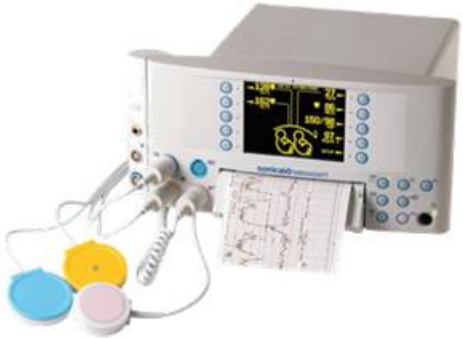
Using ISO 13485 to develop medical software for FDA & European Certification

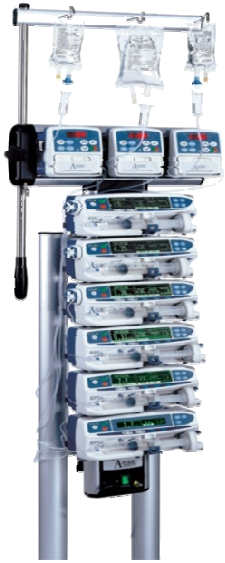
Stephen Bashford, Quality Manager

MPC Data Limited

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





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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

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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

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Benefits of certification

- Route to product approval
- Customer satisfaction
- Legal compliance
- Design controls
- Risk management
- Independent verification
- More attractive to subcontract

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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

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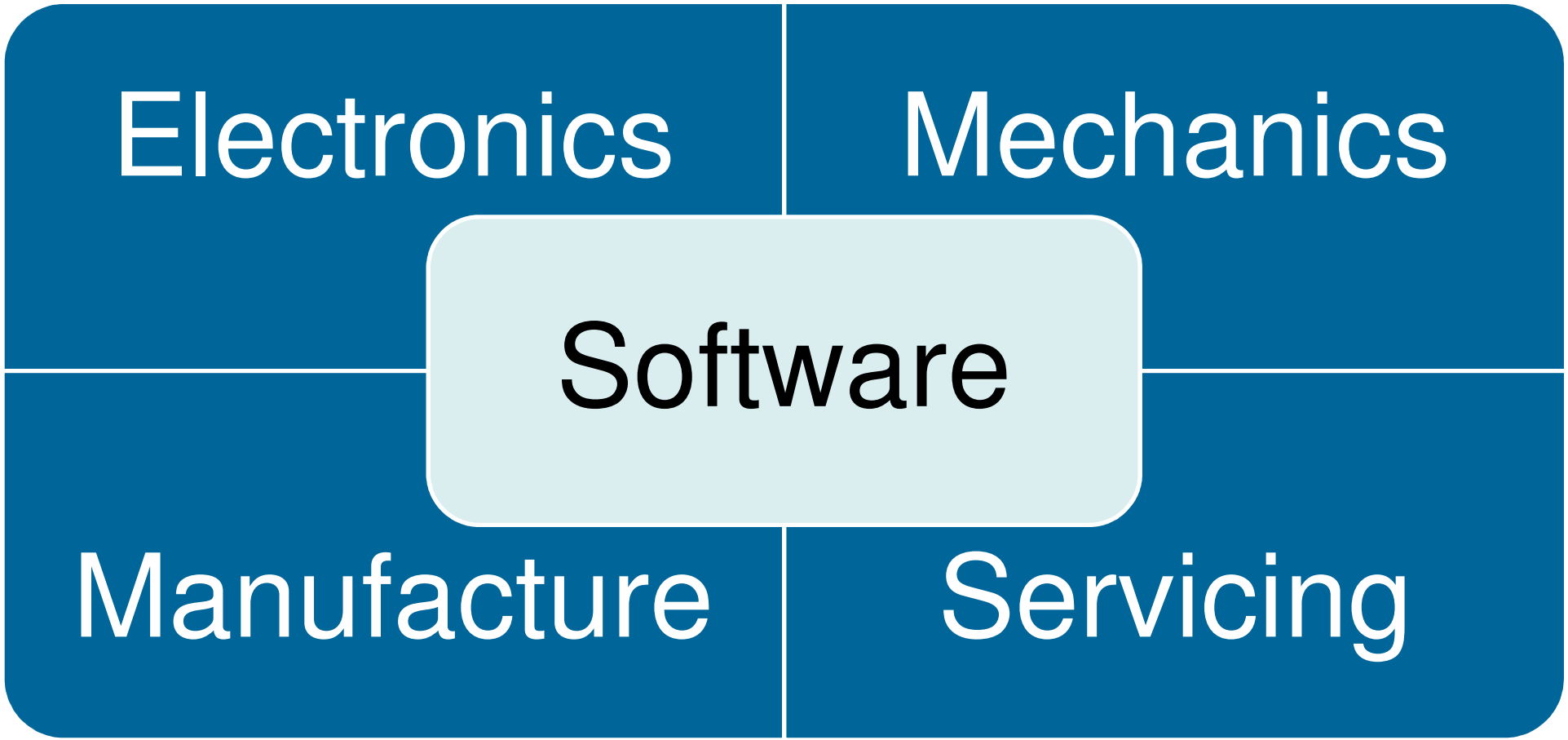
Medical Device



