

University of Southern California
Regulatory Science
Program Learning Objectives

Core Competencies for Graduates of MS Programs:

MS, Medical Product Quality

(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, 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 **511, 519, 520**
- Describe validation studies **515, 508, 509, 535**
- Create and adhere to standard operating procedures **515, 508, 509**
- Develop and retain documentation to comply with quality regulations **504,515, 508, 509**
- Describe quality principles throughout the product lifecycle in order to manage risk **504, 515, 508, 509**
- Understand the role of risk management in the development of quality systems **520, 527**
- Develop a system to comply with personnel quality requirements, including training **515, 508, 509**
- Accomplish audits that test the existing systems **515, 508, 509, 506**
- Understand how to use statistical process controls to monitor product quality during manufacturing **507**
- Develop project management strategies for new and existing products **603**

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 Good Clinical Practices and 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**

STRATEGY

Concept: Recognize the factors that influence domestic and international regulator/ quality 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**

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