

Key Points for a Successful Product Development Cycle With A Highlight On Mechanical Testing

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- ❑ Masters of Science in biomedical engineering
- ❑ Designed spinal implants for AcroMed Corp trauma/tumor team (US Patent #6,159,211)
- ❑ Active member of ASTM F04
- ❑ ISO 17025:2005 A2LA Accreditation
 - Scope of accreditation certificate #2142-01

Goal of Orthopaedic Companies

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

(source: http://www.grasupport.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



Product Development Manager

Responsibility to determine:

- Type of device/device concept
- Regulatory path
- Project timelines and milestones
- Team members and meeting expectations
- Anticipating and overcoming roadblocks

Team Players

- ❑ Surgeon Champions – Concept
- ❑ Engineering – Design of device
- ❑ Regulatory – Submission of application
- ❑ Mechanical testing – Characterize device
- ❑ Engineering – Risk assessment (FMEA), design controls, QA systems, etc.
- ❑ Manufacturing & Packaging
- ❑ Misc. – Class III (biomechanical testing, clinical trials, animal studies, etc.)

Timeline & Milestones

- Research and development
- Feasibility testing
- Surgeon team feedback
- Manufacture prototypes/test specimens
- Biocompatibility/packaging/processes
- Mechanical testing
- Regulatory submission
- Marketing approval

Device Concept

- Market need
- Market potential
- Surgeon champions
- Development cycle time
- Design freeze

Manufacturing

- Internal or external
- Prototypes – final machine processes (i.e. injection molding vs. machining)
- Final vendor(s)
- New technologies
- Inspections
- Packaging

Mechanical Testing

- ❑ Significant investment (time & \$\$\$)
 - Cost of test specimens (destructive testing)
 - Cost of testing activities (\$1K to \$250K)
 - Multiple rounds of testing
 - Time for testing
 - Usually at end of product development timeline
 - Dynamic testing can range from several weeks to 6-9 months
 - Measure for safety and effectiveness
 - Required for Class II and III devices

What Testing To Perform?

- ❑ Characterize basic mechanical properties of device or system
- ❑ Guidance documents available
- ❑ ASTM or ISO standards specific to device type or intended use
- ❑ Predicate device
 - Published data
 - Side-by-side testing

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

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
 - Deviations, environment, frequency, configuration
 - Equipment
 - Additional activities (particulate analysis, etc.)

Regulatory Submission

- Internal or external team
- Knowledge and experience with requirements
- Compiles a thorough and complete package
- Anticipates questions
- Provides feedback on overall strategy

In Summary...

- Device classification
- Team member assessments
- Project timelines and milestones
- Successfully executed plan
- Compile submission package
- Value-added relationships with vendors