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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

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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

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Documentation options

- Manual system
- Full featured system
- Specialist medical system
- Others….

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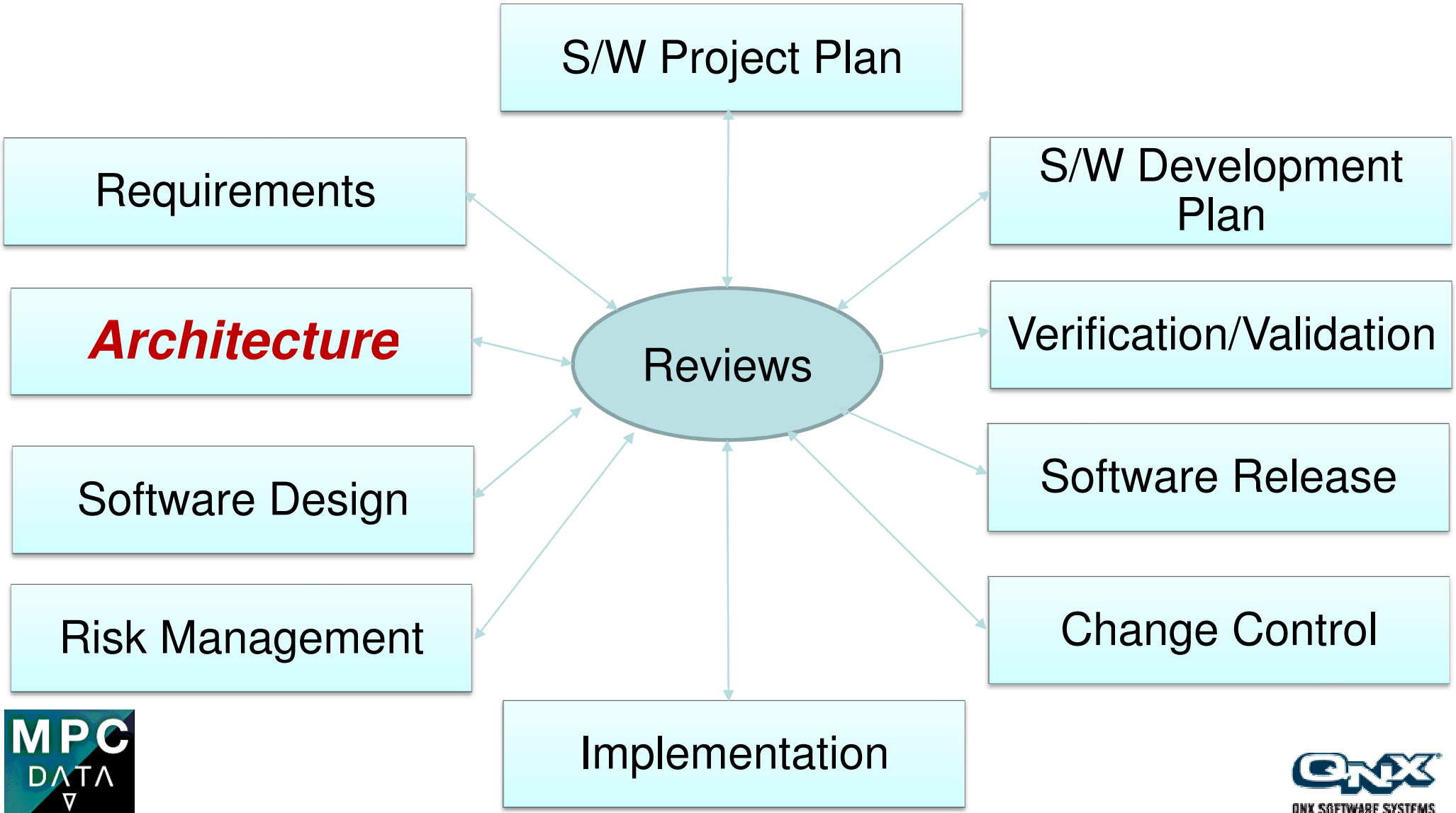
IEC 62304 Software Development



