

University of Southern California
Regulatory Science
Program Learning Objectives

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

REGULATIONS

Concept: Obtain and apply broad knowledge regarding advanced foundational regulatory training for individuals interested in the preclinical and early clinical aspects of translational medicine and associated research. Competencies in product safety, regulatory, guidance documents and law covering pre- and postmarket requirements for at least one category of medical products, with an emphasis on small molecules and biologics.

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, 531, 532**
- 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**
 - Understand and utilize safety pharmacology strategies that are mandated by the various regulatory bodies (e.g., FDA, EMA) to move a NCE from the discovery stage to market approval **531, 533**
- 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, 531**

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**
- Describe preclinical animal studies that are necessary before clinical trials can begin, and during clinical trials where important safety and pharmacology data is collected. **531, 532, 533**
- Describe the importance of Good Laboratory Practices (GLP) and International Conference on Harmonization (ICH) Guidelines to be acceptable for submission to regulatory agencies such as the Food & Drug Administration in the United States.
- Describe and use GLP testing strategies to identify potential general safety as well as organ specific toxicity including neurotoxicity and reproductive/developmental toxicology issues and how to test for them **531, 533**

- 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 U.S. 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, 532**
- 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: Translational medicine is growing in importance in the healthcare industry, and is a term whose precise definition is in evolving over time. In the case of drug discovery and development, translational medicine typically refers to the steps between fundamental discovery and its application in clinical medicine. Traditionally, basic research has been separated from the clinical practice of medicine by a series of hurdles or fences. New drugs were developed independently of the clinic, and often "thrown over the fence" for safety testing and clinical trials. The move toward translational medicine is focused on removing these fences, and stimulating "bench to bedside" research. However, this desire to see a rapid progression from laboratory bench to hospital bedside brings with it impediments, technological, regulatory and ethical, that must be addressed and overcome. The program highlights the interdependence of medical, scientific, regulatory and societal components required in modern translational research and will emphasize the discovery and development of biomedical products in a regulatory environment.

A graduate will be able to:

- Contribute effectively to multidisciplinary teams **511, 512, 513, 514, 531, 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 **531, 533, 534**
 - Develop plans for timely approvals in US and international markets **603**
 - Identify risks and unknowns with marketing strategies **601, 516, 532**
- 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, 603**

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