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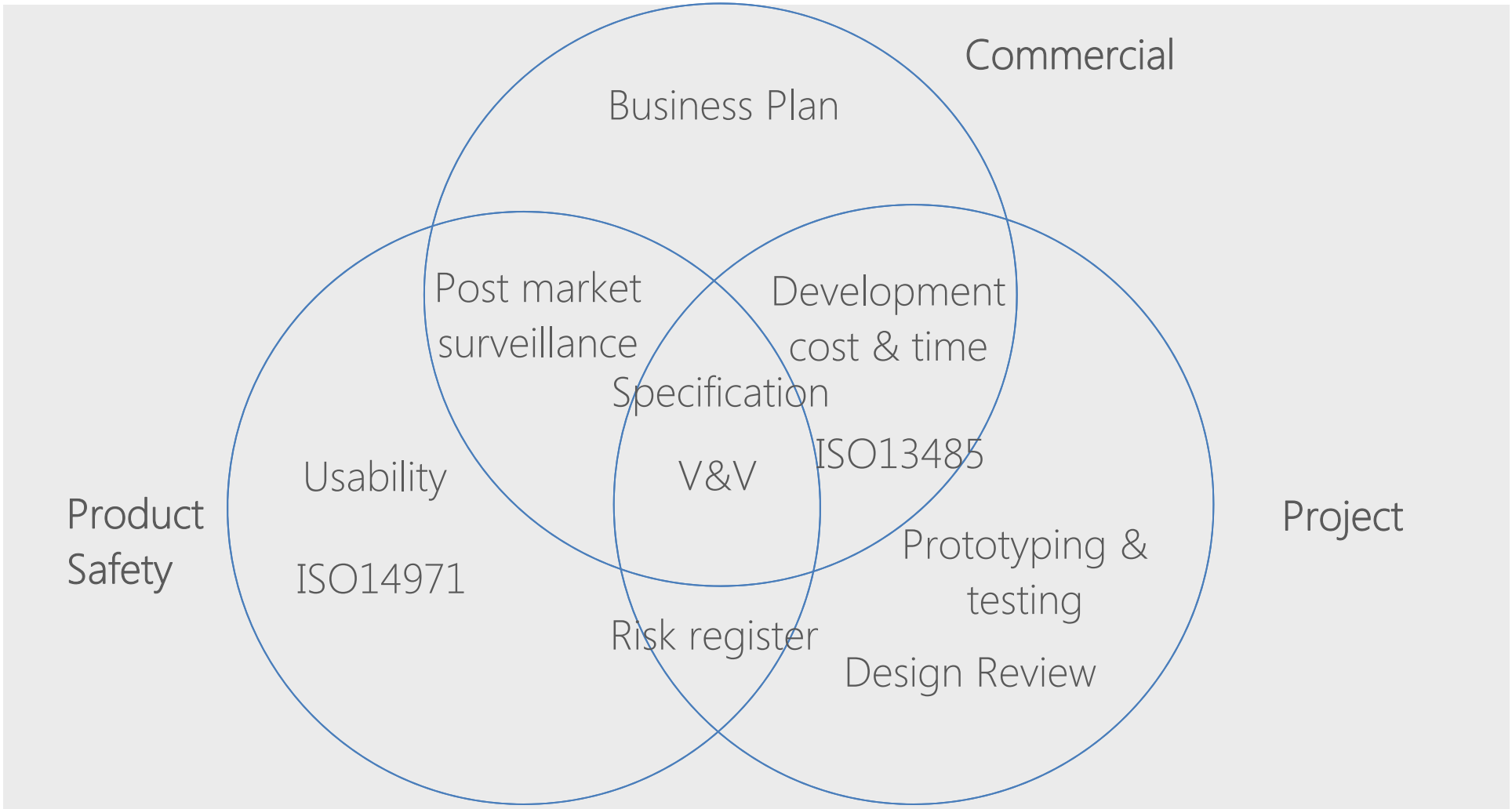
Medical Device Risk Factors



