Medical Device design & development process

MedConnect North

11th October 2023

Oliver Sowerby, Head of Surgical Technologies

Who are Team Consulting?

Team Consulting is Europe’s largest medical device development consultancy (fee for service business).

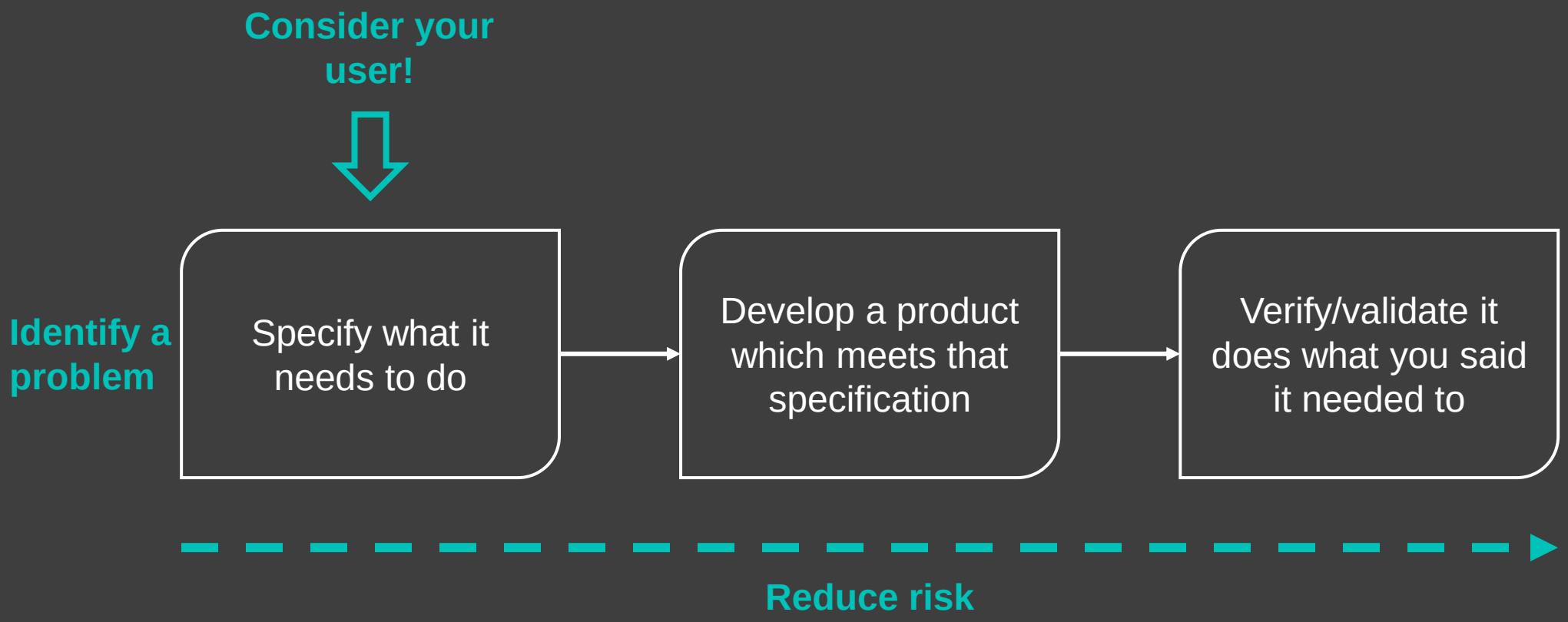
We combine user-centred design with engineering excellence to deliver medical devices that delight end users and meet unmet market needs.

