

# Regulatory Issues

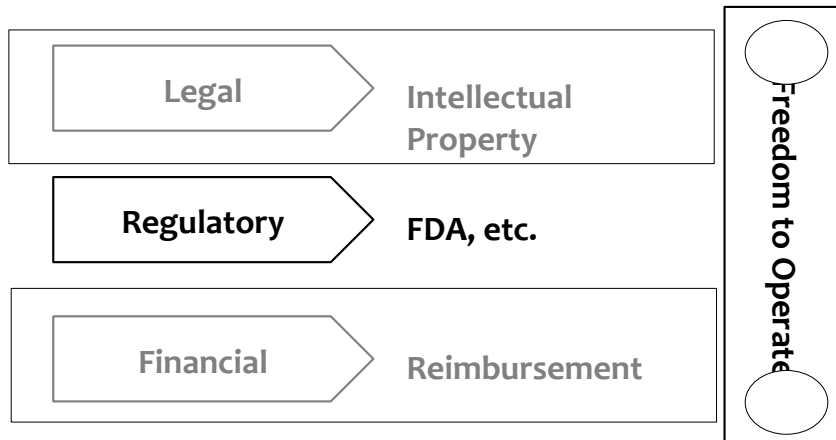
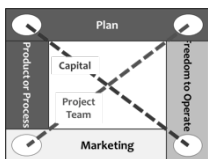


Bob Barnes and Marilyn Lombardi



1

## FTO – Legal, Regulatory, & Financial



2

## A Few References to Start

- \* USFDA Overview

<http://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM283299.pdf>

- \* US Food and Drug Administration

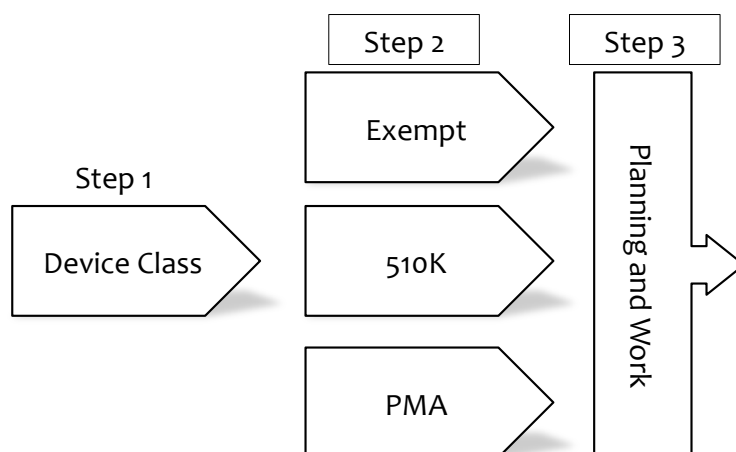
<http://en.wikipedia.org/wiki/FDA>

- \* Regulatory Basics

<http://www.stanford.edu/group/biodesign/cgi-bin/ebiodesign/index.php/concept-selection/regulatory-basics-menu>

3

## Medical Devices



4

# Device Classifications

		<u>Examples</u>
Class I	<ul style="list-style-type: none"> <li>Minimal prospective harm</li> <li>Simple design</li> </ul>	<ul style="list-style-type: none"> <li>Handheld instruments</li> <li>Gloves</li> </ul>
Class II	<ul style="list-style-type: none"> <li>Typically non-invasive</li> <li>More complicated</li> <li>Demonstrate no injury; no harm</li> </ul>	<ul style="list-style-type: none"> <li>Powered wheelchairs</li> <li>X-ray machines</li> </ul>
Class III	<ul style="list-style-type: none"> <li>Typically implantable</li> <li>Therapeutic; life sustaining</li> <li>Similar device does not exist</li> </ul>	<ul style="list-style-type: none"> <li>Pacemakers</li> <li>Breast implants</li> <li>Replacement heart valves</li> </ul>

5

## Class I

Class I	<ul style="list-style-type: none"> <li>Exempt - no predicate; no approval</li> <li>Register with FDA</li> <li>Comply with FDA labeling</li> <li>Quality system in place</li> </ul>
---------	--

6

## Class II

Class II

- Demonstrate similarity to an approved predicate device
- Meet Class I requirements
- Special controls
  - Labeling
  - Mandatory performance standards
  - Post-market surveillance

7

## Class III

Class III

- FDA Premarket Approval Process (PMA)
- All Class I and II requirements

**All Life Sustaining Products**

- **Large multi-location**
- **Statistically representative, randomized clinical trials**
- **Multi-year**
- **Panel review – all non-FDA employees (physicians, statisticians, and other experts)**

8