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Specifications

The Purpose of Specifications

- Ensure that everyone is on the same page
- Are a stake in the ground that addresses development versus commercialisation
- Are something to develop to
- Are something to test to
- Identify performance and standards
- Are something against which to manage change during development
- Help identify the unknowns and knowledge gaps

Specification setting should accommodate routine as well as challenging issues

- The things we know will happen
- Expecting the unexpected

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Specifications

An evolving specification

- How much flexibility is required in the first stages?
- Refining the specification with development
- Change is always possible, but it should be formally controlled beyond a certain point

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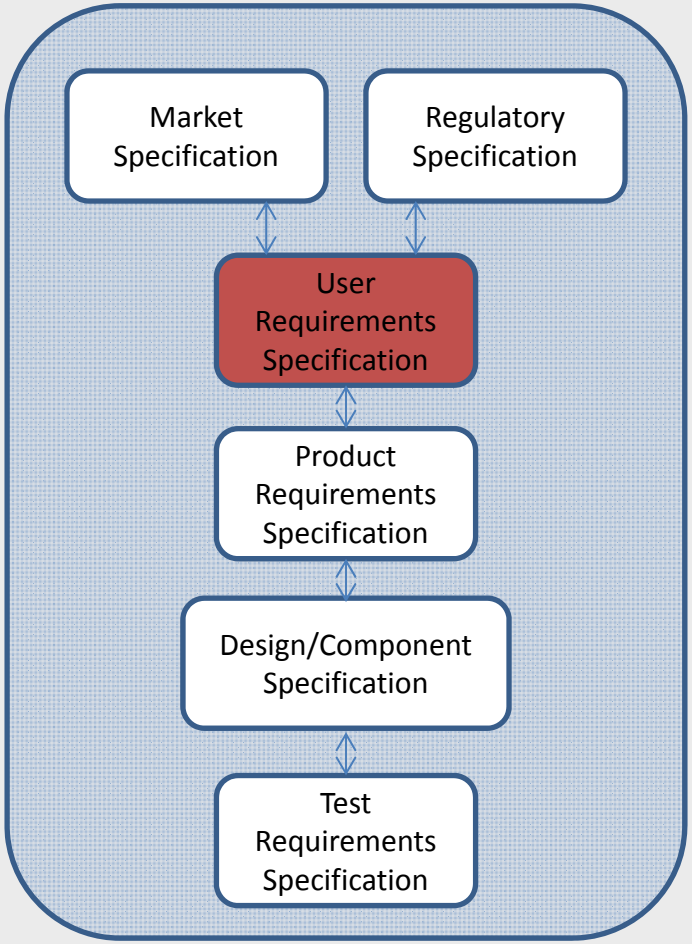
Managing Change for a Prototype

Change is not isolated

- The change effect cascade
- Clear change must be documented within the specification and fed to affected development areas
- Communication of change is important between partners and disciplines
- Feedback loops should be understood and managed
- Use of change notes / change orders / corrective action requests



