

Engineering Design

BME 590L

Outline

- Revisiting Projects and Team Formation Process
- Design vs. other stuff
- Industry Trends and PDPs
- Course Overview

Projects

- Project [Listing](#)
- Project Preference Survey
 - Due by Friday midnight
 - Expectations for team formation

First, terminology:

Design

Research

Product Development

Technology Development

Business Development

What is the relationship of these terms? Are these terms inclusive/exclusive of each other? Are they sequential or dependant?

Design: A meta-discipline

“Engineers are not the only professional designers. Everyone designs who devises courses of action aimed at changing existing situations into preferred ones. The intellectual activity that produces material artifacts is no different fundamentally from the one that prescribes remedies for a sick patient or the one that devises a new sales plan for a company or a social welfare policy for a state. Design, so construed, is the core of all professional training; it is the principal mark that distinguishes the professions from the sciences. Schools of engineering, as well as schools of architecture, business, education, law, and medicine, are all centrally concerned with the process of design.”

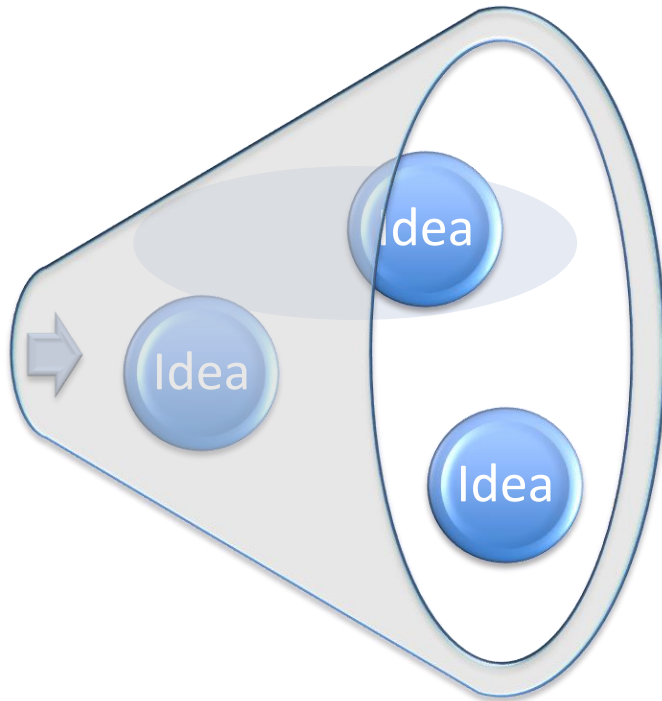
Herbert A. Simon

Engineering Design

“Engineering design is the process of devising a system, component, or process to meet desired needs.”

ABET

Design Thinking

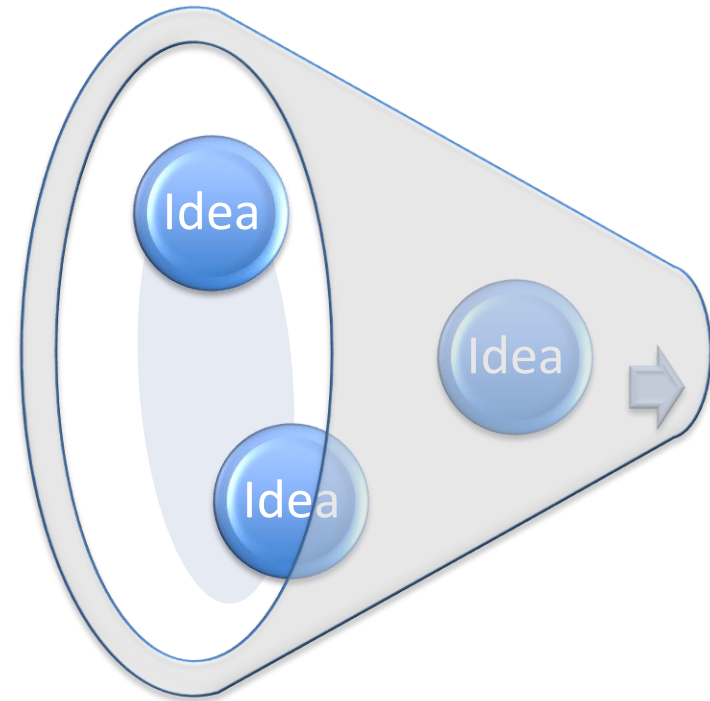


Divergent Thinking:

Asks: What is possible?

Looks for Possibilities

The more ideas the better!



