

Riskmanagement: Gedächtnisprotokoll SS26

1. Name and explain the key aspects of medical devices
2. What is risk in regard to medical devices?
3. Which is *not* a concept of risk minimization for medical devices?
 - a. Incorporating safety design
 - b. Implementing safety features
 - c. Remarks in the commercial brochure
 - d. Safety notes in the instructions for use
4. List the element phases of risk management
5. Name the dimensions of the risk diagram
6. Benefits vs. Resistance Risk Concept
7. Definition of confidence
8. Importance of process stability
9. True vs. observed Ppk.
10. Which prerequisite is needed before using the k-factor?
11. When performing a Student's t-test, which statement is true about H_0 ?
12. The knowledge of which factor is important when performing WaiBayes?
13. Form parameter beta
14. Why the OVAT test should be avoided?
15. Name the five phases of Design of Experiments (DoE)
16. What is randomization in DoE?
17. Risk of partial factorial testing
18. Downside of full factorial testing