Core Competencies for Graduates of MS Programs: MS, Regulatory Management
(linked to course syllabi)

REGULATIONS
Concept: Obtain and apply broad knowledge of domestic and international law, regulations, and guidance documents covering pre- and postmarket requirements for at least one category of medical products, including combination products.

A graduate will be able to:
- Identify and interpret regulations and guidance documents for domestic and international agencies relevant to medical products, 511, 512, 514, 519
- Describe the origins of regulations related to medical products. Support product development teams to bring new medical products to US and international markets:
  - Advise on applicable requirements
  - Plan and coordinate preparation of market approval submissions and clinical trial submissions where necessary
  - Negotiate approvals for clinical trial and market approval submissions with regulatory authorities 511, 512, 513, 514, 519
- Support postmarket compliance with FDA and international regulatory requirements:
  - Advise on applicable requirements
  - Identify medical product design and manufacturing changes requiring regulatory approvals and obtain approvals
  - Review labeling and advertising for regulatory compliance
  - Advise on requirements for postmarket clinical trials
  - Prepare required postapproval reports
  - Advise on medical product issues that may require corrective actions and/or recalls 511, 512, 513, 514, 519

QUALITY
Concept: Examine quality systems and standards and their impact on product and public safety as well as the importance of quality products from the perspective of healthcare providers.

A graduate will be able to:
- Implement quality systems to support the development, manufacturing and monitoring of medical products 515, 508, 509
- Analyze and advise on global requirements involved in marketing regulated products 515, 519, 520
- Describe validation studies 515, 508, 509
- Create and adhere to standard operating procedures 515, 508, 509
- Develop and retain documentation to comply with quality regulations 515, 508, 509
- Describe quality principles throughout the product lifecycle in order to manage risk 515, 508, 509, 520, 529
- Develop a system to comply with personnel quality requirements, including training 515, 508, 509
- Accomplish audits that test the existing systems 515, 508, 509

CLINICAL
Concept: Obtain and apply broad knowledge of US Food and Drug Administration (FDA) and international requirements for the approval and conduct of pre- and postmarket clinical studies with regulated products. Understand the basic principles of clinical study design and clinical data analysis.
A graduate will be able to:

- Explain the basics of clinical trial regulations in the US and key international markets 517, 522, 519
- Advise on requirements for product types that require clinical trials:
  - Identify the scope of clinical data necessary to support market approvals
  - Identify requirements for postmarket clinical studies
- Plan and prepare submissions to support pre- and postmarket clinical trials 517, 522, 519
- Describe basic clinical paradigms commonly used to determine safety and effectiveness/efficacy 522
- Describe the process of writing clinical study objectives and endpoints 517, 508
- Define the content, and coordinate and prepare submissions for clinical trials 517, 508, 522
- Advise on the conduct of ethical clinical studies according to international standards 517, 519, 602
- Describe the common methods for analysis of clinical data 522

STRAATEGY
Concept: Recognize the factors that influence domestic and international regulatory decisions. Develop methods to incorporate regulatory trends and practices. Think strategically about product development, market approvals and marketing.

A graduate will be able to:

- Contribute effectively to multidisciplinary teams 511, 512, 513, 514, 603
- Apply lessons from the history of domestic and international regulations and product requirements and stay current with changes and advances that could affect future requirements 511, 540, 519, 590, 630, 516
- Develop strategies to bring new medical products to market to support business objectives:
  - Describe appropriate bench, animal and clinical requirements
  - Develop plans for timely approvals in US and international markets
  - Identify risks and unknowns with marketing strategies 601, 516
- Develop strategies to balance business objectives and compliance with regulatory requirements:
  - Apply strategic planning to design and manufacturing changes, postmarket clinical trials and required regulatory reporting
- Accomplish business goals within the regulatory parameters 601, 602, 605

COMMUNICATION
Concept: Develop interpersonal, critical thinking and interpretation skills. Develop written and oral communication skills, with the scope and flexibility to address audiences with differing size, knowledge and priorities. Write and present clearly and concisely in an audience-appropriate manner.

A graduate will be able to:

- Identify and employ audience-appropriate communication strategies
- Write clear and concise technical documents and letters
- Critique own and others' written and oral communications to facilitate continual improvement
- Prepare and deliver effective presentations:
  - Design effective slides
  - Speak confidently to an audience
  - Interpret and address questions effectively
- Analyze and respond appropriately to communications from FDA and other entities:
- Work effectively in multidisciplinary committees:
  - Demonstrate interpersonal skills to establish and support credibility
  - Explain relevant regulatory issues clearly
  - Research and present alternate approaches