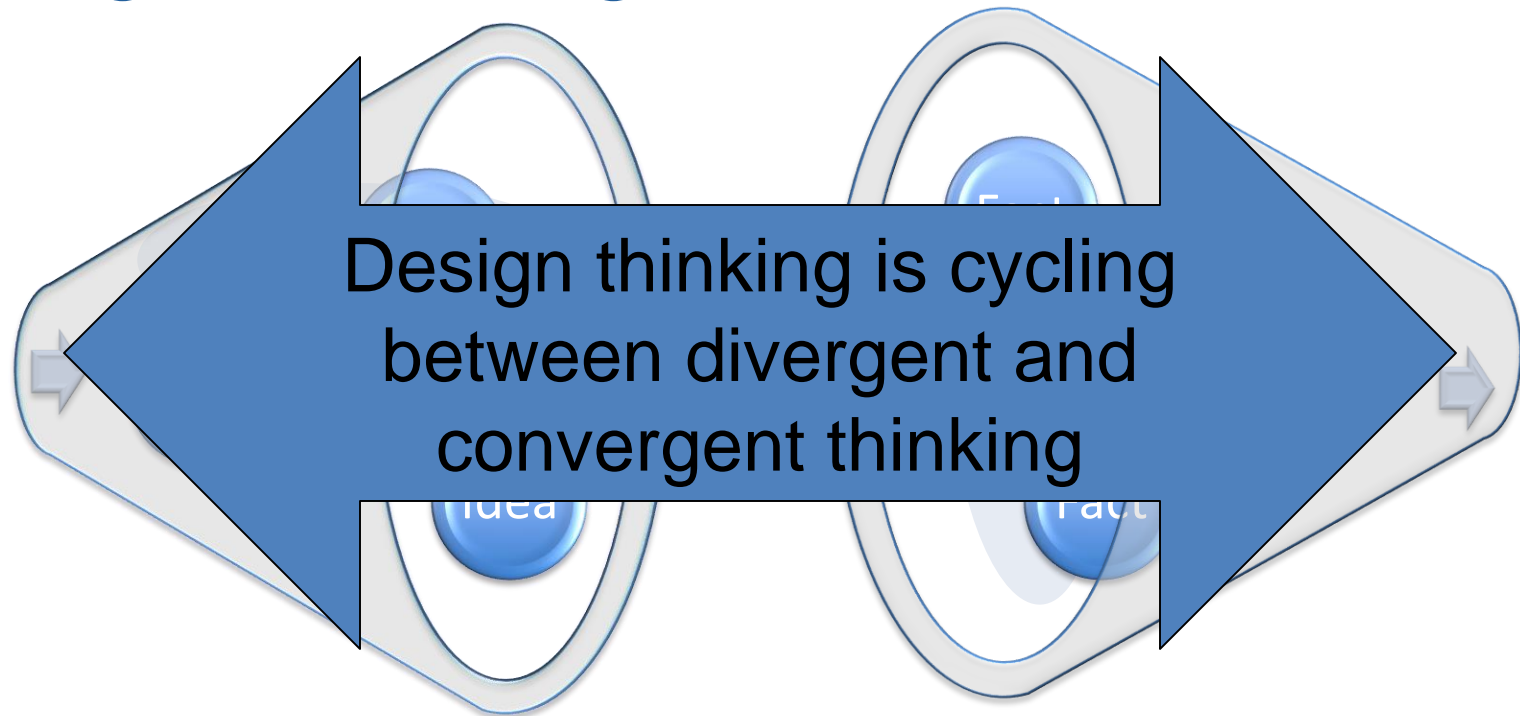
Convergent Thinking:

Asks: What is?

Looks for Fact

Most Common in Education

Design Thinking



Divergent Thinking:

*Asks: What is possible?
Looks for Possibilities
The more ideas the better!*

Convergent Thinking:

*Asks: What is?
Looks for Fact
Most Common in Education*

Design Thinking may be uncomfortable!

Common struggles/complaints:

- There is no single correct answer in design
- People feel they lack the background knowledge or skills to design
- Design thinking often does not fit neatly into one discipline

Do you have the skills of a designer?

Six Skills of Design Thinking

Thinking about
system
dynamics

Making
estimates

Reasoning
about
uncertainty

Conducting
experiments

Reverse
Engineering

Making design
decisions

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Six Skills of Design Thinking

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Making design
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Estimation practice

How many restaurants are there in Durham?

Reasoning about uncertainty

With what certainty can one predict the complete outcome of an NCAA basketball tournament bracket?

Rev. Engineering Practice

Option 1: Reverse engineer your pen by careful observation (and disassembly if you dare!). How do you think it's components were made? Why was it designed this way?