- Founded in 1986 – In Cambridge, UK
- 150+ employees
- 100 % medical focus
- 100 % employee owned
- ISO 13485:2016 certified QMS

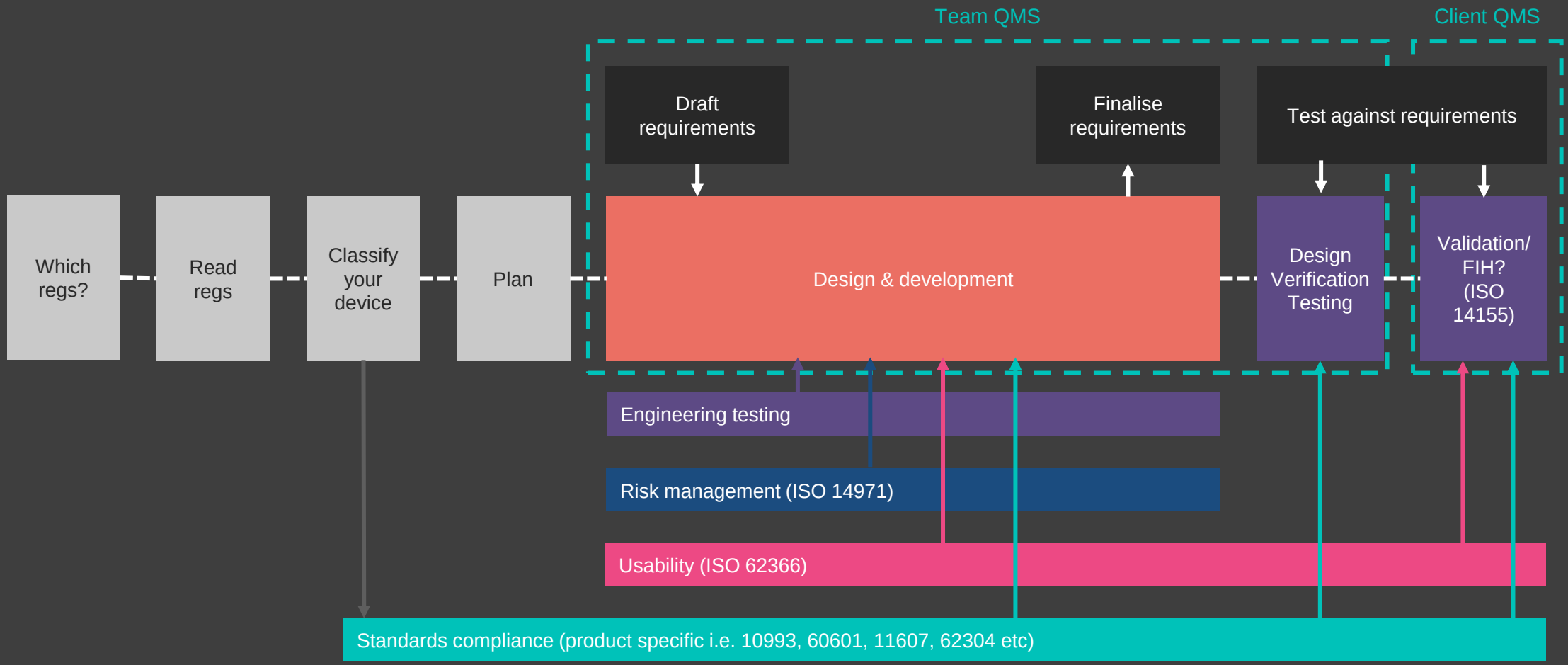
User-centred | Engineering excellence | Regulatory compliance

