Chapters 1, 2, 6, & 8

1) Transient duration of a medical device is defined as:
   a. Continuous use of less than 60 minutes*
   b. Continuous use of not more than 30 days
   c. Continuous use of greater than 30 days
   d. Both a&b

2) The difference between the EU and USA medical device definition is
   a. EU includes animals
   b. EU includes animals
   c. USA includes plants and animals
   d. USA includes animals*

3) DMAIC is the acronym for:
   A. Do, Make, Act, Incorporate, Continue
   B. Define, Measure, Analyze, Improve, Control*
   C. Define, Make, Arrange, Include, Compete
   D. Define, Measure, Act, Include, Control

4) ISO 13485: 2003, "Medical Devices – Quality Management Systems" Section 7.3 addresses the requirements for:
   A. Purchasing requirements
   B. Risk analysis
   C. Design and Development*
   D. Production requirements

5) A medical device is defined by:
   A.) Patient
   B.) Doctor
   C.) Designer
   D.) Intended use*

6) Long-term duration of a medical device is defined a
   a.) Continuous use of greater than 30 days*
   b.) Continuous use of less than 60 minutes
   c.) Continuous use of not more than 30 days
   d.) Both a&c

7) An essential tool to managing medical device design, along with team building, is:
   a.) Rework
   b.) Nonconformities
   c.) Micro Management
   d.) Project Management*

8) _____answers the question: Does the device do what you said it would?
   a.) Control
   b.) Validation*
   c.) Verification
   d.) Outputs

9) Regardless of the country classification, as the classification number (I,II,II; I, IIa, IIb, II; I,II,III,IV) increases so does the :

a.) Required documentation*
b.) Project timeline
c.) People involved
d.) Countries involved

10) _____means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

a.) Active implantable device

b) Active medical device*

c.) Custom-made device

d.) In-vitro device

Chapters 5 through 8

1) The main tool used during SWOT analysis is
    a. *Post-it Notes
    b. Internet research
    c. Outline
    d. Prato Charting
2) Are there too many variations of design features? Is a question to consider when addressing the ____design principle
    a. D4X
    b. DFA
    c. D4A
    d. *DFM
3) The difference between the EU and USA medical device definition is
    a. EU includes animals
    b. EU includes plants and animals
    c. USA includes plants and animals
    d. *USA includes animals
4) In regard to the essential elements of a Product Design Specification, a " Resume of the need" pertains to
    a. Manufacturing Requirements
    b. Environmental Requirements
    c. Introduction
    d. *Introduction and Scope

5) When addressing _____, you must be able to provide evidence that the materials you use comply with the essential requirements for a medical device:
    a. Material Handling
    b. *Biocompatibility
    c. Shipping & Receiving
    d. Product Requirements
6) The one of the three main rules for choosing a Design Specification source is it has to be:
    a. Concise
    b. Innovative
    c. Creative
    d. *Reputable
7) _____is a thing that is similar to or has the same function as another.
    a. Transient
    b. *Analogue
    c. Open Loop
    d. Closed Loop
8) A design principle that addresses If a tolerance can be lowered so that a more simple process can be used is:
    a. *DFM
    b. DFA
    c. D4A
    d. D4X
9) Which of the following oppose the rules of Brainstorming:
    a. *Criticism
    b. Creative Thought
    c. Quantity
    d. Ridiculousness
10) A Fish Bone diagram is used to yield a:
    a. *defect
    b. solution
    c. improvement
    d. design input
11) A product realization design principle, which consists of a family of design disciplines that focuses on minimizing waste is:
    a. D4M
    b. DFA
    c. D4A
    d. *D4X
12) A very simple technique used to promote lateral thinking, which involves writing down the opposite word associated with the concept is:
    a. Centrafusion
    b. Brainstorming
    c. *Inversion
    d. Immersion

13) Six Sigma is a Quality Design tool that represents:
    a. DIRTFT-Do It Right the First Time
    b. 1 defect in a million
    c. *3.4 defects in a million
    d. Failure Mode Effects Analysis

Chapters 10,11,12,14 and ISO 13485, Section 7.3.

1) During the design and development _____phase, the organization shall determine the design and development stages.
    a. Planning
    b. Input
    c. Output
    d. Review
2) _____relating to product requirements shall be determined and records maintained, which include outputs of risk management.
    a. Verification
    b. Validation
    c. Outputs
    d. Inputs
3) The _____of design and development shall be provided in a form that enables verification against the design and development_____and shall be approved prior to release.
    a. Inputs, Outputs
    b. Outputs, Inputs
    c. Verification, Outputs
    d. Validation, User needs
4) At suitable stages, systematic review of design and development shall be performed in accordance with planned arrangements to:
    a. Verify design intention
    b. Validate the intended use of the device
    c. Identify any problems and propose necessary actions
    d. Establish risk analysis and address any issued that have been established
5) _____shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.
    a. Validation
    b. Surgery
    c. Verification
    d. Risk Analysis
6) In order to claim substantial equivalence when submitting your medical device's 510(k) you must find_____through the FDA's search engine.
    a. Precedents
    b. MAUDE
    c. Complaints
    d. Verification
7) This class of medical device is considered 510(k) exempt by the FDA:

a. E Class
b. Class I
c. Class IIa
d. Class IIb
e. Class III

8) "80% of your complaints will arise from 20% of your devices", is an example of which rule:
   a. Gantt
   b. Demming
   c. 20/80
   d. Pareto
9) For all devices of class II and above, the CE mark must contain:
   a. Capital "C" & Capital "E"
   b. Bold letters
   c. Lower case ce
   d. Notified Body's number
10) It is important not to change the supplier listed on your 510(k) because it:
   a. will damage the relationship between your company and the supplier
   b. may make your 510(k) invalid
   c. will cost too much to change
   d. may cause an FDA audit to take place at your facility
11) The reason for including double sterile packaging barriers in your design is:
   a. If single packed, the packaging itself would be non-sterile and would not be allowed in the OR
   b. The cost is increase and therefore sales can charge more for the device
   c. It increases the expiration date and can be stocked longer
   d. Medical device design, development and manufacturing becomes more enjoyable as the number of sub-components increase.
12) Goods are delivered exactly when needed and little/no stock is held on the shelves is called:
   a. A pipe dream
   b. KANBAN
   c. JIT
   d. DMAIC

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