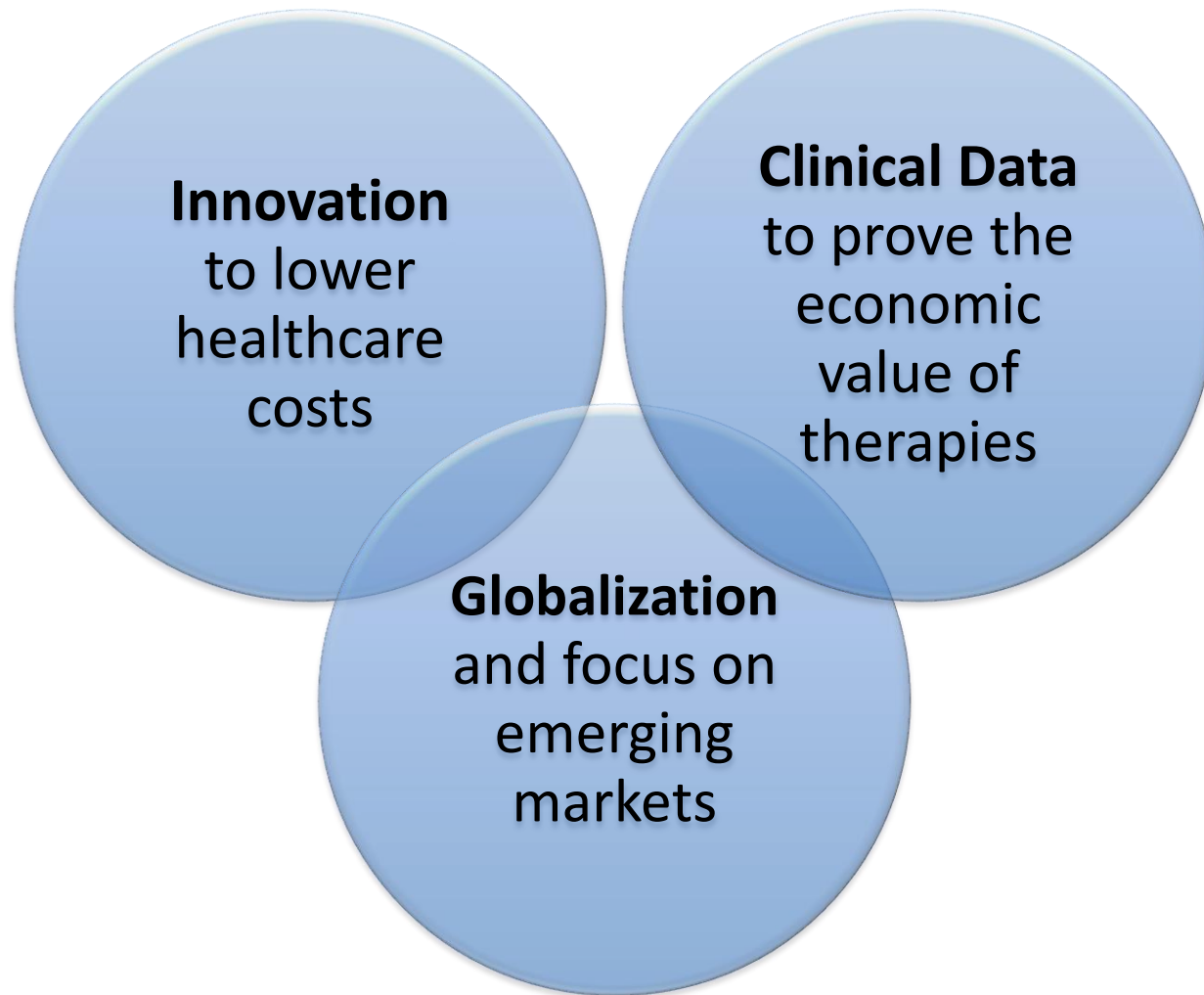


Option 2: Reverse engineer your chair by careful observation (no disassembly). How do you think it's components were made? Why was it designed this way?



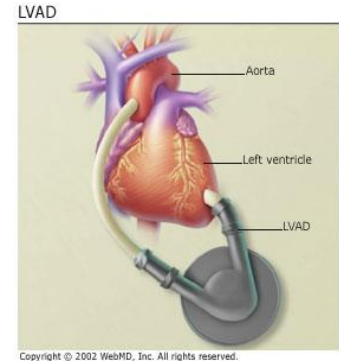
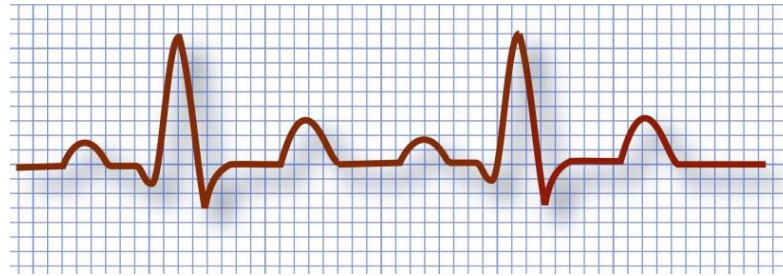
Design is need-driven, not
technology driven.

Major Industry Trends



1. www.emergogroup.com/files/2012-medical-device-industry-survey.pdf
2. <http://annualreport.medtronic.com/2013/index.htm>
3. Ernst and Young Pulse of the Industry: Medtech 2012

