chapter 21 - Cleaning a Cleanroom

1. Give three methods used for cleaning a cleanroom?
2. A vacuum is relatively efficient at removing particles of what size?
3. Why are normal household wipers not acceptable in cleanrooms?
4. List four properties of a cleanroom cleaning solution
5. List three general points to be considered when developing a cleaning protocol.