Some of our work

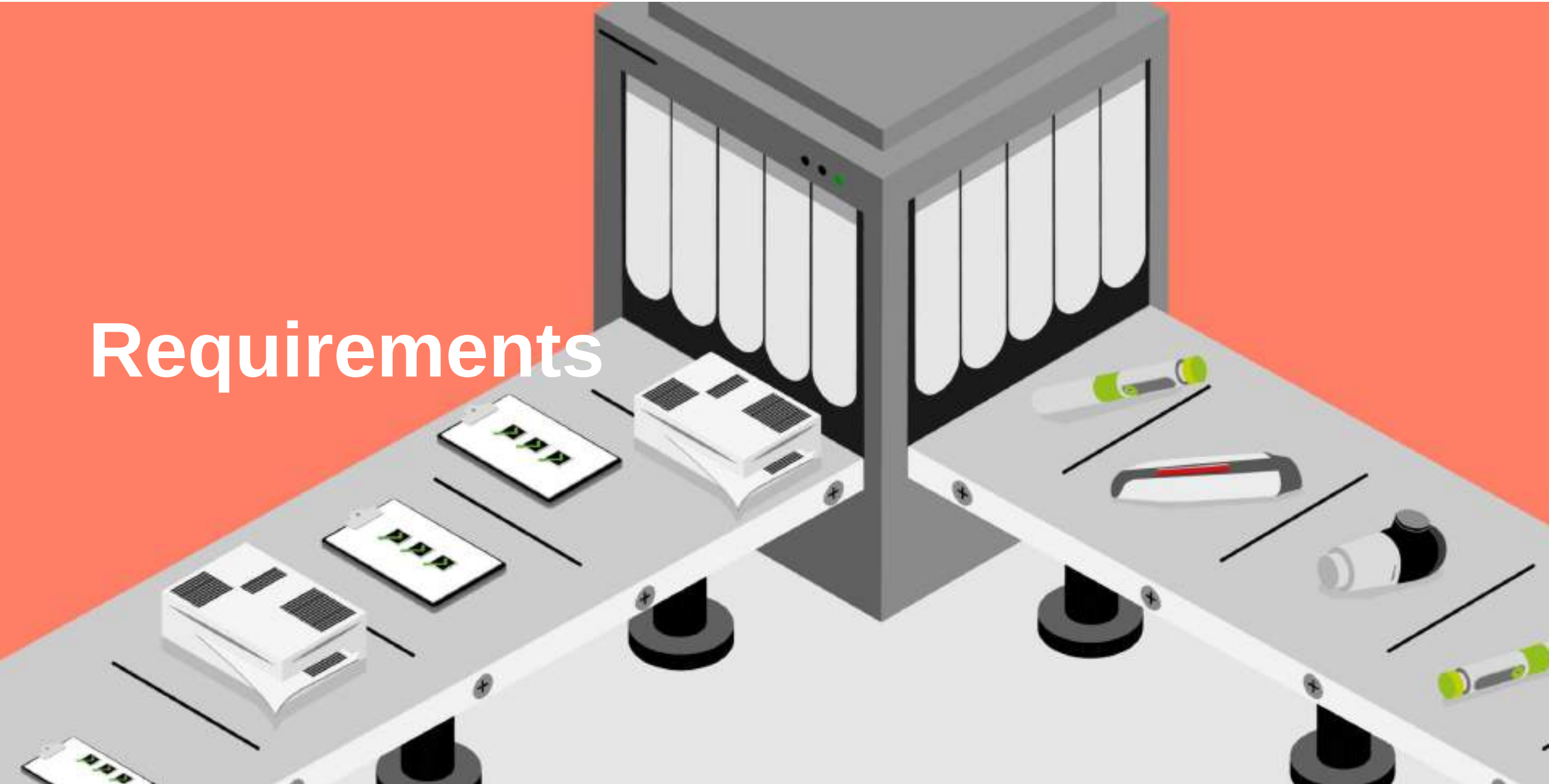
Good product design (simplified)



Medical device development overview



Requirements



The user should be at the centre of any product development. Defining what they need and feeding that into the device design is key to success.

Requirements definition enables this.

Product requirements

V

Verification

Your Design Inputs meet your Design Outputs. Your device functions correctly.

&

User requirements

V

Validation

You have designed the right device. Your device meets its intended users' needs.

An example set of requirements

User Requirement:
(URS)

The user **shall** be able to easily remove the cap from the device

Product Requirement:
(PRS)

The cap **shall** be removable from the device by a force no lower than 5N and no greater than 10N

Validation test specification:

User study shows that a user can easily remove the cap from the device

Verification test specification:

Attach a force meter to the device cap and record the removal force. The removal force must be between 5 and 10N

Standards Compliance

You must comply with regulations. They will guide you through your development and give you the best chance of getting your device past regulators

Standards compliance enables this.

