Qualification and Validation

Question

What is normally the difference between qualification and validation?

Answer

Equipment are qualified, and processes, systems and methods are validated.

Qualification and Validation

Question
What does VMP stand for?

Answer
Validation Master Plan.

Qualification and Validation

Question

Where shall cleaning of equipment and verification of cleaning be recorded?

Answer

In the batch record and in the equipment log book.

Qualification and Validation

Question

What is the difference between concurrent validation and prospective validation?

Answer

During concurrent validation, a batch can be released to the market before all reproducibility data has been collected.

Qualification and Validation

Question
HEPA-filters are common in this industry, what does HEPA stand for?

Answer
High Efficiency Particulate Air.

Qualification and Validation

Question

What is the main difference between prospective and retrospective validation?

Answer

Retrospective validation is based on evaluation of historical data, and prospective validation is done as actual production runs with real product.

Production

Question
Describe the difference between contamination and cross-contamination.

Answer
Contamination involves unwanted substances from external sources such as dust or particles while cross-contamination involves residues from another drug.

Production

Question
What does the abbreviation HVAC stand for?

Answer
Heat, Ventilation and Air Conditioning.

Production

Question
What is normally the classification code for the cleanest area in a clean room where sterile product is processed?

Answer
Class A or Class 100 or ISO 5.

Production

Question
If a production step was performed in the wrong order as compared to the batch record, but the production manager justify in writing that it cannot affect the quality of the product; do we still need to file a deviation?

Answer
Yes, it has to be justified by QA as well, and probably investigated.

Production

Question
Mention three things that should be verified by a second person during weighing.

Answer
The weight, the identity on the containers and that the material is released for use.

Production

Question
What type of pen is normally used for recording GMP data?

Answer
A ball pen with indelible ink.

Laboratory

Question

Mention at least 4 items that should be recorded in an instrument log book.

Answer

Usage, calibration, cleaning, maintenance, date, time, signatures.

Laboratory

Question

Mention at least three (3) things that should be included in a sampling procedure.

Answer

The method, the equipment to use, the amount of sample, type of sample container, how samples shall be identified, any precautions, storage instructions, cleaning and storage of sampling equipment.

Laboratory

Question
What does SST stand for?

Answer
System Suitability Test

Laboratory

Question
Can sterility testing be done in Class D?

Answer
No, it is normally done in a class A cabinet within a class B cleanroom. It may also be done in an isolator.

Laboratory

Question
What is the purpose of the requirement for an on-going stability program?

Answer
To monitor the product over its shelf life and to make sure the product does not age quicker than expected.

Laboratory

Question
How many persons need to work in the QC (Quality Control) lab to satisfy the GMP requirement?

Answer
Sufficient to deal with the duties and responsibilities for that lab.

Quality Management

Question

Can a newly hired employee skip the company introductory GMP-training if he/she had a GMP-related job earlier?

Answer

No, most certainly there are specific GMP issues that vary between companies.

Quality Management

Question

One of these sentences about Quality Risk Management is correct, which?

1: QRM contains Risk Assessment, Risk control, Risk Review and Risk Communication

2: When you do Risk Analysis you always have to do an FMEA (Failure Mode and Effect Analysis)

3: Risk Analysis is the same as Risk Management

Answer

1 is correct.

Quality Management

Question

What of the following is correct regarding Annual Review?

1: It is a voluntary activity performed to prevent problems.
2: Has to be submitted to the authorities once a year.
3: Contains a review of things like test result from release tests, recalls and deviation investigations.

Answer

3 is correct.

Quality Management

Question
What is an FDA 483?

Answer
It is the form that FDA uses to record their observations during an inspection.

Quality Management

Question

Can recalled products be returned to usable stock?

Answer

No, they have to be stored separately and a decision has to be made about how to handle them.

Quality Management

Question
What do these abbrevations stand for: QA, QC, QP?

Answer
Quality Assurance, Quality Control, Qualified Person.