The Continuum of Care



Increased Cost of intervention

The Convergence of Industries

Biomedical
Informatics and IT



Medical Devices
and Diagnostics

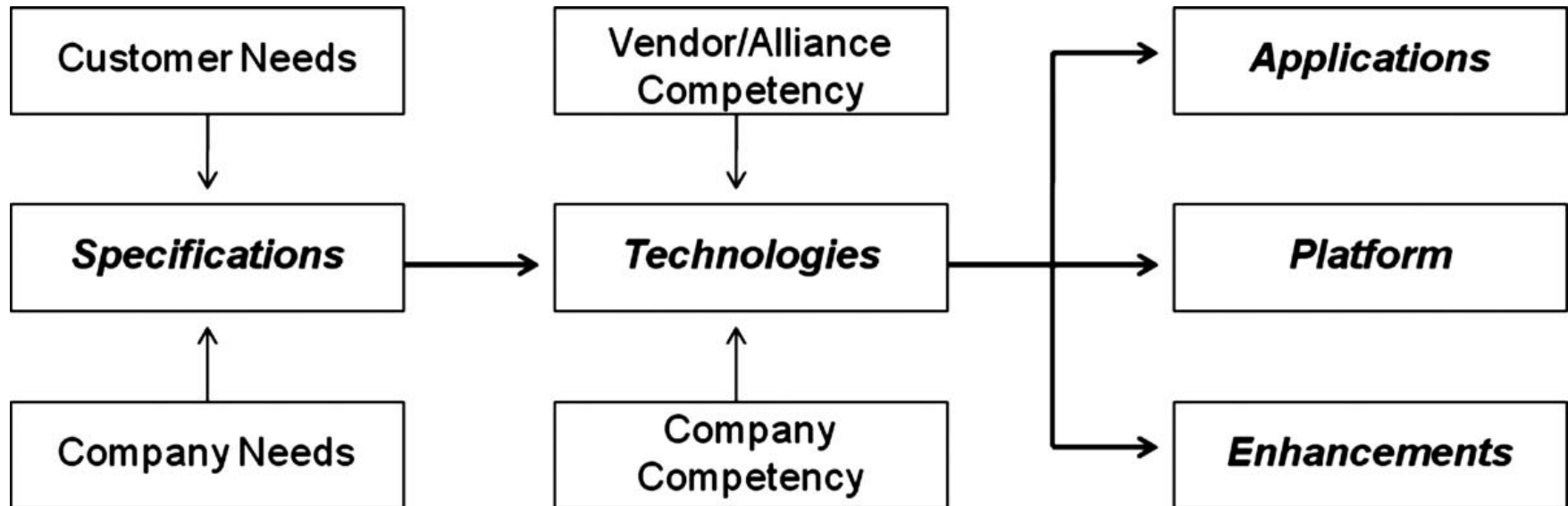
Drugs and
Biologics



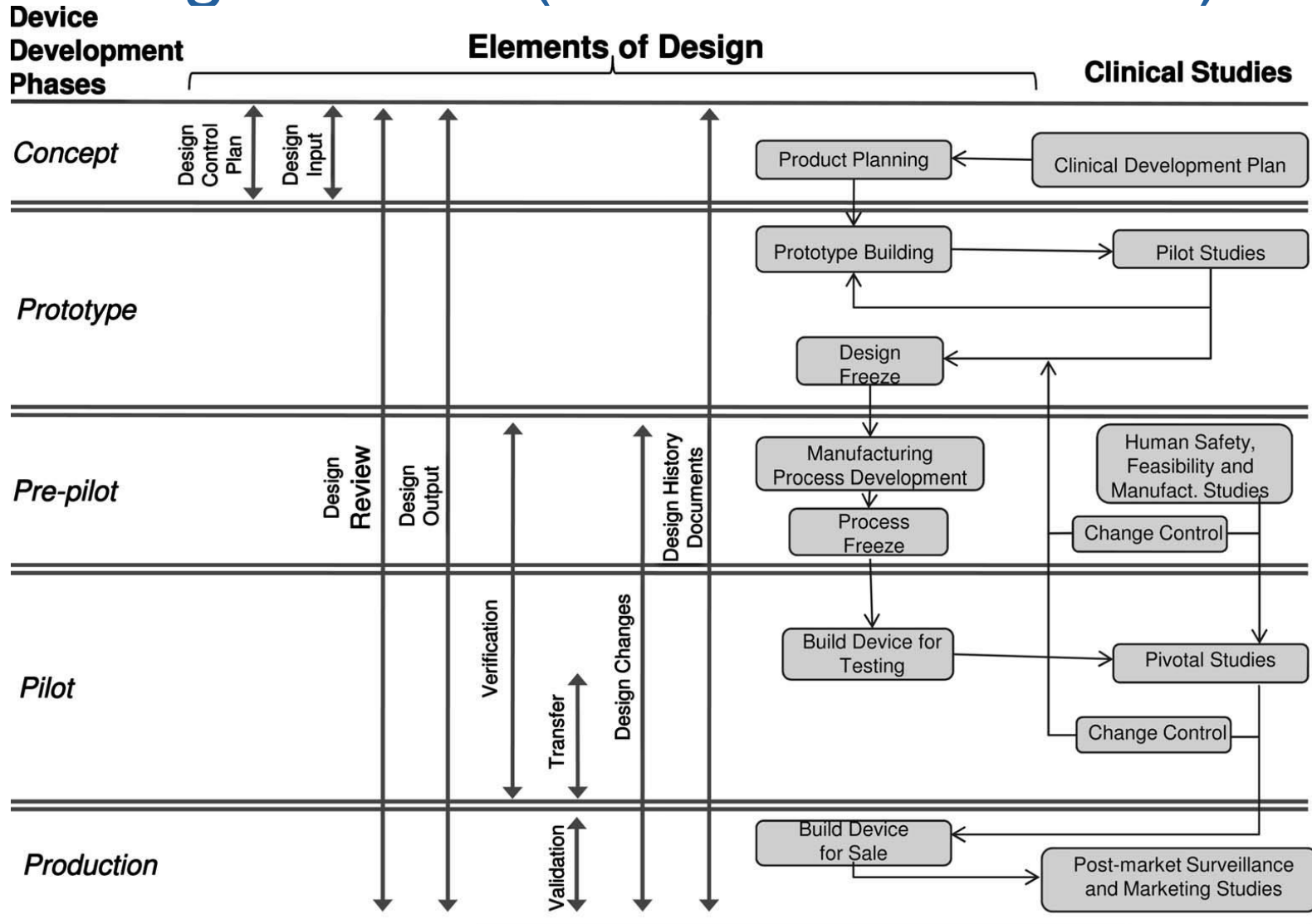
Needs are put into a Product Development Process (PDP)

- Why is a PDP needed?
 - Establishes a language for a “highly complex process”
 - Sets up a process that can be optimized
 - Captures and distributes tribal knowledge
 - It’s required! (FDA, ISO, etc.)