“In essence, a standard is an agreed way of doing something. It could be about making a product, managing a process, delivering a service or supplying materials – standards can cover a huge range of activities undertaken by organizations and used by their customers.

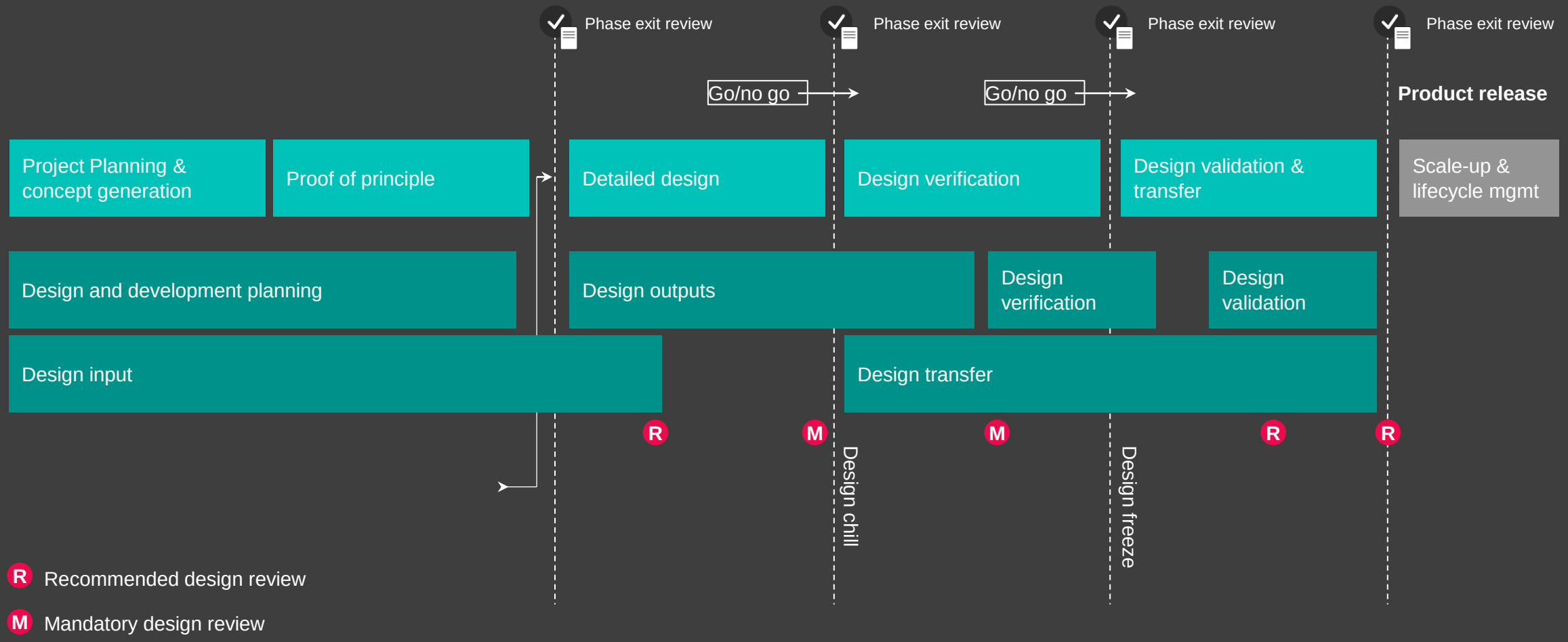
Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators.

