1 **Berner Pharmaceuticals Ltd provides employees with general information on GMP on its intranet. Read the following text and answer the questions.**

Berner Pharmaceuticals Ltd

Login User: _____ Password: _____

In the pharmaceutical industry, different **quality assurance** processes are required for each area of good practice (GxP).

It is easiest to understand how good practice works in the area of manufacturing. The quality assurance process in good manufacturing practice (GMP) includes product **quality control**, sampling, and testing. Quality control ensures that the product quality remains high. The reason for interim testing, or **product sampling**, is to check the quality of pharmaceutical products. This is important to make sure that the product is **suitable** for its intended use and for sale. **Endpoint testing** is carried out at the end of every manufacturing process. This is to ensure that all procedures have been performed in compliance with industry and company standards.

Documentation is important and necessary at every step of the processes, activities, and operations involved in drug manufacturing. If the documentation is not in order, or if the required specifications are not met, then the product is considered **contaminated**. Proper documentation not only enables **traceability**, but also allows a complete **product recall** from the market, if necessary.

Inspection and **validation** are required to prove that the manufacturing and testing equipment is functional. All operational methods and procedures must also be inspected for accuracy. Most companies do this voluntarily through internal audit processes.

However, beyond the field of manufacturing, good practice must be adhered to in all processes in a pharmaceutical company. No process can be considered isolated from the others. For example, laboratory and manufacturing processes cannot be regarded separately. A **holistic approach** looks at all these environments to make sure that the entire process meets high industry standards.

Standard operating procedures (SOPs) are written and used by companies to make it easier for them to follow GxP. These are a set of written instructions to maintain performance and results. They are also the basis of every good quality assurance and quality control system.

According to the text, which answer is not correct?

1 Why is product sampling carried out?
a To introduce product quality.
b To check product quality.
c To make sure SOPs are followed.
d To meet high industry standards.

2 Which aspect of drug manufacturing enables traceability?
a quality assurance
b quality control
c holistic approach
d documentation

3 Why do operational methods and procedures have to be validated?
a To complete the quality assurance process.
b To make sure products perform their intended function.
c To complete the inspection process.
d To isolate products of high quality.

2 Complete the following sentences with the correct word or expression in bold from the text in exercise 1.

1 The documentation required for all research processes and development steps ensures the _____ of a drug.

2 A _____ considers laboratory and manufacturing processes and environments together and not individually.

3 Quality _____ involves all manufacturing processes in GMP which make sure the goods produced are kept at high standards.

4 Quality _____ involves interim and product sampling procedures, which are carried out to check product quality.

5 At the end of every stage of a product's manufacturing process, _____ is done to maintain quality standards.

6 Even a product that has been marketed for years might have to be taken off the market in a _____ if serious adverse reactions occur.

7 Manufacturing processes and procedures must go through periodic _____ to guarantee that they are still of an acceptable standard.

8 _____ products are no longer pure and acceptable for sale or public use and, therefore, must be returned to the manufacturer, or destroyed.