IEC 62304
Medical Device Software Development Life Cycle
Agenda

• Objectives
• Relationship with other Standards
• Organisation of the Standard
• General Approach of the Standard
• Applicability of the Clauses
• EUMDD, QSR, ISO 13485 Map to IEC 62304
Objectives

• Understand 62304 compliance with respect to “the big picture” and to Projects
• Ability to Enhance Product Submissions
• Apply 62304 to the QMS for audits
• Retain 62304 Key Principles for Use with Projects
Relationship with Other Standards

Management
- ISO 13485
- ISO 14971
- IEC 80002-1

Electromedical Safety
- IEC 60601-1
- IEC 60601-2-xx
- IEC 61010-1

Process
- IEC 62304
- IEC 62366

Other Guidances
- FDA Reviewers Guidance
- FDA S/W Val Guidance
- MedDev Standalone S/W
Relationship with Other Standards

Relationship with Other Standards

FDA Reviewers Guidance
• Alignment of 62304 Classes with Level Of Concern
• Alignment of 62304 with Submission Deliverables

FDA Software Validation Guidance
• Alignment of 62304 with FDA S/W Val incl SOUP
Organisation of The Standard

9 Sections, 4 Annexes
General Approach of the Standard

- Plan the Software Development
- Preliminary Risk Analysis
- Figure out the software architecture
- Assess Software Safety Risk Class
- Develop /Risk Manage per Risk Class
Clauses

1. Scope
2. Normative References
3. Terms & Definitions
4. General Requirements
5. Software Development Process
6. Software Maintenance Process
7. Software Risk Management Process
8. Software Configuration Management Process
9. Software Problem Resolution Process
Scope

• Defines the life cycle requirements for MEDICAL DEVICE SOFTWARE.
• The set of PROCESSES, ACTIVITIES, and TASKS described establishes a common framework for MEDICAL DEVICE SOFTWARE life cycle PROCESSES.
• When software is stand alone or embedded/integral in a medical device
• Does not cover validation and final release
• Compliance determined by inspection of all required documentation including RMF and assessment of PROCESSES, ACTIVITIES, and TASKS required for the software safety class.
References

• ISO 14971 – Normative - that’s it.
    • 2007: Everyone BUT EU
    • 2012: EU

• EN 62366 – Informative reference
    • 2015: Everyone BUT EU, referenced in 2015
    • 2007: EU – but actually not mentioned in 2006
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