Standards are knowledge. They are powerful tools that can help drive innovation and increase productivity. They can make organizations more successful and people’s everyday lives easier, safer and healthier.”

https://www.bsigroup.com/en-GB/standards/Information-about-standards/what-is-a-standard/

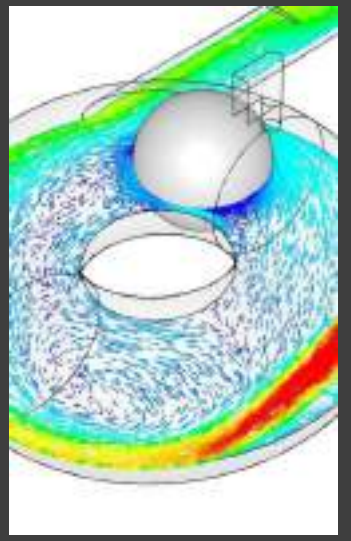
Design & Development

Team's D&D procedure is compliant with ISO 13485:2016 & FDA QSR 820.30 Design Controls



Development phases



0 Opportunity Discovery

1 Concept Generation

Are they feasible? How quickly can we find out?

i.e. no show stoppers

2 Proof of Principle

Reduce development risks and check potential of designs to meet draft requirements

3 Detailed Design

Optimise and refine the design and get ready for manufacture.

4 Pilot Manufacture & DVT

Produce devices from pilot manufacturing systems and verify that they meet requirements.

5 Industrialization

Make devices ready for sale.

Phase Descriptions

1 → 2 → 3 → 4 → 5

1 Concept Generation

A fast-paced phase to try and prove the feasibility of technology as quickly as possible.

Could be a combination of “looks-like” models and “works-like” rigs.

2 Proof of Principle

Documentation will be created to align the device development with our 13485-accredited QMS ensuring compliance with necessary regulations.

A functional set of prototypes will be produced, and performance will be characterised against draft Product and User Requirements Specifications.

A formative user study will be undertaken to evaluate the device design with end users.

3 Detailed Design

The aim of this phase is to take the Proof of Principal design and turn it into a medical device which is:

- Designed to be manufactured using the processes required for launch to market
- Optimised to meet final specifications from the Product Requirements Specification (PRS)
- De-risked so that all outstanding device risks are at an acceptable level
- Compliant with all necessary standards

Significant documentation will be required as part of this phase to ensure compliance with Team’s QMS and necessary regulations.

4 Pilot Manufacture & DVT

Pilot manufacturing will produce complete devices for Design Verification Testing.