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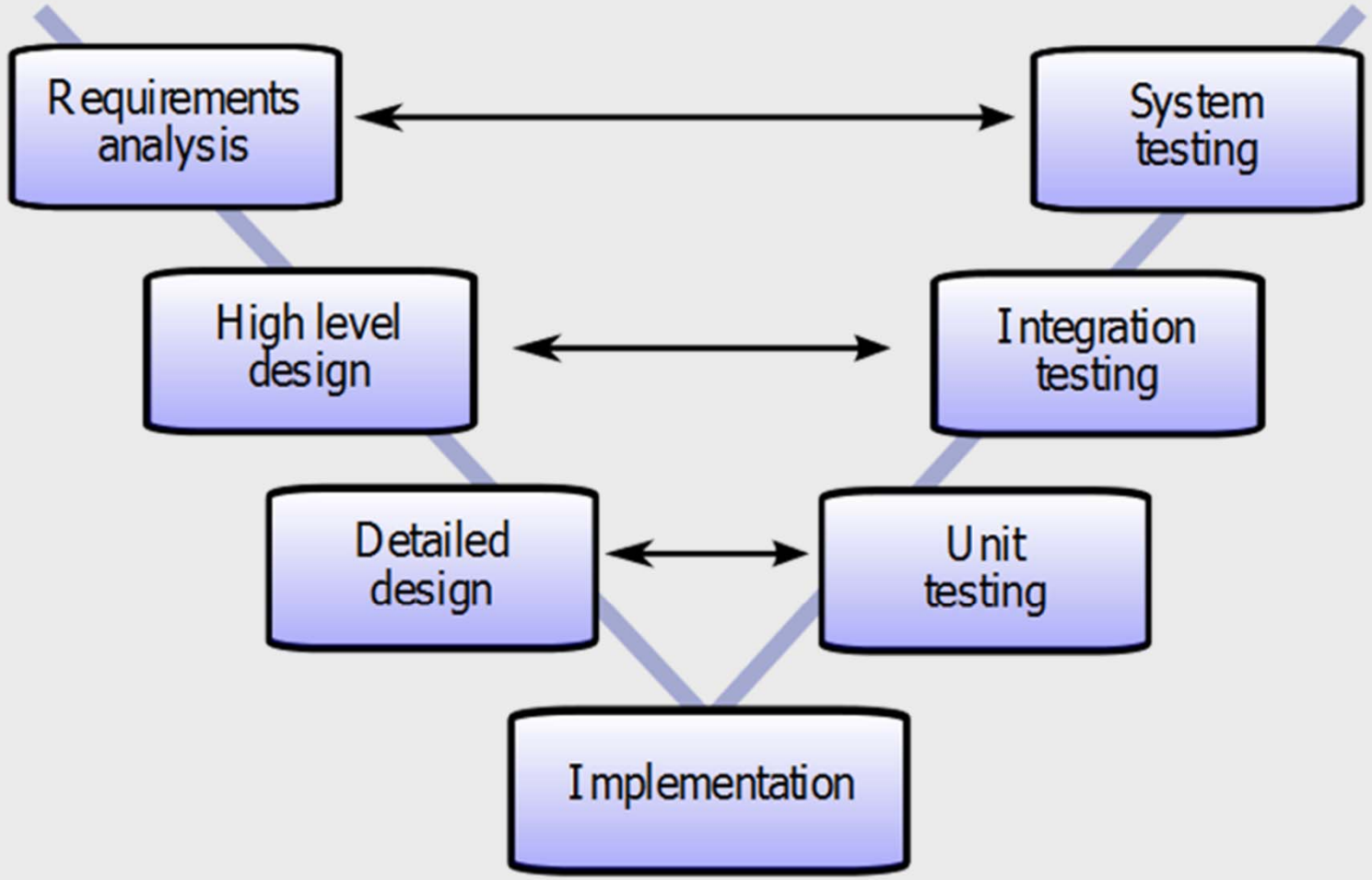
Validation & verification – V Model



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Verification

Pre- clinical verification

What is verification?

- "Verification. The evaluation of whether or not a product, service, or system complies with a regulation, requirement, specification, or imposed condition. It is often an internal process. Contrast with *validation*."
- Formal testing of a design against the full specification
- Testing agreed between the client and the developer.

"Have we done it right?"

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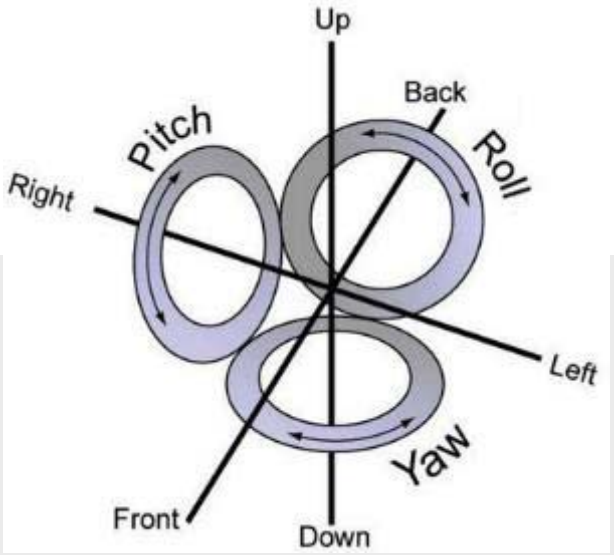
Verification



Pre- clinical verification

What are the requirements for verification?