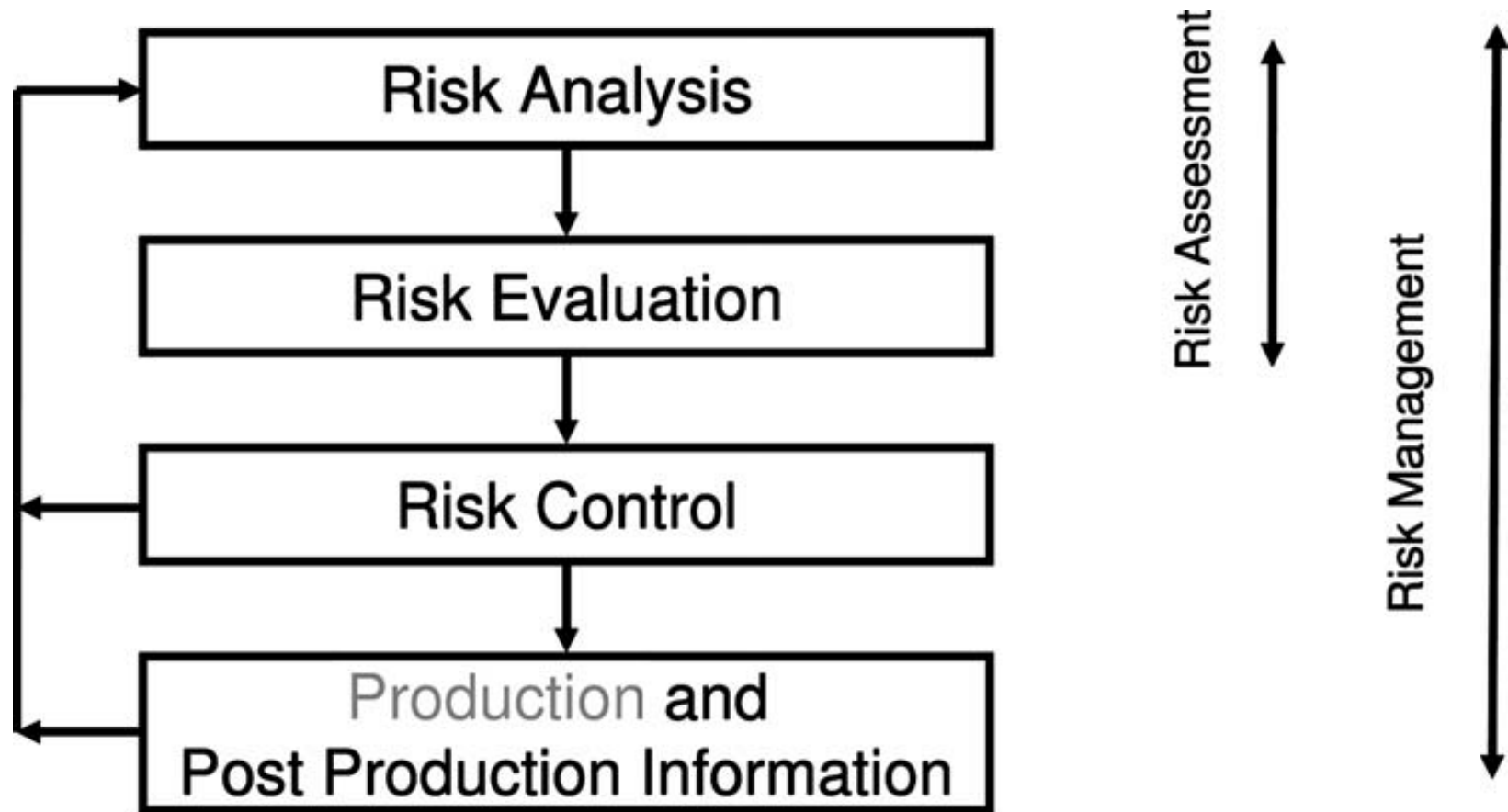
Existing Models (from Pietsch 2009)