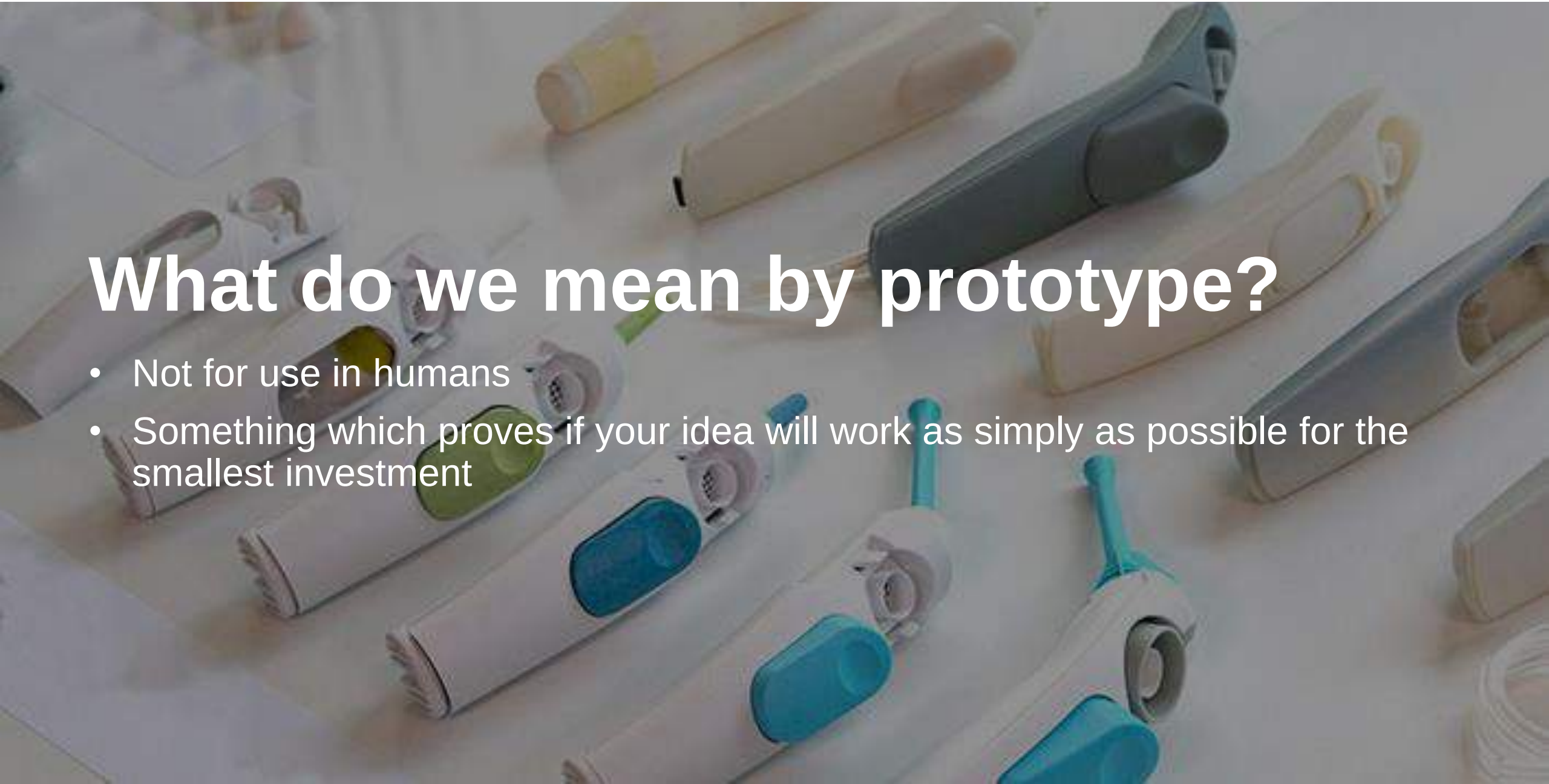
Design Verification will formally verify that design outputs meet specified design inputs.

Our device testing experts will develop validated test methods and verification protocols prior to executing and reporting on Design Verification Testing.

5 Industrialization / validation

Team will support with transfer to a selected manufacturing partner(s).

Validation (if required) will be completed by Team’s Human Factors experts.



What do we mean by prototype?

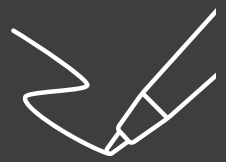
- Not for use in humans
- Something which proves if your idea will work as simply as possible for the smallest investment

Ways to prototype

Method	Rapid prototyping	Skilled manufacture	DIY
Skills required	• CAD • specialist supplier • specialist material engineering/design knowledge	• 2D drawing or 3D CAD • Engineering knowledge	• Your hands • Useful materials
Cost	**££**	**£££**	**£**
Leadtime	**Days – weeks**	**Weeks – months**	**Days**
Pros	• High fidelity • Fast • Can make anything • Huge variety of materials	• Reduces risk for future manufacturing • Material properties are great • Requires high skill to achieve	• Rapid • Low cost
Cons	• Does not require manufacturing knowledge • Can be expensive • Limited material properties	• Long lead time for low volume • Process constrained	• Not representative of final design • Rough

Top tips

1 - Sketch!



Don’t dive straight into CAD. Sketch your idea. It’s faster and makes you think.

2 - Focus

Concentrate on the key problem to solve. Forget anything not critical to the main function

3 - Get physical, early

Prototype and get things in your hands once ideas are feasible

4 - Be open to review

Get feedback on your concepts. Review the design with colleagues. Don’t be afraid and be respectful!

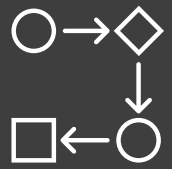
5 - Adapt

If the plan isn’t working – change it. If the concept is dead, move on.

6 - Collaborate

Don’t try and solve every problem alone.

7 - Test, iterate



Don’t try and get it perfect straight away. Build and test your ideas. Iterate and refine.

