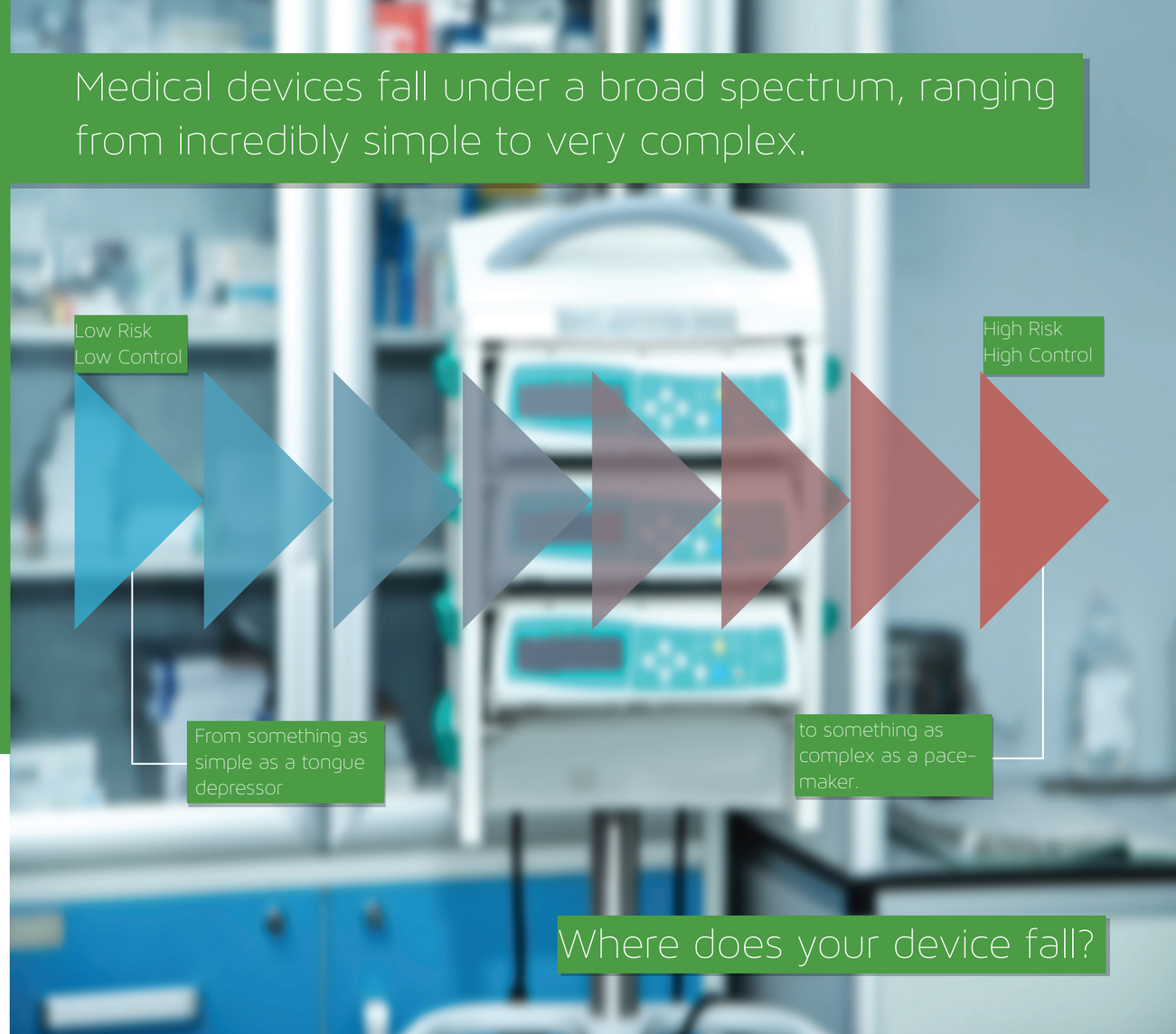
Springmatter | FDA Regulated Products

Turns out that idea you've been cultivating is a medical device... Now what?

