Medical Device Risk Factors

- Business Plan
- Development cost & time
- Specification
- ISO13485
- Prototyping & testing
- Design Review
- Risk register
- V&V
- Usability
- ISO14971
- Post market surveillance

Commercial

Product Safety

Project
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
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
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
Validation & verification – V Model
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?”
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
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?”
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
Risk reduction within the process

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