Regulations and Standards

Why you do it

This document will help your team:

- Determine how to address regulatory requirements (such as environmental regulations, or FDA approval) that may impact the development and launch of the device.
- Determine which standards are applicable to your product, and plan how your product will meet them.

Engineering Standards and Regulatory Requirements

There is an important distinction between regulations and standards that are used in product development. According to the International Organization for Standardization (ISO - www.iso.org), a standard is:

A document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

And a regulation is:

A document providing binding legislative rules, that is adopted by an authority.

Regulations may include compliance to certain standards, but regulations are not standards themselves. For example, the FDA provides regulations that govern the sale and use of medical devices in the United States. Many of those regulations include compliance to certain standards developed by the ISO.

For your product, please describe both pertinent **standards** and **regulations**. See the "Engineering Standards" section on Owlspace for more information about standards. These include:

FDA: http://www.fda.gov/cdrh/
IEEE: http://standards.ieee.org
ASME: https://www.asme.org/shop/standards
ASTM: http://www.astm.org/Standard/index.shtml
ISO: http://www.iso.org/iso/iso_catalogue.htm

Teams will fully research the regulatory requirements relevant to their project which they identified in the Design Foundation Document. The R&S document should detail how the team will address regulatory and/or standards requirements (or, in the case of designs that do not require regulatory approval or standards, provide detailed justification for this conclusion). For bioengineering projects, you will need to provide a plan for securing FDA approval. If your device will not require FDA approval, you must include a detailed justification for this conclusion.