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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

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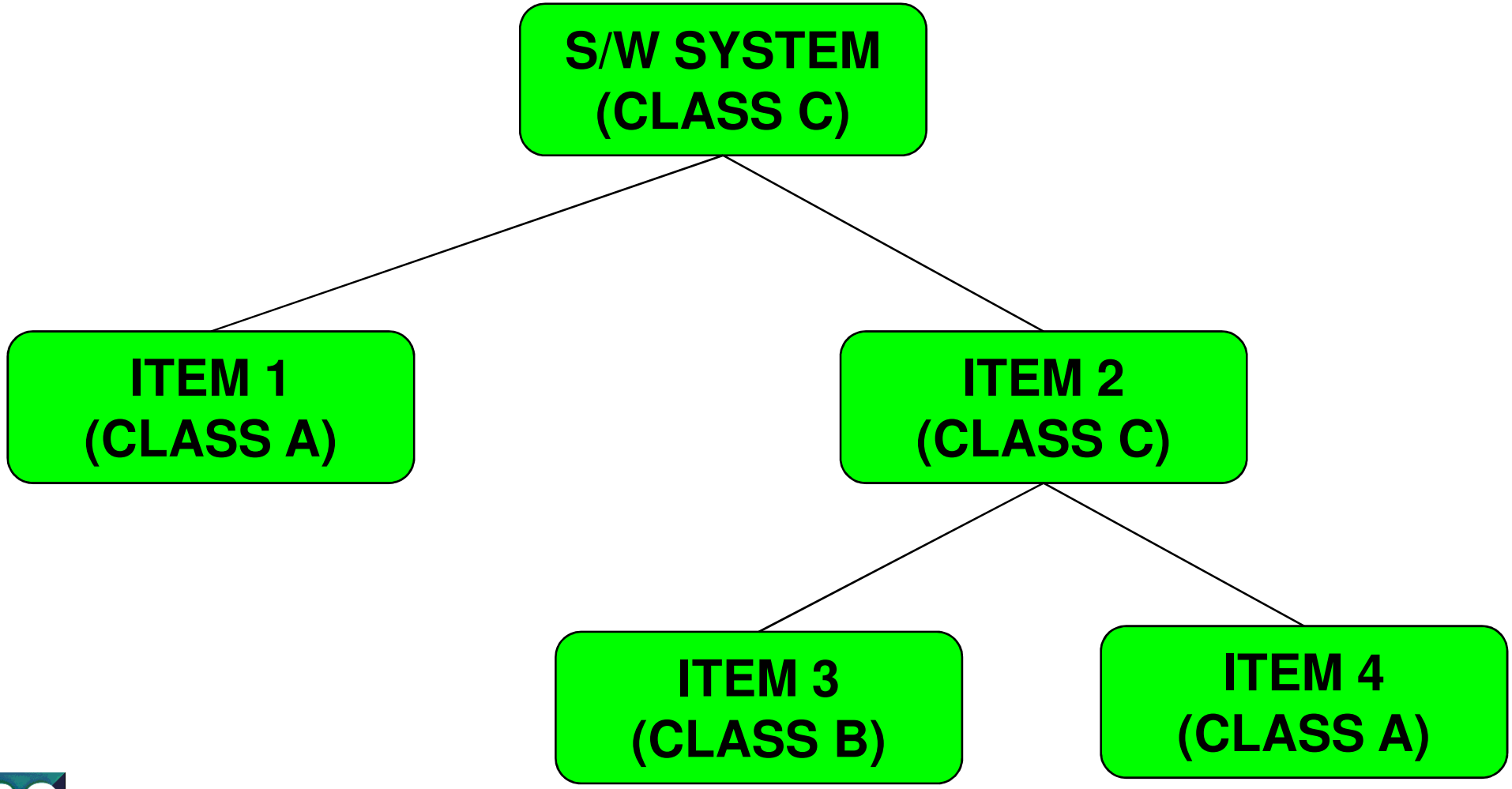
Safety Classification



