

HENRY E. RIGGS SCHOOL OF APPLIED LIFE SCIENCES

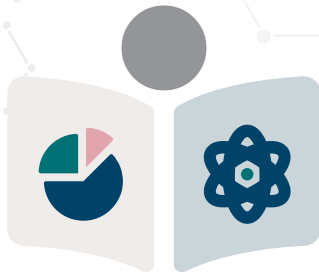
Master of Science in Regulatory Affairs

MSRA

The Master of Science in Regulatory Affairs (MSRA) is a two-year Keck Graduate Institute (KGI)–City of Hope (COH) joint program. The MSRA aims to provide students with translational and applied experience in regulatory affairs for all FDA-regulated product classes (drugs, biologics, and devices) throughout the product lifecycle (pre-clinical development, clinical development, and post-marketing).



IRELL & MANELLA GRADUATE SCHOOL
OF BIOLOGICAL SCIENCES



INDUSTRY-FOCUSED COURSES
In year one, students take rigorous graduate-level courses in applied biomedical sciences at KGI.



TRANSLATIONAL RESEARCH PROJECTS
In year two, students conduct two three-month rotation projects at COH, gaining exposure to a multitude of regulatory affairs practices.



IN-DEPTH EXPERIENTIAL OPPORTUNITIES
Students interact with multiple regulatory and operational bodies that oversee regulatory and clinical trial activities.

About the Program

Year 1

Students take rigorous **graduate-level courses** at KGI in applied biomedical sciences including core regulatory courses, advanced electives, and professional development.

Year 2

Two three-month **rotation projects** at City of Hope will consist of one or a combination of the following:

- Writing and submission of clinical trial protocol and consent to COH regulatory bodies

- Preparation of a pre-IND package or parts of an IND, including the Investigator's Brochure (IB)
- Review of material/data to be included in the regulatory material and assessment of data requirements and completeness
- Input in drug development (i.e., participation in team meetings where pre-clinical development is being discussed and evaluated)

Students choose projects from the following **rotation departments** at COH:

- T Cell Therapy Clinical Manufacturing
- Clinical & Translational Project Development
- CART Therapy Program
- Office of IND Development and Regulatory Affairs
- Office of Quality Systems
- Translational Development Center

What can I do with this degree?

Graduates will be uniquely positioned to begin careers in regulatory affairs and quality assurance for biotech and pharma companies, academic research, programs with regulatory functions, or continue onto doctorate programs in regulatory affairs.

Regulatory professionals carry titles such as:

- Regulatory affairs specialist
- Regulatory affairs manager
- Regulatory affairs director
- Compliance specialist
- Food safety inspector
- Clinical research associate
- Director of quality assurance

Average yearly salary for regulatory affairs professionals


\$150K



What is Regulatory Affairs?

Regulatory affairs deal with the government and Food and Drug Administration quality and performance standards, ensuring that the therapeutics, devices, and other healthcare tools abide by such standards. Regulatory affairs professionals are responsible for ensuring manufacturers' compliance with applicable global legislative and regulatory requirements at each stage of product development.

In the drug, medical device, and biologic product industries, these phases include:

- Research and development
- Clinical trials
- Regulatory submissions
- Manufacturing
- Marketing, distribution
- Reimbursement
- Post-market surveillance

In the food industries, regulatory professionals engage with products, facilities, manufacturing operations, and distributors along the farm-to-fork life cycle.

How to Apply

Dates and Deadlines

Start Terms: Fall

Application Deadline: Rolling admissions

Application Requirements

An online application form is required that contains questions about your personal and educational background. Additional requirements can be submitted along with your online application or separately:

- Personal Statement
- Resume
- Letter of Recommendation
- Transcripts
- Standardized Test Scores (GRE, MCAT, or GMAT)
- English Language Proficiency (TOEFL, PTE, IELTS, iTEP)
- \$75 non-refundable application fee

Admission Interviews: A phone, Skype, or on-campus interview is a requirement for admission. The Office of Admissions schedules individual interviews after an application is complete.

Application Review: The Admissions Committee is made up of faculty and senior administrators who will thoroughly and conscientiously review each application.

Admitted Students: Admitted students are required to submit a \$400 non-refundable enrollment fee to hold their spot in the program.

Contact Us

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Student Affairs

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International Students

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