

Documentation as Code

Dokumentierst Du noch, oder
programmierst Du schon?

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Dokumentationsanforderungen



Software-Dokumentation nach 62304

- ▶ Software-Entwicklungsplanung
- ▶ Softwareanforderungen
- ▶ Softwarearchitektur
- ▶ Detailliertes Softwaredesign
- ▶ Integrationstests und Testergebnisse
- ▶ Softwaresystemtests und Testergebnisse
- ▶ Freigabedokumente

Software-Dokumentation für FDA-Einreichungen

Geforderte Dokumentation	Minor LoC	Moderate LoC	Major LoC
Bestimmung des Level of Concern	X	X	X
Beschreibung der Software	X	X	X
Risikoanalyse des Gerätes	X	X	X
Softwarespezifikation	Kurzfassung	vollständig	vollständig
Softwarearchitektur		X	X
Detailliertes Design		X	X
Traceability-Analyse	X	X	X
Entwicklungsprozess		Kurzfassung	vollständig
Verifikation und Validierung	Funktions-tests	Funktions- und System-tests	vollständig
Versionshistorie	X	X	X
Liste mit bekannten Fehlern		X	X

Medical SPICE Work Products

Application Specification
Change Documentation
Change Information
Change Management Plan
Change Request
Change Review Record
Feedback
Known Anomaly List
List of Residual Anomalies
Overall Risk Evaluation
Personnel Qualification Records
Primary Operating Functions
Problem Advisory
Problem Investigation Record
Problem Report
Registry of Released Versions
Residual Anomalies Evaluation Record
Risk Analysis
Risk Management Plan
Risk Management Policy
Risk Management Process
Risk Management Report
Software Architecture Verification Record

Software Architecture
Software Build Record
Software Configuration History Record
Software Configuration Management Plan
Software Delivery Procedures
Software Detailed Design Verification Record
Software Detailed Design
Software Development Lifecycle Definition
Software Development Plan
Software Documentation Plan
Software Integration Plan
Software Integration Regression Test Record
Software Integration Test Plan
Software Integration Test Record
Software Integration Test Verification Record
Software Integration Verification Record
Software Maintenance Plan
Software Modification Kit
Software Problem Resolution Plan
Software Release Kit
Software Release Record
Software Requirements Traceability
Software Requirements Verification Record

Software Requirements
Software Risk Management Plan
Software Source Code
Software System Regression Test Record
Software System Test Plan
Software System Test Record
Software System Test Specification
Software System Test Verification Record
Software Unit Acceptance Criteria
Software Unit Verification Record
Software Verification Plan
Software Version Archive
SOP Specification
System Architecture
System Requirements
Training Material
Usability Engineering Plan
Usability Specification
Usability Verification Record
User Interface Design
Validation Plan
Validation Record

Arten von Dokumentation

Dokumente

- ▶ unterliegen einem Lebenszyklus (Prüfung, Freigabe, Aktualisierung, ...)
- ▶ verfügen über eine Version(snummer)

Aufzeichnungen

- ▶ belegen die Konformität mit dem Qualitätsmanagement-System
- ▶ werden erstellt und aufbewahrt

Strategien



Früher

Funktionalität

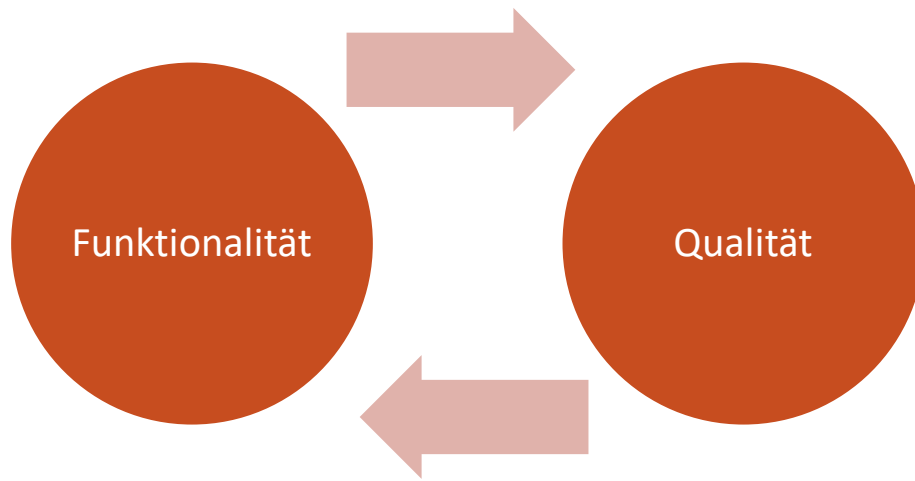


Qualität



Dokumentation

Heute



Dokumentation

Agile Ansätze