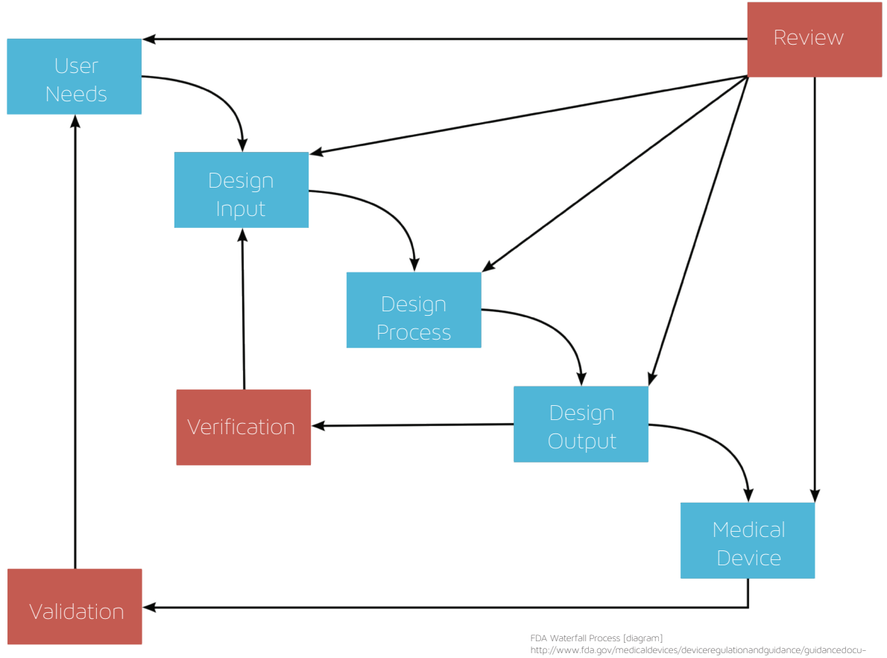
By definition, if your idea has clinical utility then it is a medical device and is subject to FDA regulation.

Have you considered a regulatory pathway?

Medical devices fall under a broad spectrum, ranging from incredibly simple to very complex.



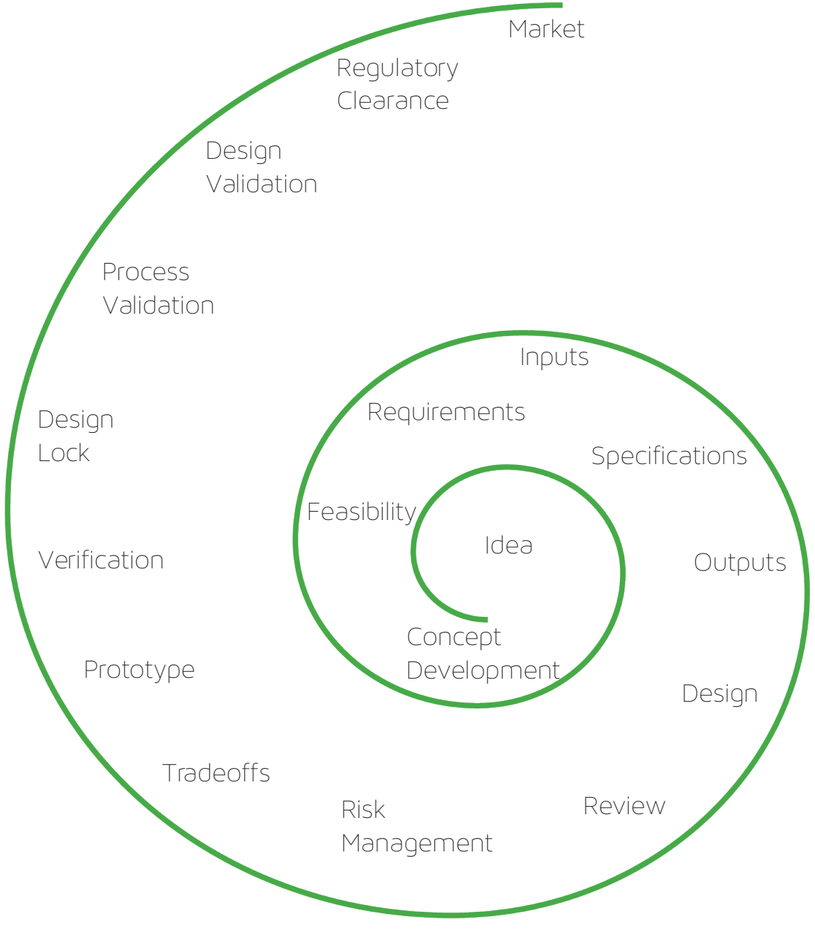
Where does your device fall?



FDA Waterfall Process [diagram]
http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070627.htm

The FDA depicts design controls using the waterfall process and expects to see a linear path to completion.