- ISO process requirements
- Regulatory requirements, 62304 Software development requirements traceability and the MDD
- Applicable standards requirements

Proof of the pudding

- Testing against specification (Visure)
- Compliance to specification
- by design
- by type testing
- by QA test on an each and every basis
- Testing must be against agreed test protocols for functionality, where the test has been rationalised and is to traceable standards where necessary

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Validation

Clinical unit validation

What is validation

- "Validation. The assurance that a product, service, or system meets the needs of the customer and other identified stakeholders. It often involves acceptance and suitability with external customers. Contrast with *verification*."
- Formal supervised testing of the final product under defined operating conditions

"Have we done the right thing?"

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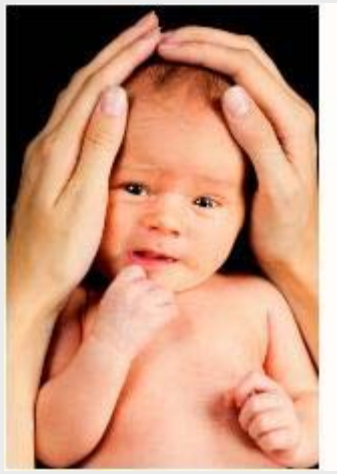
The Use of Prototypes



Clinical unit validation

Proof of the pudding

- Testing should cover the user requirements for performance and prove that the product meets the defined market requirements
- Additional information may be gained by consideration of exceptional use and miss-use in order to satisfy consideration of Human Factors outside of validation testing
- Validation test protocols should be in accordance with the output needed for the regulatory requirements such as CE or FDA submissions

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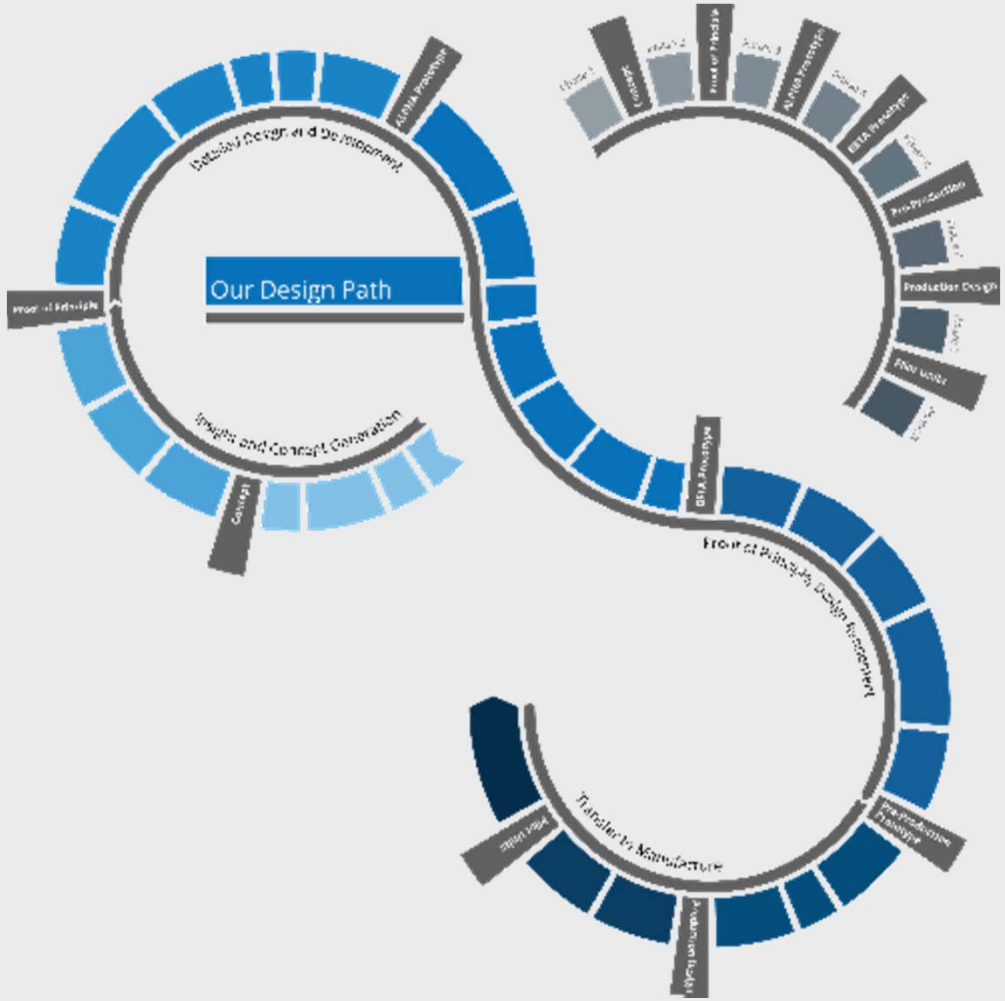
Risk reduction within the process