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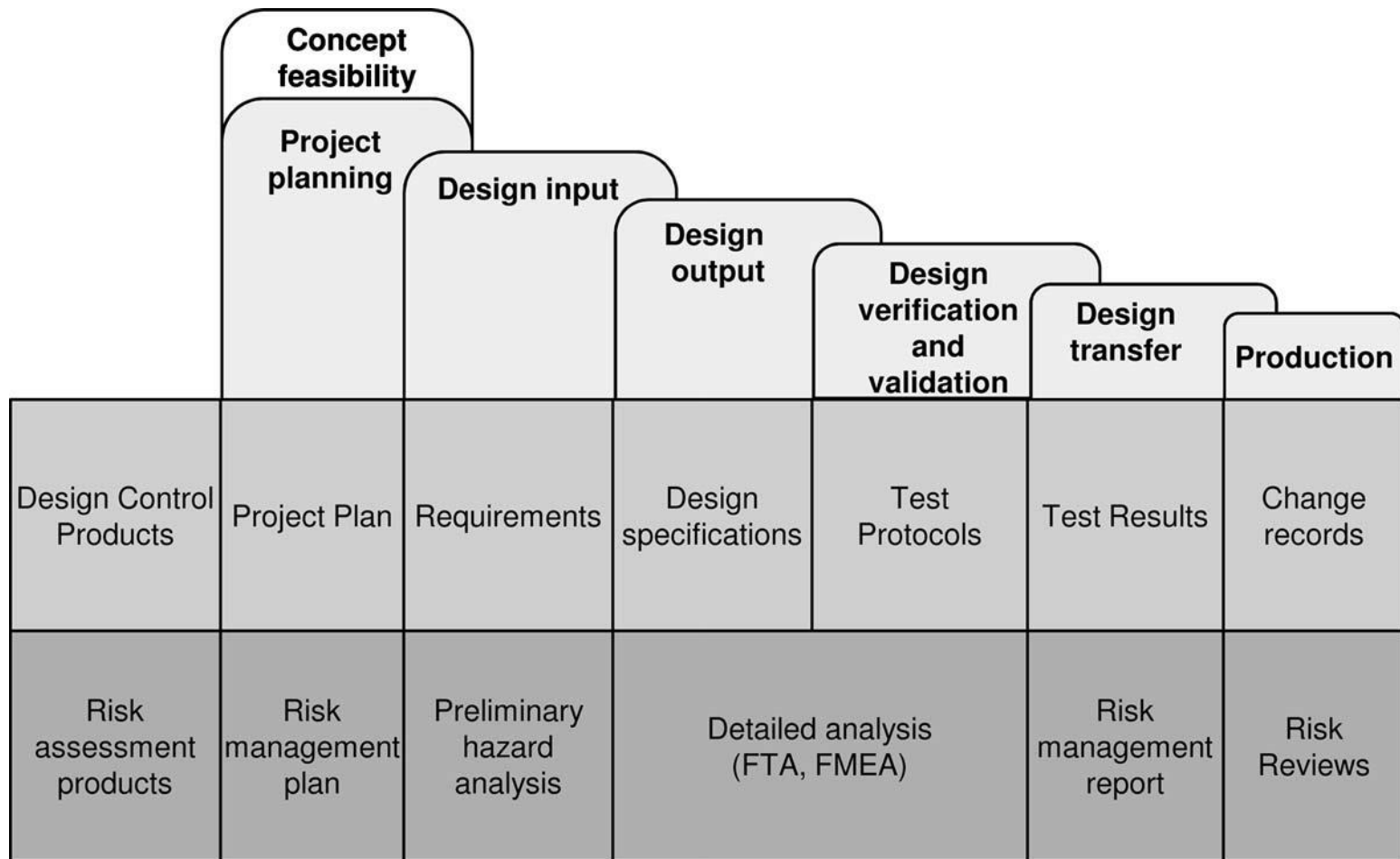