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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

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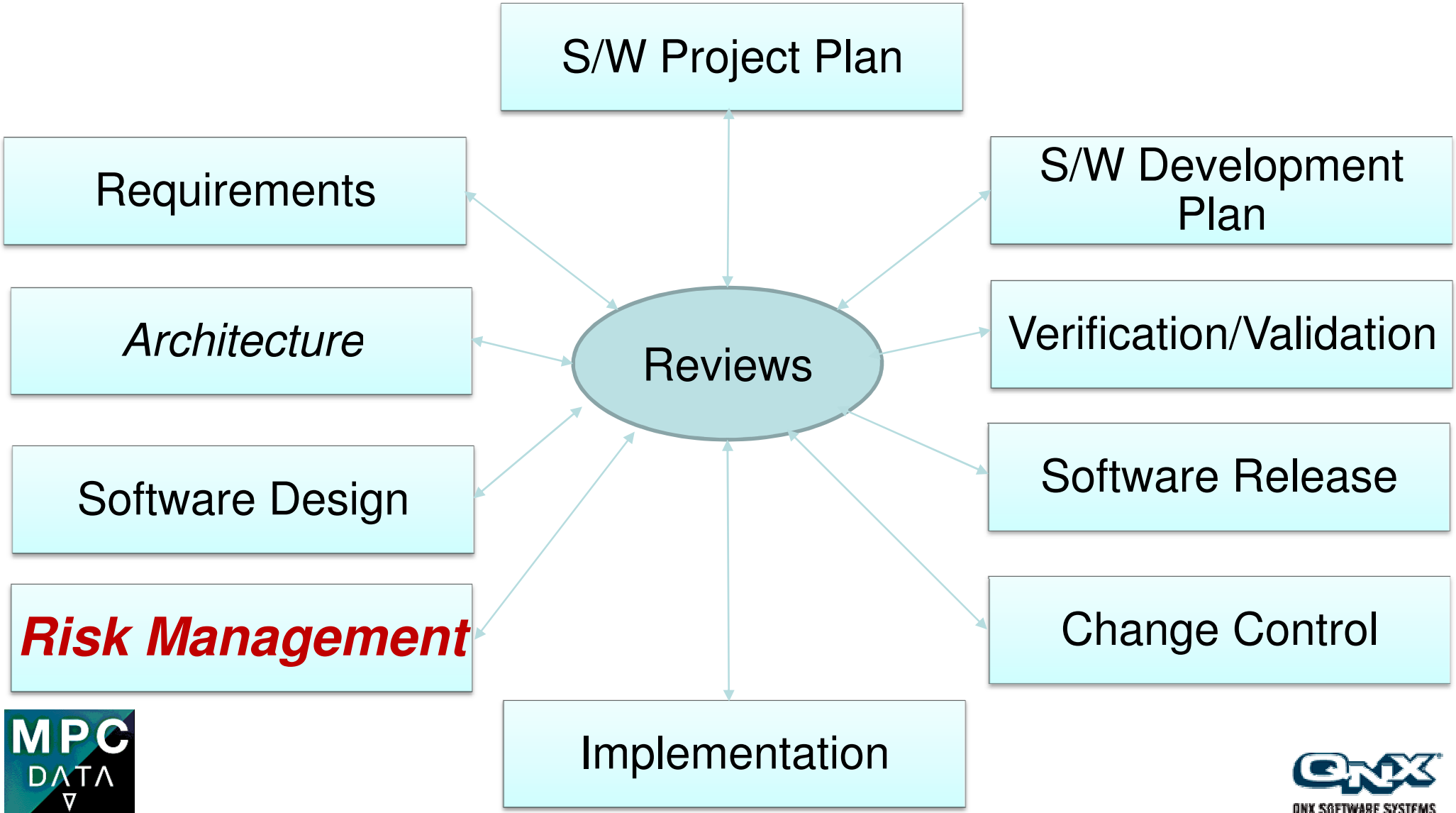
IEC 62304 Software Development



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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 3rd party software
- ISO 14971 Risk Management
- Use of certified companies

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Questions & Answers

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