- Concept
- Proof of Principle
- Alpha phase
- Beta phase
- Pre-production phase
- Clinical evaluation
- Regulatory
- Transfer to manufacture



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What is a Prototype ?

- A prototype is a unit designed to meet a need within the development pathway. It might answer specific questions about
  - usability,
  - functionality
  - ergonomics
  - technical challenges

- A prototype may be designed to meet a business plan requirement. It might provide specific input to
  - Investment (internal, external)
  - goals for funding
  - marketing

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Prototypes within the Process

Where Prototypes fit into the process ?

- Prototypes for market evaluation
  - Models
  - Mock-ups
  - Conviction kits
- Prototypes for technology evaluation
  - Breadboards
  - Proof of principle units
  - Risk reduction units
  - Alpha prototypes
  - Beta prototypes
- Prototypes for proof of manufacturability
  - Pre-production units
  - Units for regulatory approval
  - Pilot manufacture

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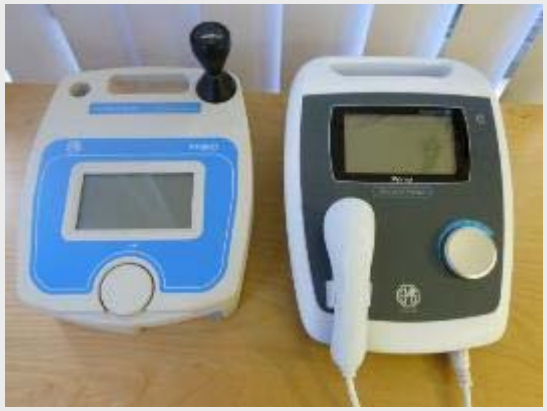
Design Review

What's the purpose of Design review?

- Keeping development on track
- Accommodating change
- Communication design evolution
- Proving QA controlled design processes
- Requirements of the MDD and FDA (documentation of input and outputs for a design review)



Where does it fit into the process ?

