

AQS 110 – Module 1 Exam – Fall 2015 (80 pts)

1. Define Quality (5 pts)

Quality is a product (service) with features and characteristics which determine desirability and can be controlled to meet certain basic requirements.

Quality is determined by Customer based on their expectation and needs.

2. Identify each acronym and provide a brief description of what it means (10 pts)

Acronym	Name	Description
CFR	<i>Code of Federal Regulations</i>	<i>Administrative law for goods sold in US</i>
cGMP	<i>current Good Manufacturing Practices</i>	<i>FDA minimum requirements for pharmaceuticals/medical devices</i>
FDA	<i>Food & Drug Administration</i>	<i>US regulator for foods/veterinary/pharma and medical device</i>
ISO	<i>International organization for standardization</i>	<i>Various guidelines for management systems</i>
TQM	<i>Total Quality Management</i>	<i>Quality management system philosophy</i>

3. Define Quality Control and Quality Assurance and describe the difference (6 pts)

Quality Assurance has general oversight and maintains standards/quality systems

Quality Control conducts measurement/inspection, determines product pass/fail

4. The following are good documentation practices (6 pts)

- | | | |
|---|--------------------|---------------------|
| a. using a signature stamp | True | <i>False</i> |
| <i>b.</i> correct a mistake using wite-out® | True | <i>False</i> |
| c. revision history is included in document | <i>True</i> | False |
| d. using a black or blue pen to record data | <i>True</i> | False |
| e. leaving blank spaces on a batch record form | True | <i>False</i> |
| <i>f.</i> initial changes, but a date is not always required | True | <i>False</i> |

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5. Match the product/practice to the regulation or standard (4 pts)

Pharmaceutical ***D) 21CFR Part 211***Medical Device ***B) ISO 13485:2003***Snowboards ***A) ISO 9001:2008***Laboratory Practices ***C) 21CFR Part 58***

6. List and define the basic elements of a quality system (10 pts)

Element	Description
<i>Say what you do</i>	<i>Documentation; provide standard instruction</i>
<i>Do what you say</i>	<i>Training, following written instructions</i>
<i>Write it all down</i>	<i>Maintain records regarding production (service)</i>
<i>Check the results</i>	<i>Compare against specifications; determine pass/fail</i>
<i>Analyze the difference</i>	<i>Continuous improvement; correct defects</i>

7. Describe how each department below is a part of the quality organization within a company (6 pts)

Marketing ***Direct contact with customers; translate customer needs/expectations into requirements; contract review, labeling, etc.***Manufacturing ***Follow documentation for product quality; monitor and improve processes***Shipping ***Follow documentation – pallet patterns, packaging, environmental***

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8. Match the quality cost to its category (4 pts)

Preventive **C) improving manufacturing line**

Internal **B) reprocessing defective product**

External **D) investigating customer returned product**

Appraisal **A) inspecting final product**

9. Describe the difference between internal versus external customer (4 pts)

Internal customer is within the organization (e.g. departments, previous/next process step)

External customer is outside the organization (e.g. end-user, vendor/manufacturere)

10. Medical device manufacturers in the US are required to follow 21CFR requirements. (1pt) **T** F

11. Taylor's Scientific Management principles allowed workers to passively train themselves. (1pt) T **F**

12. Deming's 14 Quality Principles included ceasing dependence on inspection for quality. (1pt) **T** F

13. Deming's 14 Quality Principles included numerical quotas for the workforce. (1pt) T **F**

14. Juran's Quality Trilogy included planning, control and improvement. (1pt) **T** F

15. TQM principles include customer focus and fact-based decision making. (1pt) **T** F

16. TQM principles maintain morale and motivation via effective communication. (1pt) **T** F

17. Why is the Quality department typically independent of manufacturing? (4 pts)

Quality is voice of the customer; make pass/fail decisions without potential repercussions

18. Define the following terms

a. Documented information - **procedures**

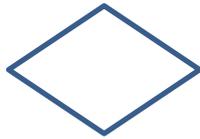
b. Recorded information – **records (i.e. batch documents)**

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19. Identify the flow chart symbols. (10pts)



Start/end



decision



document



process (task)

Using the symbols above, chart a process (i.e. pizza for dinner, planning a party, make a sandwich, etc.)

