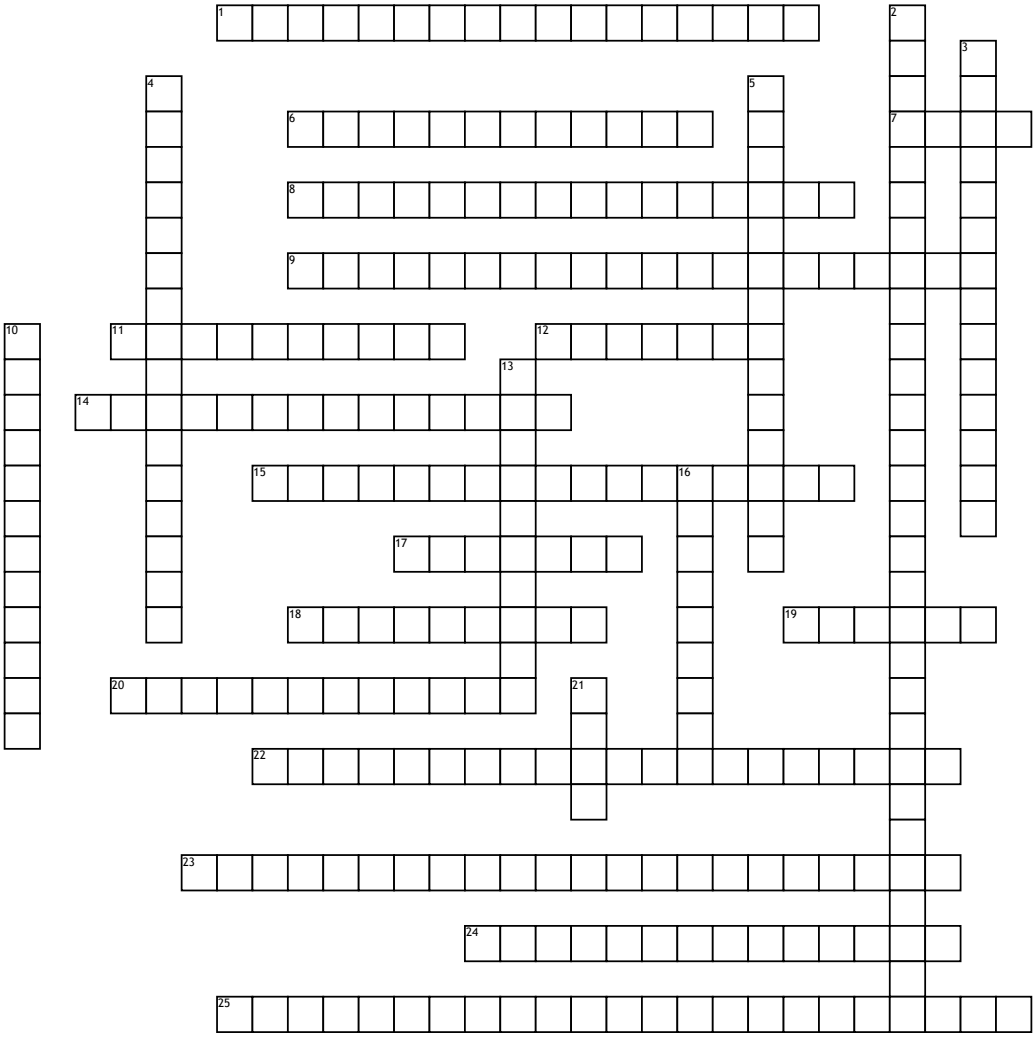
Name: _____ Date: _____

ISO 13485:2016 Terms and Definitions



Across

1. A problem solving method used to pinpoint the actual cause of a specific problem. When that cause is removed, it prevents recurrence of the problem.

6. the process that uses information to identify potential risks.

7. the probability of occurrence of harm and the severity of it/ the safety and performance of a device.

8. the action taken to eliminate the cause of the NC.

9. Information required to be controlled and maintained by a company

11. means confirmation by examination and the provision of objective evidence that the requirements for a specific intended use have been fulfilled

12. the degree to which a set of inherent characteristics fulfills requirements; achieving the agreed upon requirements of a customer.

14. the process of comparing the estimated risk against the given risk criteria.

15. written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market

17. a set of interrelated or interacting activities

18. written, printed or graphic matter affixed to the device or accompanying it, which is related to the identification, description, and use. CFR specifies minimum requirements for all devices.

19. potential source of harm

20. confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

22. Packaging which prevents microorganisms from entering, thereby allowing uncontaminated products to be provided at the point of use.

23. communication plans that need to be in a formal agreement

24. Part of the QMS focused on fulfilling the Quality Requirements

25. Manages the interacting processes and Resources required to manage resources concerning short- and long-term goals; identification of actions and consequences of product.

Down

2. Improvements to processes taken to eliminate the causes of nonconformities or other undesirable situations.

3. Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risks.

4. the QMS focuses on providing confidence in the requirements to be fulfilled

5. Notice by the company, subsequent to delivery, to provide supplementary information

10. the remaining risk after control measures have been taken.

13. An action needed to eliminate the effect of a NC

16. all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

21. physical injury or damage to the health of people, property, or environment.

Word Bank

documented arrangements
corrective action
Risk Evaluation
Risk
Root Cause Analysis
life cycle
Risk Analysis
Quality
Quality Control
Risk Management
Corrective Preventative Actions
Verification
documented informtion
Residual Risk
Quality Assurance
Quality Management System
Process
hazard
Validation
advisory notice
labelling
Correction
harm
Customer Complaint
Sterile Barrier System