8 - 80/20

You can prove 80% of a concept in 20% of time. Design to the right level of detail.

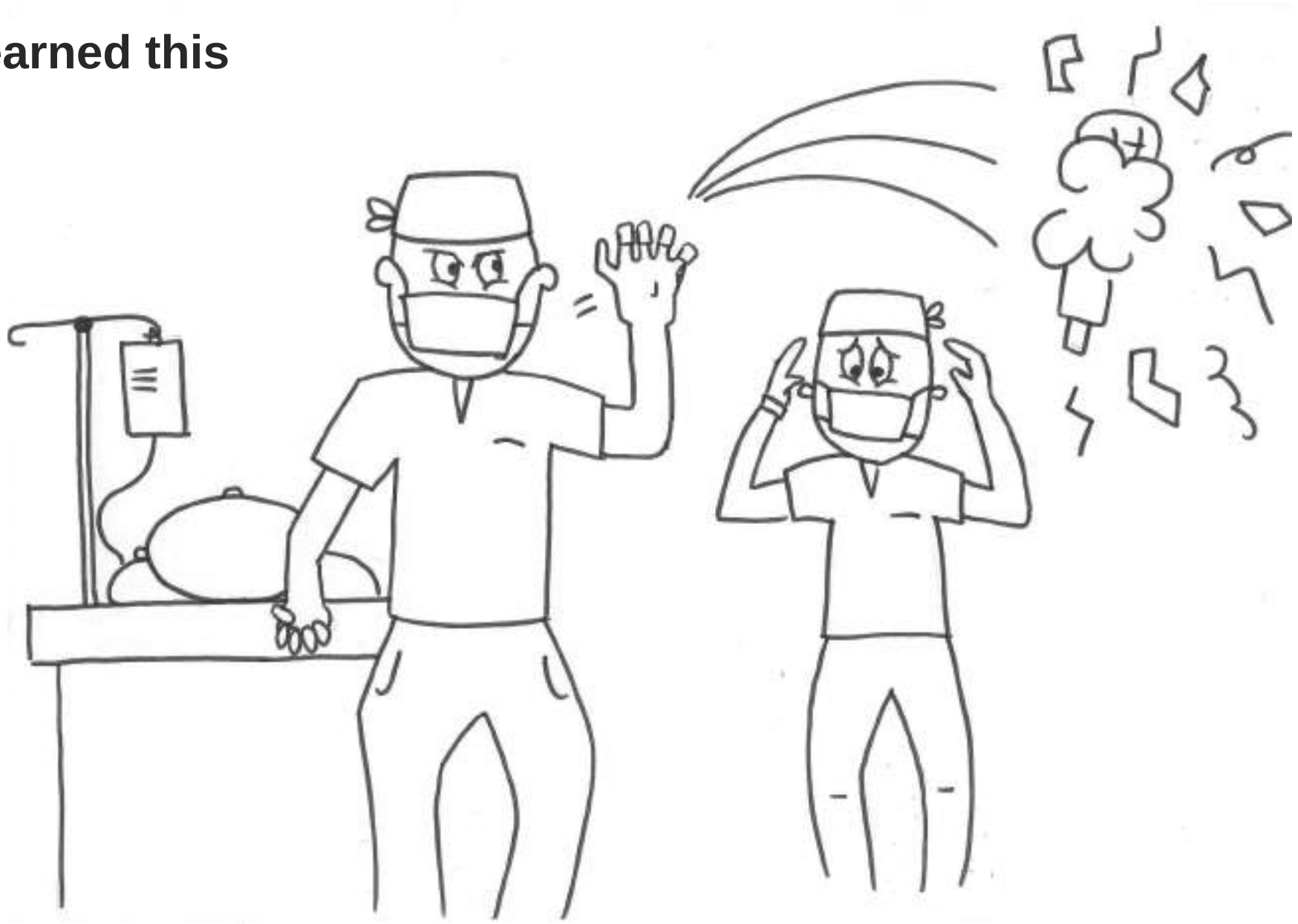
Appendix

Usability

Medical devices must be usable.