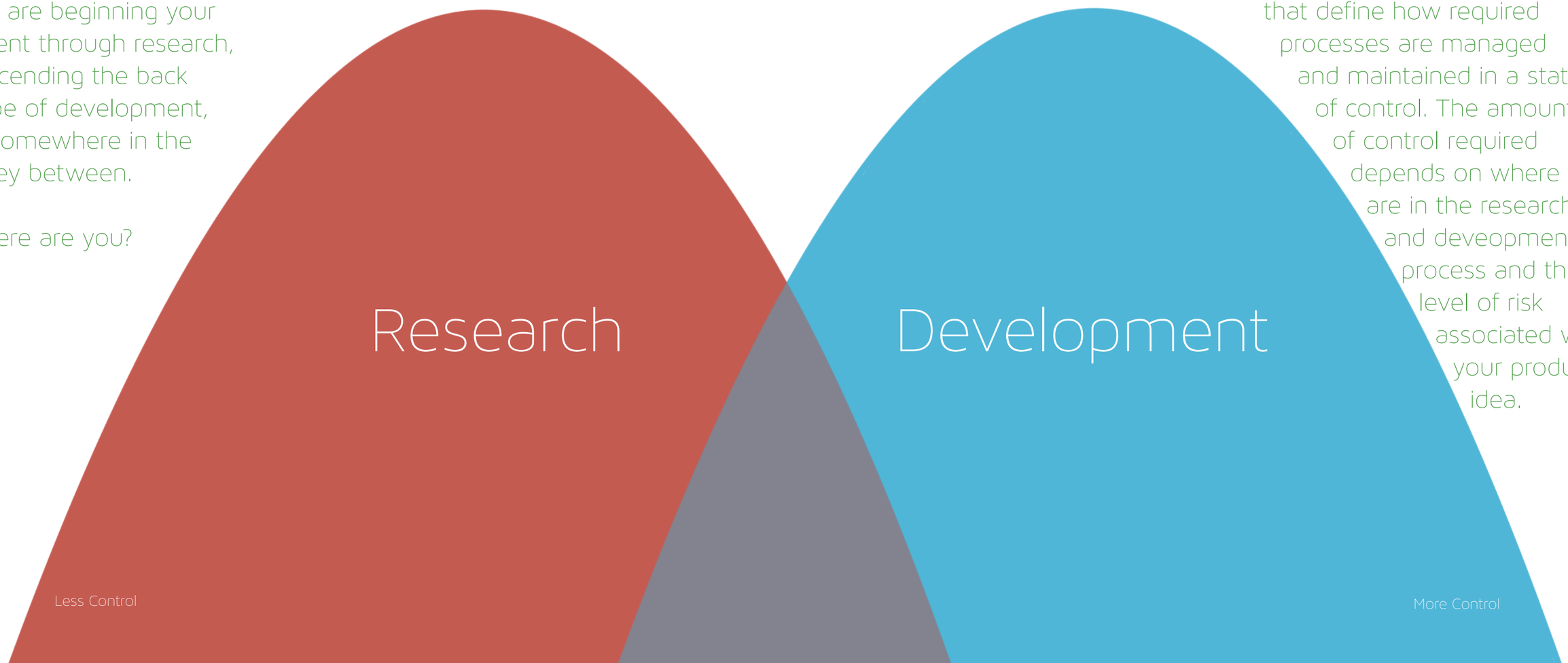
Designers realize that product development is cyclical, consisting of a series of failures and tradeoffs followed finally by success, but it need not spiral out of control.



[Adapted from Barry W. Boehm, "A Spiral Model of Software Development and Enhancement", Computer, vol.21, no. 5, pp. 61–72, May 1988, doi:10.1109/2.59]

The level of control required depends on whether you are beginning your ascent through research, descending the back slope of development, or somewhere in the valley between.

Where are you?



A quality management system is a system of procedures that define how required processes are managed and maintained in a state of control. The amount of control required depends on where you are in the research and deveopment process and the level of risk associated with your product idea.

We will help determine where you are.
We will help develop a path to where you need to go.
We will help get you there!

Along with design and development assistance in the areas of electrical, mechanical, optical, and software engineering, we will also provide assistance in project management, document preparation and remediation, QMS implementation, and regulatory compliance.

Our team specializes in developing and implementing Quality Management Systems and has experience leading 'ground-up' QMS implementation efforts through ISO certification for numerous companies. With particular expertise in Design Controls (regulated new product introduction for FDA approval), our Director of Operations has been directly involved with bringing more than 50 products to market.

Contact us today to see how we will implement the proper levels of control to streamline your business.

Organic. Sustainable. Meaningful.

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