- Design review at each stage as closure on a phase
- Acts as a gateway and trigger point to the next phase of a project

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ISO 13485

Defines the processes required to control medical device development and manufacture:

- Design input (specifications)
- Design review
- Document management and change control
- V&V
- Risk management

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ISO 14971

Sets out the requirements for risk management for medical devices

- Establish a risk management framework
- Perform a risk analysis for each device
- Evaluate risk for each hazardous situation
- Develop risk control measures
- Evaluate overall residual risk
- Monitor during production and post-market

Likelihood and impact matrix

FMEA

Risk register

Usability

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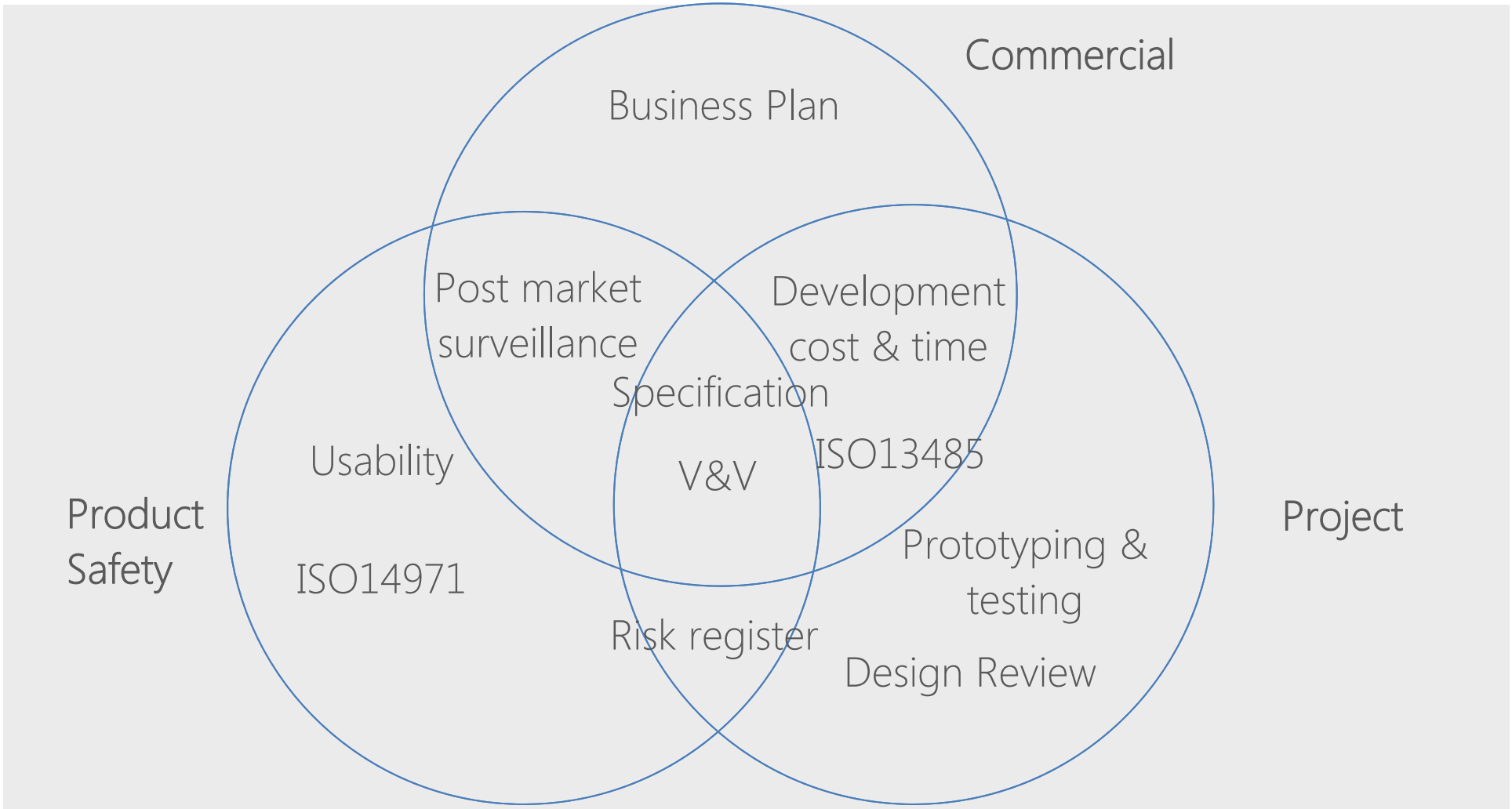
Medical Device Risk Factors



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