**Georgia Institute of Technology**

**Wallace H. Coulter Department of Biomedical Engineering**

*New Course Syllabus*

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| Course Title: **Medical Device Regulatory Requirements** | Instructor**:** Harold Shlevin, PhD |
| Course Number: **BMED 6507** | Credit Hours: 3 |
| Prerequisites: Graduate Student Enrollment in BioID Program |  |

**Course Description:** US and international regulations and standards are essential requirements for commercialization of medical products, including design & development, clinical testing, manufacturing, distribution and promotion, post market surveillance. This course will provide the US requirements; ISO standards for medical devices and those of selected other countries.

**Catalogue Description:** FDA Regulations for medical devices including clearance-approval pathways to commercialization, Quality Systems Regulations and ISO Standards for international medical devices.

**Course Objectives:**

* Analysis of US FDA Regulations and Processes and synthesis of elements and planning for compliance with applicable regulations for medical device development and commercialization.
* Formulate a regulatory plan and create a Traditional 510(k) submission for FDA product clearance for the team’s master’s project.
* Knowledge of ISO 13485 Standards for Medical Devices and obtaining a “CE” mark.
* Evaluate overlap and unique components of the FDA Quality Systems Regulations and ISO 13485 Standards.

**Course Format:**

Instructional methods include: Weekly lectures with in-class exercises and discussions. There will be two (2) class sessions of 1.5 hours each per week for the 11-week summer semester. Readings will be assigned in the designated textbooks, supplemented with reading from reference material and contemporary case information on medical device issues in the news. Grading will be from a combination of a mid-term and final exam plus team-project and presentation. Grading will be from a combination of a mid-term, final exam and composition of a Traditional 510(k) regulatory submission prepared for the team masters project.

**Grading**:

* Class Assignments (20%)
* Regulatory Project (30%)
* Exams (30%)
* Class Participation (20%)

**Class Materials:**

Required Books/Reference Materials:

* *Fundamentals of US Regulatory Affairs*, 7th Edition, Regulatory Affairs Professionals Society

Recommended Reference Materials:

* www.FDA.gov
* Center For Devices And Radiological Health, *Medical Device Quality Systems Manual,* 1996
* Leape, L. (1994). *Error in Medicine.* Journal of American Medical Association, 21(3) 272.
* FDA, *Draft Guidance - Applying Human Factors and Usability Engineering to Optimize Medical Device Design*
* European Medical Device guidance at http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index\_en.htm**Course Topics, Lectures and Presentations**

1. **US Medical Device and Biologics FDA Regulations**
2. History of Food, Drug and Device Federal Legislation
   1. Food and Drug Act of 1906
   2. Establishment of Federal Food, Drug, and Cosmetic Act 1938
      1. Congress created Food & Drug Administration (FDA)
   3. Medical Device Act of 1976
      1. Good Manufacturing Regulations (GMP)
      2. Current Good Manufacturing Regulations (cGMP)
   4. Safe Medical Devices Act (SMDA) of 1990
   5. Quality System (QS) Regulations 1996
   6. Food and Drug Administration Modernization Act (FDAMA) 1997
   7. Medical Device User Fee and Modernization Act (MDUFMA) of 2002
3. Basic Requirements for Manufacturing and Sales in the USA
   1. Establishment Registration Requirements - 21 CFR Part 807
      1. US Manufacturer
      2. Importer of Medical Devices
   2. Annual Device Listing Requirements - 21CFR Part 807
4. Device Classifications
   1. Class I
   2. Class II
   3. Class III
   4. Device Classification Codes
   5. Product Codes
   6. FDA Advisor Panels
5. Regulatory Pathways
   1. Premarket Notification Requirements and Procedures
      1. Section 510(k) Submission - 21 CFR Part 807 Subpart E
      2. Traditional 510(k) requirements
   2. Premarket Approval Requirements (PMA) and Procedures –
      1. Section 515 - 21 CFR Part 814
   3. Clearance vs. Approval
   4. Investigations Device Exemptions (IDEs) - 21CFR Part 812
   5. Orphan Device Definition and Requirements
   6. Special considerations applicable to Mobile Medical Device applications
   7. Combination Devices (Devices – Drugs – Biologics)
6. Interacting and Meeting with the FDA
   1. Pre-submission discussions
7. Device Standards and Guidance Documents
   1. For specific product categories
   2. Human Factors
8. Quality System Regulation (QSR) Requirements and Current Good Manufacturing Practice Regulations (CGMP) - 21 CFR Part 820
   1. Quality Systems
   2. Design Controls
   3. Process Validation
   4. Personnel
   5. Buildings & Environment
   6. Equipment & Calibration
   7. Device Master Record
   8. Document & Change Control
   9. Purchasing & Acceptance Activities
   10. Labeling
   11. Product Evaluation
   12. Packaging
   13. Storage, Distribution and Installation
   14. Complaints
   15. Servicing
   16. Quality Systems Audits
   17. Factory Inspections
9. Design Controls and the Product Development Process
   1. Documentation
   2. Reviews
   3. Approvals
10. Device Labeling
    1. Product Claims for Intended Use
    2. Product Use Instructions (PUI)
       1. Description
       2. Indications for use
       3. Contraindications
       4. Cautions
       5. Warnings
    3. Electronic PUI
    4. Advertising, Labeling, and Claims Review and Approvals
       1. Promotional materials, ads, brochures
       2. User and field sales training materials
       3. Sales & technical oral statements
       4. Website information – US vs. Foreign availability of information
11. Sterile Medical Device Packaging
    1. Sterilization methods
    2. Materials for sterile packaging
    3. Methods & material compatibility
    4. Sterility validation
    5. Procedure trays
12. Device Labeling Requirements
    1. Intended Use - [21CFR 801.4](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.4)
    2. Adequate Directions [21 CFR 801.5](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.5)
    3. False or Misleading Statements [21 CFR 801.6](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?FR=801.6)
    4. Use of symbols in Labeling
13. Product Vigilance and Complaint Systems - 21 CFR Part 803
    1. FDA Medwatch Reporting System
    2. Corrective and Preventive Action (CAPA) Requirements
14. FDA Establishment/Company Audits
    1. FDA’s Authority, inspection procedures and norms
    2. Company Internal Quality System Audits

**B. International Medical Device Regulations**

1. ISO 13485 Medical Device Standards – European Community
   1. Organization and Requirements
   2. ISO 13483 Standards vs. FDA QSR Regulations Comparison
   3. Process for ISO 13485 Certification and Obtaining the CE Mark
2. Overview of Other International Requirements
   1. Canada
   2. China
   3. Japan
   4. Brazil
   5. India

*Attach - Course General Guidance*