Existing Models (from Pietsch 2009)

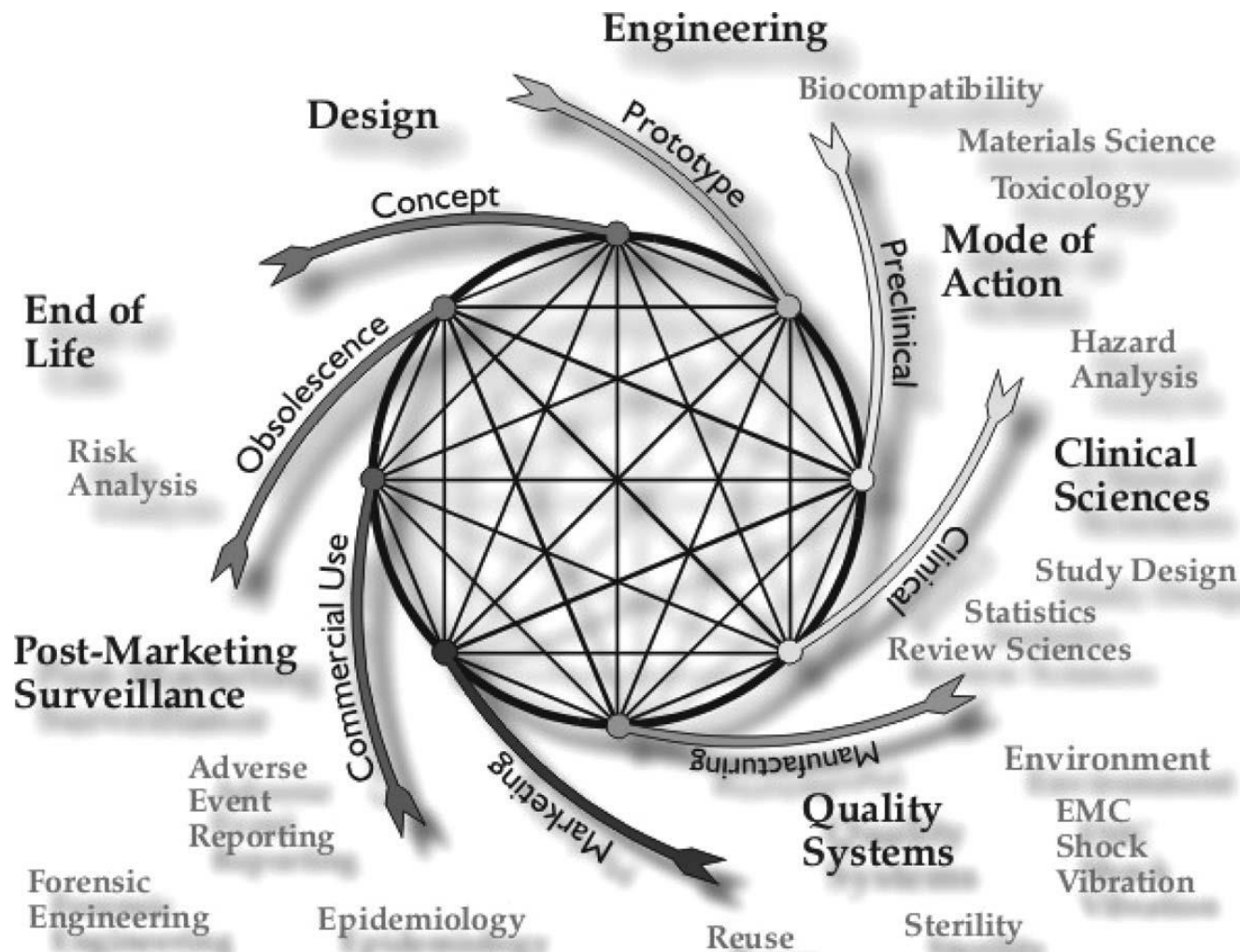


ANSI/AAMI/ISO 14971:2000

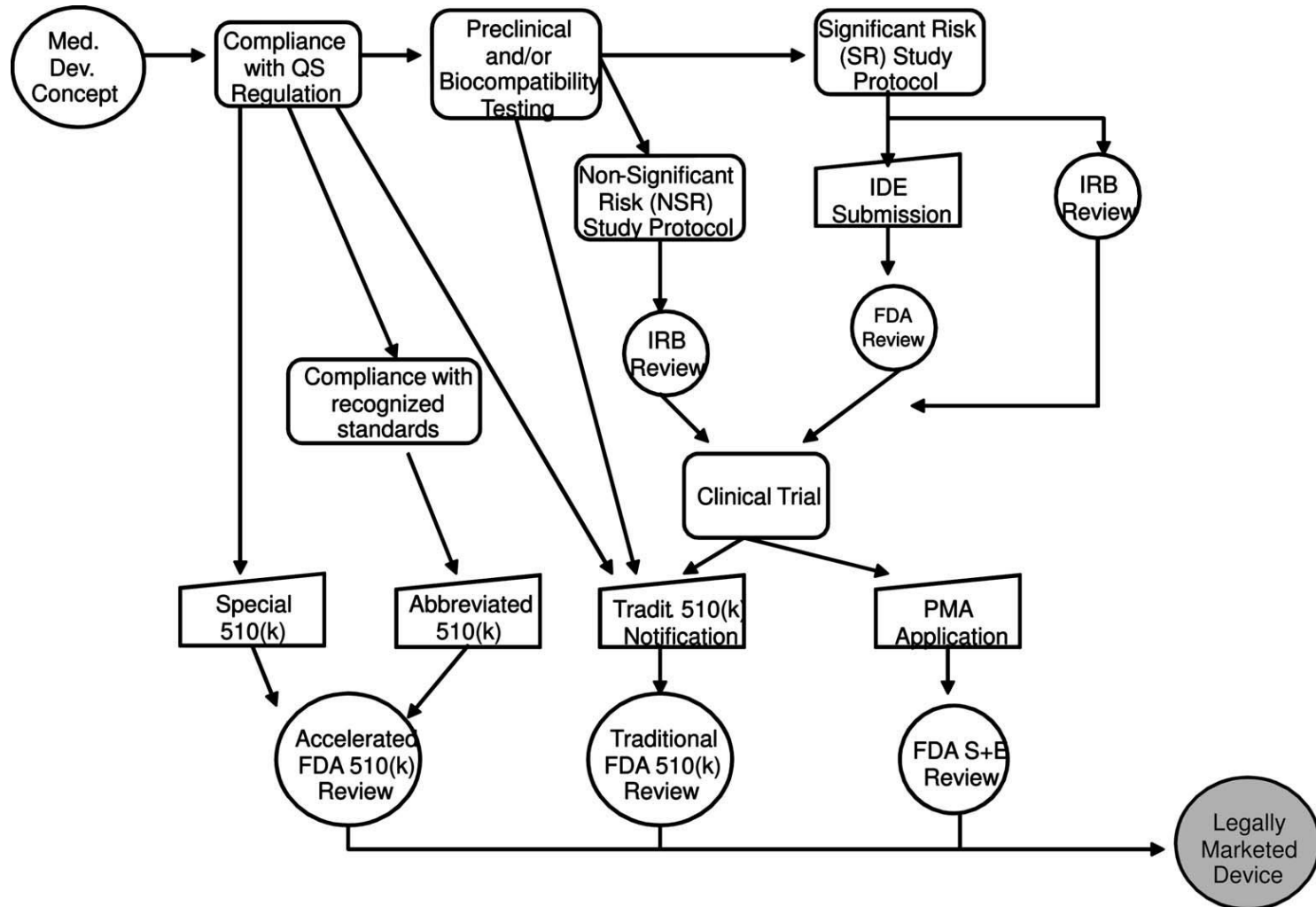
Existing Models (from Pietsch 2009)



