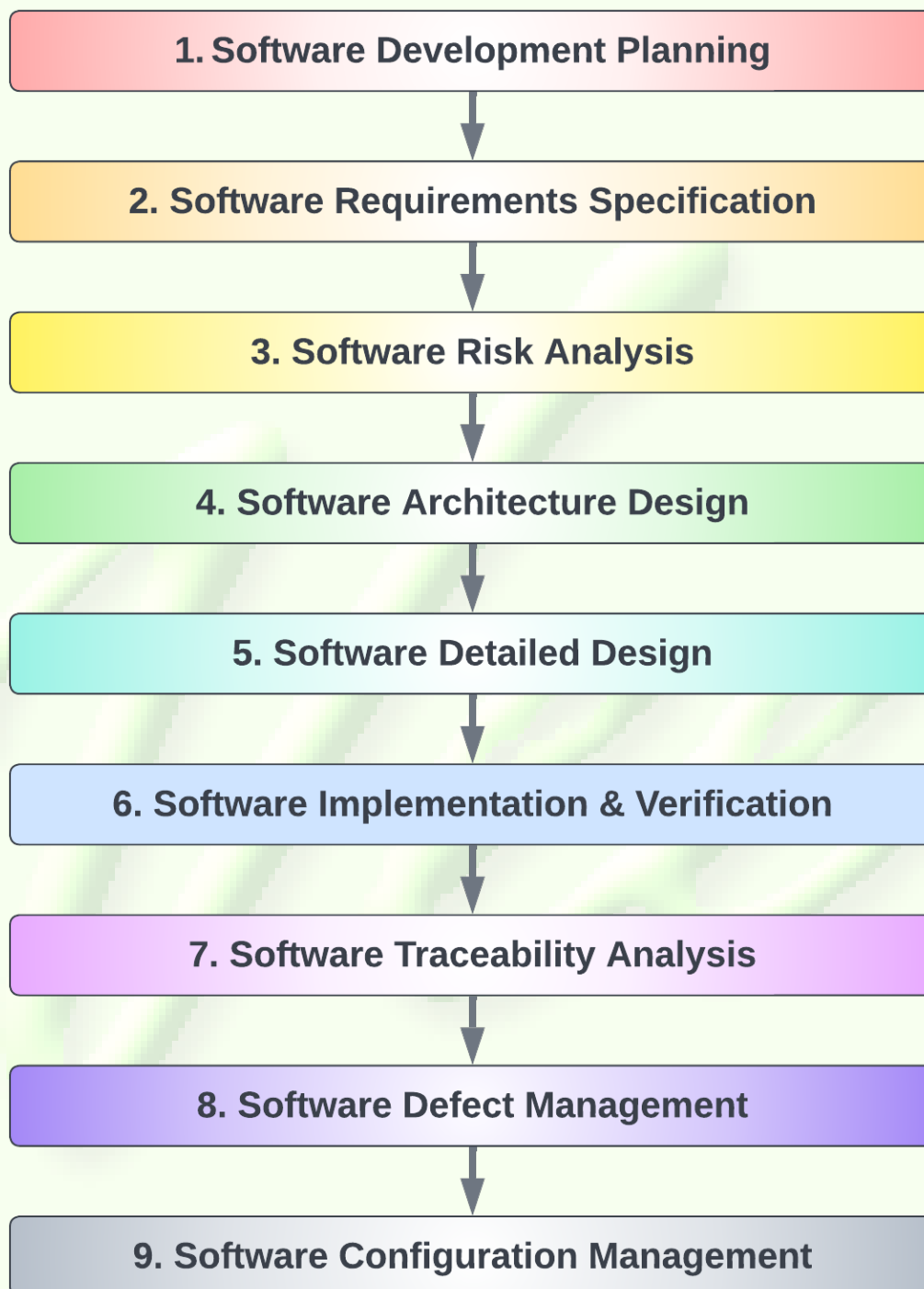


SOFTWARE VALIDATION PROCESS



SOFTWARE VALIDATION REPORT

1. SOFTWARE CLASSIFICATION

- 1.1. FDA
- 1.2. EU
- 1.3. IEC 62304

2. SOFTWARE DEVELOPMENT PLAN

3. SOFTWARE DESCRIPTION

- 3.1. Intended for use
- 3.2. Hardware Platform
- 3.3. Operating System
- 3.4. Software Algorithm Flowchart
- 3.5. Software Functional characteristics
- 3.6. User Interface
- 3.7. Operational Environment

4. SYSTEM AND SOFTWARE ARCHITECTURE DIAGRAM

5. RISK MANAGEMENT FILE

- 5.1. Risk Estimation
- 5.2. Risk Acceptance Criteria

6. SOFTWARE REQUIREMENTS SPECIFICATION (SRS)

- 6.1. Hardware requirements
- 6.2. Software Programme Language
- 6.3. Software/Hardware Interface Requirements
- 6.4. Software Performance and Functional Requirements

7. SOFTWARE DESIGN SPECIFICATION (SDS)

- 7.1. Hardware Specifications
- 7.2. Program Specifications
- 7.3. Interface Specifications
- 7.4. Performance and Functional Specifications

8. SOFTWARE IMPLEMENTATION & VERIFICATION

9. SOFTWARE AND TRACEABILITY ANALYSIS

10. SOFTWARE DEFECT MANAGEMENT

10.1. Defect Management Process

10.2. List of Anomalies remained

11. SOFTWARE CONFIGURATION AND MAINTENANCE

12. CONCLUSIONS

13. APPENDIX

13.1. Appendix One: Software Development Plan

13.2. Appendix Two: Risk Traceability Matrix Table

13.3. Appendix Three: Software Configuration Management Plan