Using ISO 13485 to develop medical software for FDA & European Certification

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Introduction

• MPC Data is a bespoke software company
• We specialise in embedded medical software
• Our clients are medical device manufacturers
• We have over 25 years experience with embedded software
• Partnerships with supporting companies
Agenda

- What is ISO 13485?
- How can it help?
- Key elements of the standard
- Product Realisation/Development
- Software Architecture
- Risk Management
- Software of Unknown Provenance
- Summary & Questions
What is ISO 13485?

• Quality Management System for medical devices
• Recognised by EU/FDA for certification
• ISO 14971 – Risk Management (medical devices)
• IEC 62304 – Software Life-Cycle for medical devices
Benefits of certification

- Route to product approval
- Customer satisfaction
- Legal compliance
- Design controls
- Risk management
- Independent verification
- More attractive to subcontract
Key elements of the standard

• Specifically for medical devices
• Harmonised with ISO 9001
• References regulatory requirements
• Defines management responsibility
• Increased documentation
• Product Realisation
• Design Transfer
Medical Device

Electronics

Mechanics

Software

Manufacture

Servicing
Using an ISO 13485 company

- Independently audited (certification body)
- Audited by customers
- Saves audit time
- Saves audit cost
- Independent experience
- Parallel working
- Reduce time to market
Documentation

- Design History File – FDA Approval
- Technical File – CE Certification
- Manufacturer’s responsibility
- Software Development Process Creates:
  - Project / Development Plans
  - Requirements
  - Design
  - Risk Management
  - Reviews
  - Quality Records
Documentation options

- Manual system
- Full featured system
- Specialist medical system
- Others….
IEC 62304 Software Development

- S/W Project Plan
- S/W Development Plan
- Verification/Validation
- Software Release
- Change Control
- Implementation
- Reviews
- Architecture
- Requirements
- Software Design
- Risk Management
Modular Software Architecture

- Software requires IEC 62304 Safety Classification
- Break down into software items
- Easy to identify developed vs 3rd party items
- Identify critical items
- Distributed Risk Management
- Re-use of items
- Reduce verification/validation effort
Safety Classification

S/W SYSTEM (CLASS C)

ITEM 1 (CLASS A)

ITEM 2 (CLASS C)

ITEM 3 (CLASS B)

ITEM 4 (CLASS A)
Software of Unknown Provenance
• Code not developed as part of the project.
• Tools
• Configuration Management System
• Issue Tracking System
• Operating System / Libraries
• Develop Intended Use Validation (IUV)
Intended Use Validation (IUV)

- Description & Intended Use
- Risk Evaluation
- Requirements
- Configuration Management
- Known Defects
- Test Plan & Procedure
- Test Results
- Analysis of Results & Conclusions
IEC 62304 Software Development

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Risk Management

• ISO 14971
• Assess software risks
• Aim to minimise risk
• Analyse/categorise risks
• Determine risk controls
• Additional requirements
• Evaluate effectiveness
Summary

• How ISO 13485 applies to medical software
• Documentation
• Software life-cycle IEC 62304
• Modular architecture
• Use of SOUP or 3\textsuperscript{rd} party software
• ISO 14971 Risk Management
• Use of certified companies
Questions & Answers

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