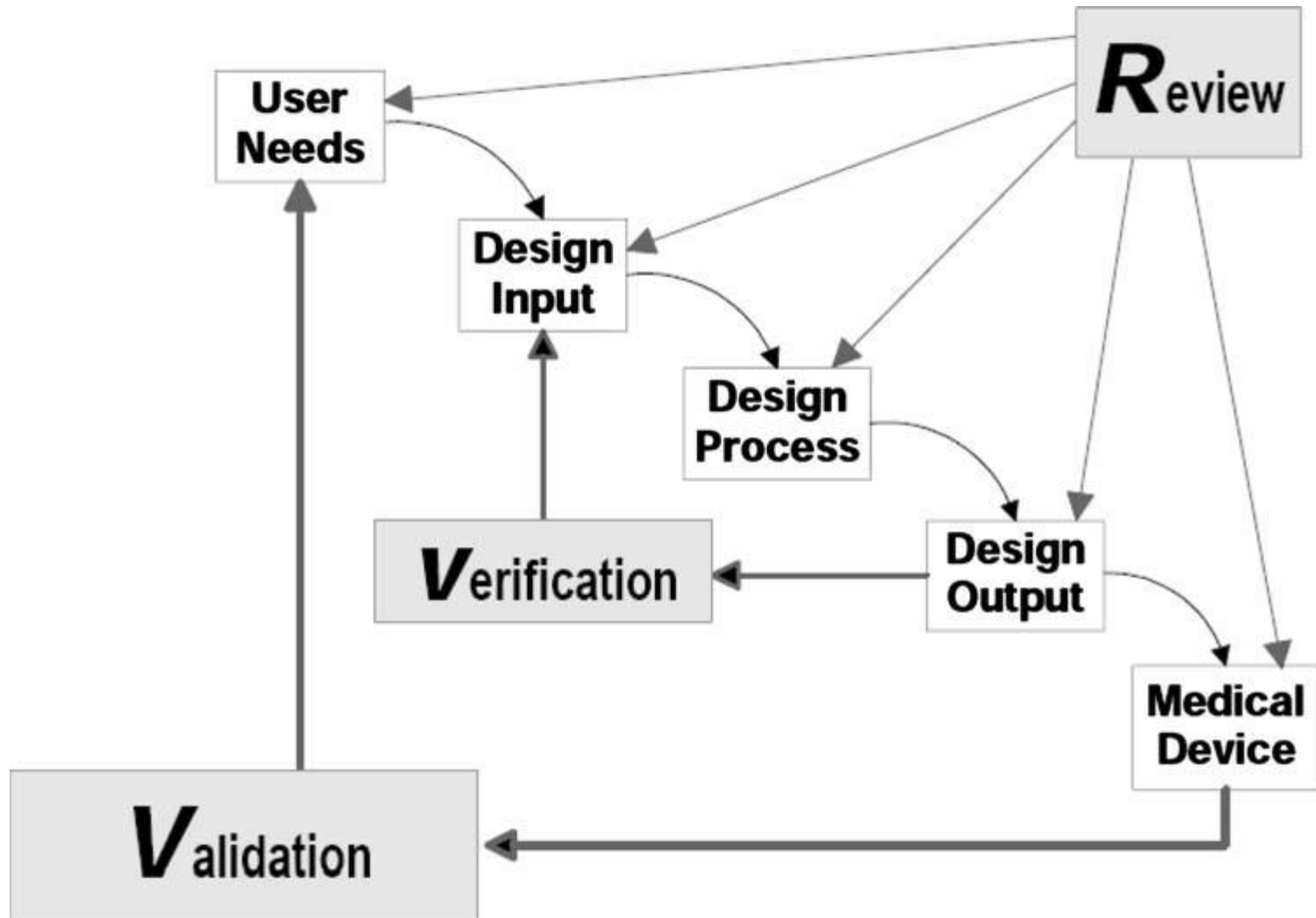
Existing Models (from Pietsch 2009)



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Existing Models (from Pietsch 2009)



Why so many models?



	Start of Course	Fall Break	Winter Break	Spring Break	End of Course
Lecture Topics	Cycle 1 - PREP/ID Disease State Analysis, Patient Flow Competitive Options, including IP landscape Market Analysis Customer Needs Specifications, Constraints (including Standards/reg)	Cycle 2- DESIGN Functional Decomposition and System-level Design Concept Generation Concept Selection Testing strategies Two "concept feedback" lectures	Cycle 3 - PROTOTYPE DFM, LBM Quality: DOE, Statistics, FMEA Clin/Reg Strategy and IRB IP Disclosure and Strategy	Cycle 4 - TESTING Design Poster Presentations Oral Presentation Tips & Tricks Final Presentation Dry-runs	
Written Deliverables	Design Foundation Document, which includes DSA, Patient Flow, IP, Market Analysis (Basically the intro section to the final report) HOQ (Customer needs mapped to preliminary specifications and constraints)	Functional Decomposition (Appendix 1 of Final Report) Sketches/CAD of top designs (Appendix 2 of Final Report) Pugh Matrices (Appendix 3 of Final Report) Updated HOQ/specs Testing Strategy (rough proposal) Rev 2 of DFD	Final design description (both form and function, including CAD/photos of prototype) Testing proposal (essentially the methods section of final report) Implementation Strategies (LBM, FMEA, Clin/reg strategy and IRB proposal (if needed)) Updated, Final HOQ/specs Rev 2 of Appendices Competition Submission Plan	Final Report, which includes: 1) DFD 2) HOQ 3) Final Design Document 4) Test Methods and Results 5) Implementation Strategies 6) Appendices Competition Submission IP Disclosure (if applicable) IRB documentation (if applicable)	
Presentation Deliverables	Project Intro slides (content of DFD, up to specs), 10 slides	Intro slides, plus five slides showing top 3 concepts/prototypes/subfunctions (Video/photos/CAD encouraged)	Intro slides, final design slides (3-4 slides showing final prototype), and implementation slides (3-4 slides showing LBM, FMEA, Clin/reg strategy)	Final Presentation (Intro slides, final design slides, testing results, implementation slides, conclusion slides - polished) Poster Presentation (leveraging their existing slide deck and final report)	
Presentation Format	10 minutes in-class presentation	30 minute time slot, with mentors and part of class (four other teams?)	15-20 minute in-class presentation	30 minute time slot, with mentors and part of class (four other teams?)	
Prototyping	Prototyping skills introduced	Initial prototyping; low to medium fidelity prototype and/or working subfunctions completed by winter break	Prototype refinement; functional, integrated prototype ready by spring break	Prototype tested against all specs in a statistically-driven approach	

Review

- Definitions (Design, Research, etc)
- Design Thinking
- PDPs
- For next time:
 - Fill out preferences by Friday night!
 - Topic for Tuesday: Teams announced, Design foundations part 1