

Exam 2 BMT - Laboratory Techniques II (Part 2)- SS 2024 - 05.08.2024 (100% Complete)

Lecturer: Jens Maschmann

Medical Information Systems & Facility Planning

1. Which of the following statements is true?

Medical Information Systems in German Hospitals

- a) Do not support administrative and clinical processes
- b) Hide data and thus complicate flow of information
- c) Usually cannot be implemented without aligning the preexisting processes of how work is done
- d) are predominantly supported by external service providers and not by the IT-staff of the hospitals themselves
- e) always provide "connectors" to easily transfer data from/into MIS from other hospitals or private practice

2. Which of the following statements is true?

Facility planning in German hospitals

- a. is easy because financing is fully provided by the states (Bundesländer) due to the system of dual funding of hospitals
- b. Is very likely to be successful when integrating the users/stakeholders in the planning process
- c. Is straightforward because there are very few regulations to be obeyed
- d. Is not popular at all because all German hospitals are newly built and perfectly designed

3. Which of the following statements is true?

Clinical pathways in German hospitals

- a. are in widespread use throughout all German hospitals
- b. Reflect the best medical care of different health care professions for a defined group of patients with a specified diagnosis or procedure
- c. Complicate the coordination of medical care and usually increase cost of care
- d. Consists of only two dimensions: timeline and variance record
- e. Can easily be implemented even without an electronic health care record

Lecturer: Frank Schulte-Hunsbeck

Design Control 1 + 2

1. Design Control...

- a) ...is a project management software tool to lead product development projects.
- b) ...is a formal methodology to the conduct of product development project activities
- c) ...is a design verification and design validation method.
- d) ...is a business plan for conducting development project.

2) What is the meaning of design validation?

- a) Means establishing by objective evidence that device specifications conform to user needs and intended use(s).
- b) Means confirmation by examination and provision of objective evidence that specified product requirements have been fulfilled.
- c) Is a system of maintaining standards in manufactured products by testing a sample of the output against the specification.
- d) The analysis of data gathered throughout the design and manufacturing of a product in order to confirm that the process can reliably output products of a determined standard.

3) What are typical project phase sequences in a development project?

- a) Idea Phase - Prototype Phase - Feasibility Phase - Design Transfer - Verification/Validation Phase.
- b) Idea Phase - Prototype Phase - Feasibility Phase - Verification/Validation Phase - Design Transfer.
- c) Idea Phase - Feasibility Phase - Prototype Phase - Verification/Validation Phase - Design Transfer.

4) Which of the following answer(s) is/are wrong for the definition of a design review? (more than one answer is correct)

- a) At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements.
- b) Design review is a documented, comprehensive and systematic examination of design outputs to evaluate the adequacy of the design input requirements, to evaluate the capability of the design output to meet these requirements.
- c) A Design Review is a documented, comprehensive and systematic examination at the end of a project to ensure the design transfer and the conformity assessment.
- d) A Design Review is an organized process by which the designed product or system is transferred from the development phase to the production phase.

5) What is the most chosen path of conformity assessment in Europe for Medical Devices?

- a) Audit of the QMS and assessment of the technical documentation (Annex IX of the MDR 2017/745).
- b) Type examination (Annex X of the MDR 2017/745) and Production Quality Assurance (Annex XI of the MDR 2017/745).
- c) Type examination (Annex X of the MDR 2017/745) and Product Verification (Annex XI of the MDR 2017/745).
- d) Audit of the QMS (Annex IX of the MDR 2017/745) and Production Quality Assurance (Annex XI of the MDR 2017/745).

Lecturer: Marion Fehlker

Clinical Evaluation – Definition and Basics

1. For which medical devices must a clinical evaluation be carried out?

- a) for implants only
- b) only for implants and class III products
- c) for all medical devices
- d) only for high-risk products

2. Which statements apply to the clinical evaluation? (more than one correct answer)

- a) All information and statements in the clinical evaluation must be substantiated by references or justified.
- b) The clinical evaluation must be prepared once for the conformity assessment of a medical device.
- c) The clinical evaluation must be updated regularly.
- d) The cost-benefit analysis is part of the clinical evaluation.

3. In the clinical evaluation, the justifiability of the risk-benefit ratio is assessed. What does not count as a clinical benefit?

- a) positive effects on the clinical outcome.
- b) Positive effects on quality of life.
- c) Positive effects on the diagnosis.
- d) Positive effects on the price of healthcare services.
- e) Positive effects on public health.

Lecturer: Marion Fehlker

Clinical Evaluation - Special Cases

1. According to Article 61 (10) of the MDR, the clinical evaluation may also be carried out without clinical data ("clinical data inappropriate"). What needs to be considered? (more than one correct answer)

- a) This route is not possible for Class III products and implants.
- b) Article 61 (10) may only be applied if the products in question are "well-established technologies".
- c) The safety and performance of a product must nevertheless be proven, e.g. by means of technical tests or preclinical data.

2. Clinical data from a comparator product ("equivalence route") can only be used if (more than one correct answer)

- a) the similarity of the products in their technical, biological and clinical characteristics can be demonstrated
- b) there are no differences in the safety and clinical performance of the products
- c) there are no clinically significant differences in the safety and clinical performance of the products

3. Clinical evaluation is generally based on clinical data. According to MDR and MDCG 2020-6, data from the following sources count as clinical data: (more than one correct answer)

- a) data from clinical studies
- b) from published clinical data on an equivalent device
- c) complaints and vigilance data
- d) from simulation tests

Lecturer: Shannon Layland

How to build a Startup

1. Choose the best 2 definitions of opportunity costs.

- a) The loss of potential gain from other alternatives when one alternative is chosen.
- b) The cost a startup pays a coach to find venture capital.
- c) The good-will costs in the P & L statement.
- d) The value of the next best thing you give up whenever you make a decision.
- e) What pitch competitions charge as a fee.

2. The business model canvas is: (choose the best 1)

- a) a marketing tool.
- b) a strategic management template used for developing new businesses.
- c) a 30+ page document describing a startup in detail.
- d) used predominantly in oil paintings.

3. What is a venture capitalist (VC)? (choose the best 1)

- a) a socialist that is interested in capitalist theory.
- b) an intrapreneur searching for internal stakeholders.
- c) an investor who provides young companies with capital in exchange for equity.
- d) a founder in a social-based startup.