

## IEC 62304 compliance checklist

- ✓ **Software Development Plan**
  - Develop a comprehensive plan that outlines the software development activities and resources required
  - Define the software safety class based on the potential risk associated with the software
  
- ✓ **Software Requirements**
  - Define and document the software requirements, including functional, performance, and safety requirements
  - Establish traceability between requirements and other software life cycle artifacts
  
- ✓ **Software Architecture**
  - Design and document the software architecture, including the overall structure, interfaces, and interactions
  - Allocate software requirements to specific software units/modules
  
- ✓ **Software Verification and Validation**
  - Develop test plans and procedures to verify and validate the software against the defined requirements
  - Execute software testing activities, including unit testing, integration testing, system testing, and acceptance testing
  - Document test results, including any issues or defects identified
  
- ✓ **Software Risk Management**
  - Perform a risk analysis to identify and assess potential risks associated with the software
  - Implement risk control measures to mitigate identified risks
  - Document the risk management activities and maintain a risk management file

- ✓ **Software Configuration Management**
  - Establish a configuration management process to control and track software changes throughout the life cycle
  - Maintain version control of software and related documentation
  
- ✓ **Software Maintenance**
  - Develop a plan for software maintenance activities, including bug fixes, updates, and patches
  - Document and track any changes made during maintenance
  
- ✓ **Software Release**
  - Prepare and document the software for release, including packaging and labeling
  - Create a release note that includes information on the software version, changes made, and known issues
  
- ✓ **Software Problem Resolution**
  - Establish a process for capturing, investigating, and resolving software-related issues, such as defects or customer complaints
  - Document the problem resolution process and maintain a record of resolved issues
  
- ✓ **Software Documentation**
  - Create and maintain comprehensive documentation throughout the software life cycle, including design documents, user manuals, and installation guides
  - Ensure that the documentation is accurate, up-to-date, and accessible to relevant stakeholders