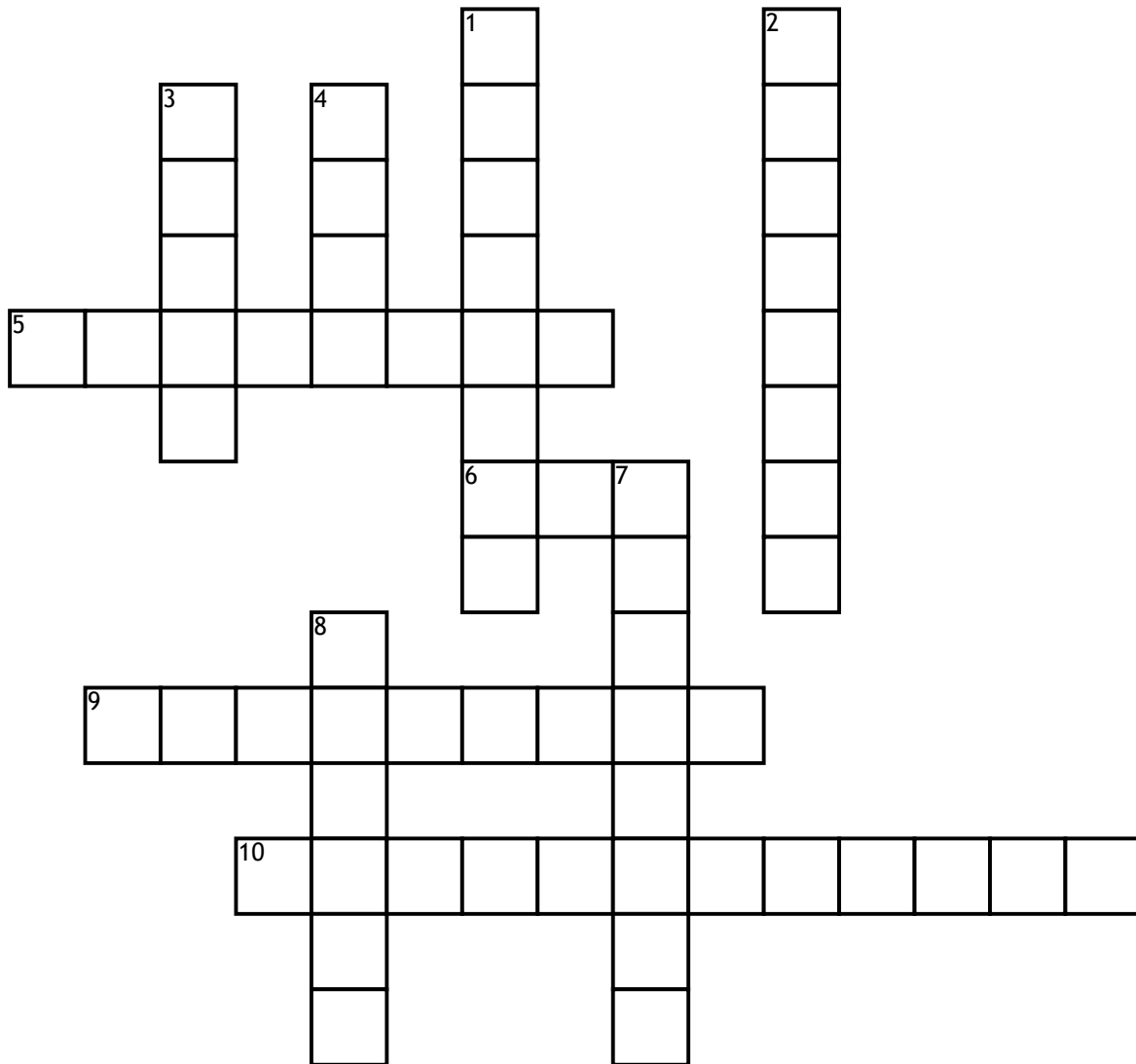


Name: _____

Date: _____

Auditing



Across

- 5. Set of policies, procedures or requirements used as a reference against which audit evidence is compared
- 6. Regulation which requires a QA statement for the final study report
- 9. Key characteristic of an auditor required to identify a finding
- 10. Third party, accredited by European authorities, to audit medical device companies and products

Down

- 1. Results of the evaluation of the collected audit evidence against audit criteria

- 2. Severity of grading when an observation is considered a GXP Show-stopper
- 3. Systematic, independent process for obtaining evidence and evaluating it objectively to determine the extent to which the criteria are fulfilled
- 4. Laboratory study on absorption, distribution, metabolism and excretion of a test item by a human or animal body
- 7. First phase in the audit process
- 8. Document in which you describe your audit observations