Mechanical Testing in the Product Development Cycle: Maximizing Outcomes

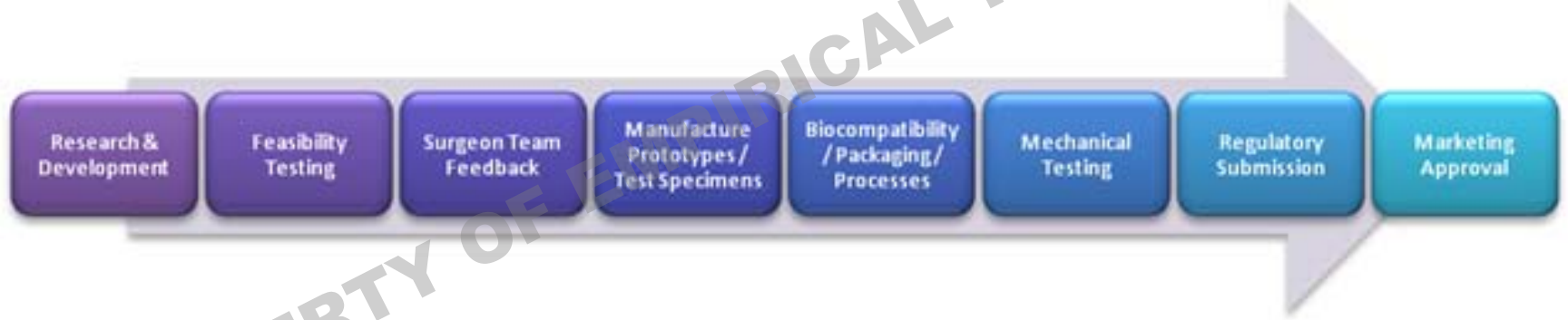
Goal of Orthopaedic Companies

- **Receive marketing approval from FDA and other regulatory governing bodies**
- **Class I, II, or III devices**

(source: http://www.qrasupport.com/FDA_MED_DEVICE.html)

- **Class I** medical devices have the least amount of regulatory control. Class I devices present minimal potential harm to the user.
- **Class II** medical devices are devices where General Controls are not sufficient to assure safety and effectiveness. Class II devices typically require pre-market notification by submission and FDA review of a 510(k) clearance to market submission.
- **Class III** medical devices have the most stringent regulatory controls. A PMA is required for FDA Approval of medical devices that present significant risk to the patient and/or require significant scientific review of the safety and effectiveness of the medical device prior to commercial introduction. Most Class III medical devices require a PMA.

Product Development Cycle



Mechanical Testing

- Significant investment (time & $$$)
  - Cost of test specimens (destructive testing)
  - Cost of testing activities ($1K to $250K)
  - Multiple rounds of testing
    - Feasibility testing
    - Regulatory submission testing
- Provides you with the fundamental information about your system

Mechanical Testing 101

- Measure for safety and efficacy
- Required for Class II or Class III devices

- Goal: Characterize the overall performance of the system and any ***unique features (FMEA)***

- Most testing per ASTM and/or ISO standard; geared towards specific device type or intended use

General Outline of a Standard

1. *Scope*
2. *References*
3. *Terminology*
4. *Summary of Test Methods*
5. *Significance and Use*
6. *Apparatus*
7. *Sampling*
8. *Procedure*
9. *Report*
10. *Precision & Bias*
11. *Appendices*

General Rules for all Mechanical Testing

- New specimens used for each test (unless non-destructive)
- New test blocks (unless non-destructive)
- Any test method can be modified – good science and justifications
- Adding/removing DOF will either test device or fixtures

Mechanical Testing 101

- Test modes:
  - Axial compression
  - Shear compression
  - Torsion
  - 4 point bend
  - Cantilever bend
  - Pullout (screws)

Mechanical Testing 101

- Static testing
  - Goal to fail specimen to determine failure mode, stiffness, yield, and peak loads (how much force does it take to “break” the specimen and how does it break)
  - n=5 to 6 specimens
  - Displacement control testing
  - Timeline 1-5 days depending on number of test modes and specimens needed
  - Peak load is starting point for building fatigue curve

Mechanical Testing 101

- Dynamic (fatigue) testing
  - Goal: to determine the highest load that can be applied to specimen to a predetermined cycle count without evidence of failure (endurance value)
  - Build a fatigue curve, with n=6 to 12 specimens
  - Load control testing
  - Consistent failure modes
  - Timeline 2 weeks to 9 months
  - Test frequency 1Hz to 10Hz
  - Endurance cycle counts: 1,2.5, 5 or 10 million

Wear Testing

- Typically for Class III devices
- Coupled motions
- Frequency 1-2Hz or less
- Specimens n=6 with 1-3 control soaks
- Typically displacement control
- Goal: to have a predefined motion with the sole purpose to see what particulate is created – volume, size, and shape

Factors that may affect the results

- Test configuration
- Deviations
- Frequency of dynamic tests
- Test block material
- Test block interface and fit
- Environment
- Data collection rate
- Test equipment (load cell size, etc.)

Feasibility Testing

- Why
- When to perform
- What
- Acceptance criteria - protocol
- How often
- Predicate device comparison

Predicate Device Testing

- When is data required?
- How many specimens?
- In what test modes?
- Economics and legalities

Predicate Device Testing

- Published data
- Side-by-side testing
  - Same test configuration
  - Same test block material
  - Same test block geometry
  - Same test environment
  - Same, same, same

Regulatory Submission Testing

- Protocol with acceptance criteria
- Follow guidance documents and ASTM/ISO
  - Deviations
- Are you characterizing your device?
- Additional testing needed?
- GOOD SCIENCE!
  - Repeatable
  - Transparent
  - Accurate

Ideal Testing Facility

- ISO 17025:2005 Accreditation
  - Specific test method on scope of accreditation
- Experience, experience, experience
- Understanding of ASTM/ISO standards
- Price vs. value
- Queue time
- Final technical document – transparent and repeatable

Value Added Points to Consider

- Partners with your team to develop your test strategy and protocol
- Delivers comprehensive and accurate quote estimate based upon testing requirements, including a realistic timeline
- Understands pitfalls of test methods
  - Additional activities (particulate analysis, etc.)
  - Equipment

In Summary…

- Testing can be expensive and time consuming
  - Plan ahead
  - Understand the information learned
  - Maximize the information learned
  - Use good science!