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|  | 1. | Informal reviews require the following items (select all that apply): |

|  | **Answers** |
| --- | --- |
|  | Names of reviewers |  |
|  | Electronic signatures |  |
|  | Date of review |  |
|  | Materials being reviewed, including appropriate version as needed |  |
|  | All of the above |  |

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| --- | --- | --- |
|  | 2. | Which Low Risk tasks require a formal review? (select all that apply) |

|  | **Answers** |
| --- | --- |
|  | Approve Requirements |  |
|  | Validate Release |  |
|  | Maintain Solution Record |  |
|  | Transfer to Production |  |
|  | Deliver Release |  |

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|  | 3. | Which document would you review if you do not understand a term used in a process task? |

|  | **Answers** |
| --- | --- |
|  | FAQ |  |
|  | ProcessIT Layout and Navigation |  |
|  | Getting Started |  |
|  | Process Education |  |
|  | Risk Based Glossary |  |

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|  | 4. | The User Experience team must be engaged if the project impacts a frequently used function in a visual component or is identified as a usability risk in the High Risk process. |

|  | **Answers** |
| --- | --- |
|  | True |  |
|  | False |  |

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|  | 5. | Each solution team must create a Solution Record; however, approval from RA/QA must be obtained before a solution team can follow which process? (select all that apply) |

|  | **Answers** |
| --- | --- |
|  | Low Risk Process |  |
|  | Medium Risk Process |  |
|  | High Risk Process |  |
|  | All of the above |  |
|  | None of the above |  |

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|  | 6. | Where is the intended use statement found? |

|  | **Answers** |
| --- | --- |
|  | Solution Description on Cerner.com |  |
|  | Solution Portal |  |
|  | Solution Record |  |
|  | Strategies Home Page |  |
|  | uCern Connect |  |

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|  | 7. | What type of strategies must be created and maintained as part of the development process? (select all that apply) |

|  | **Answers** |
| --- | --- |
|  | Release |  |
|  | Implementation |  |
|  | Traceability |  |
|  | Quality |  |
|  | Documentation |  |
|  | Testing |  |

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|  | 8. | Where do you find the information that is required to create a strategy? |

|  | **Answers** |
| --- | --- |
|  | Maintain Solution Record |  |
|  | Create Documentation |  |
|  | Manage Documents and Records |  |
|  | Manage Strategies |  |
|  | Manage Work |  |

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|  | 9. | Which task do you complete first when the request for change is valid and should be accepted? |

|  | **Answers** |
| --- | --- |
|  | Manage Submission |  |
|  | Prioritize Change Request |  |
|  | Design Tests |  |
|  | Define Detailed Requirements |  |
|  | Manage Work |  |

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|  | 10. | All third party contractors must follow a Cerner-approved software development process. If contracting out work, you must also ensure that: (select all that apply) |

|  | **Answers** |
| --- | --- |
|  | A request is submitted to Regulatory Affairs to have the supplier added to the supplier audit schedule |  |
|  | There is a method to identify known issues and new enhancement and defect resolutions |  |
|  | The organization or group engaging the third-party contractor documents requirements for the supplier and confirms the supplier can meet those requirements |  |
|  | A definition of what would constitute elimination or severed terms with the third-party contractor is documented |  |

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|  | 11. | Requirements must be documented at the system level. System-level requirements: (select all that apply) |

|  | **Answers** |
| --- | --- |
|  | Are only included within a Risk Management File |  |
|  | Are documented only once during the development of a solution |  |
|  | Describes the behaviors of a system |  |
|  | Are not required for solutions following the Low Risk process |  |
|  | Ensure that the requirements for the solution are comprehensive and evolving |  |

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|  | 12. | In the Medium and High Risk processes, what document must be included in the Design Input record when there are mitigating actions associated with the project? |

|  | **Answers** |
| --- | --- |
|  | Risk traceability document |  |
|  | Hazard analysis document |  |
|  | Risk management report |  |
|  | Risk management document |  |
|  | Hazard traceability document |  |

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|  | 13. | If updates are made to tests in the test set after the tests were executed, those tests must be reviewed again and then re-executed after the review. |

|  | **Answers** |
| --- | --- |
|  | True |  |
|  | False |  |

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|  | 14. | Who is responsible for performing the Control Risk activities? |

|  | **Answers** |
| --- | --- |
|  | Regulatory Affairs |  |
|  | Compliance Specialists |  |
|  | Project Management |  |
|  | SolutionWorks |  |
|  | Development Team |  |

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|  | 15. | In the Low, Medium, and High Risk Processes, the Design Output must include electronic signatures. |

|  | **Answers** |
| --- | --- |
|  | True |  |
|  | False |  |

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|  | 16. | What do you sign to indicate that you are accepting the risk associated with any unresolved known issues and are confirming that the defined processes were followed: |

|  | **Answers** |
| --- | --- |
|  | Design Input form |  |
|  | Deliver Release form |  |
|  | Technical Design Documentation |  |
|  | Solution Record |  |
|  | Transfer to Production form |  |

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|  | 17. | Where do you identify the method you should follow to communicate to stakeholders that the release is available? |

|  | **Answers** |
| --- | --- |
|  | Deliver Release task |  |
|  | Manage Documents and Records task |  |
|  | Documentation Strategy |  |
|  | Reference Pages |  |
|  | Release Strategy |  |

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|  | 18. | What task ensures that defects are evaluated within the context of both testing and coding? |

|  | **Answers** |
| --- | --- |
|  | Control Risk |  |
|  | Review Quality |  |
|  | Complete Root Cause Analysis |  |
|  | Complete Implementation |  |
|  | Validate Release |  |

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|  | 19. | Only the Medium and High Risk processes require a quality plan. |

|  | **Answers** |
| --- | --- |
|  | True |  |
|  | False |  |

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|  | 20. | Which task is in the High Risk process but is not in Low or Medium Risk processes? |

|  | **Answers** |
| --- | --- |
|  | Approve Implementation |  |
|  | Manage Submission |  |
|  | Manage Strategies |  |
|  | Complete Root Cause Analysis |  |
|  | Maintain Solution Record |  |