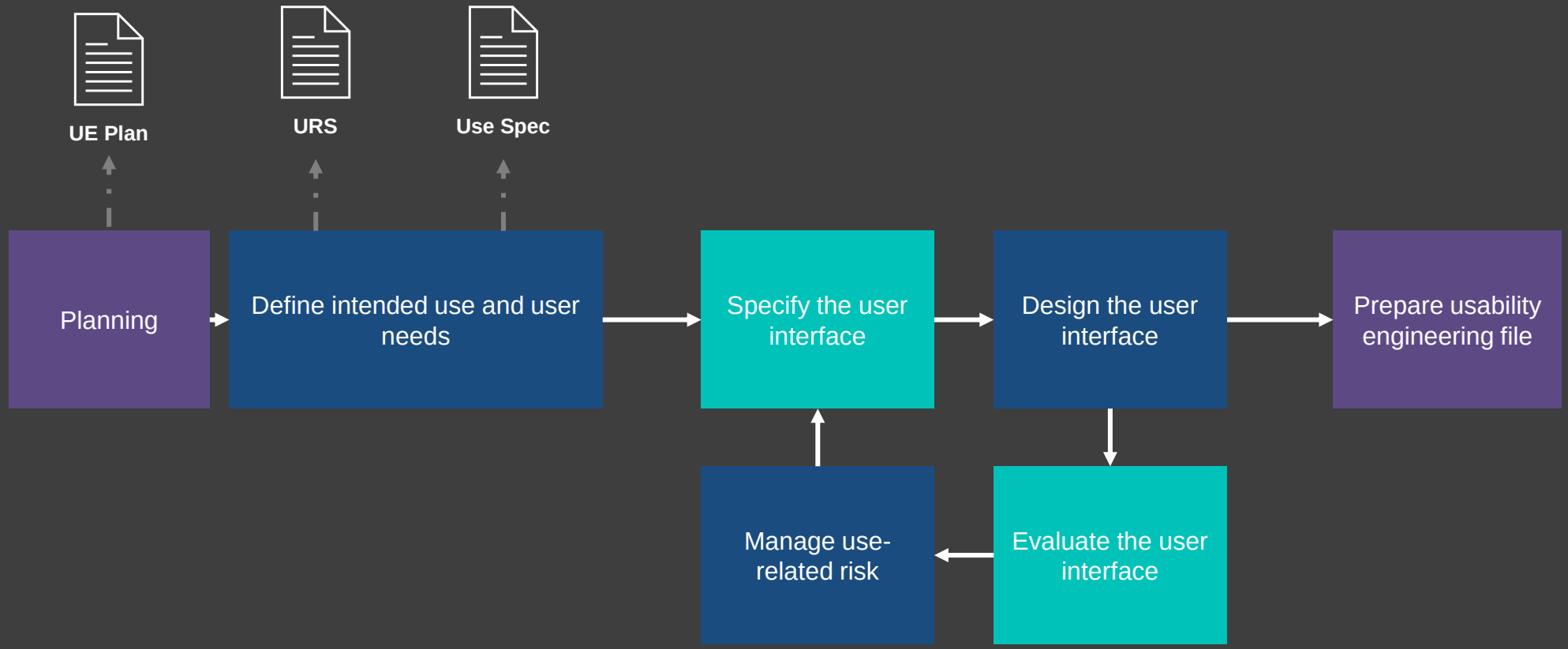
Human Factors Engineering is the science of ensuring medical devices can be used effectively by their intended users.

How I learned this



Risk management

Simplified Process (from ISO 62366)



Risk Management

Medical devices must be safe.

Risk Management is the best method to apply to ensure your device is.

Risk management

Simplified Process (from ISO 14971)

RM Plan

Hazard ID

D/UFMEAs

Planning → Identify Hazards associated with use of device → Estimate and evaluate risks → Determine risk acceptability → Monitoring

Estimate and evaluate risks ⇄ Eliminate and/or control risks